

Promoting the Quality of Medicines Plus

Strengthening National Quality Control Laboratories (NQCL) to Ensure Quality Medical Products

Webinar

April 15, 2021

8:00 – 9:30 a.m. EST



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Promoting the Quality of Medicines Plus

Welcome

Alison Collins

Agreement Officer's Representative
Office of Health Systems, USAID



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Dr. Farouk Umaru
Director, Global Public Health
Laboratory Programs,
Global Health and Manufacturing
Services Division,
US Pharmacopeia



Objectives



Participants should be able to:

- Describe the importance of quality control (QC) labs in national health systems
- Enumerate the role of QC labs in the detection of poor-quality medical products in the supply chain
- Describe the international standards used to benchmark quality management performance
- Outline PQM+ approaches to building QC labs capacity in low- and middle-income countries (LMICs)
- Share country examples of strengthened national and regional QC labs

What Is Quality Control?

“... the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical.”

– *World Health Organization*

“... the operational techniques and activities used to fulfill requirements for quality.”

– *American Society for Quality*

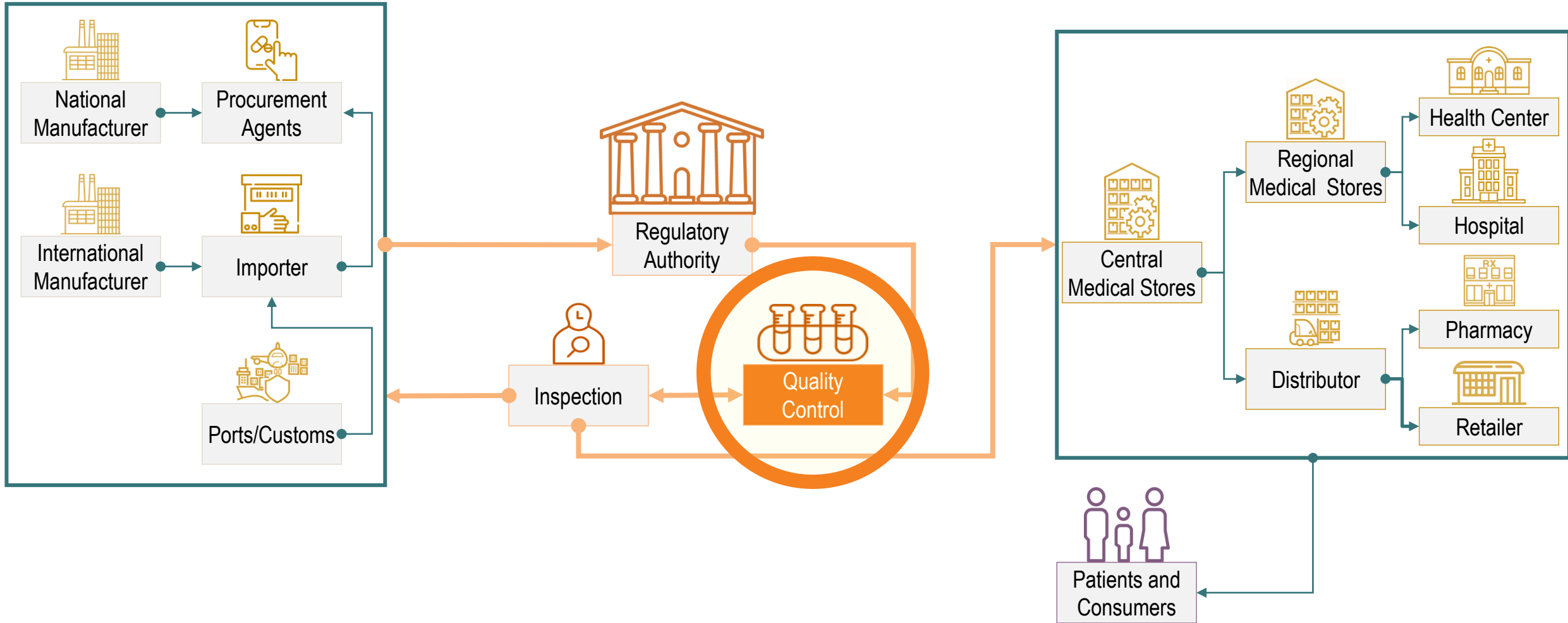


What Are National Quality Control Labs?

- NQCLs are national laboratories designated to control the quality of medical products in circulation. They are mandated to **generate quality data** for regulatory decision-making.
- NQCLs are the **backbone** of the medical products supply chain system that detects and prevents substandard and falsified (SF) medical products from circulating in country.
- They operate under **strict international standards** of practices to generate data that are reliable, accurate, consistent, and trustworthy.



Medical Products Supply Chain



Why Are NQCLs Important?

- Quality medical products, including those for tuberculosis, maternal and child health, malaria, and infectious diseases, underpin national health programs.
- Pharmaceutical supply chains in LMICs are vulnerable to the introduction and proliferation of SF medical products, including those used to prevent and treat COVID-19.
- By helping to detect SF medical products and remove them from circulation, **NQCLs save lives.**

Early Warning System

Medical Product Alert N°2/2021: Falsified COVID-19 Vaccine BNT162b2

Falsified COVID-19 Vaccine BNT162b2 identified in the WHO region of the Americas

26 March 2021 | Medical product alert | Geneva | Reading time: 2 min (443 words)

Original Investigation | Global Health

August 10, 2018

Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries

A Systematic Review and Meta-analysis

Sachiko Ozawa, PhD, MHS^{1,2}; Daniel R. Evans, MSc²; Sophia Bessias, MPH³; et al



Apps Box Yong Studios Class... Promoting the Qual... Constant Contact U.S. Pharmacopeia PQM-USAID New Mexico

died on 23 December after taking the contaminated medicine. There was bleeding from his mouth and also bleeding from his urinary tract."



Many of those affected are poor patients

Asim Saeed said: "All patients are suffering from bleeding from the mouth and urinary tracts. We have been in the hospital for seven days but no one came to



Devex

Poor-quality medicine: A global pandemic

Many developing countries also lack the resources — both in terms of personnel and ... On a bigger scale, there can be further consequences. ...

"For countries to be able to confront poor-quality medicines, they need to have
Jun 29, 2017



ScienceDaily

New study finds fake, low-quality medicines prevalent in the ...

In low- and middle-income countries, more than 13 percent of the ... limited information on the economic impact of poor quality medicines, with ... "New study finds fake, low-quality medicines prevalent in the developing world.

Aug 10, 2018

Critical Role in the Supply Chain Process

Who finds the needle in the haystack?



Who finds the evidence of poor quality?



How Do NQCLS Build Trust in Health Systems?

- Safeguard **quality**, **efficacy**, and **safety** of medical products.
 - Work on content/assay and identification to determine **quality**
 - Work on dissolution to determine **efficacy**
 - Work on related impurities and microbial contamination to determine **safety**
- Follow internationally recognized best practices of Quality Management System (QMS) standards to
 - Consistently generate reliable data for policy and regulatory decisions
 - Fulfil customer's demand for quality assured medical products

Standardized Laboratory Quality Management Systems

Building Trust, Empowering Regulators



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International Standards of Practices

WHO Prequalification (PQ) Technical Report Series 957:2010

© World Health Organization
WHO Technical Report Series, No. 957, 2010

Annex 1

WHO good practices for pharmaceutical quality control laboratories

General considerations

ISO/IEC 17025:2017

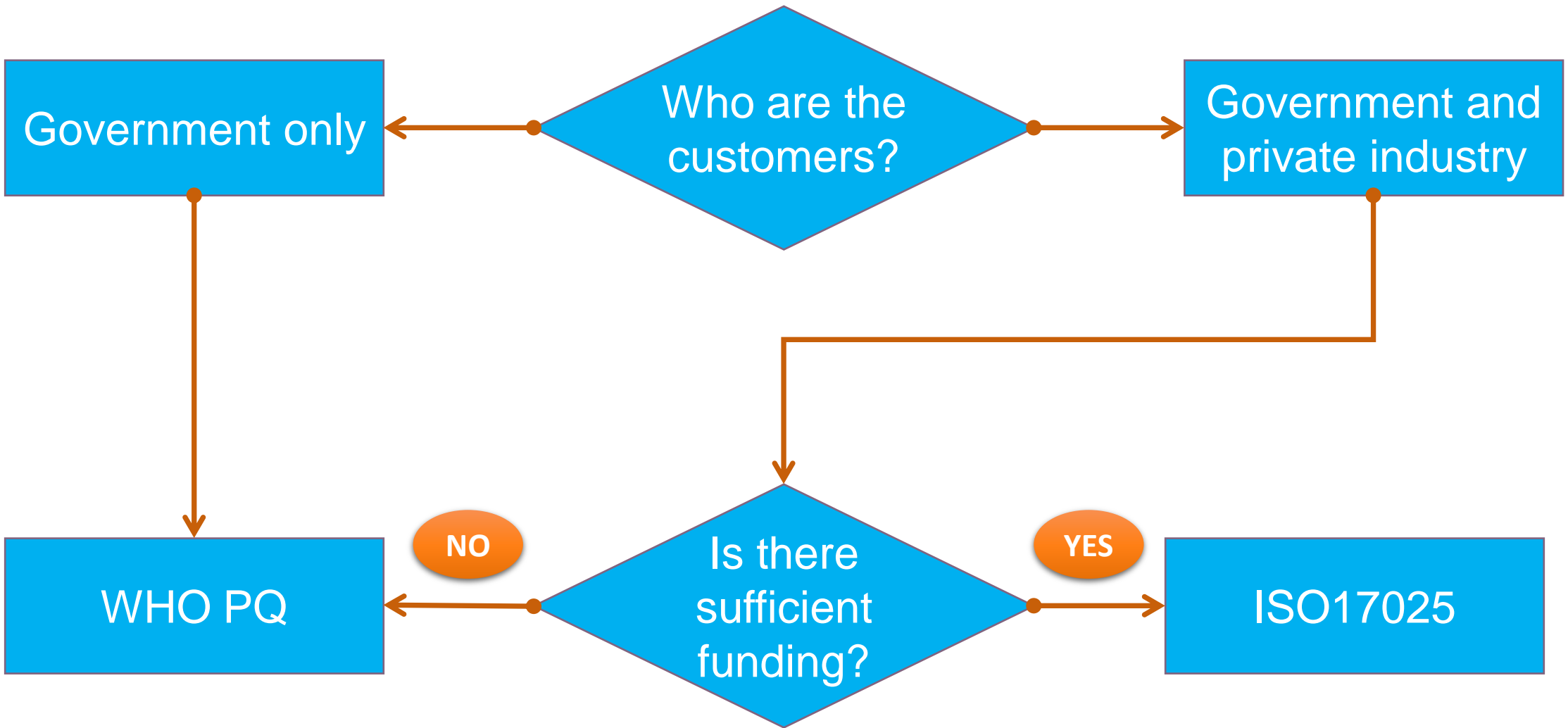
**INTERNATIONAL
STANDARD**

**ISO/IEC
17025**

Third edition
2017-11

**General requirements for the
competence of testing and calibration
laboratories**

*Exigences générales concernant la compétence des laboratoires
d'étalonnages et d'essais*





**WHO
Prequalification
Status**

| WHO | | ISO |
|-----|------------------------|-----|
| | Resources | |
| ✓ | Personnel | ✓ |
| ✓ | Equipment | ✓ |
| ✓ | Facility | ✓ |
| ✓ | Products/services | ✓ |
| | Processes | |
| ✓ | Testing | ✓ |
| ✓ | Sample handling | ✓ |
| ✓ | OOS/nonconforming work | ✓ |
| ✓ | Complaints | ✓ |
| | Management | |
| ✓ | Documents/records | ✓ |
| ✓ | Risk opportunities | ✓ |
| ✓ | Corrective action | ✓ |
| ✓ | Improvement | ✓ |
| ✓ | Internal audit | ✓ |
| ✓ | Management review | ✓ |
| ✓ | Safety | ✓ |

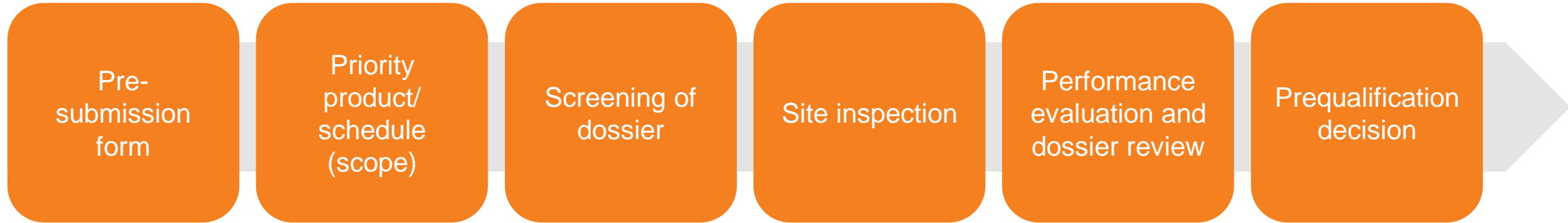


**ISO/IEC:17025
Accreditation
Certificate**





WHO Prequalification Status Process



ISO/IEC:17025 Accreditation Certificate Process



PQM and PQM+ Approach to NQCL Accreditation and Strengthening

The How and Why of Accreditation



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PQM+ Approach to Strengthening NQCLs

1 Conduct needs assessment to determine gaps and/or nonconformance to standards

Stepwise Assessment Tool Towards Accreditation (SATTA)

WHO checklist

ISO standard

2 Develop customized interventions to address specific needs and close gaps

Laboratory Development Plan to include corrective and preventive action plans (CAPAs)

Implementation work plan

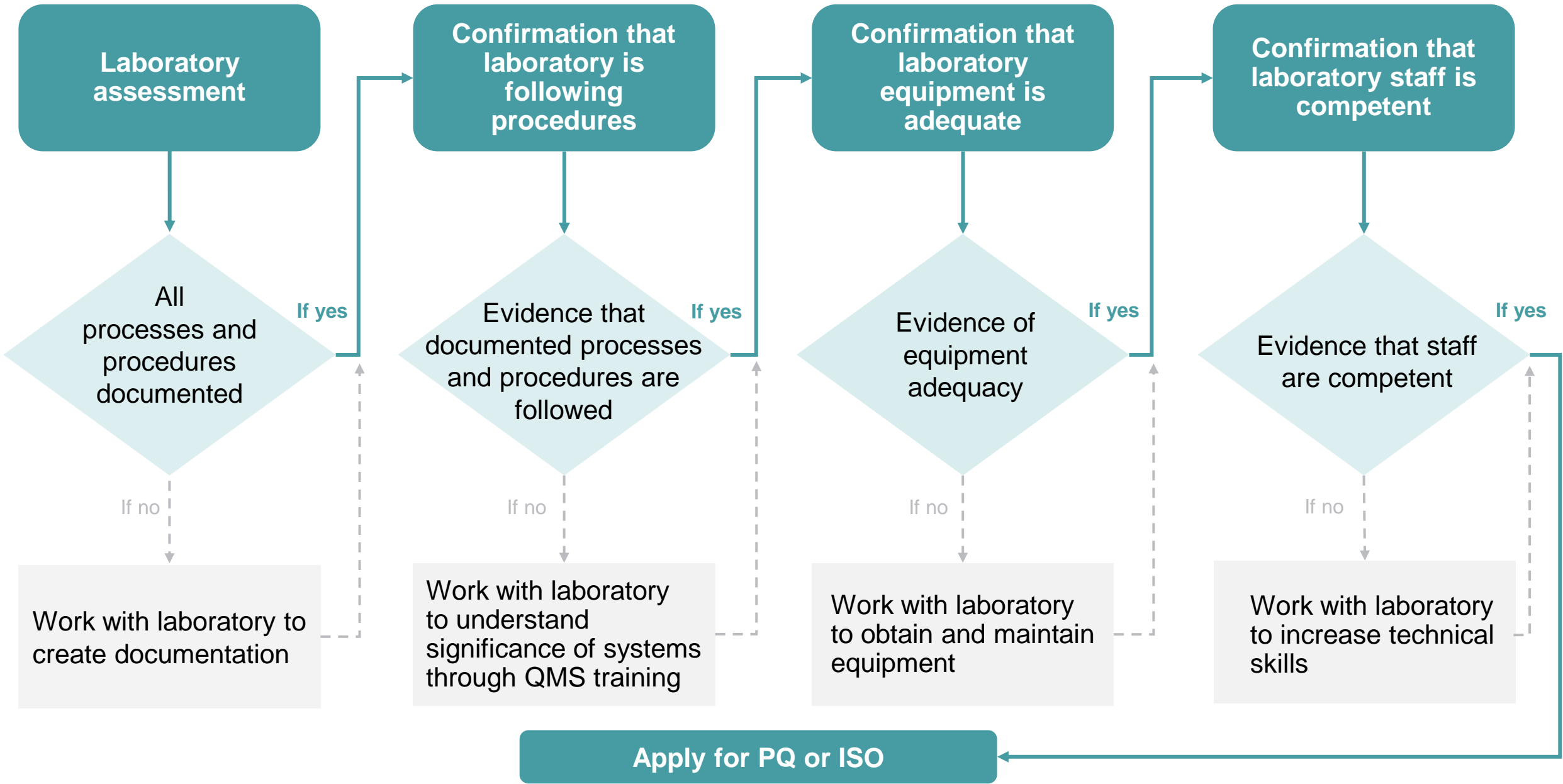
Sustainability plan

3 Collect and measure indicators and evaluate outcomes for continuous quality improvement

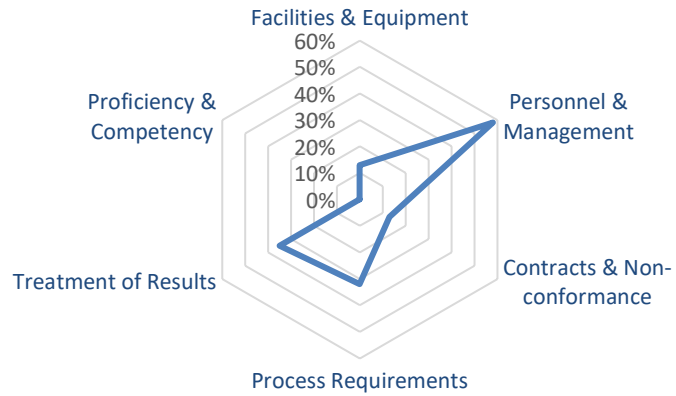
Intermediate results

Indicators and means of verification

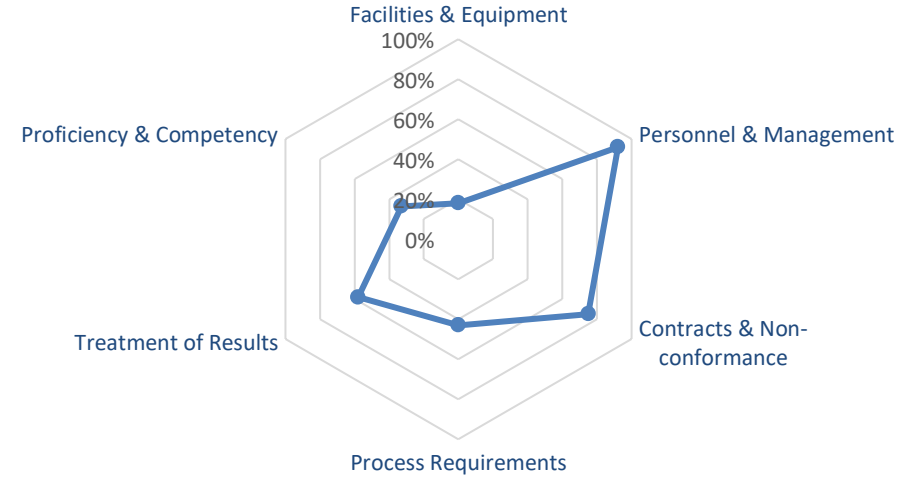
DevResults – results by numbers



Percentage Conformance Score for Niger LANSPEX National Quality Control Lab System Assessment: Nov 2020



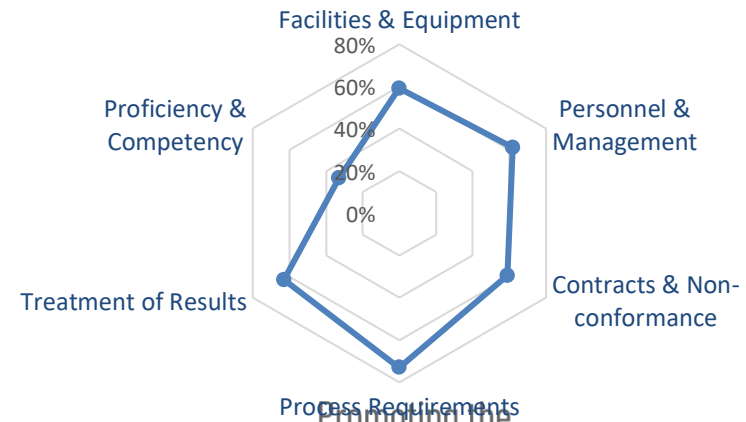
Percentage Conformance Score for DRC LAPHAKI National Quality Control Lab System Assessment: Dec 2020



Percentage Conformance Score for Cambodia National Quality Control Lab System Assessment: March 2021

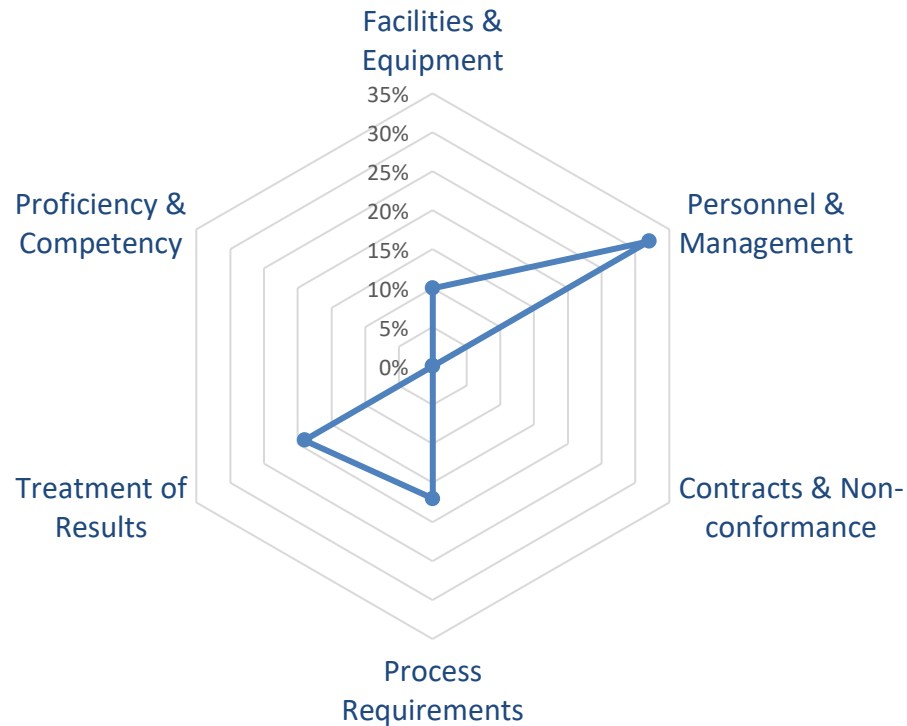


Percentage Conformance Score for Laos National Quality Control Lab System Assessment: March 2021

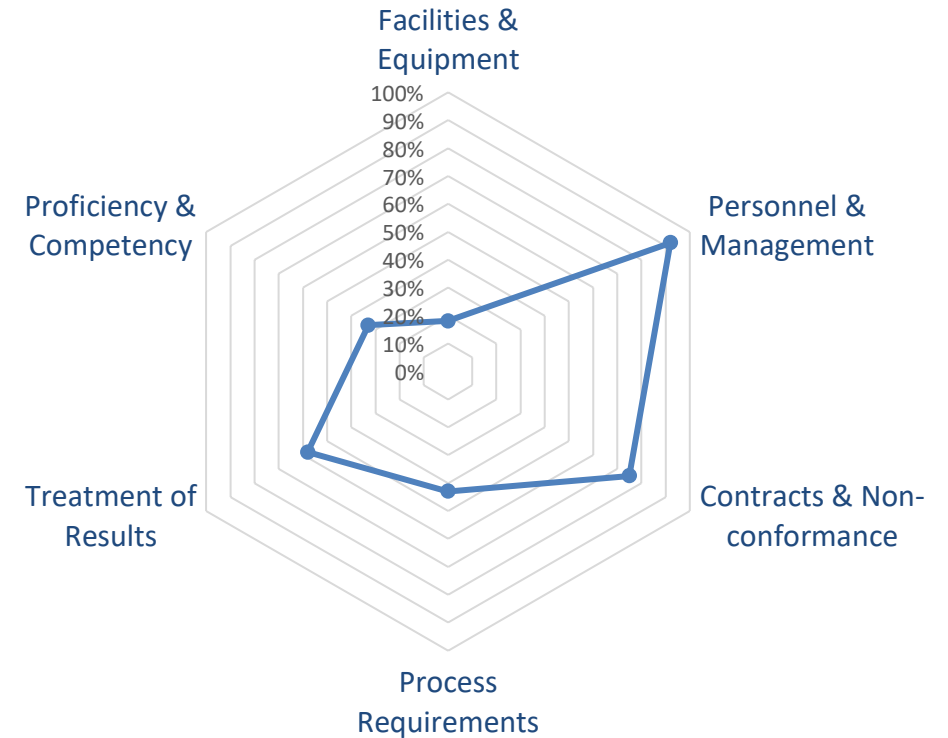


Improvement of DRC-LAPHAKI NQCL system towards achieving ISO 17025: 2017 (March – December 2020)

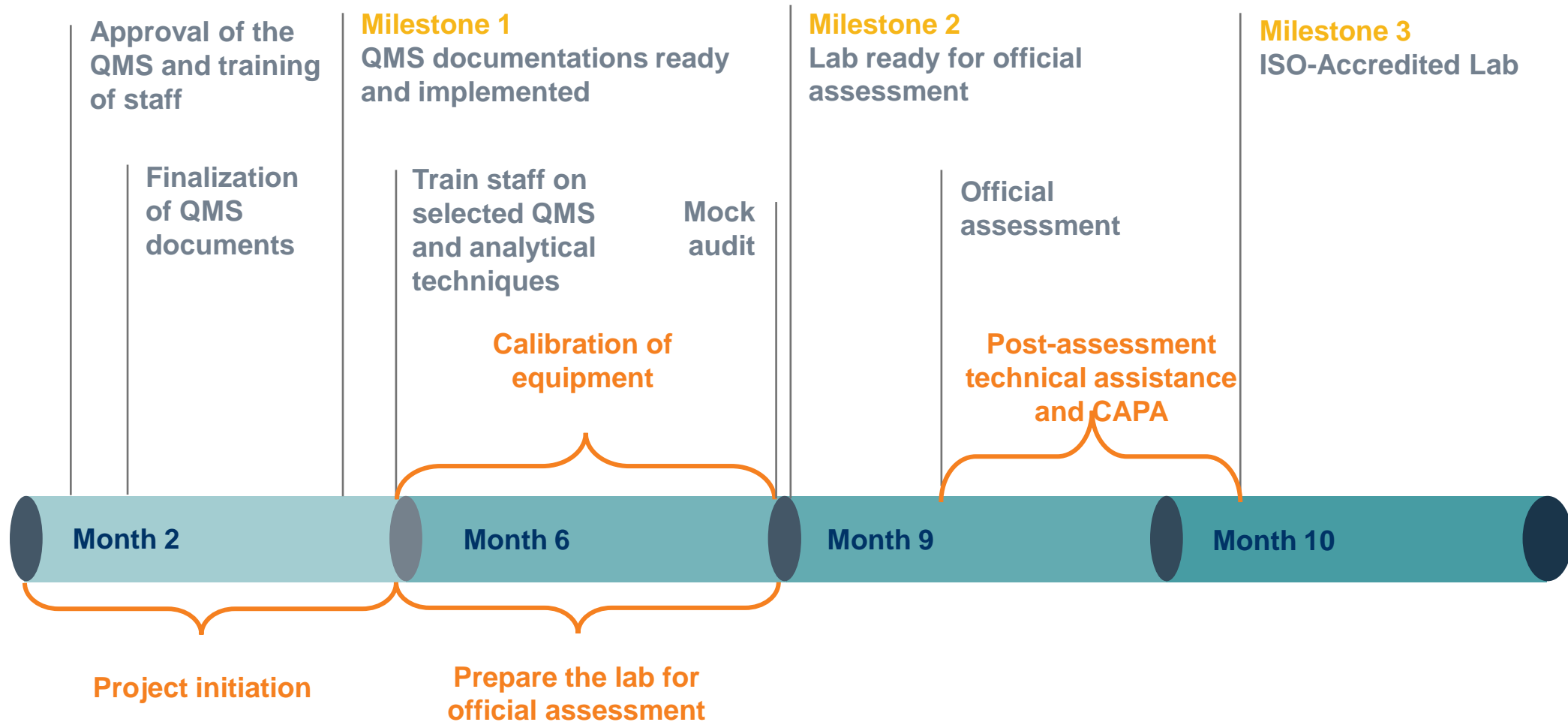
Percentage Conformance Score for DRC LAPHAKI National Quality Control Lab System Baseline Assessment: March 2020



Percentage Conformance Score for DRC LAPHAKI National Quality Control Lab System Assessment: Dec 2020



Overview of ISO 17025:2017 Accreditation Process



Building Stronger Country and Regional QC Labs to Enhance Sustainability

Country and Regional Experience



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Adebola Adekoya
Senior Technical Officer,
PQM+ Nigeria



Nigeria



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

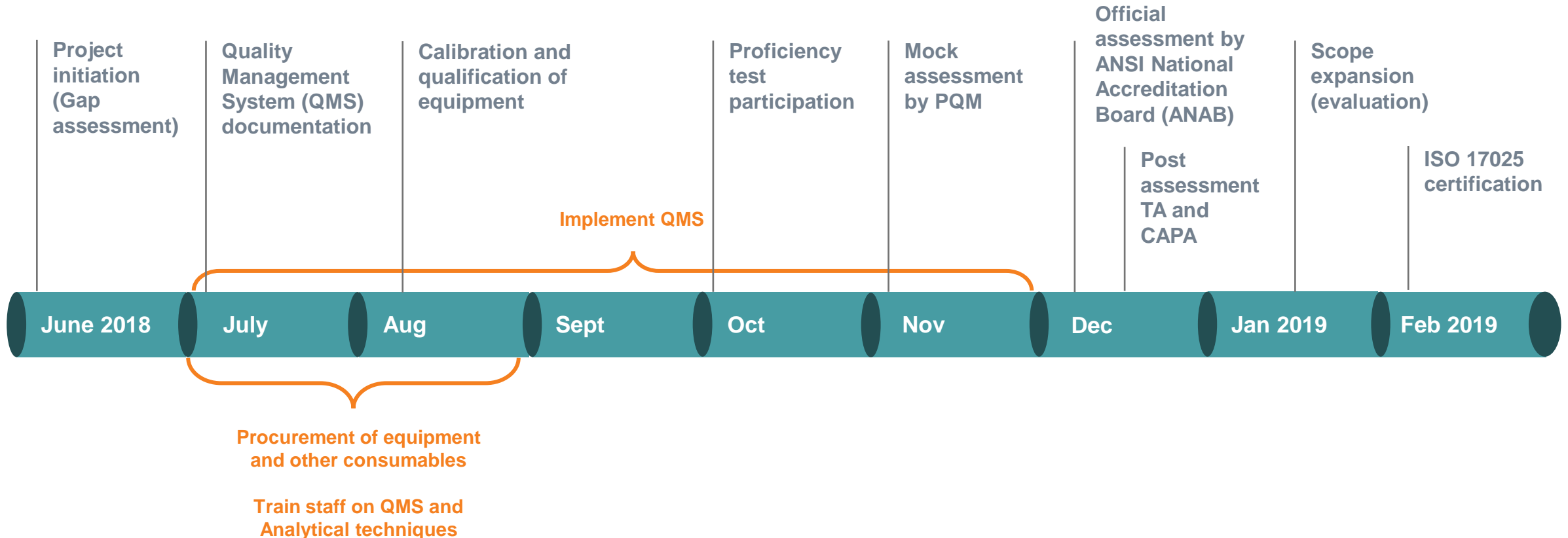
**NAFDAC National Control Laboratory for
Vaccines and Other Biologicals, Yaba-Lagos**
8/10 Edmund Crescent/Merret Road, Medical Compound
Yaba, Lagos Nigeria

Fulfills the requirements of

ISO/IEC 17025:2017

- The National Agency for Food and Drug Administration and Control (NAFDAC) oversees the country's QC labs. **Five** have achieved ISO accreditation.
- Those labs are now mentoring two additional labs toward ISO accreditation through the **collaborative learning model**.
- One National Institute for Pharmaceutical Research and Development (NIPRD) lab is now **self-sustaining** and renewed its accreditation without funding from USAID's PQM+ program, except for staff salaries.

Yaba, National Control Laboratory for Vaccines and other Biologicals, Lagos



Building Sustainability

- The National Regulatory Authority has five accredited laboratories with harmonized quality management systems (QMS) documents. It uses multisite group accreditation, thereby saving 50% of the annual accreditation cost.
- NIPRD migrated to using a local accreditation body and saved 50% annual cost.
- NIPRD also received third-party testing contract from the Malarial Consortium, earning additional funds.

Tabassum Munira
Technical Officer,
PQM+ Bangladesh



Bangladesh's National Control Lab (NCL)

Organizational Structure of NCL

PHYSICOCHEMICAL LABORATORY/
DRUG TESTING LABORATORY (DTL)
WHO PQ/ANAB achieved

VACCINE UNIT
*Working toward
WHO PQ*

MICROBIOLOGY LABORATORY
WHO PQ/BAB achieved

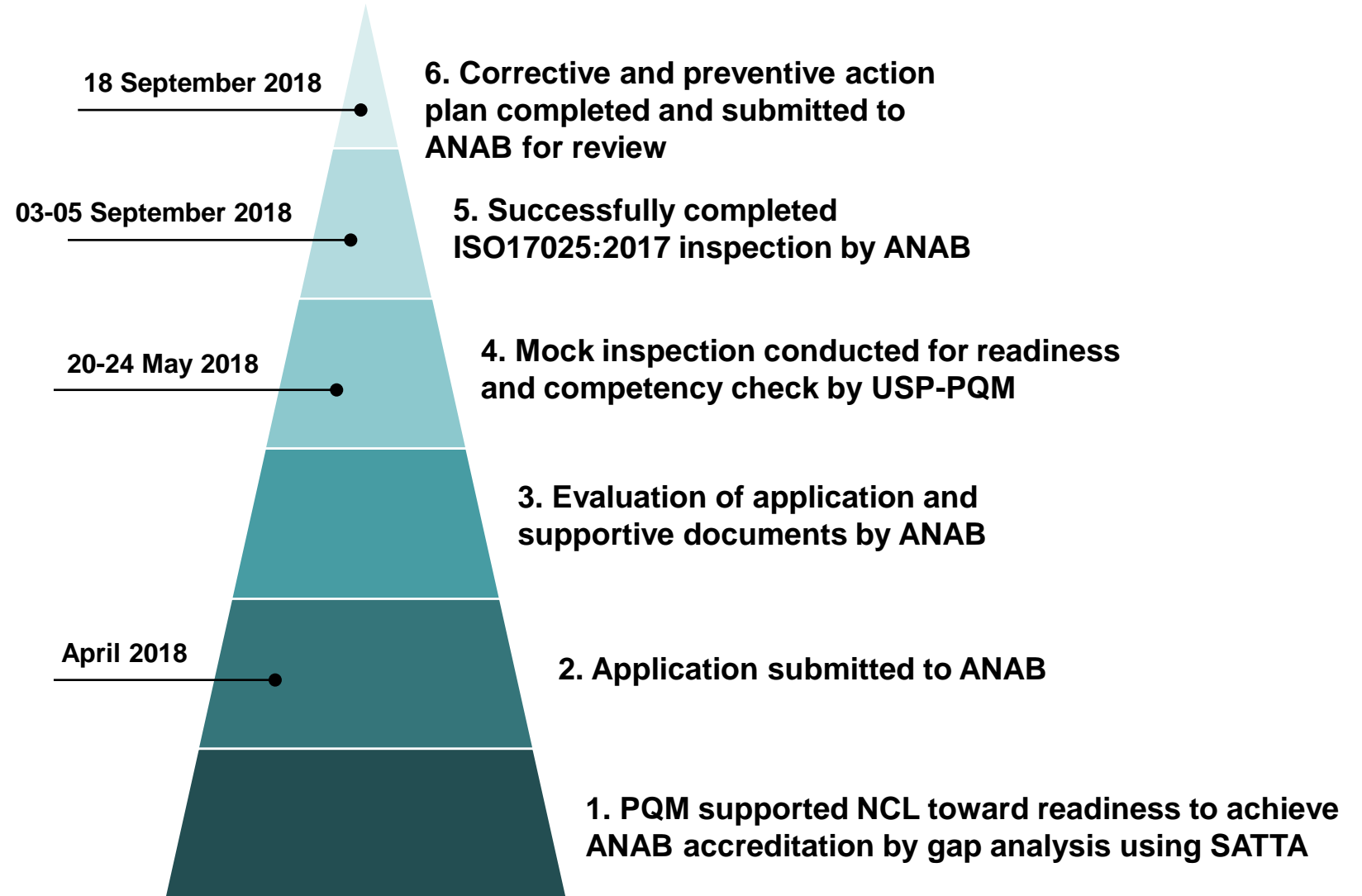
- Chemical Laboratory
- Animal Laboratory

Bangladesh's National Control Laboratory

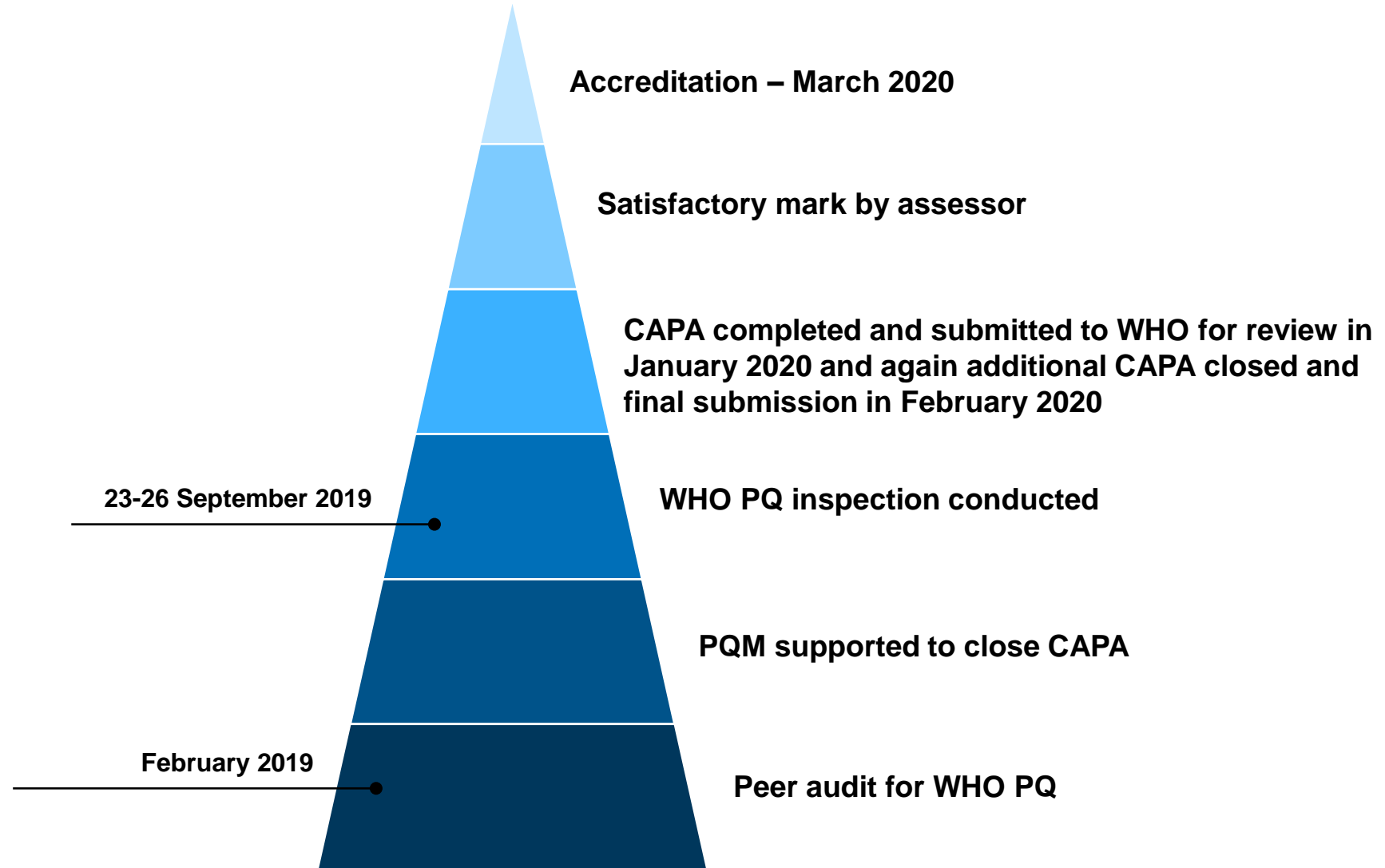


- In October 2018, the National Control Laboratory (physicochemical laboratory) became the first laboratory in the country to achieve ANAB certification – ISO/IEC 17025:2017.
- In March 2020, the National Control Laboratory became the first laboratory in the country to achieve WHO pre-qualification.

Roadmap to ISO 17025:2017 Accreditation



Roadmap Toward WHO PQ



Dr. Farouk Umaru
Director, Global Public Health
Laboratory Programs,
Global Health and Manufacturing
Services Division,
US Pharmacopeia

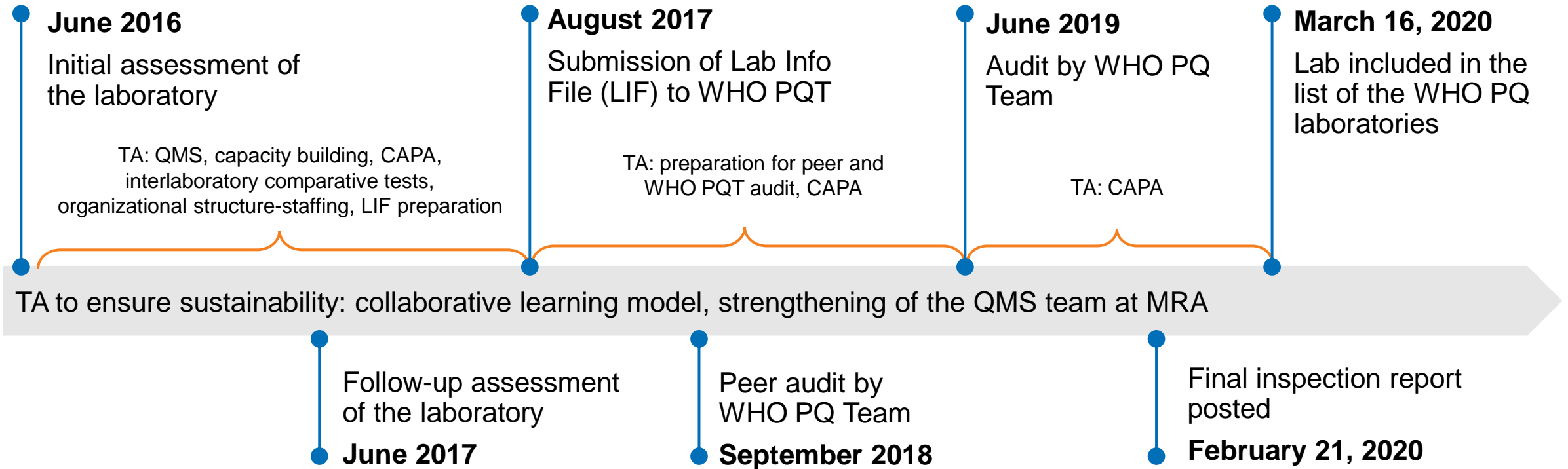


Kazakhstan

- In 2020, the regional QC laboratory in Karaganda, which is part of the national Medicines Regulatory Authority, became the first WHO-prequalified laboratory in Central Asia.
- The QC lab in Almaty is also in the process of achieving WHO PQ.
- To ensure sustainability, the collaborative learning model was used and collaboration between the laboratories has been encouraged.



Kazakhstan: WHO Prequalification of Karaganda Medicines Quality Control Laboratory



Conclusions

- QC labs are critical to ensuring the quality of medical products circulating in country and used by national health programs.
- NQCLs help save lives and reduce morbidity.
- PQM+'s approach and tools build internationally recognized quality management systems and stronger labs.
- At present, PQM+ is working with 34 labs in 13 countries; 17 labs have either achieved or maintained international accreditation.
- PQM+ builds on the legacy of USAID's PQM program, which between 2009 and 2020 strengthened more than 90 QC labs in 33 countries.

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Questions?



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Thank you!

www.usp.org/global-public-health/promoting-quality-of-medicines

