

Promoting the Quality of Medicines Plus

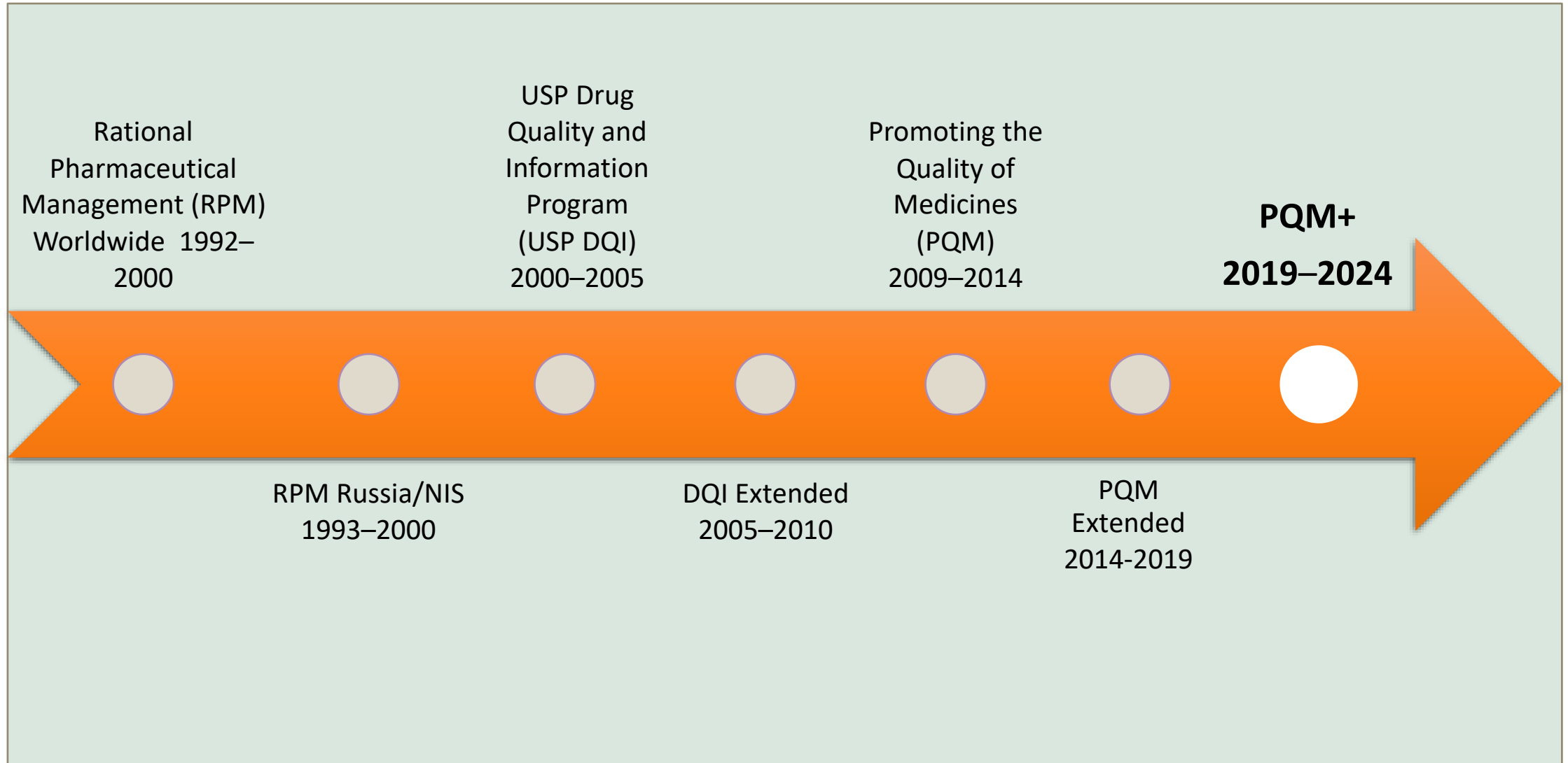
Overview of the Promoting the Quality of Medicines Plus (PQM+) Program

Presented at the FDA-USP webinar on Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines

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USP–USAID Cooperative Agreements



PQM+ Goal

To sustainably strengthen
medical product quality
assurance systems in
low-and middle-income
countries.



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+



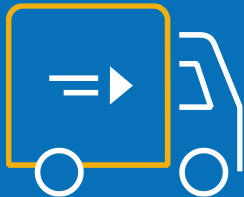
PQM+ Results Areas

1



Improve **governance** for medical product quality assurance systems

2



Improve country and regional **regulatory** systems to assure the quality of medical products in the public and private sectors

3



Optimize and increase **financial** resources for medical product quality assurance

4



Increase **supply** of quality-assured essential medical products of public health importance

5



Advance global medical products **quality** assurance learning and operational agenda

PQM/PQM+ Achievements

Support to Regulatory Authorities towards WHO Maturity Level 3

11 countries

In following regulatory functions:

- Laboratory testing (10 countries)
- Regulatory inspection (9)
- Regulatory systems (7)
- Market surveillance & control (7)
- Lot release (7)
- **Market authorization (6)**
- Vigilance (5)
- Licensing establishments (3)
- Clinical trials (3)

QC Laboratory ISO 17025 accreditation or WHO PQ

16 countries, 91 laboratories

- 19 new ISO 17025:2017 accreditations
- 11 new WHO Prequalifications



WHO PQ or WLA approvals for PQM/PQM+ supported manufacturers

15 countries, 100s manufacturers, 40 WHO PQ or WLA approvals

- 27 TB medicine approvals
- 8 NTD medicine approvals
- 4 MNCH medicine approvals
- 1 HIV opportunistic infection medicine approval
- 24 API approvals
- 16 FPP approvals

Marketing Authorization in LMICs benefits from Reliance



- Regulatory review is highly resource intensive
- FDA review experience is treasured
- Review products e.g., PARs can be regarded as public goods
- FDA – USP conference provides reliance opportunity and will help LMICs capacity to approve medicines.

**“Access to medicines
alone, without quality
assurance, is not
enough.”**

Dr. Matshidiso Moeti,
WHO Regional Director for Africa

