Immunization Devices | In Vitro Diagnostics | Medicines | Vaccines | Vector Control Products

Introduction to WHO Prequalification Inspection Services

Mustapha Chafai, Team Lead,

WHO Access to Medicines and Health Products (MHP) Division,

Regulation and Prequalification (RPQ) Department, Prequalification unit (PQT), Inspection Services

Outline

Introduction of Inspection session

Who & where we are at WHO HQ

Overview of Inspection Services and activities

Brief update on ePQS

SESSION 6 – PARALLEL TRACK 14:00 – 17:00	WHO INSPECTION SERVICES Session Chair: Mustapha Chafai, Team Lead, PQT/INS, WHO Attendance mode: Hybrid
14:00–14:15	**Introduction to PQT/INS programme of activities,** Mustapha Chafai, Team Lead, INS
14:15–14:30	**Medicines Inspection Updates (APIs and FPPs),** Dimitrios Catsoulacos, Technical officer
14:30–14:45	**Bioequivalence Inspection Updates,** Elham Kossary, Technical officer
14:45–15:00	**Vaccines Inspection Updates,** Andrea Geyer, Technical officer
15:00-15:30	**Questions and Answers**
15:30-15:45	**Coffee/Tea break**
15:45–16:00	**In-vitro diagnostics Inspection Updates,** Philippe Boeuf, Technical officer,
16:00-16:15	**Vector Control Inspection Updates,** Mark Conrad, Technical officer
16:15-16:30	**Desk assessment and reliance approaches,** Mohamed Refaat/Stephanie Croft, Technical officer
16:30 – 16:45	**Update on new guidelines, DEG/EG contamination, and the use of new technologies,** Vimal Sachdeva, Technical officer
16:45 – 17:00	**Questions and answers**

WHO Division of **Access to Medicines and Health Products (MHP)**

Assistant Director General Yukiko Nakatani

Dept. Health Products Policy and Standards (HPS) — **Deus Mubangizi**

Dept. Regulation and Prequalification (RPQ) — **Rogério Gaspar**

Dept. Innovation and Emerging Technologies (IET) — **Deus Mubangizi (a.i.)**

Technical Standards & Specifications Deus Mubangizi (a.i.)	**INN & classification of medical products** Raffaella Balocco	**Access to Health Product Policies** Deus Mubangizi (a.i.)

Norms & Standards for Biological products

Norms & Standards for Pharmaceuticals

Blood & other products of human origin

Expert Committee on Drug Dependence

Assistive Technology

Medical Devices & Diagnostics

Essential Medicines List

Knowledge Management Advisor

Quality Management Advisor

Prequalification Rogério Gaspar (a.i.)

Regulation and Safety Hiiti Sillo

Inspection Services

IVD Assessment

Medicines Assessment

Vaccines & Immunization Devices Assessment

Vector Control Products Assessment

Regulatory Systems Strengthening

Regulatory Convergence and Networks
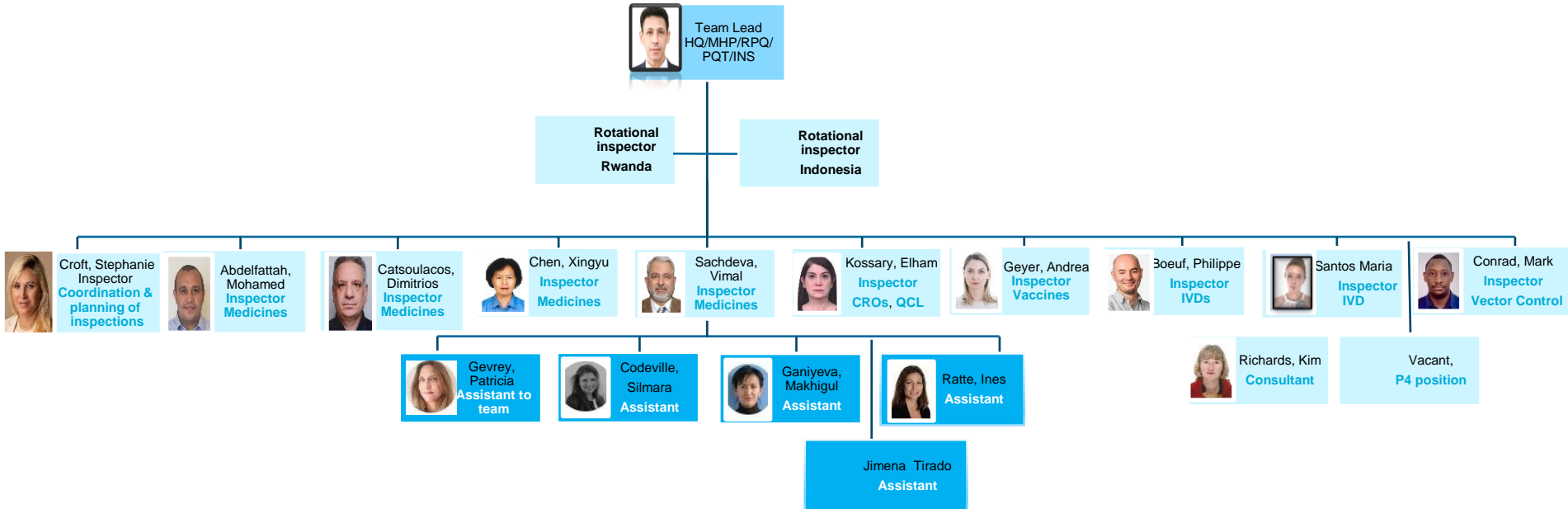
Facilitated Product Introduction
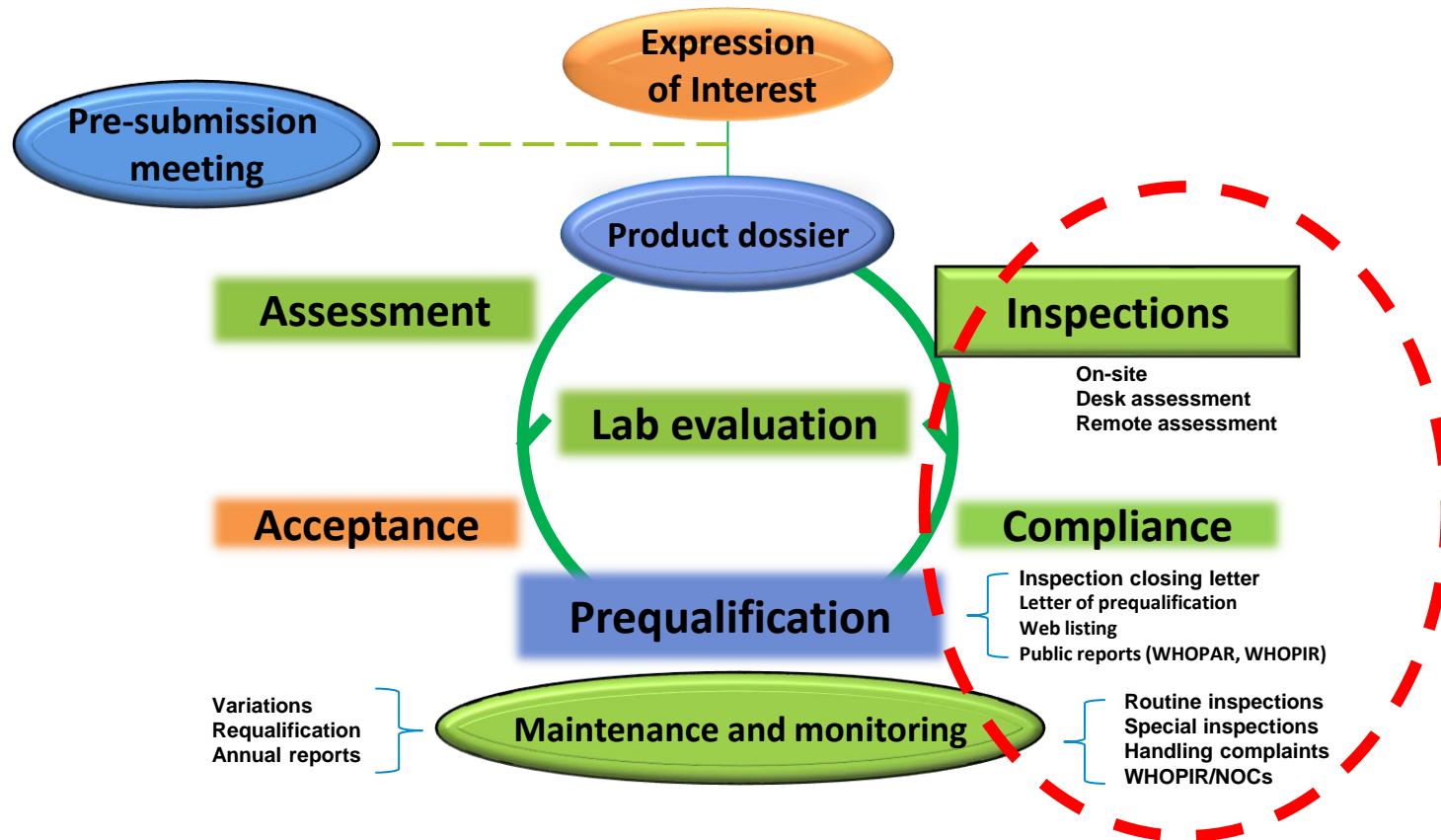
Laboratory Network and Services

Pharmacovigilance

Local Production & Assistance Jicui Dong

Health Technology Access Management Team

Special Assistance & Projects Team

HTAP & mRNA Technology Transfer Team

Inspection Services Team

Team Lead
HQ/MHP/RPQ/PQT/INS

Rotational inspector Rwanda

Rotational inspector Indonesia

Croft, Stephanie
Inspector
Coordination & planning of inspections

Abdelfattah, Mohamed
Inspector Medicines

Catsoulacos, Dimitrios
Inspector Medicines

Chen, Xingyu
Inspector Medicines

Sachdeva, Vimal
Inspector Medicines

Kossary, Elham
Inspector CROs, QCL

Geyer, Andrea
Inspector Vaccines

Boeuf, Philippe
Inspector IVDs

Santos Maria
Inspector IVD

Conrad, Mark
Inspector Vector Control

Gevrey, Patricia
Assistant to team

Codeville, Silmara
Assistant

Ganiyeva, Makhigul
Assistant

Ratte, Ines
Assistant

Richards, Kim
Consultant

Vacant,
P4 position

Jimena Tirado
Assistant

Role of Inspections for Prequalification

Expression of Interest

Pre-submission meeting

Product dossier

Assessment

Lab evaluation

Inspections
On-site
Desk assessment
Remote assessment

Acceptance

Compliance

Prequalification

Inspection closing letter
Letter of prequalification
Web listing
Public reports (WHOPAR, WHOPIR)

Variations
Requalification
Annual reports

Maintenance and monitoring

Routine inspections
Special inspections
Handling complaints
WHOPIR/NOCs

Role of Inspection Services

Inspection Services plays an integral role in the prequalification process of priority health products, ensuring their quality, safety and efficacy/performance by means of initial and repeated inspections, where necessary.

Finished pharmaceutical product manufacturing sites	**Active pharmaceutical ingredient manufacturing sites**	**Contract research organizations**
Quality control laboratories	**Vaccine manufacturing sites**	**In Vitro Diagnostics**
	Vector control product manufacturing sites	

Prequalification: Ensuring quality-assured medical products (Dec 2023)

Diagnostics

In vitro diagnostics (IVD), male circumcision device (MCD) & Emergency Use Listing (EUL)

- Cholera
- G6PD
- Glucose meter & test strips*
- HbA1c point of care test*
- Hep B
- Hep C
- HIV/AIDS
- HPV
- Malaria
- SARS-CoV-2
- Syphilis
- Tuberculosis

113 IVDs, 1 MCD

EUL: 40 COVID-19, 6 Ebola, 4 Zika

* Completed the development of technical specifications

Medicines

Finished pharmaceutical product (FPP), active pharmaceutical ingredient (API), quality control lab (QCL), biotherapeutic product (BTP) & similar biotherapeutic product (SBP)

- BTP/SBP (cancer, COVID-19, insulin)
- Child health
- COVID-19
- Diarrhoea
- Ebola virus diseases
- Hep B
- Hep C
- HIV/AIDS
- Influenza
- Malaria
- MDR bacterial infections
- Neglected tropical diseases
- New-born & young infants**
- Nicotine replacement therapy**
- Reproductive health
- Tuberculosis

657 FPPs (inc. 15 BTPs, 12 SBPs), 168 APIs, 58 QCLs

** Call for expression of interest issued. No PQed product yet

Medical devices

Immunization device (ImD) & cold chain equipment (CCE)

- Cold/freezer room
- Cold box & Vaccine carrier
- Cold chain accessory
- Coolant pack
- Injection device for vaccine
- Injection device for therapeutic
- Refrigerated vehicle
- Refrigerator & freezer
- Temperature monitoring device
- Waste management equipment

443 ImDs/CCEs

Vaccines

Vaccine (Vx), snake antivenom & Emergency Use Listing (EUL)

- 24 priority diseases, covering all vaccines required for routine immunization
- Cholera
- COVID-19
- Dengue
- Ebola virus diseases
- Malaria
- Snake antivenom

151 Vx, EUL: 13 Vx

Vector control

Vector control product (VCP) & active ingredient

- Aircraft disinfection product
- Indoor residual spraying product
- Insecticide-treated net
- Larvicide
- Space spraying product

87 VCPs

Inspection

- BTP, SBP
- FPP, API
- ImD
- IVD
- VCP
- Vaccine
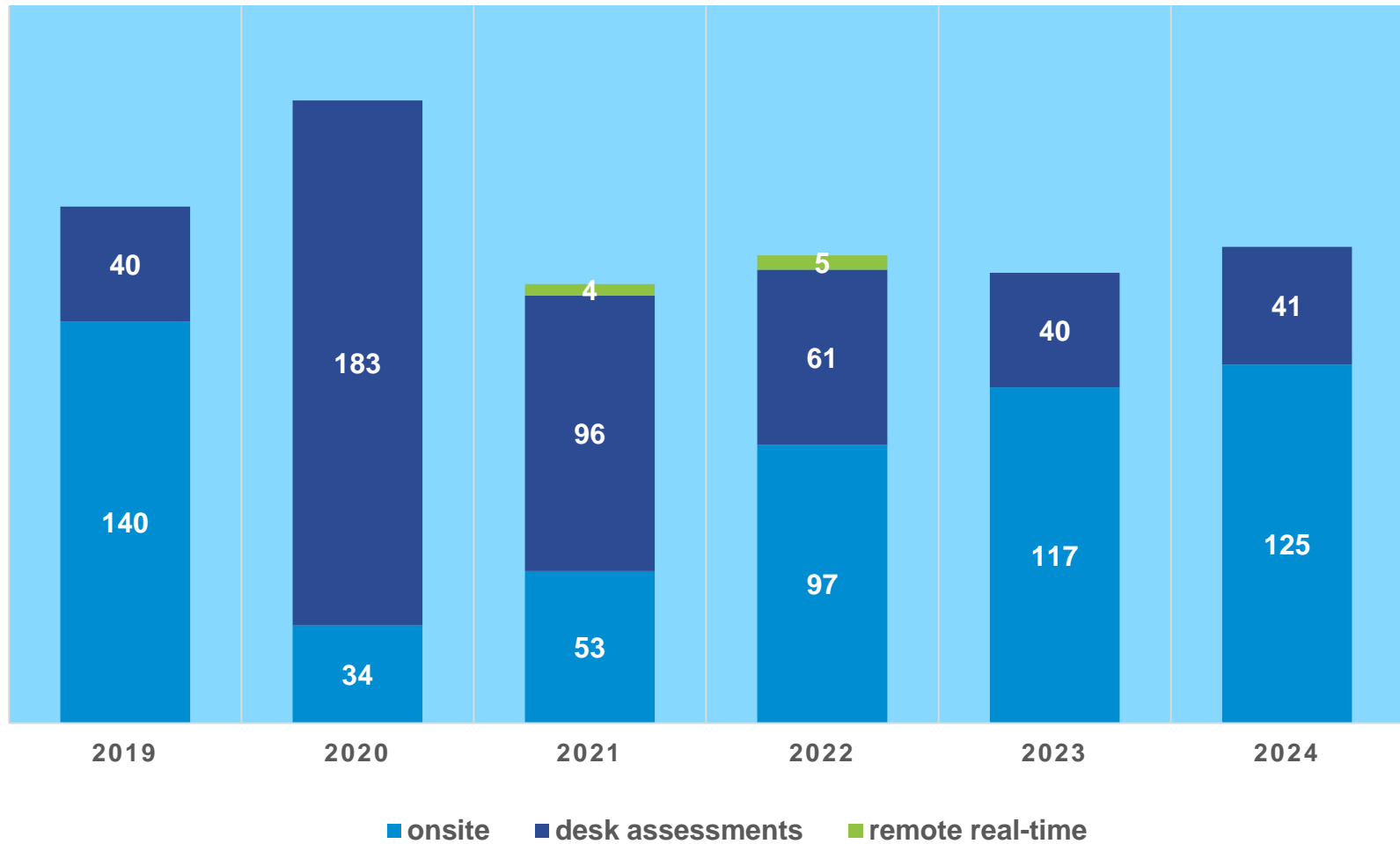- Bioequivalent study
- Clinical trial
- Laboratory

636 inspections (2020–2023)

Cumulative numbers of PQed/EULed products as of December 2023

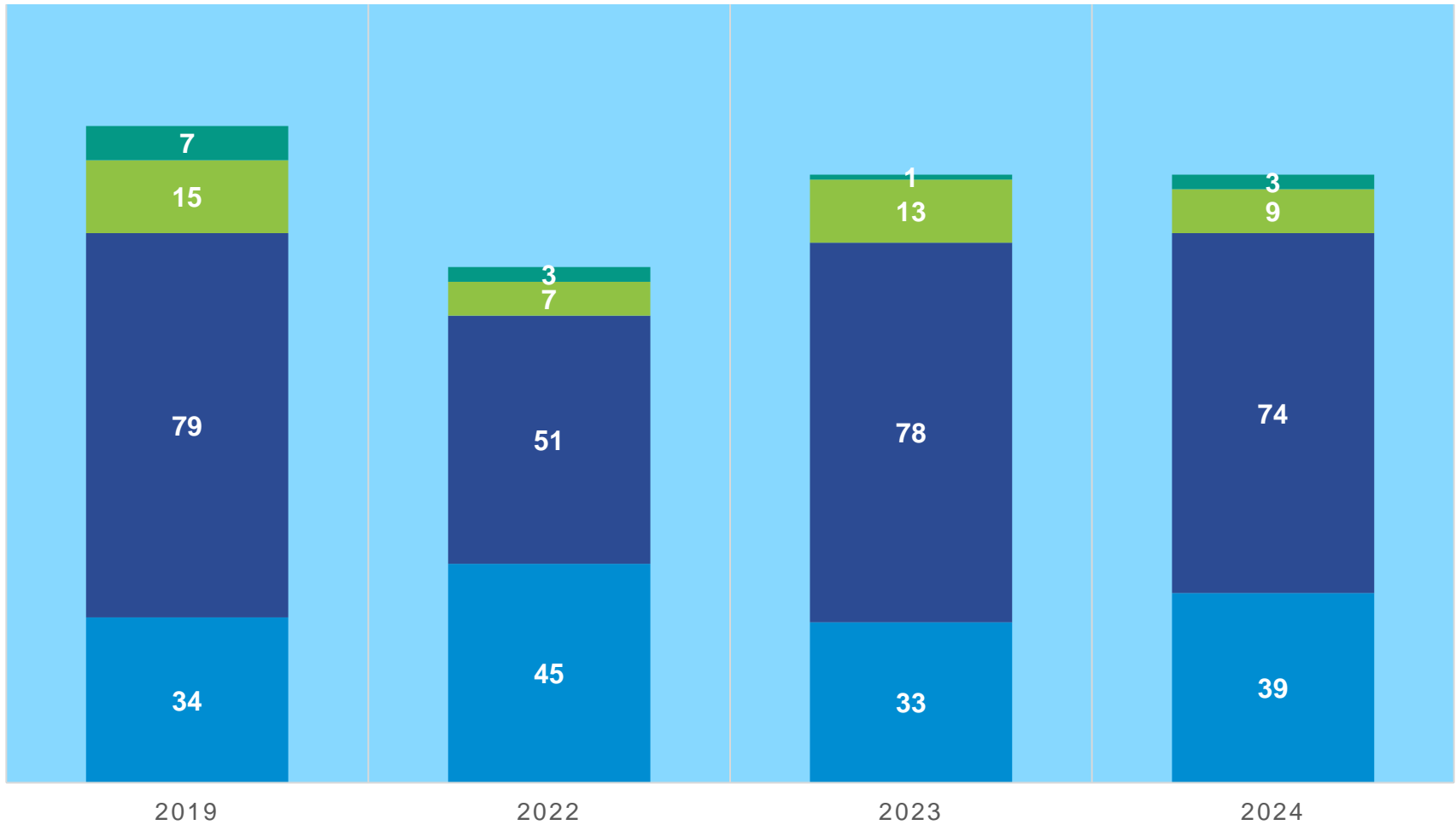- **Around 1'700 products are either prequalified or recommended for Emergency Use Listing (EUL)**

- **Inspection Services is instrumental to ensure the compliance of the manufacturing sites**

ONSITE INSPECTIONS VS DESK ASSESSMENTS

Chart: Onsite inspections vs desk assessments by year

Year	onsite	desk assessments	remote real-time
2019	140	40	
2020	34	183	
2021	53	96	4
2022	97	61	5
2023	117	40	
2024	125	41	

Legend: ■ onsite ■ desk assessments ■ remote real-time

TYPE OF INSPECTIONS (ALL STREAMS)

Inspection outcomes vs. Total onsite inspections (all streams)

Pre-COVID ·· Post-COVID

number of inspections

2018: 145, 13 (9%), 23 (16%)
2019: 140, 13 (9%), 27 (19%)
2023: 117, 5 (4%), 7 (6%)
2024: 125, 4 (3%), 10 (8%)

■ Total onsite inspections   ■ Non-compliant   ■ Follow-up required
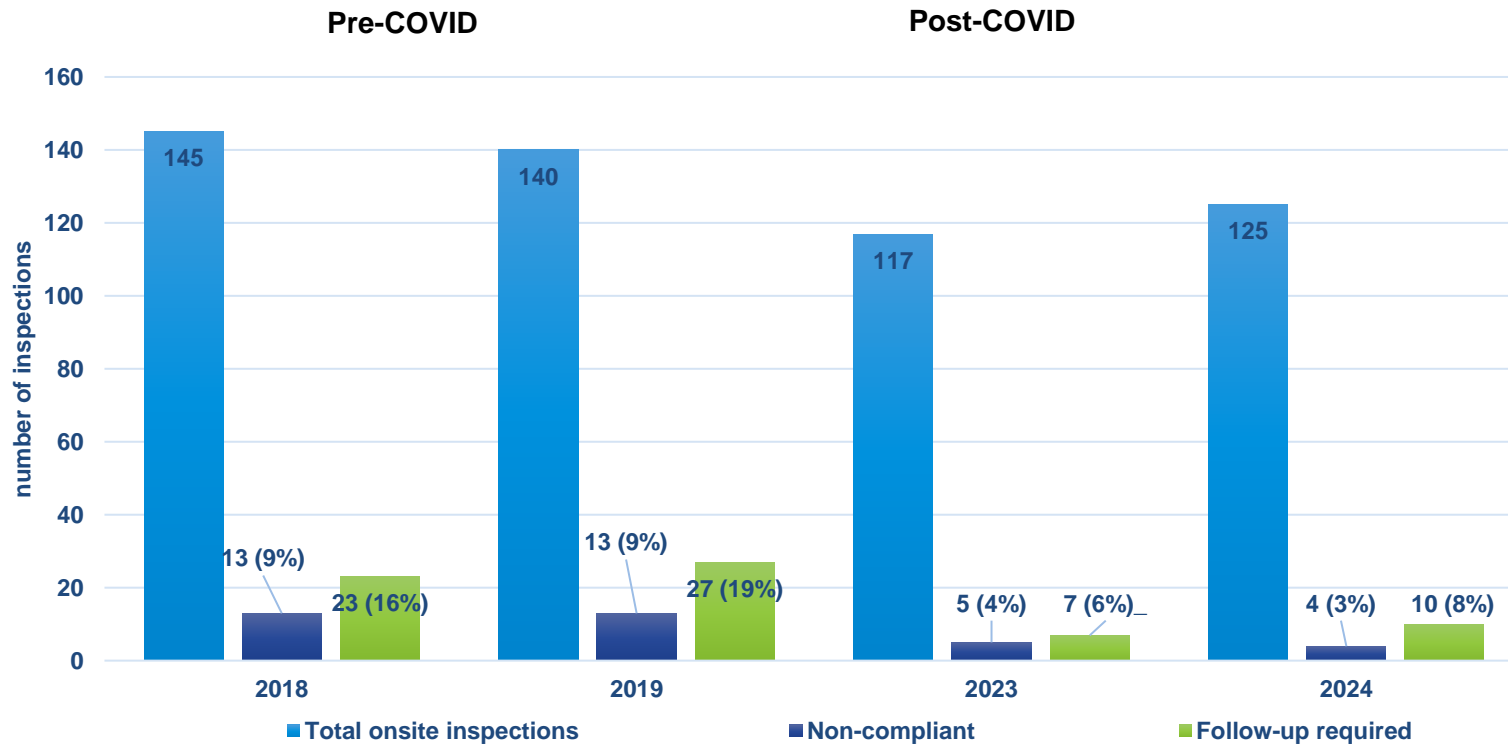
Top countries and regions inspected in 2024 per stream
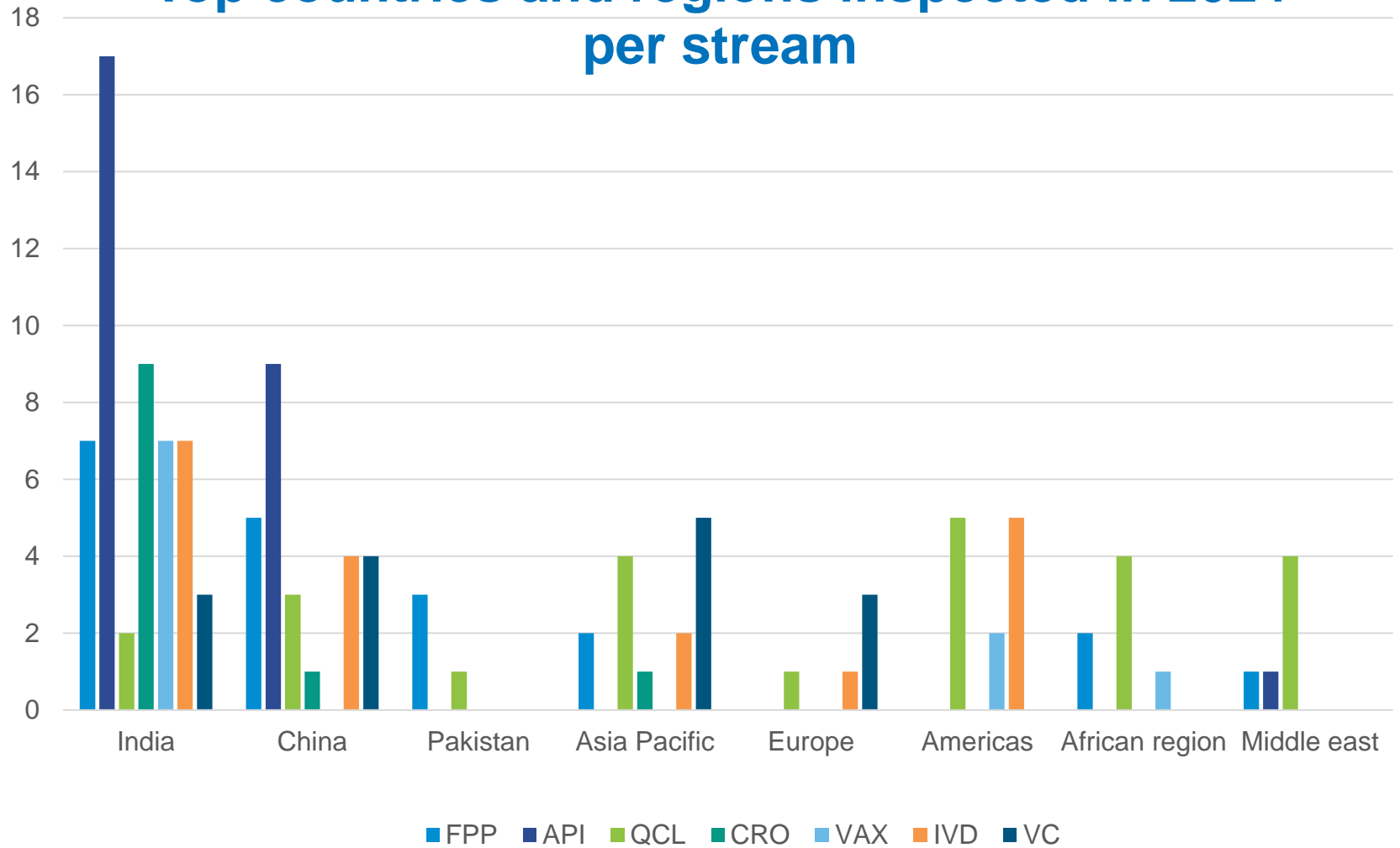
ePQS Overview
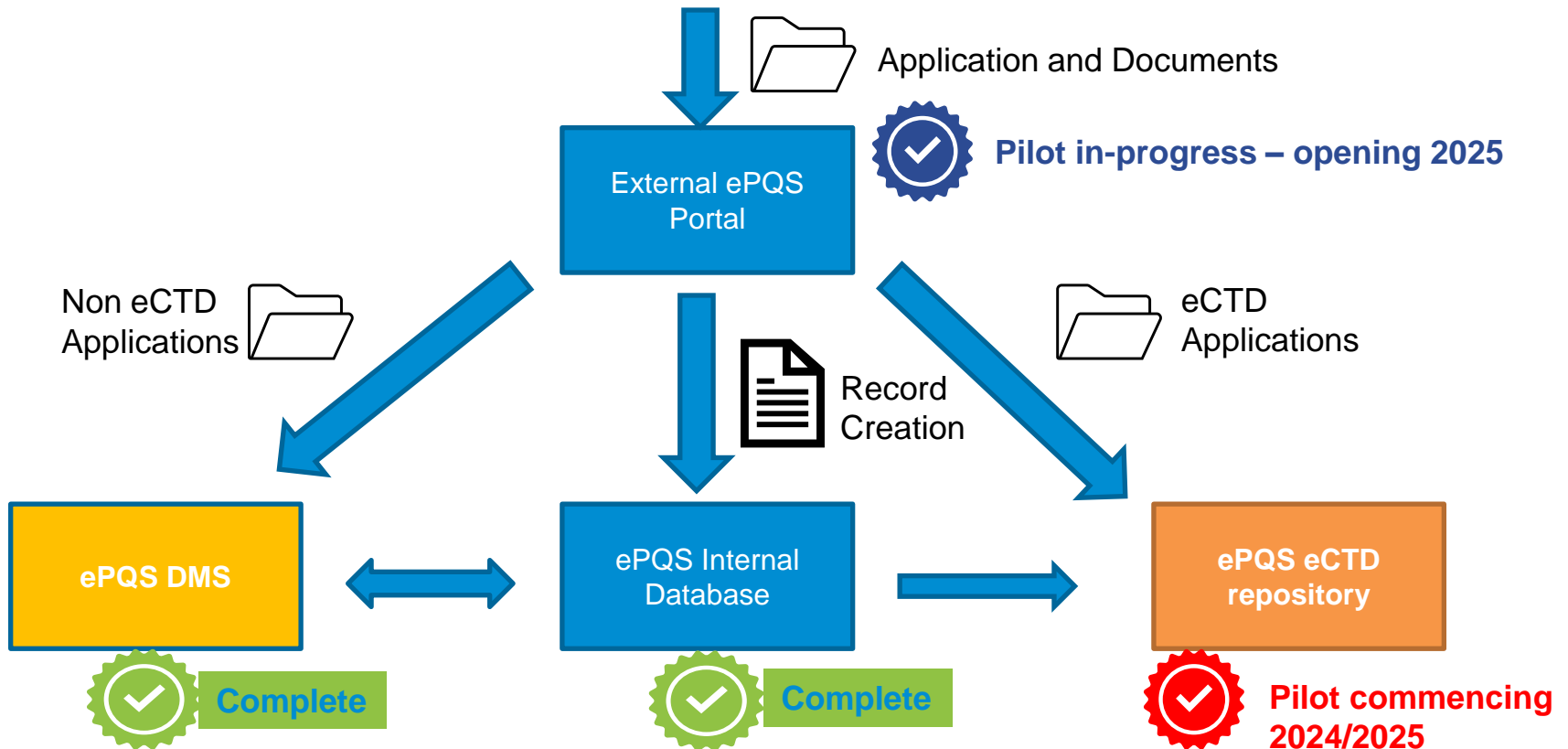
ePQS Portal

➢ A secure platform for external users

➢ It uses WHO's Microsoft Azure Active Directory, which ensures only authorized users with the right username and password are granted access to the ePQS portal and all related systems

➢ Applicants, NRAs, External experts each have different visibility of records

➢ Permits filing of applications, responses and general tracking of applications

➢ Secure document transfer to and from WHO

See dedicated page: https://extranet.who.int/prequal/epqs-portal

Pilot has commenced. Opening Q1 2025

chafaim@who.int

prequalinspection@who.int

Back slides for more information on inspection team and timelines

Inspection Team

- **WHO Qualified inspector from PQT Inspection Services**

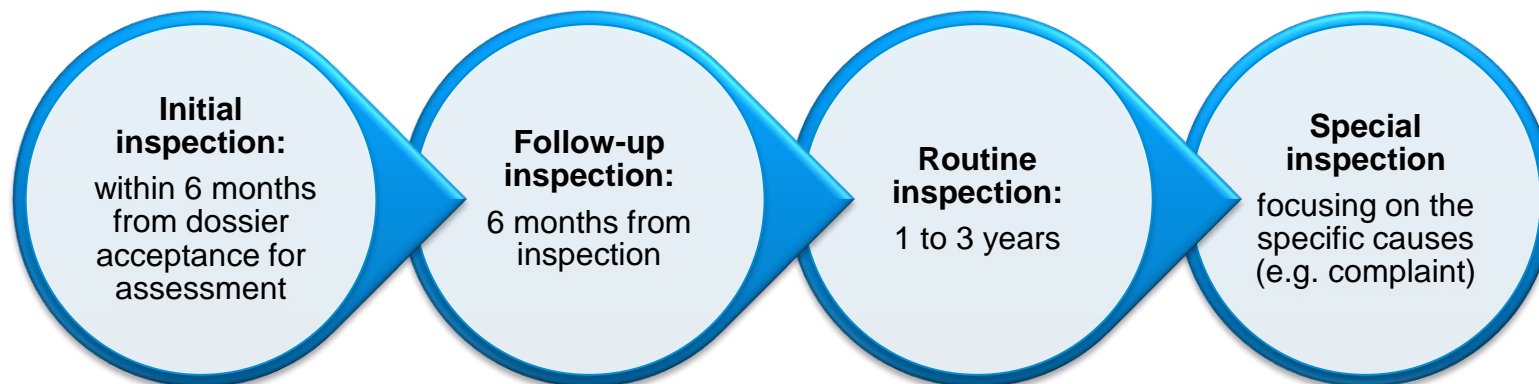- **Co-inspector from well-established inspectorate (e.g. PIC/S)**

- **Product Assessor, where required**

- **Inspectors from invited to participate/observe the inspection**

- **Co-Inspector from the WHO rotational fellowship program**

- **Observer from procurement agencies and UN organizations**

Inspection Timelines

Notification — 2 months before the inspection

Inspection — 3-5 days

Inspection Report — 30 days from the last day of inspection

CAPA — 30 days from receipt of report (max. 2 rounds)

CAPA Evaluation — 30 days from receipt of CAPA

Closing of Inspection — 6 months from last day of inspection

Initial inspection: within 6 months from dossier acceptance for assessment

Follow-up inspection: 6 months from inspection

Routine inspection: 1 to 3 years

Special inspection focusing on the specific causes (e.g. complaint)

WHO Public Inspection Reports (WHOPIRs)

WHOPIRs are published within 30 days of the date of closure of an inspection

WHOPIRs are used by procurement agencies to verify the level of GMP compliance of sites prior to purchases

WHOPIRs are publicly available inspection reports for sites that are found to be compliant.

https://extranet.who.int/pqweb/inspection-services/whopirs

Notices of Concern

Critical or more than 6 major deficiencies and data integrity concerns

A letter is drafted to the site, and the site is given 10 days to respond

Published on the WHO website if the issues are not resolved in timely manner

removed from the WHO website only once issues are adequately resolved.

Communicated to WHO international partners and member states

https://extranet.who.int/pqweb/inspection-services/notice-concern