



Expert from USP training the staff of DFDA on drugs quality analysis in Nay Pyi Taw Laboratory

FINAL REPORT

USAID HEALTH SECTOR ASSESSMENT OF INSTITUTIONAL CAPACITY BUILDING OF MYANMAR DEPARTMENT OF FOOD AND DRUG ADMINISTRATION (DFDA)

October 2018

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USAID
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FINAL REPORT

USAID HEALTH SECTOR ASSESSMENT OF INSTITUTIONAL CAPACITY
BUILDING OF MYANMAR DEPARTMENT OF FOOD AND DRUG
ADMINISTRATION (DFDA)

USAID Program Development Office

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ABSTRACT

The United States Agency for International Development engaged Social Impact to conduct an assessment of a USAID-supported institutional capacity-building Activity with the country's Department of Food and Drug Administration (DFDA). The Promoting the Quality of Medicines (PQM) program implemented by the United States Pharmacopeial Convention was responsible for building the capacity of the DFDA to monitor drug quality.

An assessment of the Activity was conducted by a two-person team in July-August 2018. It concluded that successes of the Drug Quality Monitoring Activity—in particular, earlier-than-anticipated achievement of ISO 17025 accreditation of the country's Pharmaceutical Chemistry Laboratory in the capital of Nay Pyi Taw—was a result of both exemplary Government resource mobilization to support DFDA's development and PQM's state-of-the-art, facilitative support. The Activity also highlighted the importance of the Government of Myanmar investments and commitment to leverage external institutional strengthening support. Implementing partner approaches that built on local strengths, fostered trust and rapport with Government counterparts, and supported the institutionalization of sustainable capacity-building and quality assurance mechanisms were key to the Activity's success.

ACKNOWLEDGEMENTS

The assessment team would like to acknowledge The Promoting the Quality of Medicines program implemented by the United States Pharmacopeial Convention, whose staff were forthcoming with insights and information that were invaluable to the capacity assessment process.

We would also like to extend gratitude to Department of Food and Drug Administration (DFDA) staff within Myanmar's Ministry of Health and Sports (MOHS). Their well-articulated and honest reflections on what did and did not work with respect to the Drug Quality Monitoring Activity, as well as their expressed desire to translate donor inputs into meaningful outcomes for the country, were appreciated.

The team also acknowledges USAID staff who met with the assessment team and/or facilitated the assessment team's work to ensure an objective and comprehensive assessment process that will yield insights and recommendations to inform the way forward.

Finally, we appreciate the support of Social Impact headquarters staff, who have been instrumental in all phases of the assessment process.

ACRONYMS

DFDA	Department of Food and Drug Administration	M&E	Monitoring and Evaluation
DG	Director General	MOHS	Ministry of Health and Sports
DMR	Department of Medical Research	PMI	President's Malaria Initiative
DPH	Department of Public Health	PMP	Performance Management Plan
AQ	Assessment Question	PMS	Post-marketing Surveillance
CAPA	Corrective Action Protective Action	PQM	Promoting the Quality of Medicines
ERC	Ethics Review Committee	RDMA	Regional Development Mission for Asia
FY	Fiscal Year	QA	Quality Assurance
GC	Gas Chromatography	QMS	Quality Management System
GDP	Good Distribution Practices	SI	Social Impact
GLP	Good Laboratory Practices	SOP	Standard Operating Procedure
HPLC	High-Performance Liquid Chromatography	TA	Technical Assistance
HR	Human Resources	TOT	Training of Trainers
HRMIS	Human Resource Management Information System	UNICEF	United Nations Children's Fund
IP	Implementing Partner	UPLC/LC-MS	Ultra-Performance Liquid Chromatography/Liquid Chromatography–Mass Spectrometry
ISO	International Organization for Standardization	USD	United States Dollar
KII	Key Informant Interview	USP	United States Pharmacopeial Convention
LIS	Laboratory Information System	USAID	United States Agency for International Development
LOD	Limit of Detection	USAID/W	United States Agency for International Development/Washington
LOE	Level of Effort		

EXECUTIVE SUMMARY

PROGRAM BACKGROUND

USAID invests in many activities that promote institutional strengthening. One such activity was the “Strengthening Drug Quality Monitoring Capacity of the Department of Food and Drug Administration (DFDA)” (10/1/2014-9/30/2018), implemented by The Promoting the Quality of Medicines (PQM) program of the United States Pharmacopeial Convention (USP).

ASSESSMENT PURPOSE

This report presents findings from a capacity assessment intended to document the achievements, challenges, and lessons learned of the Drug Quality Monitoring Activity. The assessment examined the extent to which technical assistance (TA) strengthened DFDA and beyond, and identified key factors associated with USAID programming that enabled or impeded capacity strengthening and local ownership. Assessment findings will inform the design of future TA and institutional strengthening activities in Myanmar.

ASSESSMENT DESIGN AND METHODOLOGY

There were two main assessment questions (AQs): (1) In what ways and to what extent was the DFDA’s institutional capacity strengthened to monitor drug quality as a result of USAID assistance? (2) What specific lessons can be learned and applied to other future programs and activities in Myanmar?

Data Collection Methods. The assessment team used a mixed-methods design involving document review, primary qualitative data from key informant interviews (KIIs), and review of secondary data. Key informants were PQM staff, DFDA technical and management staff, and USAID personnel.

Sampling. There were three selected locations in Myanmar (Yangon, Mandalay, and Nay Pyi Taw) for data gathering and 19 purposively selected respondents, yielding 10 KIIs.

Data Analysis. In answering the AQs, the assessment team triangulated evidence across stakeholders and qualitative and quantitative data sources. The evaluators used content and comparative analysis of coded KII interview notes to answer each AQ.

Key Challenges/Limitations. There was an inherent gender imbalance among respondents, due to the fact that (a) females predominate among DFDA laboratory personnel and (b) males predominate among PQM TA providers. The evaluators have presented gender-disaggregated evidence, where feasible.

ASSESSMENT FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

AQ 1. IN WHAT WAYS AND TO WHAT EXTENT WAS THE DFDA’S INSTITUTIONAL CAPACITY STRENGTHENED TO MONITOR DRUG QUALITY AS A RESULT OF USAID ASSISTANCE?

USAID assistance via PQM was a necessary input, but political will already existed within DFDA to strengthen institutional capacity. PQM’s infusion of TA in the form of laboratory design and capacity-building support (9 different trainings) helped DFDA rationalize the use of Government resources to support both individual and organizational capacity strengthening. Pharmacists accounted for the majority of PQM training participants, followed by lab technicians. PQM trainings also extended to some DFDA supervisors and managers (e.g., Supervising Officer, Deputy Lab Officer, Assistant Director, Quality Managers).

IA. FACTORS CONTRIBUTING TO EARLY ISO ACCREDITATION

Earlier-than-anticipated ISO 17025 accreditation in Nay Pyi Taw exemplifies DFDA’s heightened capacity, which was achieved through DFDA’s resource mobilization to meet ISO 17025 accreditation standards

and PQM's expertise and systems approach. Both were necessary factors underlying the accreditation achievement.

IB. FACTORS IN PLACE TO SUSTAIN STRENGTHENED CAPACITY

Increased financing and an expanded, motivated HR pool were demonstrations of DFDA's commitment to capacity strengthening. However, inputs and processes need to be optimized to sustain capacity gains. For example, there were gaps related to sustainable financing and in-country capacity to perform advanced laboratory functions, which must be addressed to maintain DFDA on a path of organizational growth. Also, although Government efforts have been underway to strengthen DFDA's presence and capacity nationwide, the enabling environment (e.g., critical mass of trainers, state-of-the-art infrastructure, state-of-the-art equipment) for sustained capacity strengthening is still evolving. PQM has, however, supported DFDA in considering options related to sustainable financing; for example, through marketing its high-quality services to generate revenue from different entities (e.g., for testing long-lasting insecticidal bed nets).

IC. CAPACITY STRENGTHENING OUTCOMES

Routine monitoring of capacity building was largely limited to tracking training outputs (e.g., numbers of trainings/trainees), not changes in performance. There were, however, high-level milestones and achievements (e.g., achievement and maintenance of ISO accreditation) that both DFDA and PQM regard as indicative of enhanced DFDA capacity. Investments in strengthening drug monitoring capacity also manifested as enhanced surveillance and fewer substandard/falsified drugs in the marketplace.

ID. HOW PROJECT DESIGN PROMOTED TO OWNERSHIP/ENGAGEMENT

Country engagement and ownership were internal factors that already existed as a complement to, not a by-product of, PQM's activity design. There were no particularly unique or innovative aspects of PQM's activity design in Myanmar, although how it structured its support to DFDA was effective and appropriate in leveraging local commitment and elevating engagement and buy-in to strengthen both individual and institutional capacity. Although DFDA personnel are predominantly female, and PQM experts providing support to Myanmar were predominantly male, this gender dynamic had no perceptible negative impact on the USAID-supported Drug Quality Monitoring Activity or its outcomes.

IE. HOW DFDA INTERNAL FACTORS AFFECT CAPACITY STRENGTHENING

DFDA's rapid and extensive growth requires a re-examination of its institutional policies and practices related recruitment and human resource management (e.g., academic credentials for recruitment/hiring of laboratory personnel such as distinguishing between a degree in chemistry versus pharmacy versus medicine) in order to maximize individual capacity strengthening and minimize the erosion of institutional capacity, which might result from staff attrition. In addition, although some measures were being taken to strengthen/expand DFDA across the country, the nucleus of lab standards and capacity remains in Nay Pyi Taw, which is not yet fully aligned with the need for state-of-the-art lab capacity to exist throughout the country, especially in "hot spots" for falsified drugs (e.g., Mandalay). DFDA has made efforts to leverage increased capacity of the Pharmaceutical Chemistry Laboratory to benefit DFDA as a whole, but approaches and mechanisms need to be formalized through clear arrangements related to training, for example. In addition, suboptimal financing for decentralized implementation of state-of-the-art laboratory practices and functions (e.g., fieldwork for drug quality enforcement) persists.

AQ I RECOMMENDATIONS

For USAID, in support of DFDA: (I) Building on insights from DFDA's exemplary approach to institutional strengthening over the past five years, support the new DFDA Director General and other senior leadership to systematically assess and further strengthen building blocks for sustainable institutional capacity development. One way this can be achieved is by supporting an institutional review of internal policies that can support further development and retention of Government-sector laboratory

capacity. Policies in the areas of information system(s) to monitor performance at different levels (including a set of indicators that can be used as part of a ‘critical alert system’ for Quality Managers to identify and respond to individual and institutional capacity gaps), policies on infrastructure development (including the quality of existing infrastructure and in-country laboratory design capacity) and policies on the current DFDA HR system (including the levels and distribution of different competencies/skillsets across the country).

For DFDA: (2) Develop/revise a DFDA-specific HR strategy and an approach to (a) optimize recruitment of qualified females and males with appropriate credentials for laboratory work (e.g., degree in chemistry) and (b) cultivate in-country capacities that can introduce cost savings and/or optimize and sustain outcomes (e.g., in calibration and equipment maintenance, state-of-the-art/fit-for-purpose laboratory design). **(3)** Develop a five-year costed work plan to: (a) maintain ISO 17025 accreditation status of the Nay Pyi Taw Pharmaceutical Laboratory and (b) achieve ISO 17025 accreditation in Mandalay and Yangon. In addition to maintaining ISO accreditation, it is advised that the plan support implementation of DFDA’s vision for systems and mechanisms that link main laboratories (e.g., through enhanced inter-lab communications) to optimize the transfer of data, learning, processes, and protocols. This might also entail formalizing the Nay Pyi Taw lab as a Center of Excellence where staff from the other labs can hone state-of-the-art laboratory skills and be coached in cascading skills within their home states/regions.

For PQM: (4) Support DFDA in enhancing its cascade approach to individual and institutional strengthening, with explicit aims of: (a) minimizing the training and quality assurance (QA) burden placed on master trainers/Quality Managers in Nay Pyi Taw; (b) extending training reach to DFDA’s ever-expanding HR (e.g., through the use of digital platforms); (c) leveraging newly developed capacities that may exist at state and/or regional levels (including but not limited to former Nay Pyi Taw Lab staff who now work in other parts of the country); (d) strengthening DFDA information systems to support HR management, performance monitoring, and post-training follow up; (e) addressing system requirements for transitioning from trainings to improved implementation (e.g., ensuring that the budget and operational requirements are in place to support drug quality monitoring enforcement) in critical hubs such as Mandalay; and (f) exploring the introduction of innovative technologies to improve frontline performance, as DFDA becomes increasingly decentralized. **(5)** Provide support to DFDA in the development and implementation of a strategy/plan for sustainable financing, including a revised fee structure for laboratory services.

AQ 2. WHAT SPECIFIC LESSONS CAN BE LEARNED AND APPLIED TO OTHER FUTURE PROGRAMS AND ACTIVITIES IN MYANMAR?

The biggest lesson relates to required Government of Myanmar investments to fully leverage external TA and capacity building. Mutual accountability between the IP and counterparts, and an enabling environment for strong managers of organizational change are also key.

2A. ELEMENTS AND KEY INPUTS THAT LED TO ACTIVITY SUCCESS

The activity demonstrated that effective institutional strengthening was predicated on resource commitments from the Government of Myanmar, not just an infusion of TA. Relationship building and trust building between the PQM and DFDA were also critical success factors in the institutional strengthening of DFDA. Staff willingness to learn and their motivation for DFDA’s work to be recognized as being on par with international standards were other enabling factors for institutional strengthening. However, they also can contribute to staff attrition and eventual erosion of institutional capacity if measures are not put in place to retain and further develop qualified, high-performing individuals. Strong management capacity—not just technical capacity—existed in focal persons/leaders, particularly senior leaders, who had the vision and ability to manage organizational change.

2B. PRACTICES FOR FUTURE INSTITUTIONAL STRENGTHENING ACTIVITIES

As a complement to institutional strengthening, counterparts should provide requisite inputs (e.g., HR, equipment, infrastructure) to leverage institutional strengthening. A clear strategy for institutional strengthening and handover must be in place, serving as a benchmark for activity implementation. At its core, institutional strengthening must be pursued as a behavior change endeavor, with “incentives” for change/improved performance (e.g., through staff recognition and/or awards) and an enabling environment to support and sustain those changes (e.g., supporting personnel who are assuming new or expanded functions such as master trainers or Quality Managers).

2C. PRACTICES FOR FUTURE TA ACTIVITIES

As a result of their increased capacity, which was honed through PQM-supported trainings, DFDA lab personnel were extremely attractive targets for other employers, particularly those that can offer salaries that exceed the MOHS salary scale. Activity design and administrative arrangements must facilitate nimbleness/responsiveness to on-the-ground support needs within a dynamic, ever-changing program context (e.g., changes in political landscape, international trade limitations).

AQ 2 RECOMMENDATIONS

For USAID, in support of DFDA/MOHS: (1) Consider “phase-gate” provisions to foster mutual accountability between PQM and DFDA. Under that scenario, the project cycle would be divided into distinct phases, each culminating in a specific set of capacity development/handover milestones. At the end of each phase, decisions would be made between USAID, DFDA, and PQM regarding the scale and/or scope of program activities for the subsequent phase. Before initiating Mission-supported activities, develop and apply criteria to establish the state of “readiness” of the counterpart agency/recipient institution for TA and/or capacity-building support. Two such criteria might relate to the existence of a costed workplan/investment plan and the availability of counterpart resources (human, financial, infrastructural) to fully leverage TA and capacity-building inputs from PQM. In the spirit of mutual accountability, USAID should require PQM to report on pre-determined milestones and indicators to monitor handover and risk management over the course of activity implementation. **(2)** To assist DFDA in fully exploiting investments in lab quality improvement (e.g., processes, equipment, infrastructure), USAID should support HR system strengthening (e.g., recruitment of lab technicians with appropriate academic/professional credentials, post-training follow-up and supportive supervision) within DFDA.

For PQM: (3) Institute mechanisms and checkpoints over the course of implementation to re-assess and, if necessary, re-prioritize support needs to ensure timeliness and responsiveness of technical support. For example, this can be achieved through periodic (e.g., quarterly or semi-annual) TA needs assessments within the course of each program/fiscal year to ensure alignment and responsiveness of external, USAID-supported TA provision to local TA needs. **(4)** In the interest of fostering rapport and trust with counterparts, maintain continuity of mentors/TA providers (i.e., the same focal person/pool of experts assigned to the country to provide TA and capacity-building support over the life of the program).

INTRODUCTION

BACKGROUND AND CONTEXT

Myanmar ended nearly 50 years of military rule in 2011, and the U.S. Government (USG) has since supported the country's peaceful transition toward democratic governance, national reconciliation, economic integration, and healthy and resilient communities. USAID prioritizes health as one of the key approaches to creating stability and resilience in Myanmar, as its population continues to face some of the highest maternal and child mortality and morbidity rates and HIV, TB and malaria burdens in the region.

Malaria is a priority issue in Myanmar. Between 2011 and 2016, Myanmar reduced the number of confirmed malaria cases by 80%, but the country still has the highest malaria burden in the Greater Mekong Region.¹ The Myanmar National Strategic Plan (NSP) for malaria aims to reduce the availability of falsified and substandard drugs that not only could have a negative impact on the treatment outcomes for malaria patients, but also could be a driver for the development of multi-drug resistance to malaria. The Department of Food and Drug Administration (DFDA) within the Ministry of Health and Sports (MOHS) is a key player in fulfilling this objective and takes responsibility for monitoring drug quality, quality assurance (QA) in the laboratory and building the capacity of inspectors. The International Organization for Standardization (ISO) 17025 accreditation confers international recognition of a laboratory's competence in producing accurate and precise laboratory tests and calibration data. As such, it can facilitate cooperation between the accredited laboratory and other entities, as well acceptance of test reports and certificates between countries.

USAID funded the Promoting the Quality of Medicines (PQM) program, which was implemented by the United States Pharmacopeial Convention (USP), to implement the "Strengthening Drug Quality Monitoring Capacity of DFDA," activity which aimed to support capacity strengthening of DFDA to monitor drug quality and to achieve ISO accreditation.

This report presents assessment findings on the Drug Quality Monitoring Activity. The assessment was part of a larger USAID Health Sector Capacity Evaluation conducted by Social Impact (SI).

PROGRAM DESCRIPTION

Box 1 provides summary information on the Drug Quality Monitoring Activity.

USAID is the conduit through which the President's Malaria Initiative (PMI) (supporting malaria-related activities in Myanmar since FY2011),² was providing support to PQM. The

Box 1. Program Description STRENGTHENING DRUG QUALITY MONITORING CAPACITY OF DFDA

- **IP:** Promoting the Quality of Medicines (PQM), implemented by the U.S. Pharmacopeia (USP)
- **Type of Assistance:** Cooperative Agreement (#: GHS-A-00-09-0003-00)
- **Activity Start Date:** 10/1/2014
- **Activity End Date:** 9/17/2019
- **Counterpart Entity:** Department of Food and Drug Administration (DFDA)
- **Total Funding Amount:** USD 845,000
- **Scope:** Nationwide

¹ President's Malaria Initiative (PMI). 2018. Myanmar Country Profile. https://www.pmi.gov/docs/default-source/default-document-library/country-profiles/Myanmar_profile.pdf. Accessed on August 5, 2018.

² PMI. 2018. Myanmar Country Profile. https://www.pmi.gov/docs/default-source/default-document-library/country-profiles/Myanmar_profile.pdf. Accessed on August 5, 2018.

primary recipient of PQM's technical assistance (TA) was Myanmar's DFDA.^{3,4} PQM was a US \$110 million cooperative agreement (GHS-A-00-09-0003-00) between USAID/Washington (USAID/W) and USP that started on September 18, 2009. Funding for PQM's Myanmar activities transitioned from the USAID Regional Development Mission for Asia to direct field support through USAID in FY14.⁵

ASSESSMENT PURPOSE AND ASSESSMENT QUESTIONS

ASSESSMENT PURPOSE

The purpose of this assessment was to document the achievements, challenges, and lessons learned from strengthening the drug quality monitoring capacity of the Myanmar DFDA (see [Annex A](#)). The assessment was intended to document the extent to which TA strengthened these two institutions and beyond, as well as identify key factors associated with USAID programming that enabled and/or impeded capacity strengthening and local ownership. The assessment will be used to inform the design of future technical assistance and institutional strengthening activities in Myanmar.

ASSESSMENT QUESTIONS

There were two main assessment questions (AQs), as noted below.

AQ 1. In what ways and to what extent was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

AQ 1. Sub-questions:

- a. What factors (internal and external, including enabling environment) contributed to the earlier-than-anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory?
- b. What factors are/are not in place to ensure that strengthened capacity can/will be sustained?
- c. Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?
- d. How did the project's design contribute to country engagement and ownership?
- e. How do the DFDA's internal factors (structure, policy, human resource management practices, etc.) affect capacity strengthening at individual and institutional levels?

AQ 2. What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ 2. Sub-questions:

- a. What experiences, elements, or key inputs were common for these two cases that led to their success?
- b. What practices should (not) be applied for future institutional strengthening activities?
- c. What practices should (not) be applied for future technical assistance activities (where the primary objective may not be institutional strengthening)?

³ President's Malaria Initiative Myanmar. 2017. Malaria Operational Plan FY 2018. <https://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy-2018/fy-2018-Myanmar-malaria-operational-plan.pdf?sfvrsn=5>. Accessed August 5, 2018.

⁴ President's Malaria Initiative – Table 2a - Myanmar Malaria Operational Plan Planned Obligations for FY2014 (Revised June 5, 2015). <https://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy14/fy-2014-Myanmar---revised-funding-table.pdf?sfvrsn=12>. Accessed August 5, 2018.

⁵ Promoting the Quality of Medicines (PQM). (2017). *Summary of Key Program Accomplishments and Outcomes: PQM/RDMA Close Out Report (2010–2017)*. Rockville, MD: U.S. Pharmacopeial Convention. [Page 14](#).

ASSESSMENT METHODS AND LIMITATIONS

DATA COLLECTION METHODS

The assessment team employed a mixed-methods design that drew upon document review, primary qualitative data collection, and review and analysis of available secondary quantitative data ([Annex B](#)).

DOCUMENT REVIEW

A comprehensive document review provided background knowledge on existing national policies, international standards and best practices, regional programming with similar scope, capacity strengthening initiatives undertaken, and critical information on the status and outcomes for the Activity. A list of all documents consulted for this assessment appear in [Annex C](#). Although the assessment team did not conduct a special desk-based gender assessment, as will be described in subsequent sections of this report, gender and social considerations underlie data collection, analysis, and report preparation.

KEY INFORMANT INTERVIEWS (KIIs)

Key Informant Interviews (KIIs) were the primary method of qualitative data collection for the assessment. Key informants were PQM technical and program management team, DFDA senior administrators and senior staff, technical staff and trainers of Myanmar Pharmaceutical Chemistry Laboratory, and MOHS senior staff. These key informants were asked for perceptions of and data on improved drug quality monitoring, activity QA, and capacity strengthening for inspection and surveillance (please see [Annex D](#) for data collection protocols and [Annex E](#) for list of interviewees).

Figure 1. Locations selected for Fieldwork

DIRECT OBSERVATION

Direct observation was not an explicit feature of the original assessment design, but fieldwork in Mandalay and Nay Pyi Taw (*Figure 1*) enabled the assessment team to briefly visit DFDA laboratory facilities in those locations.

SAMPLING

LOCATIONS/SITES

As depicted in *Figure 1*, three locations were selected for primary data gathering: Yangon, Mandalay, and Nay Pyi Taw. These locations were purposively selected based on the specific KII target stakeholder groups (see next section for description of respondents). There were also remote (virtual) KIIs with individuals who were not physically available to the team during the designated period of data collection.

RESPONDENTS

There were 10 total KIIs. *Table 1* presents target and actual sample sizes by respondent type. Some KIIs were conducted as individual interviews and some were conducted as two-person interviews. Sixty-two percent of respondents were female. Four out of the 5 Drug Quality Monitoring KIIs with DFDA respondents were with females. All PQM respondents were male.



TABLE 1. SAMPLE SIZES, ACCORDING TO LOCATION, RESPONDENT

LOCATION	RESPONDENT TYPE	NUMBER OF KIIs	
		TARGET	ACTUAL
Yangon	PQM	1-2	1
	USAID	--	2
Nay Pyi Taw	DFDA—Senior Personnel	1-2	1
	DFDA Pharma Reps (Chem Lab Quality Monitoring)	1-2	1
Mandalay	DFDA—Drug Monitoring	--	1
	Pharma Chem Labs	--	2
Remote	PQM (USA)	As needed	2
ALL LOCATIONS/RESPONDENT CATEGORIES FOR DRUG MONITORING		10	

ETHICAL ISSUES

The assessment was conducted in accordance with USAID Ethics Standards in Research Policies and the ethical guidelines and processes of the Department of Public Health's (DPH) Ethics Review Committee (ERC), including an in-person briefing of the DPH ERC in Nay Pyi Taw in July 2018.

FIELDWORK

Most KIIs were conducted by a two-person SI Team consisting of the Team Leader and the Research Specialist ([Annex F](#)). All three Mandalay-based interviews were conducted in a combination of English and Myanmar language, and the remaining KIIs were conducted in English.

DATA ANALYSIS

In answering the AQs, the assessment team triangulated evidence across stakeholders and data sources. The assessment team disaggregated the data by task and used content and comparative analysis with the coded KII notes. The team analyzed the qualitative data in tandem with any available quantitative data (e.g., in progress reports, workplans, performance management plans (PMPs), and other records shared by the IP). Data were associated with each assessment question, draft conclusions based on these data, and recommendations developed based on this evidence.

LIMITATIONS

Considerations of gender equality and social inclusion were central to the assessment team's approach to the assessment design, data collection, analysis and report writing. However, an inherent gender imbalance in most key respondent categories, as highlighted in the sampling section, limits the extent to which gender-disaggregated findings could be presented.

- ❖ **Mitigation strategy:** For some quantitative evidence (e.g., number of training participants), the assessment team has presented gender-disaggregated data. As will be described in subsequent sections of this report, there are also some noteworthy gender-related qualitative findings and conclusions.

Staff turnover/flux in most respondent groups increased the level of difficulty in either gaining access to originally targeted respondents or capturing the perspectives and/or experiences of particular types of respondent.

- ❖ **Mitigation strategy:** The assessment team was successful in tracking down a number of originally targeted respondents and conducted in-person or virtual interviews with those individuals.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

AQ 1: IN WHAT WAYS AND TO WHAT EXTENT WAS THE DFDA'S INSTITUTIONAL CAPACITY STRENGTHENED TO MONITOR DRUG QUALITY AS A RESULT OF USAID ASSISTANCE?

1A. WHAT FACTORS (INTERNAL AND EXTERNAL, INCLUDING ENABLING ENVIRONMENT) CONTRIBUTED TO THE EARLIER-THAN-ANTICIPATED ATTAINMENT OF DFDA'S ISO ACCREDITATION OF THE NAY PYI TAW LABORATORY?

FINDINGS

Internal Factors

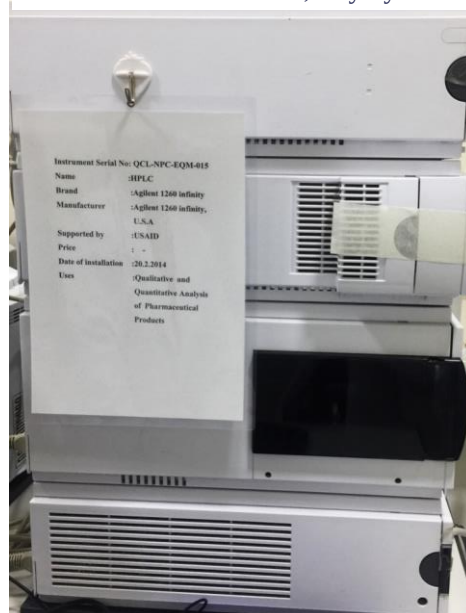
In 2017, Myanmar obtained ISO 17025 accreditation for its Pharmaceutical Lab in Nay Pyi Taw.⁶ In multiple countries, PQM has supported labs through the process of achieving ISO accreditation that generally takes 18–24 months. Myanmar was able to achieve accreditation in 12 months. The assessment documented that key internal factors were at play, namely political will and MOHS commitment. Respondents overwhelmingly reported that DFDA leadership and staff were invested in achieving ISO 17025 accreditation and were highly receptive to PQM TA. This core internal factor was supported by the large increase in available DFDA staff over the past five years and mobilization of additional financial resources to support institutional strengthening (e.g., for construction of new laboratory facilities. Equipment procurement and other requirements for accreditation).

External Factors

TA and capacity-building support provided by PQM was the primary external factor that contributed to the early achievement of ISO 17025 accreditation. PQM donated one dissolution tester and one High-Performance Liquid Chromatography system (HPLC) to DFDA's Nay Pyi Taw Lab in FY14 (*Figure 2*), along with a maintenance warranty plan that was valid for up to two years after the date of installation of the equipment.⁷ PQM also assisted the Nay Pyi Taw Lab in preparing for ISO 17025 accreditation by helping DFDA establish the Quality Management System (QMS) at the lab.

Since December 2013, PQM conducted nine different training events in Myanmar (*Box 2*).⁸ PQM's data dashboard for Myanmar indicates that 114 quality assurance guidelines or procedures were developed/updated and submitted for adoption since the start of PQM's work in Myanmar. These guidelines/SOPs were updated on an annual basis. Stakeholders noted how all PQM inputs were vital, since DFDA had the will but not the technical know-how to achieve ISO 17025 accreditation of its Nay Pyi Taw Pharmaceutical Lab.

Figure 2. HPLC Donated by PQM to DFDA Pharmaceutical Lab, Nay Pyi Taw



⁶ PQM. 2018. Annual Performance Report FY 2017, October 1, 2016–September 30, 2017.

⁷ PQM. 2014. Proposed FY15 Work Plan for Technical Assistance on Improving Antimalarial Medicines Quality in Myanmar, Implementing Period: October 1, 2014 – September 30, 2015. Re-submitted 11/29/2014.

⁸ Spreadsheets with data/information on training details, training participants provided by PQM in July/August 2018.

Box 2. PQM Trainings by Topic

1. Training on Standards of ISO 17025 and Quality Management System (QMS)
2. Hands on training on Ultra Performance Liquid Chromatography/ Liquid Chromatography–Mass Spectrometry (UPLC/LC-MS) and determining the assay and dissolution properties of DHA and Piperaquine
3. Training on Internal Audit, Corrective Action and Preventive Action (CAPA), Root Cause Analysis and standard operating procedure (SOP) writing
4. Technical Training on 8 scopes of ISO 17025 Accreditation
5. Training on Uncertainty of Measurement
6. Training on Titrimetry
7. Method training for DFDA Nay Pyi Taw, Mandalay and Yangon on Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Data Integrity, HPLC, Dissolution and Limit of Detection (LOD)
8. Quality Management System (QMS) Training
9. Capacity Building Workshop on testing of Deltamethrin Coated Long-lasting Insecticidal Nets (LLINs) by Gas Chromatography and HPLC

DATA SOURCES: PQM spreadsheets on Drug Quality Monitoring trainings

DFDA used the specifications for the PQM-donated equipment to guide its procurement of additional quantities of the same equipment, using resources mobilized by the Government of Myanmar.⁹

The issue of substandard laboratory infrastructure was one that had to be addressed to achieve international accreditation. PQM's gap assessment revealed that poor infrastructure had to be prioritized to achieve accreditation, and DFDA reshuffled its budget to address this gap accordingly. Although DFDA had the dedicated financial resources, it did not have the requisite lab design capacity. PQM provided lab design TA for the Nay Pyi Taw Lab, as well as the yet-to-be-opened Mandalay Lab, to ensure that lab rooms and

overall construction enhanced: (a) workflow, (b) physical safety, and (c) compliance with ISO 17025 and WHO prequalification building requirements. Respondents gave specific examples of critical issues that were addressed including airflow/ventilation, maintaining sample integrity, specimen transport and storage within the facility, removal of fire hazards and other safety threats to staff and the general public (e.g., suboptimal waste management), and secured access to the compound (to prevent break-ins and drug/property theft).

CONCLUSION

The main conclusion is that earlier-than-anticipated ISO accreditation for the Nay Pyi Taw Laboratory exemplified DFDA's heightened capacity, which was achieved through (I) DFDA's mobilization of requisite resources to meet ISO 17025 accreditation standards (internal) and PQM's infusion of state-of-the-art TA and capacity-building support (external). Both were necessary factors underlying the accreditation achievement.

1B. WHAT FACTORS ARE/ARE NOT IN PLACE TO ENSURE THAT STRENGTHENED CAPACITY CAN/WILL BE SUSTAINED?

FINDINGS

Facilitative Factors

The assessment revealed that the following factors were in place to ensure that strengthened capacity will be sustained:

⁹ PQM. 2017. Proposed Work Plan for Myanmar, Implementation Period: October 1, 2017–September 30, 2018 (FY18), page 7.

Government Financing: Financing was, by far, the most-prominent factor mentioned. Respondents noted that DFDA had increased financial resource allocation for some key aspects of institutional strengthening (e.g., infrastructure strengthening, accreditation).

Availability of State-of-the-art Equipment to Put Acquired Technical Capacities into Practice: Since the start of the Drug Quality Monitoring Activity, DFDA has made major strides in terms of the availability of state-of-the-art equipment, including the deployment of Minilabs to states/regions. PQM only donated one HPLC system and one dissolution tester, which have served as benchmark for subsequent DFDA procurements. The Government of Myanmar has made all other equipment procurements.

Improved Lab Infrastructure: Almost all KII respondents consulted for the capacity assessment noted that improvements in lab infrastructure will bode well for sustainability, if matched by the requisite budgetary resources to finish construction projects (e.g., in Mandalay), in compliance with the ISO specifications advised by PQM.

A Burgeoning Organizational Structure as the Groundwork for Enhanced Lab Capacity Nationwide: Between 2014 and 2015 alone, DFDA opened 12 regional field offices and five border offices; in 2017, DFDA opened 28 district field offices.¹⁰

In-house Training Capacity: As will be described in further detail under AQ 1e, with support from PQM, DFDA established a critical mass of master trainers within its Nay Pyi Taw Lab. One senior PQM respondent noted that DFDA is now conducting multiple trainings to a very high standard, with only remote (virtual) PQM support.

Gaps

Timely Allocation of Available Financial Resources: Despite increased overall availability of funds to support institutional strengthening, there are perceived issues with how those financial resources are being allocated. For example, respondents in seven KIIs expressed concerns that staff salaries and critical DFDA functions/activities that are vital to ensuring drug quality such as post-marketing surveillance and enforcement and maintenance/servicing of equipment are still underfunded.

Diversified Financing: Some key informants expressed concerns that DFDA relied heavily on Government of Myanmar funding, with its labs charging nominal client fees for quality control testing services. PQM proposed a fee-for-service model for adoption by the DFDA to enable the lab to become more self-sustainable and be a step closer with other internationally accredited laboratories in the region.

Reliance on External Providers for Some Key Aspects of Drug Quality Monitoring: The country does not have metrology capacity and has relied on proficiency testing services from a provider in England, including sourcing essential supplies such as lab reagents externally (e.g., from Europe). PQM and DFDA respondents raised the issue of the US and European Union trade sanctions¹¹ and underscored the need for the country to develop the capacity or identify alternative channels for supplies and support. Some DFDA informants also expressed concerns about the cost and sustainability implications of the country's reliance on external providers for instrument calibration support.

Human Resources: According to half of the KII respondents, some qualified Nay Pyi Taw Main Lab staff who underwent PQM training and coaching are not currently posted within the Nay Pyi Taw Lab. For example, a small number of Nay Pyi Taw staff transferred to state/regional labs, one left the public sector altogether, and two are currently out of the country pursuing PhDs with Government support.

¹⁰ PQM. 2017. Proposed Work Plan for Myanmar, Implementation Period: October 1, 2017–September 30, 2018 (FY18), page 9.

¹¹ According to the following source, the US imposed targeted sanctions (under the Global Magnitsky Act) in December 2017 for human rights abuses involving the Rohingya people US State Department. July 1, 2018. *US Relations with Myanmar*. <https://www.state.gov/r/pa/ei/bgn/35910.htm>. Accessed September 1, 2018.

One PQM key informant noted that there were attempts to reduce turnover. The previous DFDA Director General (DG) instituted a requirement for Nay Pyi Taw personnel to be based in the lab for a minimum of 2-3 years before leaving. However, because most Nay Pyi Taw staff are young females—20-30 years old, on average—and have no personal ties to (and limited social options in) Nay Pyi Taw, once they meet that obligation, they leave.

Keeping Pace with Expansion: The Nay Pyi Taw Pharmaceutical Lab has become a training hub and has established a core group of laboratory master trainers for DFDA, with coaching support from PQM. However, at present, only a small proportion of DFDA's ever-expanding staff pool can benefit directly from the structured trainings provided at the Nay Pyi Taw facility by the trainers. This point was raised by half of key informants. Some DFDA respondents expressed the need to increase the number of trainings being offered to reach more staff.

CONCLUSIONS

Increased financing and an expanded, motivated human resource pool were demonstrations of DFDA's commitment to institutional strengthening. However, inputs and processes related to those two factors still need to be optimized to sustain capacity gains.

Critical gaps remain such as the need for sustainable financing mechanisms and in-country capacity to perform advanced laboratory functions. These gaps must be addressed to empower DFDA to remain on an upward trajectory of resource mobilization and organizational growth.

Although Government efforts were underway to strengthen DFDA's presence and capacity nationwide, the enabling environment (e.g., critical mass of trainers, state-of-the-art infrastructure, state-of-the-art equipment) for sustained capacity strengthening remains fairly concentrated in and limited to Nay Pyi Taw.

1C. ARE CAPACITY STRENGTHENING OUTCOMES AT INDIVIDUAL AND ORGANIZATIONAL LEVELS MEASURED FOR LEARNING AND IMPROVEMENT, AS WELL AS FOR ACCOUNTABILITY?

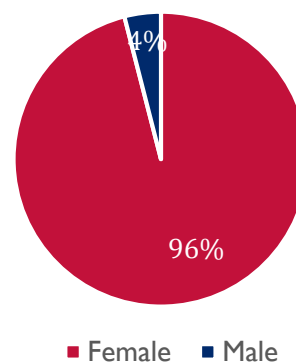
FINDINGS

All stakeholder types consulted for the assessment mentioned that DFDA did not have robust information systems, whether for its technical work or for HR management. However, the ISO 17025 accreditation/re-accreditation of the Nay Pyi Taw Main Lab was the major priority in terms of level of effort for both DFDA and PQM over the past five years. In all 10 KIs, respondents regarded the accreditation achievement as a sign of capacity strengthening at the organizational level.

Assessing individual capacity strengthening: There were no readily available longitudinal data on individual DFDA trainees, whether by DFDA or by PQM. Nonetheless, PQM's training records for Myanmar indicated there were 177 participants across 9 different Drug Quality Monitoring trainings for specific lab competencies, with 96% of those participants being female (Figure 3). This large number of female trainees reflects the predominance of females among lab personnel, not a deliberate targeting strategy by PQM.

Two lab technicians who attended multiple PQM-supported trainings noted that changes in their knowledge and skills were assessed via pre- and post-tests during the actual trainings. There was no post-training follow up or assessment. A former Nay Pyi Taw

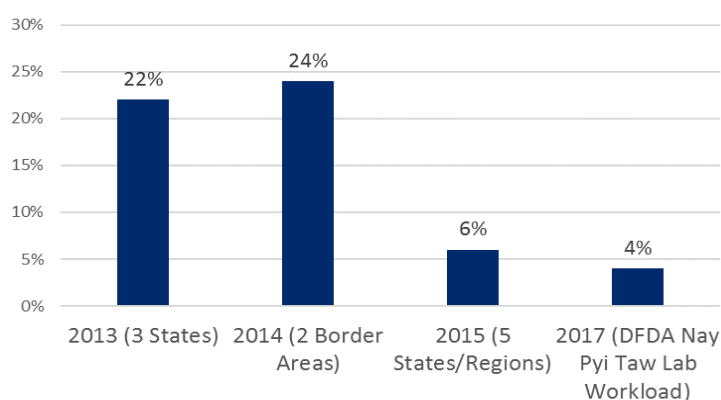
Figure 3. Proportion of Female versus Male Drug Quality Monitoring Training Participants (n=177)



Quality Officer who is now based elsewhere corroborated that post-training follow-up and supportive supervision needed to improve.

Additional outcomes used to gauge organizational capacity strengthening: As an Activity, PQM's Monitoring and Evaluation (M&E) Framework included indicators such as "Number of quality control laboratories that have passed the proficiency test/inter-laboratory test." Through September 2017, only the Nay Pyi Taw quality control laboratory had participated in proficiency test/inter-laboratory testing, which resulted in a pass.¹²

Figure 4. Drug Failure Rates (Falsified/Substandard) from Different PMS Assessments in Different Locations, Myanmar, 2013-2017



DFDA's ability to perform laboratory functions for external clients was documented by PQM. For example, PQM's FY18 Second Quarter report noted "In FY 2018 Q2, DFDA laboratory tested samples from external clients such as Defeat Malaria and it was sought to test insecticide-treated nets."

DFDA achieved other milestones. Drug quality was one arena in which there were strides. PQM supported post-marketing surveillance (PMS). While data were not directly comparable due to the fact that the surveys focused on different geographies, there appeared

to be an improving trend (Figure 4). The surveys found lower drug failure rates over time.¹³ According to one PQM key informant, for the past two years, DFDA was able to conduct PMS surveys without any TA from PQM. Also, in 2017, DFDA successfully made one presentation on medical products quality assurance at the Burmese Annual Research Congress ("Quality Assessment of Antimalarials in Two Border Areas, Tamu and Muse") and later published their results in the *Myanmar Health Sciences Research Journal*, Vol. 28(1) in 2016. Dr. Khin Chit, Deputy DG of DFDA, was the lead author, with PQM's in-country adviser, Dr. Lu Lu Kyaw, listed among the co-authors.

CONCLUSIONS

Routine monitoring of capacity building within DFDA was largely limited to tracking training outputs (e.g., numbers of trainings, numbers of trainees), not changes in performance.

There were, however, high-level milestones and achievements (e.g., ISO 17025 accreditation, DFDA ability to produce presentations/publications on medical products quality) that both DFDA and PQM regarded as indicative of enhanced DFDA capacity.

Investments in strengthening drug monitoring capacity were exhibited in the form of enhanced surveillance and the documented lowered presence of substandard/falsified drugs in the marketplace.

ID. HOW DID THE PROJECT'S DESIGN CONTRIBUTE TO COUNTRY ENGAGEMENT AND OWNERSHIP?

FINDINGS

¹² PQM PMP for FY18.

¹³ DATA SOURCES: Myanmar Baseline Survey on Priority Antimicrobial Medicines in Selected Areas. 201; PQM Dashboard for Myanmar; PQM Factsheet on 2017 Lab Data, Myanmar.

PQM used a field-tested, internationally endorsed technical approach to ensure drug quality, which entailed: (1) visual and physical inspection, (2) rapid analytical tests, and (3) quality control testing according to the product's registration specifications.¹⁴ As described below, there were also ways in which its activity design in Myanmar contributed to country engagement and ownership.

Collaborative Learning Model to Diffuse Learning and Practices across DFDA: According to both PQM and DFDA respondents, PQM trainings took place in Nay Pyi Taw, with participation from multiple regions and states. Respondents noted that DFDA leadership embraced the cascade training and training of trainers approach on which PQM's Collaborative Learning Model was centered.

Given the nature of funding for Myanmar support (PMI), PQM had a very defined scope of work, focusing extensively on DFDA's Nay Pyi Taw Pharmaceutical Chemistry Laboratory, and on antimalarial drug quality. One PQM TA provider lauded DFDA staff for initiative taken to leverage PQM's inputs for wider institutional capacity strengthening. The respondent described how DFDA's PQM-trained master trainers from the Pharmaceutical Chemistry Laboratory invited other DFDA personnel (e.g., from Food and Cosmetics Labs) to raise their capacity in key areas (e.g., Quality Monitoring System), using skills, knowledge, and tools introduced by PQM.

Placement of an In-country PQM Adviser: With a limited operational budget for Myanmar activities, PQM drew on the expertise and contextual understanding of a laboratory expert who is a Myanmar national and is based in Yangon to serve as PQM's in-country technical resource for DFDA. This feature was mentioned specifically by USAID and PQM respondents as a departure from PQM's normal approach but crucial to ensuring counterpart engagement in Myanmar.

All DFDA respondents (male and female) expressed great satisfaction with the professional and collegial manner in which PQM TA providers, who are largely male, administered state-of-the-art TA and capacity-building support.

PQM TA Provider Relationship-building with DFDA: As noted in a 2016 report on gender in Myanmar, the country "has a mixed narrative on gender equality and women's rights."¹⁵ DFDA personnel were largely female and PQM TA providers for the Myanmar Activity have been largely male. Male and female DFDA respondents expressed great satisfaction with the professional and collegial manner in which PQM TA providers administered state-of-the-art TA and capacity-building support.

No KII respondents, whether from DFDA or PQM, expressed any challenges or concerns with the relationship or dynamics between PQM TA providers and DFDA personnel.

PQM maintained continuity of its in-country focal points and TA providers over the course of the Activity. Both DFDA and PQM key informants acknowledged that this helped to establish rapport and trust, and was effective in shifting the way in which DFDA as an institution approaches capacity building and human resource development. According to one IP and one DFDA respondent, PQM oriented DFDA leadership on the requirements for high-quality lab support, drug quality monitoring and accreditation. DFDA leadership, in turn, advocated with MOHS leadership (e.g., Minister) for additional resources for HR, lab infrastructure, equipment).

The strong relationship between the two entities is also reflected in how DFDA leveraged PQM in the midst of a drug quality scare in 2015, when DFDA did not have the capacity to perform the requisite drug

¹⁴ Pribluda VS, Barojas A, Coignez V, Bradby S, Dijiba Y, El-Hadri L, et al. The Three-Level Approach: A Framework for Ensuring Medicines Quality in Limited-Resource Countries. *Pharmaceutical Regulatory Affairs*. 2014, 3:1. <http://dx.doi.org/10.4172/2167-7689.1000117>.

¹⁵ Asian Development Bank, United Nations Development Programme, United Nations Population Fund, and the United Nations Entity for Gender equality and the Empowerment of Women. 2016. *Gender equality and Women's Rights in Myanmar: A Situation Analysis*. Asian Development Bank, United Nations Development Programme, United Nations Population Fund, and the United Nations Entity for Gender equality and the Empowerment of Women. <https://openaccess.adb.org>. Page xvii.

quality testing to thwart the occurrence of observed adverse drug reactions in the country. As noted in a 2015 report on “Quality Testing of TAZID”,¹⁶ and corroborated by a senior DFDA respondent, per DFDA’s request, PQM conducted quality testing of TAZID (1g Ceftriaxone) Injections, after several adverse drug reactions were observed in public hospitals in Myanmar. PQM found that samples did not comply with the requirements for the limit of pyridine and failed multiple impurities tests. According to one senior MOHS respondent, the country did not have the capacity to perform such testing, and this advanced drug testing support from PQM helped save lives.

SPOTLIGHT ON GENDER

Gender-related issues are discussed throughout this report. The following were some highlights:

- Across PQM’s 9 different Drug Quality Monitoring trainings, 96% of training participants were female. This large number of female trainees reflects the predominance of women among lab personnel, not a deliberate targeting strategy by PQM.
- Some qualified Nay Pyi Taw Main Lab staff who underwent PQM training and coaching were not currently posted within the Nay Pyi Taw Lab. Some stakeholders reported that most Nay Pyi Taw staff were young females—20-30 years old, on average—and had no personal ties to (and limited social options in) Nay Pyi Taw.
- DFDA personnel were largely female and PQM TA providers for the Myanmar activity were largely male. Male and female DFDA respondents expressed great satisfaction with the professional and collegial manner in which PQM TA providers administered state-of-the-art TA and capacity-building support. No respondents, whether from DFDA or PQM, expressed any challenges or concerns with the relationship or dynamics between TA providers and DFDA personnel.
- Stakeholders widely laud Dr. Khin Chit, Deputy Director General of DFDA, for both her technical and managerial leadership through all phases of the DFDA Activity.

CONCLUSIONS

Country engagement and ownership were internal factors that already existed as a complement to, not a by-product of, PQM’s activity design or program approach. There were no particularly unique or innovative aspects of PQM’s activity design in Myanmar, although how it structured its support to DFDA was effective and appropriate in leveraging local commitment and elevating engagement and buy-in to strengthen both individual and institutional capacity.

Although DFDA personnel were predominantly female, and PQM experts providing support to Myanmar were predominantly male, this gender dynamic had no perceptible negative impact on the USAID-supported Drug Quality Monitoring Activity or its outcomes.

IE. HOW DO THE DFDA’S INTERNAL FACTORS (STRUCTURE, POLICY, HUMAN RESOURCE MANAGEMENT PRACTICES, ETC.) AFFECT CAPACITY STRENGTHENING AT INDIVIDUAL AND INSTITUTIONAL LEVELS?

FINDINGS

Strong Political Will within DFDA Senior Management: The majority of stakeholders noted political will within DFDA was a critical success factor. More specifically, the former DG for DFDA and the Deputy DG (who has been a DFDA senior official since 2014) were committed to operationalizing technical knowledge and advice received from PQM to strengthen capacity at individual and institutional levels.

¹⁶ PQM. 2015. Report on the Quality Testing of TAZID* (1 g Ceftriaxone) for Injection Sample, August 26, 2015

Recruitment and HR Management Practices: Since initiation of the Drug Quality Monitoring Activity, many new laboratory and DFDA staff have been hired, including staff for new field offices in many states. The assessment highlighted numerous human-resource-related findings. First, both DFDA and PQM respondents expressed a need to recruit more individuals whose academic credentials are aligned with lab functions (e.g., attracting more pharmacists to apply for DFDA Pharmaceutical Chemistry Laboratory positions). Second, PQM-supported training reach did not keep pace with the unprecedented, rapid growth of DFDA as an institution—a point that was underscored in the majority of KII as a factor affecting institutional capacity strengthening. Notably, however, PQM’s focus on Nay Pyi Taw-based trainings was in compliance with Central-level DFDA’s request to host PQM-supported training on DFDA’s Nay Pyi Taw campus. Third, as mentioned in findings for AQ 1b, there were social dynamics that are specific to Nay Pyi Taw. However, a more-systemic factor was DFDA’s salary scale. DFDA’s below-market salaries were frequently mentioned as a deterrent to staff retention, particularly as trained staff were increasingly being recognized for their high individual capacity, domestically, regionally, and internationally. Fourth, as alluded to earlier, lab personnel are predominantly female. One PQM key informant noted that there was a push for gender diversity within DFDA. Although gender dynamics did not come into play between PQM and DFDA, the respondent noted that cultural beliefs related to the male-female dynamic among DFDA staff will be salient as the greater gender diversity is achieved in the workplace within DFDA (e.g., male lab employees’ receptivity/respect toward predominantly female master trainers and Quality Managers).

In-House Training Capacity: The Nay Pyi Taw Lab has become the training hub for DFDA. PQM provided training to support the rollout of Minilabs to identify falsified and substandard drugs in border areas. This Activity was consistent with the Government’s vision to rollout Minilabs nationwide. One senior PQM TA provider noted that DFDA’s trainers now conducted this training on their own and did it to an extremely high standard, without support from PQM. A PQM key informant noted that DFDA has operationalized a “Duty Station” concept, whereby staff from other parts of the country (e.g., Mandalay, Yangon) are based in Nay Pyi Taw for 3–4 months to undergo training, mentoring, and exposure to the most-state-of-the-art equipment. However, multiple DFDA key informants noted that there was the absence of an institutionalized mechanism for continuous, refresher training of DFDA’s ever-growing human resource pool.

Highly Centralized Structure: According to one IP respondent who was actively involved in PQM’s Myanmar activities, unlike in the Yangon and Mandalay Labs, the Nay Pyi Taw Pharmaceutical Lab has a clear structure and hierarchy to help institutionalize QA expertise and internal capacity building. More specifically, there is a tiered structure, whereby the QA Manager identified a suitable backup (or “Deputy”), amongst her subordinates. That person was mentored by the QA Manager to lead, train, and provide QA oversight in the absence of the QA Manager. In a separate KII, a DFDA respondent noted that a similar structure did not exist outside of Nay Pyi Taw, which has implications in terms of institutional capacity strengthening and sustained QA.

Resources to Transition from Policy to Practice: Half of stakeholders consulted expressed concern with the availability of operational resources. They noted that overarching DFDA-related policies (e.g., Food Law) existed or were being updated. However, enforcement of laws was limited. They noted that there were isolated cases of drug quality enforcement that received media attention. However, one DFDA respondent mentioned the limited operational resources to support fieldwork for enforcement of drug quality monitoring, with some DFDA staff assuming out-of-pocket expenses and using personal vehicles to conduct drug quality monitoring fieldwork.

In-country Expertise related to Lab Infrastructure: The limited in-country expertise related to laboratory design was raised in half of KIIs. PQM was informally consulted to improve lab designs in Nay Pyi Taw and Mandalay, although input was solicited after original designs were prepared and, in the case of Mandalay, when construction was near-complete. Nonetheless, PQM supported DFDA (e.g., by engaging German expertise in lab design to provide design support to DFDA) in preparing new lab

designs/plans and taking corrective measures to render existing infrastructure more fit for purpose. Some of the key design support provided was in the areas of air flow and ventilation, waste management, sample transport, maintenance of sample integrity and room design. Physical safety was another key area of design support and included ensuring fire exits are functional and placement of the canteen away from the chemical lab.

Institutional Level of Effort in Geographical “Hot Spots” vis-à-vis Drug Quality: Because substandard and falsified drugs were most commonly found in Yangon and Mandalay, and not Nay Pyi Taw, two PQM key informants and one MOHS key informant underscored that there is a need to decentralize some of the enhanced capacity established in Nay Pyi Taw to the other two main labs in Yangon and Mandalay.

CONCLUSIONS

DFDA’s rapid and extensive growth requires a re-examination of its institutional policies and practices related recruitment and human resource management (e.g., academic credentials for recruitment/hiring of laboratory personnel (e.g., distinguishing between a degree in chemistry versus pharmacy versus medicine) in order to maximize both individual and institutional capacity strengthening.

Although some measures are being taken to strengthen/expand DFDA across the country, the nucleus of state-of-the-art lab standards and capacity was in Nay Pyi Taw, which was not necessarily aligned with need. There is a need to adopt approaches and tools that can amplify capacity strengthening across the country, not just in Nay Pyi Taw.

DFDA made efforts to leverage increased capacity of the Pharmaceutical Chemistry Lab to benefit DFDA as a whole, but its approaches and mechanisms need to be formalized to further extend the reach of those capacity-building practices.

There were signs of suboptimal financing for decentralized implementation of state-of-the-art laboratory practices and functions, including drug quality enforcement.

RECOMMENDATIONS FOR AQ I

For USAID

- I. Building on insights from DFDA’s exemplary approach to institutional strengthening over the past five years, USAID should **support the new DFDA Director General and other senior DFDA/MOHS leadership to systematically assess and further strengthen building blocks for sustainable institutional capacity development.** For example, this can be achieved by supporting an institutional review of:
 - i. internal policies (e.g., on HR recruitment and management) that can support further development and retention of government-sector laboratory capacity
 - ii. information system(s) to monitor performance at different levels, including a set of indicators (e.g., drug failure rates in sentinel locations, proficiency testing scores of main laboratories) that can be used as part of a ‘critical alert system’ for Quality Managers to identify and respond to individual and institutional capacity gaps within DFDA
 - iii. infrastructure (including the maintenance of existing infrastructure and in-country laboratory design capacity)
 - iv. the current state of DFDA HR (including the levels and distribution of different competencies/skillsets across the country)

For DFDA

2. DFDA should develop/revise a DFDA-specific HR strategy and an approach to (a) optimize recruitment of qualified females and males with appropriate credentials for laboratory work (e.g., degree in chemistry) and (b) cultivate in-country capacities that can introduce cost savings and/or optimize and sustain outcomes, specifically in:
 - a. Calibration and equipment maintenance
 - b. State-of-the-art/fit-for-purpose laboratory design
3. DFDA should **develop a five-year costed work plan to: (a) maintain ISO 17025 accreditation status of the Nay Pyi Taw Pharmaceutical Laboratory and (b) achieve ISO 17025 accreditation in Mandalay and Yangon laboratories.** It is advised that, in addition to addressing requirements to maintain ISO accreditation, the plan supports the long-term vision to strengthen systems and mechanisms to link the three main laboratories (e.g., through enhanced inter-lab communications) to optimize the transfer of learning, processes and protocols from Nay Pyi Taw laboratories to the other main laboratories. This might also entail formalizing the Nay Pyi Taw lab as a Center of Excellence where staff from the other labs can hone state-of-the-art laboratory skills and be coached in cascading skills to others in their labs.

For PQM

4. PQM should **support DFDA in enhancing its cascade approach to individual and institutional strengthening**, with explicit aims of:
 - a. Minimizing the training and quality assurance (QA) burden placed on the corps of master trainers/Quality Managers based in the Nay Pyi Taw main laboratory
 - b. Extending training reach (e.g., through the introduction of digital platforms for theoretical learning) for DFDA's ever-expanding HR pool
 - c. Leveraging newly developed capacities that may exist at state and/or regional levels (including but not limited to former Nay Pyi Taw Lab staff who now work in other parts of the country)
 - d. Strengthening DFDA information systems to support HR management and performance monitoring, including post-training follow up assessment
 - e. Addressing system requirements for transitioning from trainings to improved implementation (e.g., ensuring that the budget and operational requirements are in place to support drug quality monitoring enforcement, enhancing supportive supervision) in critical hubs such as Mandalay
 - f. Exploring the introduction of innovative technologies to support and improve frontline performance, as DFDA becomes increasingly decentralized
5. PQM should provide support to DFDA in the development and implementation of a **strategy/plan for sustainable financing, including a revised fee structure** for laboratory services.

AQ 2: WHAT SPECIFIC LESSONS CAN BE LEARNED AND APPLIED TO OTHER FUTURE PROGRAMS AND ACTIVITIES IN MYANMAR?

2A. WHAT EXPERIENCES, ELEMENTS, OR KEY INPUTS WERE COMMON FOR THESE TWO CASES THAT LED TO THEIR SUCCESS?

FINDINGS

Exemplary Senior-level Leadership within MOHS: All stakeholders have lauded the strong leadership from high-ranking officials within MOHS. In addition to the DG, Dr. Khin Chit (Deputy DG, DFDA) was widely mentioned as a manager of organizational change, not just as an excellent manager of technical implementation of USAID-supported activities within the MOHS. She was also one of the inaugural recipients of the US Embassy’s “Women of Change” award in 2017 (Figure 5).¹⁷

Extremely High Government Buy-In: Even with turnover in the highest MOHS position (Minister), there was continuous support by DFDA’s senior leaders (DGs, Deputy DGs). Respondents specifically highlighted that DFDA “matched” USAID-funded TA with Government of Myanmar resources (e.g., equipment) and highly motivated and receptive staff. A strong desire on the part of DFDA senior and junior staff for Myanmar’s performance to stand up to international scrutiny such as in the area of compliance with international lab accreditation standards, was mentioned as a driver of success.

Trust and Rapport between Government Counterpart and TA Provider: Respondents identified that maintaining the continuity of TA providers assigned to the country set the stage for trust- and rapport-building between PQM and DFDA.

CONCLUSIONS

- Effective institutional strengthening was predicated on demonstrated resource commitments from DFDA counterparts, not just an infusion of TA.
- Relationship building and trust building between the PQM and DFDA were critical success factors in the institutional strengthening of DFDA.
- Staff willingness to learn and their motivation for DFDA’s work to be recognized as being on par with international standards are enabling factors for institutional strengthening.
- Within DFDA, strong management capacity—not just technical capacity—existed within focal persons/leaders, particularly senior female leadership, who had the vision and ability to manage organizational change.

Figure 5. Photo of Women of Change Recipients—Dr. Khin Chit, third from left (SOURCE: US Embassy/Myanmar website)



2B. WHAT PRACTICES SHOULD (NOT) BE APPLIED FOR FUTURE INSTITUTIONAL STRENGTHENING ACTIVITIES?

FINDINGS

¹⁷ US Embassy in Myanmar. Program from US Embassy Yangon Women of Change 2018 Awards Ceremony. <https://mm.usembassy.gov/wp-content/uploads/sites/41/2018-Women-of-Change-Award-Reception-Pamplet-English.pdf>. Accessed on August 3, 2018.

Government Mobilization of Resources: Government of Myanmar mobilization of resources (e.g., financing, HR, equipment, infrastructure) to fully leverage TA and institutional strengthening inputs was widely acknowledged to be a key practice that should be replicated in future institutional strengthening activities.

Structured Management of Handover between PQM and DFDA: One PQM respondent mentioned that a clear handover and risk management strategy must be developed to structure and manage the systematic transfer of knowledge, skills, and responsibilities between the IP and the Government of Myanmar counterpart. Both PQM and DFDA stakeholders mentioned having mechanisms for quality monitoring (e.g., via direct observation, virtual monitoring) of counterpart performance, as well as the provision of troubleshooting support as counterparts assume more responsibilities, as part important aspects of handover.

Multiple stakeholders also mentioned the importance of developing a mechanism for tracking and maintaining the engagement of persons who have benefitted from skills development and capacity building. This way, their newly-acquired capacity could be tapped, even if they left the specific unit or position in which they were originally trained.

Tangible, Internationally-recognized Outcomes Products, with a Clearly-defined Path toward Achievement: Respondents noted that identification of ambitious international standards were key in keeping DFDA staff motivated and engaged and served as the basis for a tangible, common goal between PQM and DFDA. ISO 17025 accreditation was the achievement of focus. Both USAID and PQM stakeholders held the belief that, in striving for this goal that learning how to function as a coherent yet adaptive system was key, and that PQM provided tried-and-true models for accomplishing that.

Cultivating Skills Transfer: Although shared by multiple stakeholders, DFDA stakeholders, in particular, underscored that, in addition to investing in the development of technical capacity within a critical mass of individuals, it was important to dedicate resources and tools to strengthen teaching and training capacity and mechanisms to institutionalize learning and support effective cascading of knowledge and skills.

CONCLUSIONS

- As a complement to institutional strengthening, counterparts must provide requisite inputs (e.g., HR, equipment, infrastructure) to leverage institutional strengthening.
- A clear strategy for institutional strengthening, preferably linked to international standards and international recognition, as well as a strategy for handover between Government counterpart and TA provider must be in place.

3C. WHAT PRACTICES SHOULD (NOT) BE APPLIED FOR FUTURE TECHNICAL ASSISTANCE ACTIVITIES (WHERE THE PRIMARY OBJECTIVE MAY NOT BE INSTITUTIONAL STRENGTHENING)?

FINDINGS

Mitigating Capacity Erosion that May Result from Staff Attrition: The overwhelming majority of respondents mentioned that, with both national and international recognition of the increased capacity of trained DFDA personnel, DFDA staff were now extremely attractive targets for other employers, particularly those that can offer salaries that exceed the MOHS salary scale. There was evidence that some DFDA staff have left MOHS to pursue opportunities in the private sector and/or have considered higher-paying opportunities outside of the Government sector.

Recruitment and Placement of an In-Country Adviser: Both DFDA and PQM respondents spoke about the recruitment and placement of an in-country adviser who can be the primary liaison between the IP and Government counterpart to: (a) maintain open lines of communication, (b) facilitate timeliness of TA provider actions in response to identified and/or expressed TA needs, and (c) elevate the rigor/quality of on-going counterpart efforts that are within the IP's mandate/scope of work.

Open Line of Communication between Donor, Counterpart, and TA Provider: USAID and PQM staff also placed a high value on mutual commitment to fostering a collegial, open, and productive relationship between the IP and the Government of Myanmar counterparts, as well as ensuring that there was a direct line of communication between the PQM and DFDA. The Mission was also kept abreast to ensure that it had a clear understanding of: (a) priority TA needs that might have a major bearing on the achievement of quality outcomes and (b) the importance of timely funding release to support effective TA to address identified support needs.

CONCLUSIONS

The main conclusion drawn from the above findings is that when the primary objective is not institutional strengthening, activity design and administrative arrangements must facilitate nimbleness/responsiveness to on-the-ground support needs within a dynamic, ever-changing program context (e.g., changing socio-political landscape, changes in international trade conditions).

RECOMMENDATIONS FOR AQ 2

For USAID

1. USAID should consider **“phase-gate” provisions to foster mutual accountability between TA providers and Government counterparts such as DFDA**. The project cycle would be divided into distinct phases, each culminating in a specific set of capacity development/handover milestones. At the end of each phase, decisions would be made between USAID, DFDA and PQM regarding the scale and/or scope of program activities for the subsequent phase. For example, before initiating Mission-supported program activities and interventions, develop and apply criteria to establish the state of “readiness” of the counterpart agency/recipient institution for TA and/or capacity-building support. Two such criteria might relate to the existence of a costed workplan/investment plan and the availability of Government of Myanmar counterpart resources (human, financial, infrastructural) to fully leverage TA and capacity-building inputs from USAID IPs. In the spirit of mutual accountability, USAID would require IPs to report on pre-determined milestones and indicators to monitor handover and risk management over the course of Activity implementation.
2. To assist DFDA in fully exploiting investments in lab quality improvement (e.g., processes, equipment, infrastructure), USAID should support **HR system strengthening** (e.g., recruitment of lab technicians with appropriate academic/professional credentials, post-training follow-up and supportive supervision) within DFDA.

For PQM

3. PQM should institute mechanisms and checkpoints over the course of implementation to **re-assess and, if necessary, reprioritize support needs to ensure timeliness and responsiveness of technical support**. For example, this can be achieved through periodic (e.g., quarterly or semi-annual) TA needs assessment (e.g., quarterly, semi-annually) within the course of each program/fiscal year to ensure alignment and responsiveness of external, USAID-supported TA provision to local TA needs.
4. In the interest of fostering rapport and trust with counterparts, **maintain continuity of mentors/TA providers** (i.e., the same focal person/pool of experts assigned to the country to provide TA and capacity-building support over the life of the program).

ANNEXES

ANNEX A. ASSESSMENT SCOPE OF WORK

EVALUATION OF HEALTH SECTOR CAPACITY DEVELOPMENT THROUGH USAID PROGRAMMING IN MIDWIFERY, DRUG QUALITY MONITORING, AND SURVEY IMPLEMENTATION

I. PURPOSE OF THE EVALUATION

This evaluation will examine how USAID-supported programming has affected the development of Myanmar national capacity in several areas, looking at key dimensions of human and institutional capacity and commitment. The study is divided into two components with two distinct deliverables, one focused on midwifery and in-service training for health care workers in maternal, neonatal and child health, and the other focused on two specific departments in the Ministry of Health and Sports (MOHS) that have received technical assistance through USAID programs: Department of Food and Drug Administration (DFDA) and the Department of Health Planning (DHP). At the conclusion of the studies, a dissemination event will be organized to share findings with key stakeholders, including implementing partners and the MOHS.

A. Component A: End-line Performance Evaluation of Maternal and Child Survival Program (MCSP)

Contractor will conduct an external endline performance evaluation for the Maternal and Child Survival Program (MCSP), a 3-year, \$8.1 million field support buy-in to the MCSP global mechanism, and support dissemination of findings.

The purpose of this evaluation will be to examine the extent to which MCSP's interventions influenced the country's capacity and systems for in-service training of health workers to improve availability and quality of maternal and newborn care services. The evaluation will analyze the effectiveness of the in-service capacity building approaches supported by MCSP, including the Learning and Performance Improvement Center (L&PIC) model, the roll-out approach for competency based capacity building at the state/regional level and below, the standards-based quality improvement model introduced at selected training sites, and complementary efforts to strengthen institutions such as the Myanmar Nurse and Midwifery Council and Myanmar Nurse and Midwives Association (MNNMC and MNMA).

This information will be used to inform approaches for continued strengthening of in-service training at lower levels of the health system under USAID's follow-on Essential Health program, and to generate recommendations for USAID or other development partners on how to optimize support to the MOHS to deliver integrated in-service training interventions and build related country systems through future programs.

B. Component B: Assessment of Institutional Capacity Building of

Myanmar Department of Food and Drug Administration (DFDA) and Department of Health Planning (DHP)

This assessment will document the achievements, challenges, and lessons learned from two USAID-funded institutional capacity strengthening activities: 1) Strengthening drug quality monitoring capacity of the Myanmar Department of Food and Drug Administration (DFDA) and 2) Implementation of the Myanmar Demographic and Health Survey (DHS) in 2015-2016 and associated support to the Ministry of Health and Sports, Department of Health Planning. The purpose of this assessment is to better understand and document the extent to which institutional capacity was strengthened in these two institutions, and the key factors associated with USAID's programming approaches that enabled and/or worked against capacity strengthening and local ownership, in order to inform the design of future technical assistance and institutional strengthening activities in Myanmar. The contractor will also support the dissemination of findings.

II. SUMMARY INFORMATION

COMPONENT A	
Strategy/Project/Activity Name	Maternal and Child Survival Program (MCSP)
Implementer	Jhpiego
Cooperative Agreement #	OAA-A-14-00028
Total Estimated Ceiling (TEC) of the Project/Activity to be Assessed	8.1 million
Life of Project	July 2015-June 2018 for Myanmar country program (global award dates are from March 1, 2014 to June 30, 2018)
Active Geographic Regions	Rakhine State (3 townships), Southern Shan State (2 townships), Northern Shan State (3 townships), Ayeyarwaddy Region (3 townships), Kayin, and Magway Region (3 townships)

COMPONENT B				
Activity Name	Implementer	Agreement/ Contract #	Budget	Active Geographic Regions
Strengthening drug quality monitoring capacity of DFDA	United States Pharmacopeial Convention	Cooperative Agreement (Field Support)	\$845k	National
Strengthening DHP's capacity to	ICF	Contract	\$2.3	National

implement DHS 2015 in Myanmar	International		million	
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Both activities fall under:

Development Objective(s) (DOs)	Activities support the Mission's health Mission Objective (3.2): <i>Improve health of the people of Myanmar through stronger, inclusive health systems.</i>
USAID Office	USAID Myanmar, Office of Public Health

III. BACKGROUND

A. Component A: End-line Performance Evaluation of Maternal and Child Survival Program (MCSP)

The Maternal and Child Survival Program (MCSP) is a global U.S. Agency for International Development (USAID) cooperative agreement to introduce and support high-impact health interventions in 25 priority countries, in support of the global goal of reducing preventable child and maternal deaths (EPCMD). In Myanmar, MCSP began in 2014 with an initial focus on supporting discrete in-service training and capacity-building interventions partnering with professional associations; the scope of MCSP's program and Mission funding expanded steadily, leading to MCSP serving as the Mission's flagship MCH activity by 2016-2017.

MCSP's program in Myanmar supports the MOHS' strategic priority to strengthen human resources for health by building the capacity of existing health workers to deliver lifesaving maternal, newborn and child health interventions. Health workers often do not receive adequate technical updates, and education and training is heavily classroom-based, theoretical learning. Additionally, systems to ensure health facilities deliver care according to evidence-based technical standards are not in place, meaning that they likely are not suitable to serve as effective training grounds for health care workers.

MCSP is in its fourth and final year in Myanmar, and has had a significant evolution in its SOW since inception in 2014, when the initial focus was on developing a clinical skills training center in Yangon, and following up on national-level technical assistance initiated under MCHIP. In early fall 2015, an opportunity to link with and leverage funds from the Three Millennium Development Goal (3MDG) Fund midwifery strengthening project, led by Jhpiego and focused on midwifery pre-service training institutions, was identified. The workplan of MCSP was updated to add another program year and to shift more explicitly to in-service training and licensing of midwifery, complementing 3MDG support for pre-service training and accreditation of training institutions. Support for strengthening midwifery regulation (licensing and accreditation) is shared between the two programs, and funds are leveraged by both programs for implementation of this comprehensive approach to improving midwifery working with the Myanmar Nurse and Midwife Council (MNMCC).

In the last two quarters of FY16, MCSP prepared and submitted two new work plans in response to additional funding made available by the Mission. The first submission was a President's

Malaria Initiative (PMI) addendum to the ongoing MCSP work plan to respond to guidance from the Mission and the FY15 Malaria Operational Plan, to add activities to strengthen antenatal care (ANC) practices around malaria in pregnancy and support development of an integrated community case management (iCCM) model for Myanmar. The second was a new set of ‘catalytic’ activities written based on guidance from the Mission to respond rapidly to the then new government of Myanmar’s priorities and call to “intensify maternal and child health activities.”

In early 2017, the project integrated all 3 of its work plans (MCH+PMI, PMI addendum, catalytic) to guide implementation through June 2018. All activities in this work plan are an expansion of ideas and activities initiated in these previous work plans, with an expanded focus on systems, and an aim to generate evidence and tools for replication and scale up by the MOHS and/or other actors to improve the health system.

MCSP works with the MOHS to ensure that activities are in line with national priorities of improving health worker capacity to deliver the high-quality life-saving care included in the Essential Package of Health Services (EPHS) and thereby improved health outcomes. MCSP also coordinates with partners to leverage funding and complement efforts wherever possible. MCSP is explicitly linking with and leveraging 3MDG-funded projects for midwifery pre-service education and human resources for health strengthening to work across the continuum of pre-service, regulation, in-service capacity building and continuing professional development to improve the health workforce. MCSP is also coordinating with and leveraging activities led by organizations working in the border areas on activities with Ethnic Health Organization (EHOs) and is complementing activities funded by the World Bank and other partners wherever possible. Some activities, facility based integrated management of newborn and child illness (F-IMNCI) for example, are explicitly complementary to activities already initiated by other partners. MCSP’s investment builds the power of the approach through a larger demonstration. MCSP may possibly receive funding to continue support for the LPICs in Sittwe hospital in Rakhine State, though that extension will be outside the scope of this evaluation.

B. Component B: Assessment of Institutional Capacity Building of Myanmar Department of Food and Drug Administration (DFDA) and Department of Health Planning (DHP)

The USAID Health draft strategy prioritizes addressing key constraints that directly affect health programming – including strengthening the capacity of national institutions, expanding the role of civil society and media, and increasing the quality of life of the people of Myanmar through increased incomes and improved access to health services.

USAID invests in a number of activities where institutional strengthening is either a primary or secondary objective, including capacity strengthening of the Myanmar Department of Food and Drug Administration (DFDA) to monitor drug quality and to achieve International Organization for Standardization (ISO) accreditation. Capacity-building was also a secondary objective in USAID support for Myanmar’s first Demographic and Health Survey, which included assistance to the Government of Myanmar’s Department of Health Planning (DHP) to plan, and implement the survey in 2015 and publish and disseminate the findings in 2016-17

1. Drug quality monitoring

The Myanmar National Strategic Plan (NSP) for malaria aims to address the availability of falsified and substandard drugs that not only could have a negative impact on the treatment outcomes for malaria patients but also could be a driver for the development of multi-drug resistance. The DFDA is a key player in fulfilling this objective and takes responsibility in monitoring drug quality as well as upgrading its quality assurance laboratory and building the capacity of inspectors. The DFDA currently has offices in Nay Pyi Taw, Yangon, and Mandalay and plans to establish branch offices in 14 districts and laboratories at 14 more border trade zones over the next few years.

Building the institutional capacity of DFDA towards meeting international standards is one of the main outcomes to date of PMI technical assistance since 2014. In addition to this technical support, PMI has supported the procurement of essential equipment including a dissolution tester, a high-performance liquid chromatography system, and other necessary laboratory and personal safety supplies for use by the DFDA laboratories. In December 2016, the pharmaceutical chemistry laboratory of DFDA in Nay Pyi Taw was assessed by ANSI/ASQ National Accreditation Board (ANAB) from the US and obtained the accreditation of the International Organization for Standardization 17025:2005. With technical assistance provided by USAID/PMI through the Promoting the Quality of Medicines (PQM) Activity and other donors such as the Global Fund for equipment and maintenance, the DFDA was able to achieve ISO accreditation much earlier than anticipated, and became the only laboratory in the SE Asia region with ANAB accreditation. PQM is the key partner DFDA works with to provide technical assistance with regards to capacity building of its human resources and strengthening the existing Quality Assurance (QA)/ Quality Control (QC) systems.

2. Demographic and Health Survey (DHS)

USAID Demographic and Health Surveys (DHS) in various countries globally to measure progress on key population, health, and nutrition statistics. In the past, Myanmar has conducted several population and health surveys: 1) Fertility and Reproductive and Health Surveys (FRHS) were implemented in 1991, 1997, 2001, and 2007 by the Department of Population within the Ministry of Immigration and Population; and 2) Multiple Indicator Cluster Surveys (MICS) were implemented in 1995, 2003, and 2009-2010 by the Department of Planning of the Ministry of Planning and Economic Development, in collaboration with the Department of Health and the Department of Health Planning within the Ministry of Health.

In 2015-2016, USAID with contributions from 3MDG through the DHS7 program, supported the Ministry of Health and Sports (MOHS) to implement the first-ever nationally representative DHS covering 16,575 women of reproductive age 15-49 and approximately 8,287 men 15-49 in 12,750 households. Implemented by the Department of Health Planning with technical assistance provided by ICF International (DHS7 program), the DHS collected data on demographic rates, particularly of fertility rates, and infant and child mortality rates, at the national level, state/region levels (States: Chin, Kachin, Kayah, Kayin, Mon, Rakhine, and Shan; and Regions: Ayeyarwady, Bago, Magway, Mandalay, Sagaing, Tanintharyi, and Yangon) and

Naypyidaw Union Territory, and for the urban and rural strata of the population. This survey succeeded in covering all parts of the country despite many ongoing conflicts. This first-of-its-kind nationwide survey provided valuable baseline data upon which future health policies and programs can be tracked.

To gain country buy-in and government ownership, a Steering Committee, chaired by the Minister of Health and Sports with representatives from the Ministry of Planning and Economic Development, Ministry of Immigration and Population, and other relevant departments and ministries was established. The Steering Committee also included representatives from development partners, including USAID, UNICEF, UNFPA, the World Bank, 3MDG, and other international and bilateral organizations. The DHP/MOHS led the entire process from data collection to analysis, and final dissemination by the end of 2016.

Strengthening the capacity of host countries to implement high quality, representative household and facility-based surveys and disseminate and use the results in country is an explicit and critical focus of the DHS Program globally. As a result, DHS developed a Global Capacity Strengthening Strategy (CSS) to help guide, monitor and evaluate the program's capacity strengthening efforts aimed at increasing country ownership and helping to reduce host-country dependence on foreign technical assistance for conducting surveys. The capacity strengthening approach utilizes a whole-systems approach based on USAID's Human and Institutional Capacity Development (HICD) model. Recognizing that individual performance is highly influenced by institutional context, the DHS program provided technical assistance in a holistic manner, while ensuring that the capacities of counterparts are strengthened during survey design, implementation, processing, analysis, dissemination, monitoring, and evaluation. In Myanmar, due to restrictions around provision of funding directly to the host government, the DHS program also established a unique financing mechanism using an intermediary accounting firm to disburse funds to support field implementation, which enabled the MOHS team to exert due leadership and management of the survey. Similar mechanisms are used by the Global Fund (UNOPS) to provide resources for program implementation under GOM leadership, while upholding restrictions on direct financing to government.

This assessment will document the achievements, challenges, and lessons learned from capacity strengthening in order to understand the common experiences and enabling environment required for sustainable knowledge transfer to inform future institutional strengthening activities in country.

III.

A. **Description of the Problem, Development Hypothesis(es), and Theory of Change**

1. a. **Component A:** MCSP's theory of change is:

→ If MCSP builds on past experience to...

- Strengthen and build coordination among the institutions and systems that govern

capacity development for health workers;

- Introduce transformative, coordinated and targeted competency-based approaches to provider education (in-service training and continuing professional development), including on-the-job at facilities where quality improvement (QI) efforts, based on standards of quality care are implemented; and at the same time
- Strengthen the regulation of practice to improve the governance and practice of health providers in maternal, newborn and child health;

And if these pilot activities are well documented and shown to be effective,

→Then they can be scaled up by the government and/or other actors; and as services improve, maternal, newborn and child lives will be saved.

The intermediate results in the approved MCSP work plan for 2017-2018 include working with the MOHS and key partners to achieve the following:

1. Policy environment strengthened for improving quality and equitable access to maternal, newborn and child health services
2. Health workforce strengthened to support effective delivery of MNCH components of the Essential Package of Health Services (EPHS)
3. Quality health service delivery strengthened in targeted technical and geographical areas

1.b. Component A: Summary of MCSP's goal and approaches to be assessed

The activity's stated goal is to respond to the Ministry of Health and Sports' (MOHS) strategic priorities for improving maternal, newborn and child health by demonstrating, documenting and transitioning capacity to counterparts to make sustainable improvements in the health system.

One purpose of the final performance evaluation is to assess MCSP's efforts to build capacity and systems for in-service training, which covers a sub-set of the overall package of interventions supported by the project in Myanmar. Specifically, in-service training approaches have centered around four key "models" or approaches being introduced by MCSP, and for each, a documentation package intended to support adoption and scale up of these models will be developed by the implementing partner. The project implementation shifted over time from a focus on training to an increased systems strengthening-oriented approach. The assessment should account for the fact that the project emphasis and model shifted between project years.

The four models include:

1. The Learning and Performance Improvement Center (L&PICs) model for in-service capacity building, established in five states & regions and at MNMA, MNMC, and Taw Naw Teaching Hospital in Kayin State (L&PICs were also established to support pre-service training in two Nursing Universities with USAID funding, and in midwifery training schools with 3MDG funding);
2. The roll out approach for competency based capacity building, using the L&PICs combined with complementary support to MOHS counterparts to plan and execute in-

service training at the state/regional level and below;

3. A model for strengthening the institutions that the International Confederation of Midwives (ICM) has identified as central to strengthening the midwifery profession (MNMC and MNMA);
4. A standards-based quality improvement model for clinical training sites affiliated with selected L&PICs.

2. a. Component B: If the PQM and DHS strengthen the institutional capacities of the two departments - DFDA and DHP, the performance on drug quality monitoring and health survey implementation will be improved.

2. b. Component B:

(1) Summary of PQM goal and approaches to be evaluated.

PQM is aimed to achieve its strategic objectives by providing technical assistance in three key intermediate result (IR) areas using a systems-based approach tailored to fit the needs of individual countries or regions. Activities include building the capacity of countries' medicines regulatory authorities (MRAs) to review and approve quality-assured essential medicines and strengthening their ability to protect their own population from poor-quality medicines. PQM works with national and regional MRAs to build sustainable capacity for medicines evaluation, manufacturing inspection, and surveillance. PQM supports national quality control laboratories (NQCLs) through hands-on training and technical assistance to improve laboratory standards and compliance with internationally recognized standards.

(2) Summary of DHS goal and approaches to be evaluated.

The 2015 Myanmar Demographic and Health Survey (MDHS) is aimed at ascertaining nationally representative indicators on fertility, family planning, adult and childhood mortality, maternal and child health, nutrition, knowledge on HIV and AIDS, and women empowerment.

B. Summary of the Monitoring, Evaluation, and Learning (MEL) Plans

1. Maternal and Child Survival Program (MCSP) MEL Plan

MCSP's MEL plan is the tool for managing and documenting the performance of the program during the course of implementation, providing a framework for information to measure progress in project implementation and performance by objectives. The measurement, monitoring, evaluation and action-oriented learning for MCSP rely on program as well as counterpart institution data sources. Specific data sources, and the timing and methods of data collection are detailed in MCSP's FY 17 and 18 MEL Plan. The revised MEL Plan was approved in October 2017, with an expanded set of indicators intended to reflect progress on outputs as well as impact on system functioning (for instance, capturing the utilization of L&PICs by counterpart institutions independent of project resources, and changes in quality measures). A baseline assessment was not conducted overall for this project as it began with a limited work scope that expanded over time. On some measures of quality, a limited baseline assessment was done in 5 clinical sites affiliated with L&PIC: Taunggyi, Lashio, Sittwe, Magway and Patheingyi.

Developing and disseminating high quality, informative program documentation is a central goal for the remaining period of the program to document the models and approaches supported by MCSP. By Dec. 2017, the MCSP project plans to complete documentation of its L&PIC model as well as the roll-out approach, documented in the form of several special studies and reports developed by MCSP. The L&PIC model will include detail on components such as modules that are being implemented, training requirements, roll out process including township selection, and establishment of training teams. A sustainability plan under development will include data on costs of implementation and resources needed, possible sources of funding, and capacity to manage L&PIC.

Program documentation will have several key objectives: describing in detail the processes, systems and models developed/strengthened through MCSP so that they can be used in other contexts; advocating for, and providing the necessary information for, others to take on these approaches, so that they can be scaled up; disseminating key findings that can be used to inform future efforts related to MCSP's approaches.

It will also allow the external assessment team to analyze critical information on how implementation of MCSP's approach in country. The team can compare this information to other data sources on implementation of approaches for systems strengthening for maternity care in Myanmar to understand how the project approach can be improved.

2. PQM MEL Plan

PQM has a robust M&E system that promotes continuous learning, accountability, and informed decision-making across its entire portfolio of programs. PQM monitors its progress against agreed-upon intermediate results and sub-intermediate results by collecting data from sources such as national laboratories, regulatory agencies, manufacturers, WHO, and the Global Drug Facility. Data are captured in Excel-based tracking sheets that help PQM to monitor key achievements related to accreditations/reaccreditation/expanded scopes of accreditation; samples tested and testing results; SOPs, policies, and guidelines developed; presentations, publications, media events and network meetings promoting the quality of medicines; sampling sites of the (Medicine Regulatory Authorities) MRA; turnaround time from sample test to final report, and priority medicines achieving local or global approval for manufacture and sale.

3. DHS MEL Plan

N/A (But DHS Work Plan will be provided)

IV. EVALUATION AND ASSESSMENT QUESTIONS

A. Component A: End-line Performance Evaluation of Maternal and Child Survival Program (MCSP)

Question 1: To what extent did MCSP assistance influence in-service training practices and related systems to improve maternal, neonatal and child health? In answering this question,

the contractor must address the following:

- a) To what extent have the MCSP's in-service capacity building activities, including the models outlined in Section B and associated interventions, influenced policies, practices and the enabling environment for in-service training at different levels of the system (regulatory and professional bodies, central MOHS, state/regional level, and township level and below)? To what extent have health system actors been able to apply and replicate interventions introduced by MCSP?
- b) To what extent were MCSP approach and interventions aligned to health system realities in order to address the key barriers for strengthening in-service training at State/Region and Township levels, and;
- c) To what extent were MCSP's interventions and program design aligned to address drivers of maternal and child mortality and morbidity?

In addressing this question, the evaluator is to consider alternative ways of developing health human resource capacity and how the chosen model implemented compares with other alternatives in terms of effectiveness and efficiency in international best practice.

Question 2: How have MCSP's approaches contributed to potential sustainability of project results? In answering this question, the Contractor must address the following:

- a) What interventions will likely be/not be sustained or scaled up by the Government of Myanmar?
- b) What are key factors/evidence that support such conclusion(s)?

Question 3: What are the specific lessons that can be learned to inform future programs that aim to strengthen systems for capacity building related to maternal and child health, particularly at the township level?

- a) Any similar approaches/interventions that should/should not be supported/replicated through future assistance? Why/why not?;
- b) Any challenge(s) in the health system that MCSP did not address which would need to be addressed for future programs to be successful, particularly toward affecting improvements at the township level and below;
- c) Any intervention(s)/support(s) that should be removed or modified to better adjust interventions to health system realities; and
- d) Any necessary modifications to the models and interventions supported by MCSP, including their mode of delivery, if future replication is considered.

B. Component B: Assessment of Institutional Capacity Building of Myanmar Department of Food and Drug Administration (DFDA) and Department of Health Planning (DHP)

Question 1: In what ways and to what extent was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

- a) What factors (internal and external) contributed to the earlier-than-anticipated

attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory? (including enabling environment)

- b) How was capacity strengthened from USG-funded assistance?
- c) What factors are/are not in place to ensure that strengthened capacity can/will be sustained?
- d) Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?
- e) How did the project's design contribute to country engagement and ownership?
- f) How do the DFDA's internal factors (structure, policy or human resource management practice etc.) affect capacity strengthening at individual and institutional levels?

Question 2: In what ways and to what extent was the MOHS's capacity strengthened in the Department of Health Planning and elsewhere through implementation of the 2015-2016 Myanmar DHS and associated technical support provided by USAID and the DHS Program?

- a) What factors (internal and external) facilitated the implementation, analysis, and utilization of the 2015-16 DHS survey? (Including enabling environment)
- b) What capacities and skills in the MOHS were strengthened through support from the DHS project, USAID and 3MDG, and to what extent?
- c) How was DHS' global capacity-strengthening strategy applied in the Myanmar context, and were capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?
- d) How did the project's design and implementation approach contribute to country engagement and ownership?
- e) How did the implementation of the DHS, and associated efforts to engage ethnic groups to collect and disseminate data in contested and non-government-controlled areas, build MOHS experience and capacity to engage with ethnic health organizations (EHOs) and other community groups in the future?
- f) To what extent have Myanmar health sector stakeholders been able to use and apply DHS data to influence decision-making around the planning and delivery of health services and reforms?

Question 3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

- a) What experiences, elements, or key inputs were common for these two cases that led to their success?
- b) What practices should (not) be applied for future institutional strengthening activities?
- c) What practices should (not) be applied for future technical assistance activities (where the primary objective may not be institutional strengthening)?

V. DESIGN AND METHODOLOGY

A. Component A: End-line Performance Evaluation of Maternal and Child Survival Program (MCSP)

Qualitative and quantitative data should be collected and analyzed using case study methodology or other appropriate methods, such as systems analysis and complexity-aware methods that

account for the short period of project intervention while helping to understand the suitability and replicability of MCSP-supported models and interventions around in-service training. The evaluation team will propose an appropriate method in consultation with USAID.

There is no overall baseline data that would allow for before-after comparison or with a control group to assess change over time. The project only has limited baseline data on a few quality measures in selected sites available which may allow for some limited secondary analysis to show the extent or reach of MCSP interventions over time. Availability and comprehensiveness of project-produced data and documentation varies given that the approach for MCSP shifted significantly between workplan years. The existing data include performance statistics from MCSP on program implementation over time and detailed project documentation on project components, cost, and details of the model rollout.

In addition to existing project data, the evaluation team may have to draw on evidence from other donor programs in similar contexts.

To answer the evaluation questions, the evaluation team will have to collect supplementary qualitative (and, as relevant, quantitative) information through key informant interviews, focus group discussions, and survey questionnaires. Questions may focus, for example, on perceived changes due to project activities, project sustainability, and intended and unintended outcomes. Key informants may include project staff, USAID staff, ministry staff at the central level and state health training team members and counterparts at the state and regional level, township medical officers and members of township training teams at the township level and below including midwives, patients, and targeted beneficiaries. Other donors and partners active in the MCH space (including 3MDG technical advisors, UNICEF, WHO, MNMC, MNMA, and MMA-OB/GYN Society), also will likely have valuable perspectives on the role and impact of USAID support for in-service training strengthening in midwifery.

The design matrix and methods below are the illustrative and the contractor may propose other methods as appropriate. The evaluator may also propose alternative wording of evaluation questions if desired:

Questions	Suggested Data Sources (*)	Suggested Data Collection Methods	Data Analysis Methods
Question 1: To what extent did MCSP assistance influence in-service training practices and related systems to improve maternal, neonatal and child health? In answering this questions, the contractor must address the following: a) To what extent have the MCSP's in-service capacity building activities,	MCSP learning agenda documentation (to be completed by Dec 2017), workplans and reports from MCSP project and other MCH projects reports in country, other relevant in country document such as Annual Operational Plan of National	Qualitative (key informant interview and/or focus group discussions etc. as relevant), Desk review, secondary analysis	To be determined by the contractor

including the models outlined in Section B and associated interventions, influenced policies, practices and the enabling environment for in-service training at different levels of the system (regulatory and professional bodies, central MOHS, state/regional level, and township level and below)? To what extent have health system actors been able to apply and replicate interventions introduced by MCSP? b) To what extent were MCSP approach and interventions aligned to health system realities in order to address the key barriers for strengthening in-service training at State/Region and Township levels, and; c) To what extent were MCSP's interventions and program design aligned to address drivers of maternal and child mortality and morbidity? In addressing this question, the evaluator is to consider alternative ways of developing health human resource capacity and how the chosen model implemented compares with other alternatives in terms of effectiveness and efficiency in international best practice.	Health Plan (NHP), Yearly NHP implementation report if available, routine facility data, stakeholders & project beneficiaries, finding from the surveys.	as necessary.	
Question 2: How have MCSP's approaches contributed to the potential sustainability of project results? What interventions will likely be/not be sustained or scaled up by the Government of Myanmar? What are key factors/evidence that support such conclusion(s)?	MCSP learning agenda documentation (to be completed by Dec 2017), workplans and reports from MCS'P project and other MCH projects reports in country, other relevant in country document such AOP of NHP, Yearly NHP implementation report if available, routine facility data, stakeholders & project beneficiaries, finding from the surveys.	Qualitative (key informant interview and/or focus group discussions etc. as relevant), Desk review, secondary analysis as necessarily.	To be determined by the contractor

What are the specific lessons that can be learned to inform future programs that aim to strengthen systems for capacity building and in-service training related to maternal and child health, particularly at the township level? a. Any similar approaches/interventions that should/should not be supported/replicated through future assistance? Why/why not?; b. Any challenge(s) in the health system that MCSP did not address at Township level which would need to be addressed for future programs to be successful; c. Any intervention(s)/support(s) that should be removed or modified to better adjust interventions to health	MCSP learning agenda documentation (to be completed by Dec 2017), workplans and reports from MCSP project and other MCH projects reports in country, other relevant in country document such AOP of NHP, Yearly NHP implementation report if available, routine facility data, stakeholders & project beneficiaries, finding from the surveys.	Qualitative (key informant interview and/or focus group discussions etc. as relevant), Desk review, secondary analysis as necessarily.	To be determined by the contractor
system realities.; and d. Any necessary modifications to the models and interventions supported by MCSP, including their mode of delivery, if future replication is considered.			

B. Component B: Assessment of Institutional Capacity Building of Myanmar Department of Food and Drug Administration (DFDA) and Department of Health Planning (DHP)

To answer all the questions, the assessment team should select/develop a capacity development framework/model that reflects global best understanding. The team should propose an approach to assessing capacity development that draws on the most important available sources, including reports and documents, including Monitoring, Evaluation, and Learning (MEL) plans and indicators, workplans, agreements, quarterly and yearly reports, assessments and special survey reports.

In addition to existing data and reports, the assessment team should collect supplementary qualitative information through key informant interviews, focus group discussions, and stakeholder consultations to understand project context. Questions may focus on perceived changes due to project activities, project sustainability, and intended and unintended outcomes. Key informants may include project staff, USAID staff, ministry officials, and targeted beneficiaries. For FDA, this will include FDA laboratory staff and officials in Nay Pyi Taw. For the DHS, this will include MOHS counterparts in the Dept. of Medical Research, Health Information Systems and selected technical offices, other relevant Ministries responsible for population-based surveys, key partners and stakeholders (3MDG, UNICEF, World Bank, UNFPA, WHO and others), and NGOs, civil society and ethnic group representatives engaged in the survey implementation and dissemination of findings. Qualitative and quantitative data should be analyzed using appropriate methods.

The evaluator will propose an appropriate method in consultation with USAID. The design matrix and

methods below are the illustrative and the contractor should propose other methods as appropriate. The evaluator may also propose alternative wording of evaluation questions if desired:

Questions	Suggested Data Sources	Suggested Data Collection Methods	Data Analysis Methods
Question 1: In what ways and to what extent was the DFDA's institutional capacity strengthened to monitor drug quality? . What factors (internal and external) contributed to the earlier- than-anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory? (including enabling environment) . How was capacity strengthened from PMI-supported activities? Other project support?	Project quarterly and annual reports, Project MEL plans and indicators, assessment reports and evaluations, capacity strengthening strategies, National Human Resource Development strategy, DFDA's 5-year Strategic Plan, consultancy trip reports	Desk/literature review; key informant interviews, focus group discussions; questionnaires	[To be determined by the contractor] - Disaggregate by gender as applicable.
Questions	Suggested Data Sources	Suggested Data Collection Methods	Data Analysis Methods
c. Are systems in place to ensure that strengthened capacity can/will be sustained?			
d. Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?			
e. How did the project's design contribute to country engagement and ownership?			
f. How does the DFDA's organizational structure affect capacity strengthening at individual and institutional levels?			
Question 2: In what ways and to what extent was the DHP's capacity strengthened to implement the 2015-2016 Myanmar DHS?	Project work plan and quarterly and annual reports, activity and trip reports from DHS, MOUs and implementation documents developed to support program implementation, consultancy trip reports	Desk/literature review; key informant interviews, focus group discussions; questionnaires	[To be determined by the contractor] - Disaggregate by gender as applicable.
a. What factors (internal and external) facilitated the implementation, analysis,			

and utilization of the 2015-16 DHS survey? (Including enabling environment)			
b. What capacity and skills were strengthened through the Global DHS project?			
c. Are systems in place to ensure that capacity to implement nationwide, representative surveys can/will be sustained?			
d. Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?			
e. How did the project's design contribute to country engagement and ownership?			
Question 3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?	Partner project quarterly and annual reports, Project MEL plans and indicators, assessment reports and evaluations, capacity strengthening strategies, national human resource development strategy	Desk/literature review; key informant interviews; focus group discussions; questionnaires	
a. What experiences, elements, or key inputs were common for these two cases that led to their success?			
b. What practices should (not) be applied for future institutional strengthening activities?			
c. What practices should (not) be applied for future technical assistance activities (where the primary objective may not be institutional strengthening)?			

V. FINAL REPORT FORMAT

(THIS SECTION APPLIES TO BOTH COMPONENT A AND B)

The final reports (for each Component) must include an abstract; executive summary; background of the local context and the project being assessed; the evaluation/assessment purposes and main evaluation/ assessment questions; the methodology or methodologies; the limitations to the evaluation/assessment; findings, conclusions, and recommendations. For more detail, see “How- To Note: Preparing Evaluation Reports” (Attachment 2) and [ADS 201mah, USAID Evaluation Report Requirements](#). An optional evaluation report [template](#) is available in the Evaluation Toolkit.

Each executive summary must be 2–5 pages in length and summarize the purpose, background

of the project being assessed , main assessment questions, methods, findings, conclusions, and recommendations and lessons learned (if applicable).

The methodology must be explained in the report in detail. Limitations to the assessment/evaluation must be disclosed in the report, with particular attention to the limitations associated with the assessment/evaluation methodology (e.g., selection bias, recall bias, unobservable differences between comparator groups, etc.)

The annexes to each report must include:

- The task order Statement of Work (SOW);
- Any statements of difference regarding significant unresolved differences of opinion by funders, implementers, and/or members of the assessment/evaluation team;
- All data collection and analysis tools used in conducting the evaluation/assessment, such as questionnaires, checklists, and discussion guides;
- All sources of information, properly identified and listed; and
- Signed disclosure of conflict of interest forms for all evaluation/assessment team members, either attesting to a lack of conflicts of interest or describing existing conflicts of interest.
- Summary information about evaluation/assessment team members, including qualifications, experience, and role on the team.

VI. CRITERIA TO ENSURE THE QUALITY OF THE EVALUATION/ASSESSMENT REPORTS

(THIS SECTION APPLIES TO BOTH COMPONENT A AND B)

Per **ADS 201maa, Criteria to Ensure the Quality of the Evaluation Report**, the draft and final reports will be evaluated against the following criteria to ensure the quality.

- The report must represent a thoughtful, well-researched, and well-organized effort to objectively evaluate/assess the project.
- The report must be readily understood and should identify key points clearly, distinctly, and succinctly.
- The Executive Summaries of the report must present a concise and accurate statement of the most critical elements of the reports.
- The report must adequately address all questions included in the SOW, or the questions subsequently revised and documented in consultation and agreement with USAID.
- The evaluation/assessment methodology must be explained in detail and sources of information properly identified.
- Limitations to the evaluation/assessment must be adequately disclosed in the reports, with particular attention to the limitations associated with the methodology (selection bias, recall bias, unobservable differences between comparator groups, etc.).
- Findings must be presented as analyzed facts, evidence, and data and not based on anecdotes, hearsay, or simply the compilation of people's opinions.
- Findings and conclusions must be specific, concise, and supported by strong

- quantitative or qualitative evidence.
- If findings assess person-level outcomes or impact, they should also be separately assessed for both males and females. If recommendations are included, they should be supported by a specific set of findings and should be action-oriented, practical, and specific.

VII. OTHER REQUIREMENTS

All modifications to the required elements of the SOW of the contract, whether in technical requirements, evaluation/assessment questions, evaluation/assessment team compositions, methodology, or timeline, need to be agreed upon in writing by the Contracting Officer (CO). Any revisions must be updated in the SOW and only the final SOW shall be included as an annex to the Report.

ANNEX B. DOCUMENT REVIEW SOURCES

- Ministry of Health and Sports. *Myanmar National Health Plan 2017-2021*. MoHS, 2016.
- Ministry of Health and Sports. National Health Plan 2017-2021: Draft Document for Review. MoHS, 2016. Pp. 2-40.
- Ministry of Health 2012. *Health Workforce Strategic Plan 2012-2017*. Myanmar Ministry of Health, 2012. Pp. 1-30.
- Ministry of Health and Sports, Republic of the Union of Myanmar. *National Health Plan 2017-2021 Annual Operational Plan 2017-2018*. MoHS, 2017. Pp. 1-48.
- Ministry of National Planning and Economic Development and Ministry of Health, Myanmar.
- President's Malaria Initiative (PMI). 2018. *Myanmar Country Profile*. https://www.pmi.gov/docs/default-source/default-document-library/country-profiles/Myanmar_profile.pdf. Accessed on August 5, 2018.
- President's Malaria Initiative (PMI). 2017. *Malaria Operational Plan FY 2018*. <https://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy-2018/fy-2018-Myanmar-malaria-operational-plan.pdf?sfvrsn=5>.
- President's Malaria Initiative (PMI). 2015. Table 2A: President's Malaria Initiative - Myanmar Malaria Operational Plan Planned Obligations for FY2014 (Revised June 5, 2015). <https://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy14/fy-2014-Myanmar---revised-funding-table.pdf?sfvrsn=12>.
- Pribluda VS, Barojas A, Coignez V, Bradby S, Dijiba Y, El-Hadri L, et al. The Three-Level Approach: A Framework for Ensuring Medicines Quality in Limited-Resource Countries. *Pharmaceutical Regulatory Affairs*. 2014, 3:1. <http://dx.doi.org/10.4172/2167-7689.1000117>.
- Promoting the Quality of Medicines. *Proposed Work Plan for Myanmar*. USAID PQM, 2017. Pp. 1-24.
- Promoting the Quality of Medicines. *Promoting the Quality of Medicines Program Fact Sheet*. USAID PQM, 2018.
- Promoting the Quality of Medicines (PQM). 2018. *PQM Factsheet on 2017 Lab Data, Myanmar*.
- Promoting the Quality of Medicines (PQM). *Annual Performance Report FY2017*. Rockville, M.D.: USAID PQM, 2017.
- Promoting the Quality of Medicines. 2017. *Promoting the Quality of Medicines (PQM) Program FY 2017 Third Quarter Report*. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicine (PQM) Program. Rockville, MD: United States Pharmacopeial Convention (USP).
- Promoting the Quality of Medicines. 2017. *Promoting the Quality of Medicines (PQM) Program FY 2017 Fourth Quarter Report*. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines (PQM) Program. Rockville, MD: U.S. Pharmacopeial Convention (USP).
- Promoting the Quality of Medicines. 2018. *Promoting the Quality of Medicines (PQM) Program FY 2018 First Quarter Report*. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines (PQM) Program. Rockville, MD: U.S. Pharmacopeial Convention (USP).
- Promoting the Quality of Medicines (PQM). (2017). *Summary of Key Program Accomplishments and Outcomes: PQM/RDMA Close Out Report (2010–2017)*. Rockville, MD: U.S. Pharmacopeial Convention.
- Promoting the Quality of Medicines (PQM). 2015. *Report on the Quality Testing of TAZID* (1 g Ceftazidime) for Injection Sample, August 26, 2015*.

Promoting the Quality of Medicines (PQM). 2014. Myanmar Baseline Survey on Priority Antimicrobial Medicines in Selected Areas.

Promoting the Quality of Medicines. 2014. Proposed FY15 Work Plan for Technical Assistance on Improving Antimalarial Medicines Quality in Myanmar, Implementing Period: October 1, 2014 – September 30, 2015. Re-submitted 11/29/2014.

ANNEX C. ASSESSMENT DESIGN MATRIX

Data Collection and Analysis Matrix, Component B

Assessment Questions	Data Source	Data Collection Methods	Data Analysis Methods
AQ1: In what ways and to what extent was the DFDA's institutional capacity strengthened to monitor drug quality?	<u>Document</u>: Quarterly/annual reports, MEL plans, capacity strengthening strategies, assessment reports/evaluations, trip reports, National Human Resource Development strategy, DFDA's 5-year Strategic Plan, <u>Qualitative</u>: KIIs with USAID, MOHS, PQM staff in-country and at headquarters, DFDA, laboratory staff	Desk review, secondary data analysis, KIIs	• Content analysis for identifying project successes and challenges • Thematic organization for qualitative analysis • Summary statistics used to assess progress against program indicators • Disaggregate by gender as applicable
AQ 2: In what ways and to what extent was the MOHS's capacity strengthened in the Department of Public Health and elsewhere through implementation of the 2015-2016 Myanmar DHS and associated technical support provided by USAID and the DHS Program?	<u>Document</u>: Project work plan and quarterly/annual reports, activity and trip reports from DHS, MOUs and implementation documents developed to support program implementation, consultancy trip reports <u>Qualitative</u>: KIIs with USAID, MOHS, Central Statistics Office, ICF International, DHS program staff, Department of Medical Research, DPH / Health Information Division, FGD with workshop attendees.	Desk review, secondary data analysis, KIIs, FGDs	• Thematic organization for qualitative analysis
AQ 3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?	<u>Document</u>: Quarterly and annual reports, Project MEL plans, assessment reports/ evaluations, capacity strengthening strategies, national strategy documents <u>Qualitative</u>: KIIs with ICF International, PQM, DFDA staff, laboratory staff	Desk review, secondary data analysis, KIIs, FGDs	• Analysis of key program indicators • Thematic organization for qualitative analysis

ANNEX D. DATA COLLECTION TOOLS

Component B – Assessment of Institutional Capacity Building of Myanmar Department of Food and Drug Administration (DFDA)

Key Informant Interview:

PQM (Program Manager)

Other PQM team staff, including technical and administrative staff

Informed Consent and Confidentiality: Hi, my name is X, and I work for Social Impact, which is an independent research company based in the Washington, DC area. We are collecting data about the *Promoting the Quality of Medicines* program that launched in 2013 in Myanmar. As you may know, the program was designed to support a sustainable system to ensure that Myanmar has a ready supply of quality medication and drugs. Our evaluation is intended to inform the Dept. of Food and Drug Administration, MOHS as well as the U.S. Government's design of future technical assistance and institutional strengthening activities in Myanmar.

We selected you and other respondents to interview because we understand that you may have perspective on the *Promoting the Quality of Medicines* program and/or on relevant subject matter. We expect the duration of this interview to be one hour. We plan to ask you about the drug quality process in Myanmar, as well as program activities, Technical Assistance and Capacity Building, conducted by US Pharmacopeial Convention with funding from USAID. There are no known risks or direct benefits related to your participation; however, your inputs may lead to recommendations that benefit actors engaged in Myanmar quality drug supply—and, thereby, the general public.

All information that you share will be kept confidential. We will aggregate and present our findings to USAID in a way that cannot be attributed to any individual or organization. Therefore, please feel free to speak openly and candidly with us. Your participation is voluntary. Please feel free to ask to skip any question that you do not feel comfortable answering, end this interview at any point, or withdraw your responses after the interview.

Do you confirm your consent to participate in this interview? ☐ Yes ☐ No

To guarantee accuracy, we find it useful to keep an audio record of the conversation. If you prefer, however, we will not use recording devices.

Do you confirm your consent for us to record this interview? ☐ Yes ☐ No

Interview Place and Date: _____

Interviewer(s):

Interviewee Name & Title:

Sex: ☐ Female ☐ Male

Introduction:

- a. Tell me about the PQM project in Myanmar?
- b. What was your role on the project? (Probes: how involved were you with the program and in what ways were you involved?)
- c. What would you say are the strengths and what are the weaknesses of this program?

- d. What worked well in this project? And what did not work very well?

AQI: In what ways, and to what extent, was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

Probes:

- a. How successful, would you say, this program was in improving DFDA's institutional capacity to monitor drug quality?
- b. What has changed? What has not changed that you would like to see changed?
- c. What have you seen happening at DFDA that you can point to as evidence of this?
- d. How has the information on product quality been used for decision making?
- e. How many and what types of policies have been developed because of this capacity building program? How well are these policies being carried out?

AQIa: What factors (internal and external, including enabling environment) contributed to the earlier than anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory?

Probes:

- a. What internal DFDA individual, systems or organizational factors may have helped or hindered the process?
- b. What aspects of the PQM project may have contributed most to this?

AQIb: What factors are/are not in place to ensure that strengthened capacity and/will be sustained?

Probes:

- a. How likely will this drug quality assurance process be sustained after this project ends?
- b. What would a sustained system look like?
- c. What will be done to ensure that staff in the labs remain up-to-date with training?
- d. How will these labs be funded in the future?
- e. Who will be responsible for conducting supervisory observations?
- f. How will the working relationships with other key stakeholders (MOHS, hospitals, pharmacies, PC labs) effect the sustainability of this program results?

AQIc: Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?

Probes:

- a. If yes, what is done to measure these outcomes?
- b. How do you know that strengthening has occurred?
- c. What variables are measured and how often? (accreditation? Re-accreditation? Number of samples tested and results? SOPs, Policies, and guidelines developed? turnaround time from sample test to final report?)
- d. Can you share the results of any measures you have taken?
- e. What is your overall assessment of whether individuals have had their capacity strengthened? And what about the organization itself? What is your overall assessment of the organizational capacity strengthening?
- f. If you have not been measuring individual and organizational capacity, tell me what has prevented this from taking place.
- g. What could be done in the future to measure individual and organizational strengthening?

AQ1d: How did the project's design contribute to country engagement and ownership?

Probes:

- In your opinion, to what degree do you believe the government is now taking responsibility for this process?
- Why are they? Or why are they not taking ownership?
- What aspects of the project's design are contributing to this?

AQ1e: How do the DFDA's internal factors (structure, policy, human resource management practices, etc.) affect capacity strengthening at individual and institutional levels?

Probes:

- In your opinion, would you address each of these internal factors and talk about how you see them affecting capacity strengthening at both the individual and institutional levels.

	Individual	Institutional
DFDA's Structure		
Organizational policies		
HR management practices		
Other (_____)		

AQ3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ3b: In your experience, what practices should, or should not, be applied for future activities specifically focused on strengthening an organization or institution?

AQ3c: In your experience, what practices should, or should not, be applied for future technical assistance activities where the primary objective may not be institutional strengthening?

Important issues to listen for and probe into are:

- Comments on provision of Equipment and its effect on capacity strengthened,
- Comments on training frequency and quality and the effect it had on CS,
- Comments on the successes and challenges of the TA for moving/construction of new laboratories in Mandalay and Yangon,
- The role of other donors in facilitating the work of PQM, in particular the Global Fund, and the potential for confounding the results as attributable to PQM alone,

Key Informant Interview:

Department of Food and Drug Administration: Senior Administrators and Senior Staff

Informed Consent and Confidentiality: Hi, my name is X, and I work for Social Impact, which is an independent research company based in the Washington, DC area. We are collecting data about the *Promoting the Quality of Medicines* program that launched in 2013 in Myanmar. As you may know, the program was designed to support a sustainable system to ensure that Myanmar has a ready supply of quality medication and drugs. Our evaluation is intended to inform the Dept. of Food and Drug Administration, MOHS as well as the U.S. Government's design of future technical assistance and institutional strengthening activities in Myanmar.

We selected you and other respondents to interview because we understand that you may have perspective on the *Promoting the Quality of Medicines* program and/or on relevant subject matter. We expect the duration of this interview to be one hour. We plan to ask you about the drug quality process in Myanmar, as well as program activities, Technical Assistance and Capacity Building, conducted by US Pharmacopeial Convention with funding from USAID. There are no known risks or direct benefits related to your participation; however, your inputs may lead to recommendations that benefit actors engaged in Myanmar quality drug supply—and, thereby, the general public.

All information that you share will be kept confidential. We will aggregate and present our findings to USAID in a way that cannot be attributed to any individual or organization. Therefore, please feel free to speak openly and candidly with us. Your participation is voluntary. Please feel free to ask to skip any question that you do not feel comfortable answering, end this interview at any point, or withdraw your responses after the interview.

Do you confirm your consent to participate in this interview? ☐ Yes ☐ No

To guarantee accuracy, we find it useful to keep an audio record of the conversation. If you prefer, however, we will not use recording devices.

Do you confirm your consent for us to record this interview? ☐ Yes ☐ No

Interview Place and Date: _____

Interviewer(s):

Interviewee Name & Title:

Sex: ☐ Female ☐ Male

Introduction:

- Tell me about the PQM project in Myanmar?
- What was your role on the project? (Probes: how involved were you with the program and in what ways were you involved?)
- What would you say are the strengths and what are the weaknesses of this program?
- What worked well in this project? And what did not work very well?

AQ1: In what ways, and to what extent, was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

Probes:

- a. How successful, would you say, this program was in improving DFDA's institutional capacity to monitor drug quality?
- b. What has changed? What has not changed that you would like to see changed?
- c. What have you seen happening at DFDA that you can point to as evidence of this?
- d. How has the information on product quality been used for decision making?
- e. How many and what types of policies have been developed because of this capacity building program? How well are these policies being carried out?
- f. How would you rate the level of drug quality in Myanmar today, especially in comparison to 5 years ago?
- g. How has the Quality Assurance system changed over the recent years?

AQ1a: What factors (internal and external, including enabling environment) contributed to the earlier than anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory?

Probes:

- a. What internal DFDA individual, systems or organizational factors may have helped or hindered the process?
- b. What aspects of the PQM project may have contributed most to this?

AQ1b: What factors are/are not in place to ensure that strengthened capacity and/will be sustained?

Probes:

- a. How likely will this drug quality assurance process be sustained after this project ends?
- b. What would a sustained system look like?
- c. What will be done to ensure that staff in the labs remain up-to-date with training?
- d. How will these labs be funded in the future?
- e. Who will be responsible for conducting supervisory observations?
- f. How will the working relationships with other key stakeholders (MOHS, hospitals, pharmacies, PC labs) effect the sustainability of this program results?

AQ1c: Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?

Probes:

- a. If yes, what is done to measure these outcomes?
- b. How do you know that strengthening has occurred?
- c. What variables are measured and how often? (accreditation? Re-accreditation? Number of samples tested and results? SOPs, Policies, and guidelines developed? turnaround time from sample test to final report?)
- d. Can you share the results of any measures you have taken?
- e. What is your overall assessment of whether individuals have had their capacity strengthened? And what about the organization itself? What is your overall assessment of the organizational capacity strengthening?
- f. If you have not been measuring individual and organizational capacity, tell me what has prevented this from taking place.
- g. What could be done in the future to measure individual and organizational strengthening?

AQ1d: How did the project's design contribute to country engagement and ownership?

Probes:

- In your opinion, to what degree do you believe the government is now taking responsibility for this process?
- Why are they? Or why are they not taking ownership?
- What aspects of the project's design are contributing to this?

AQ1e: How do the DFDA's internal factors (structure, policy, human resource management practices, etc.) affect capacity strengthening at individual and institutional levels?

Probes:

- In your opinion, would you address each of these internal factors and talk about how you see them affecting capacity strengthening at both the individual and institutional levels.

	Individual	institutional
DFDA's Structure		
Organizational policies		
HR management practices		
Other (_____)		

AQ3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ3b: In your experience, what practices should, or should not, be applied for future activities specifically focused on strengthening an organization or institution?

AQ3c: In your experience, what practices should, or should not, be applied for future technical assistance activities where the primary objective may not be institutional strengthening?

Important issues to listen for and probe into are:

- Comments on provision of Equipment and its effect on capacity strengthened,
- Comments on training frequency and quality and the effect it had on CS,
- Comments on the successes and challenges of the TA for moving/construction of new laboratories in Mandalay and Yangon,
- The role of other donors in facilitating the work of PQM, in particular the Global Fund, and the potential for confounding the results as attributable to PQM alone.

Key Informant Interview:

Myanmar Pharmaceutical Chemistry Laboratory (Nay Pyi Taw): Site administrative staff, technical staff, and trainers

Informed Consent and Confidentiality: Hi, my name is X, and I work for Social Impact, which is an independent research company based in the Washington, DC area. We are collecting data about the *Promoting the Quality of Medicines* program that launched in 2013 in Myanmar. As you may know, the program was designed to support a sustainable system to ensure that Myanmar has a ready supply of quality medication and drugs. Our evaluation is intended to inform the Dept. of Food and Drug Administration, MOHS as well as the U.S. Government's design of future technical assistance and institutional strengthening activities in Myanmar.

We selected you and other respondents to interview because we understand that you may have perspective on the *Promoting the Quality of Medicines* program and/or on relevant subject matter. We expect the duration of this interview to be one hour. We plan to ask you about the drug quality process in Myanmar, as well as program activities, Technical Assistance and Capacity Building, conducted by US Pharmacopeial Convention with funding from USAID. There are no known risks or direct benefits related to your participation; however, your inputs may lead to recommendations that benefit actors engaged in Myanmar quality drug supply—and, thereby, the general public.

All information that you share will be kept confidential. We will aggregate and present our findings to USAID in a way that cannot be attributed to any individual or organization. Therefore, please feel free to speak openly and candidly with us. Your participation is voluntary. Please feel free to ask to skip any question that you do not feel comfortable answering, end this interview at any point, or withdraw your responses after the interview.

Do you confirm your consent to participate in this interview? ☐ Yes ☐ No

To guarantee accuracy, we find it useful to keep an audio record of the conversation. If you prefer, however, we will not use recording devices.

Do you confirm your consent for us to record this interview? ☐ Yes ☐ No

Interview Place and Date: _____

Interviewer(s):

Interviewee Name & Title:

Sex: ☐ Female ☐ Male

Introduction:

- a. Tell me about the PQM project in Myanmar?
- b. What was your role on the project? (Probes: how involved were you with the program and in what ways were you involved?)
- c. What would you say are the strengths and what are the weaknesses of this program?
- d. What worked well in this project? And what did not work very well?

AQ1: In what ways, and to what extent, was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

Probes:

- a. How successful, would you say, this program was in improving DFDA's institutional capacity to monitor drug quality?
- b. What has changed? What has not changed that you would like to see changed?
- c. What have you seen happening at DFDA that you can point to as evidence of this?
- d. How has the information on product quality been used for decision making?
- e. How many and what types of policies have been developed because of this capacity building program? How well are these policies being carried out?
- f. How would you rate the level of drug quality in Myanmar today, especially in comparison to 5 years ago?
- g. How has the Quality Assurance system changed over the recent years?
- h. What changes have you seen here in the lab?
- i. How are staffing decisions made here at the lab?
- j. How is the lab Equipment maintained and repaired?
- k. How are staff supported by the senior staff? (Probe for whether they are coached, mentored and provided with supportive supervision/guidance.)
- l. How do you learn about the latest technology and best practices?

AQ1a: What factors (internal and external, including enabling environment) contributed to the earlier than anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory?

Probes:

- a. What internal DFDA individual, systems or organizational factors may have helped or hindered the process?
- b. What aspects of the PQM project may have contributed most to this?

AQ1b: What factors are/are not in place to ensure that strengthened capacity and/will be sustained?

Probes:

- a. How likely will this drug quality assurance process be sustained after this project ends?
- b. What would a sustained system look like?
- c. What will be done to ensure that staff in the labs remain up-to-date with training?
- d. How will these labs be funded in the future?
- e. Who will be responsible for conducting supervisory observations?
- f. How will the working relationships with other key stakeholders (MOHS, hospitals, pharmacies, PC labs) effect the sustainability of this program results?

AQ1c: Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?

Probes:

- a. If yes, what is done to measure these outcomes?
- b. How do you know that strengthening has occurred?
- c. What variables are measured and how often? (accreditation? Re-accreditation? Number of samples tested and results? SOPs, Policies, and guidelines developed? turnaround time from sample test to final report?)
- d. Can you share the results of any measures you have taken?

- e. What is your overall assessment of whether individuals have had their capacity strengthened? And what about the organization itself? What is your overall assessment of the organizational capacity strengthening?
- f. If you have not been measuring individual and organizational capacity, tell me what has prevented this from taking place.
- g. What could be done in the future to measure individual and organizational strengthening?

AQ1d: How did the project's design contribute to country engagement and ownership?

Probes:

- a. In your opinion, to what degree do you believe the government is now taking responsibility for this process?
- b. Why are they? Or why are they not taking ownership?
- c. What aspects of the project's design are contributing to this?

AQ1e: How do the DFDA's internal factors (structure, policy, human resource management practices, etc.) affect capacity strengthening at individual and institutional levels?

Probes:

- a. In your opinion, would you address each of these internal factors and talk about how you see them affecting capacity strengthening at both the individual and institutional levels.

	Individual	Institutional
DFDA's Structure		
Organizational policies		
HR management practices		
Other (_____)		

AQ3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ3b: In your experience, what practices should, or should not, be applied for future activities specifically focused on strengthening an organization or institution?

AQ3c: In your experience, what practices should, or should not, be applied for future technical assistance activities where the primary objective may not be institutional strengthening?

Important issues to listen for and probe into are:

- Comments on provision of Equipment and its effect on capacity strengthened,
- Comments on training frequency and quality and the effect it had on CS,
- Comments on the successes and challenges of the TA for moving/construction of new laboratories in Mandalay and Yangon,
- The role of other donors in facilitating the work of PQM, in particular the Global Fund, and the potential for confounding the results as attributable to PQM alone.

Key Informant Interview:

Ministry of Health and Sports Senior Staff/Leaders (DGs and PSs)

Informed Consent and Confidentiality: Hi, my name is X, and I work for Social Impact, which is an independent research company based in the Washington, DC area. We are collecting data about the *Promoting the Quality of Medicines* program that launched in 2013 in Myanmar. As you may know, the program was designed to support a sustainable system to ensure that Myanmar has a ready supply of quality medication and drugs. Our evaluation is intended to inform the Dept. of Food and Drug Administration, MOHS as well as the U.S. Government's design of future technical assistance and institutional strengthening activities in Myanmar.

We selected you and other respondents to interview because we understand that you may have perspective on the *Promoting the Quality of Medicines* program and/or on relevant subject matter. We expect the duration of this interview to be one hour. We plan to ask you about the drug quality process in Myanmar, as well as program activities, Technical Assistance and Capacity Building, conducted by US Pharmacopeial Convention with funding from USAID. There are no known risks or direct benefits related to your participation; however, your inputs may lead to recommendations that benefit actors engaged in Myanmar quality drug supply—and, thereby, the general public.

All information that you share will be kept confidential. We will aggregate and present our findings to USAID in a way that cannot be attributed to any individual or organization. Therefore, please feel free to speak openly and candidly with us. Your participation is voluntary. Please feel free to ask to skip any question that you do not feel comfortable answering, end this interview at any point, or withdraw your responses after the interview.

Do you confirm your consent to participate in this interview? ☐ Yes ☐ No

To guarantee accuracy, we find it useful to keep an audio record of the conversation. If you prefer, however, we will not use recording devices.

Do you confirm your consent for us to record this interview? ☐ Yes ☐ No

Interview Place and Date:

Interviewer(s):

Interviewee Name & Title:

Sex: ☐ Female ☐ Male

Introduction:

- a. What do you know about the PQM project in Myanmar?
- b. What was your role at the MOHS?
- c. Have you been involved with the PQM project? If so, in what ways were you involved?
- d. What would you say are the strengths and what are the weaknesses of this drug monitoring system?

AQ1: In what ways, and to what extent, was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

Probes:

- a. How successful, would you say, this program was in improving DFDA's institutional capacity to monitor drug quality?

- b. What worked well in this project? And what did not work very well?
- c. What has changed at the DFDA? What has not changed that you would like to see changed?
 - i. What have you seen happening at DFDA that you can point to as evidence of this?
- d. How has the information on product quality been used for decision making?
 - i. Have you used the information on product quality for anything? If so, what have you used it for?
- e. How many and what types of policies have been developed because of this capacity building program? How well are these policies being carried out?
- f. How would you rate the level of drug quality in Myanmar today, especially in comparison to 5 years ago?
- g. How has the Quality Assurance system changed over the recent years?

AQ1a: What factors (internal and external, including enabling environment) contributed to the earlier than anticipated attainment of DFDA's ISO accreditation of the Nay Pyi Taw laboratory?

Probes:

- a. What internal DFDA individual, systems or organizational factors may have helped or hindered the process?
- b. What aspects of the PQM project may have contributed most to this?

AQ1b: What factors are/are not in place to ensure that strengthened capacity and/will be sustained?

Probes:

- a. How likely will this drug quality assurance process be sustained after this project ends?
- b. What would a sustained system look like?
- c. What will be done to ensure that staff in the labs remain up-to-date with training?
- d. How will these labs be funded in the future?
- e. Who will be responsible for conducting supervisory observations?
- f. How will the working relationships with other key stakeholders (MOHS, hospitals, pharmacies, PC labs) effect the sustainability of this program results?

AQ1c: Are capacity strengthening outcomes at individual and organizational levels measured for learning and improvement, as well as for accountability?

Probes:

- a. If yes, what is done to measure these outcomes?
- b. How do you know that strengthening has occurred?
- c. What variables are measured and how often? (accreditation? Re-accreditation? Number of samples tested and results? SOPs, Policies, and guidelines developed? turnaround time from sample test to final report?)
- d. Can you share the results of any measures you have taken?
- e. What is your overall assessment of whether individuals have had their capacity strengthened (such things as individual knowledge of procedures, individual skills in conducting drug quality procedures)? And what about the organization itself? What is your overall assessment of the organizational capacity strengthening (such things as maintaining Standard Operating Procedures, ensuring SOPs are being followed, ability to provide supervision of procedures, ability to keep the staff up-to-date with latest information)?
- f. If you have not been measuring individual and organizational capacity, tell me what has prevented this from taking place.
- g. What could be done in the future to measure individual and organizational strengthening?

AQ1d: How did the project's design contribute to country engagement and ownership?

Probes:

- a. In your opinion, to what degree do you believe the government is now taking responsibility for this process?
- b. Why are they? Or why are they not taking ownership?
- c. What aspects of the project's design are contributing to this?

AQ1e: How do the DFDA's internal factors (structure, policy, human resource management practices, etc.) affect capacity strengthening at individual and institutional levels?

Probes:

- a. In your opinion, would you address each of these internal factors and talk about how you see them affecting capacity strengthening at both the individual and institutional levels.

Individual

Institutional

DFDA's Structure

Organizational policies

HR management practices

Other (_____)

AQ3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ3b: In your experience, what practices should, or should not, be applied for future activities specifically focused on strengthening an organization or institution?

AQ3c: In your experience, what practices should, or should not, be applied for future technical assistance activities where the primary objective may not be institutional strengthening?

Key Informant Interview:

Myanmar Pharmaceutical Representatives

Informed Consent and Confidentiality: Hi, my name is X, and I work for Social Impact, which is an independent research company based in the Washington, DC area. We are collecting data about the *Promoting the Quality of Medicines* program that launched in 2013 in Myanmar. As you may know, the program was designed to support a sustainable system to ensure that Myanmar has a ready supply of quality medication and drugs. Our evaluation is intended to inform the Dept. of Food and Drug Administration, MOHS as well as the U.S. Government's design of future technical assistance and institutional strengthening activities in Myanmar.

We selected you and other respondents to interview because we understand that you may have perspective on the *Promoting the Quality of Medicines* program and/or on relevant subject matter. We expect the duration of this interview to be one hour. We plan to ask you about the drug quality process in Myanmar, as well as program activities, Technical Assistance and Capacity Building, conducted by US Pharmacopeial Convention with funding from USAID. There are no known risks or direct benefits related to your participation; however, your inputs may lead to recommendations that benefit actors engaged in Myanmar quality drug supply—and, thereby, the general public.

All information that you share will be kept confidential. We will aggregate and present our findings to USAID in a way that cannot be attributed to any individual or organization. Therefore, please feel free to speak openly and candidly with us. Your participation is voluntary. Please feel free to ask to skip any question that you do not feel comfortable answering, end this interview at any point, or withdraw your responses after the interview.

Do you confirm your consent to participate in this interview? ☐ Yes ☐ No

To guarantee accuracy, we find it useful to keep an audio record of the conversation. If you prefer, however, we will not use recording devices.

Do you confirm your consent for us to record this interview? ☐ Yes ☐ No

Interview Place and Date: _____

Interviewer(s):

Interviewee Name & Title:

Sex: ☐ Female ☐ Male

Introduction:

- a. Tell me what you have heard, if anything, about the PQM project in Myanmar?
- b. Tell me about your job, what do you do?
- c. How do you interact with the Department of Food and Drug Administration?
- d. Please share with me what you know about the process for monitoring drug quality here in Myanmar.
- e. What would you say are the strengths and what are the weaknesses of the current drug quality assurance system here in Myanmar?
- f. What is working well in the drug quality assurance system? And what is not work very well?

AQ1: In what ways, and to what extent, was the DFDA's institutional capacity strengthened to monitor drug quality as a result of USAID assistance?

Probes:

- a. How would you rate the level of drug quality in Myanmar today, especially in comparison to 5 years ago?
 - a. How satisfied are you, today, with the drug quality assurance support provided by the DFDA's?
 - b. How satisfied were you 5 years ago with the drug quality assurance support provided by the DFDA's?
- b. How has the process changed over time? What has changed? What has not changed that you would like to see changed?
 - a. What have you seen happening at DFDA that you can point to as evidence of this?
- c. How has the information on product quality been used for decision making?
- d. How many and what types of policies have been developed because of this capacity building program? How well are these policies being carried out?
- e. What effect(s), if any, have you seen on your own work?

AQ1d: How did the project's design contribute to country engagement and ownership?

Probes:

- a. In your opinion, to what degree do you believe the government is now taking responsibility for this process?
- b. Why are they? Or why are they not taking ownership?
- c. What aspects of the project's design are contributing to this?

AQ3: What specific lessons can be learned and applied to other future programs and activities in Myanmar?

AQ3b: In your experience, what practices should, or should not, be applied for future activities specifically focused on strengthening an organization or institution?

AQ3c: In your experience, what practices should, or should not, be applied for future technical assistance activities where the primary objective may not be institutional strengthening?

ANNEX E. INTERVIEWEE LIST

STAKEHOLDER GROUP	RESPONDENT NAME	ORGANIZATIONAL AFFILIATION	SEX
Drug Quality Monitoring			
Government of Myanmar	1. Dr. Khin Chit	DFDA – Nay Pyi Taw	Female
	2. Hlaing Hlaing Htet	DFDA – Nay Pyi Taw	Female
	3. Khint Su Han	DFDA – Nay Pyi Taw	Female
	4. Phyu Khine Thet	DFDA – Nay Pyi Taw	Female
	5. Sai Phone Myint Kyaw	DFDA - Mandalay	Male
	6. Yin Myo Thu	DFDA - Mandalay	Female
	7. Ma Shwe Sin Nyein	DFDA - Mandalay	Female
	8. Ma Phyu Sin Ko	DFDA - Mandalay	Female
IP	9. Dr. Donnell Charles	USP-PQM (USA)	Male
	10. Dr. Yanga Dijiba	USP-PQM (USA)	Male
	11. Dr. Lu Lu Kyaw	USP-PQM (Myanmar)	Male
USAID	12. Karen Cavanaugh	USAID	Female
	13. Feliciano Monti	USAID	Male

ANNEX F. EVALUATION TEAM MEMBERS

Overall Team Leader, Principal Investigator/Institutional Capacity Building Specialist, Component B: Dr. Donna A. Espeut is a public health specialist with extensive experience in monitoring and evaluation (M&E), health systems strengthening and maternal and child health. She has over 20 years of experience designing, implementing and evaluating public health programs. Dr. Donna Espeut has served as an evaluation team leader for USAID and other donor-funded evaluations in Africa, Asia and the Caribbean with extensive experience conducting qualitative research and implementing mixed-methods evaluations of large-scale and complex multi-sectoral programs. She is an accomplished implementer and evaluator of Maternal, Newborn, and Child Health (MNCH) programs and demographic and health survey program. Notably, as the Deputy Director at Concern Worldwide US, she provided strategic direction, technical leadership, management and quality assurance for a \$41 million, multi-country MNCH innovation initiative funded by the Bill & Melinda Gates Foundation. In addition, she has conducted analysis of nutritional and health status of young children and mothers in Mozambique for the MEASURE DHS+ Project. Dr. Espeut is deeply familiar with USAID, with experience both implementing and evaluating USAID-funded public health programs. In 2015 and 2016, she has led the meta-evaluation of USAID/Kenya's APHIAplus health program and the baseline assessment of USAID's Nilotde Orphans and Vulnerable Children program in Kenya. Dr. Espeut holds a Ph.D. in Reproductive Health and Family Planning and a Master of Health Science in Maternal and Child Health from Johns Hopkins University, and a B.A. in Human Biology from Stanford University. She is fluent in English and proficient in Spanish.

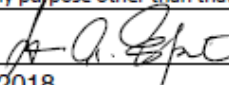
Research Specialist, Component B: Ms. Angela Thaung is a skilled researcher and program coordination specialist with more than two decades of experience monitoring and evaluating capacity building in organizations and interventions. As an Individual Capacity Building Trainer/Consultant with the Myanmar Institute for Gender Studies, she promotes institutional and individual capacity building with the aim of enhancing and building dialogue skills in practice. Most recently as Local DG and Civil Society Specialist on the Mid-term Performance Evaluation of USAID Civil Society and Media Activity, Ms. Thaung evaluated the project's achievements and contributions, especially as it related to gender, ethnic minorities and people with disabilities. As Evaluation Team Member for the Midterm Evaluation Shan State: Peace, Reconciliation, and Development through Community Empowerment project, she assessed project design, measured contribution to the peace process; identified changes that occurred; documented lessons learned, and made recommendations. As a native Burmese, Ms. Thaung, brings extensive knowledge of Myanmar's operating environment. She holds a Master of Public Administration from the Institute of Economics in Yangon, and speaks, reads and writes in Myanmar and English.

ANNEX G. DISCLOSURE OF CONFLICT OF INTEREST

Disclosure of Conflict of Interest for USAID Evaluation Team Members

Name	DONNA A. ESPEUT, PhD, MHS
Title	Independent Consultant
Organization	Social Impact
Evaluation Position?	☒ Team Leader ☐ Team member
Evaluation Award Number (contract or other instrument)	
USAID Project(s) Evaluated (Include project name(s), implementer name(s) and award number(s), if applicable)	
I have real or potential conflicts of interest to disclose.	☐ Yes ☒ No
If yes answered above, I disclose the following facts: <i>Real or potential conflicts of interest may include, but are not limited to:</i> 1. Close family member who is an employee of the USAID operating unit managing the project(s) being evaluated or the implementing organization(s) whose project(s) are being evaluated. 2. Financial interest that is direct, or is significant though indirect, in the implementing organization(s) whose projects are being evaluated or in the outcome of the evaluation. 3. Current or previous direct or significant though indirect experience with the project(s) being evaluated, including involvement in the project design or previous iterations of the project. 4. Current or previous work experience or seeking employment with the USAID operating unit managing the evaluation or the implementing organization(s) whose project(s) are being evaluated. 5. Current or previous work experience with an organization that may be seen as an industry competitor with the implementing organization(s) whose project(s) are being evaluated. 6. Preconceived ideas toward individuals, groups, organizations, or objectives of the particular projects and organizations being evaluated that could bias the evaluation.	

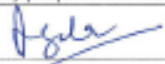
I certify (1) that I have completed this disclosure form fully and to the best of my ability and (2) that I will update this disclosure form promptly if relevant circumstances change. If I gain access to proprietary information of other companies, then I agree to protect their information from unauthorized use or disclosure for as long as it remains proprietary and refrain from using the information for any purpose other than that for which it was furnished.

Signature	
Date	08 May 2018

Disclosure of Conflict of Interest for USAID Evaluation Team Members

Name	Ms. Angela B. Thuang
Title	Research Specialist
Organization	Social Impact
Evaluation Position?	☐ Team Leader ☒ Team member
Evaluation Award Number (contract or other instrument)	AID-486-1-14-00001 (IDIQ) / 720-482-18-F-00003 (Task Order)
USAID Project(s) Evaluated (Include project name(s), implementer name(s) and award number(s), if applicable)	USAID/Burma Health Sector Evaluation: Assessment of Capacity Building of Myanmar Department of Food and Drug Administration (DFDA) / Promoting the Quality of Medicines (PQM) - US Pharmacopoeia Assessment of Capacity Building of Myanmar Department of Health Planning (DHP) / Demographic and Health Survey (DHS) - ICF International
I have real or potential conflicts of interest to disclose.	☐ Yes ☒ No
If yes answered above, I disclose the following facts: <i>Real or potential conflicts of interest may include, but are not limited to:</i> 1. Close family member who is an employee of the USAID operating unit managing the project(s) being evaluated or the implementing organization(s) whose project(s) are being evaluated. 2. Financial interest that is direct, or is significant though indirect, in the implementing organization(s) whose projects are being evaluated or in the outcome of the evaluation. 3. Current or previous direct or significant though indirect experience with the project(s) being evaluated, including involvement in the project design or previous iterations of the project. 4. Current or previous work experience or seeking employment with the USAID operating unit managing the evaluation or the implementing organization(s) whose project(s) are being evaluated. 5. Current or previous work experience with an organization that may be seen as an industry competitor with the implementing organization(s) whose project(s) are being evaluated. 6. Preconceived ideas toward individuals, groups, organizations, or objectives of the particular projects and organizations being evaluated that could bias the evaluation.	N/A

I certify (1) that I have completed this disclosure form fully and to the best of my ability and (2) that I will update this disclosure form promptly if relevant circumstances change. If I gain access to proprietary information of other companies, then I agree to protect their information from unauthorized use or disclosure for as long as it remains proprietary and refrain from using the information for any purpose other than that for which it was furnished.

Signature	
Date	15 August 2018

U.S. Agency for International Development
1300 Pennsylvania Avenue, NW
Washington, DC 20523