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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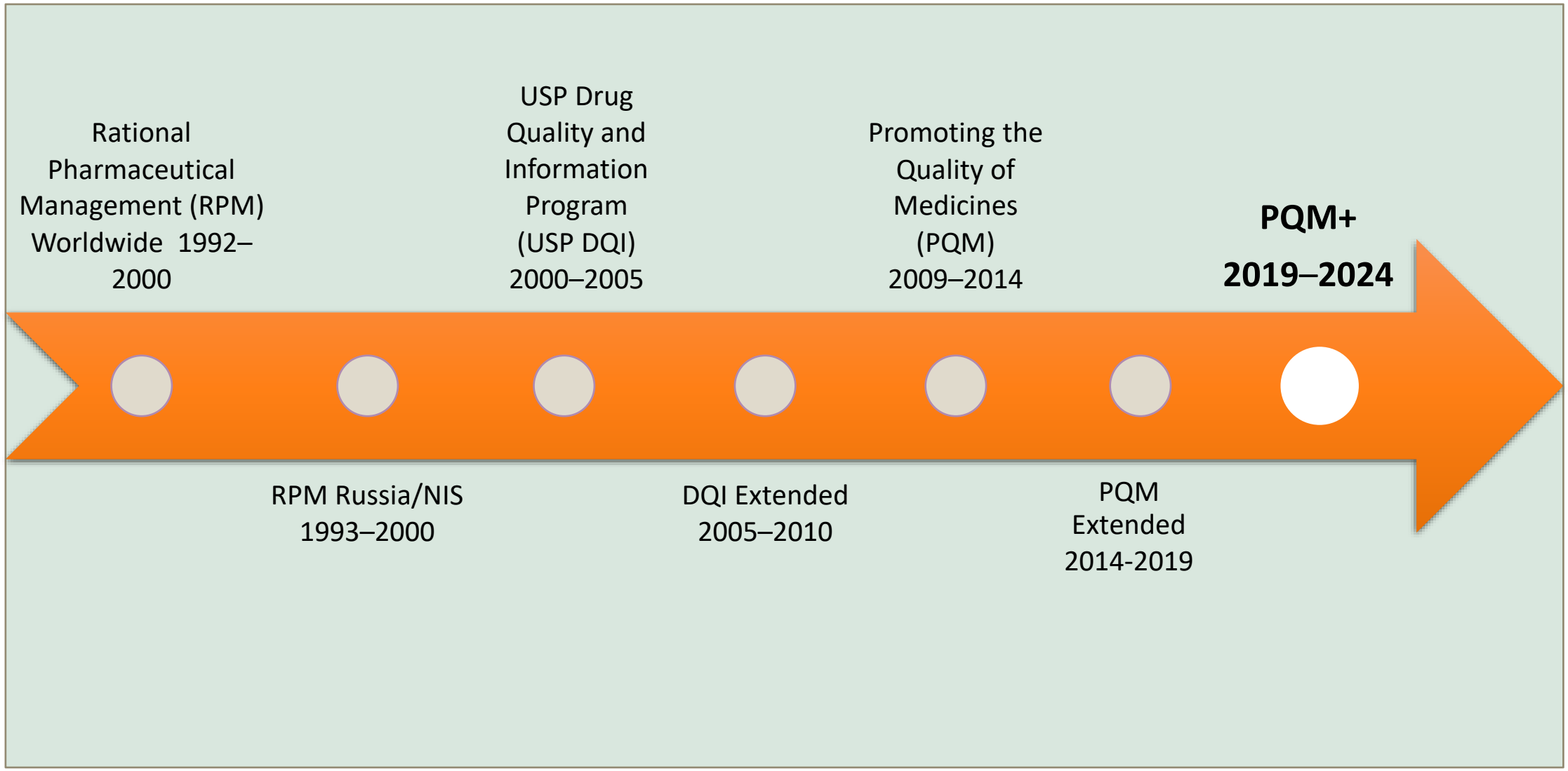
USP–USAID Cooperative Agreements



PQM+ Goal

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

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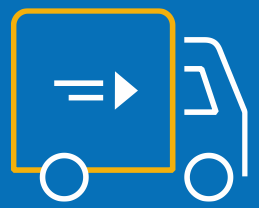
PQM+ Results Areas

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