EQALM SYMPOSIUM VIENNA

IVD-R and EQA

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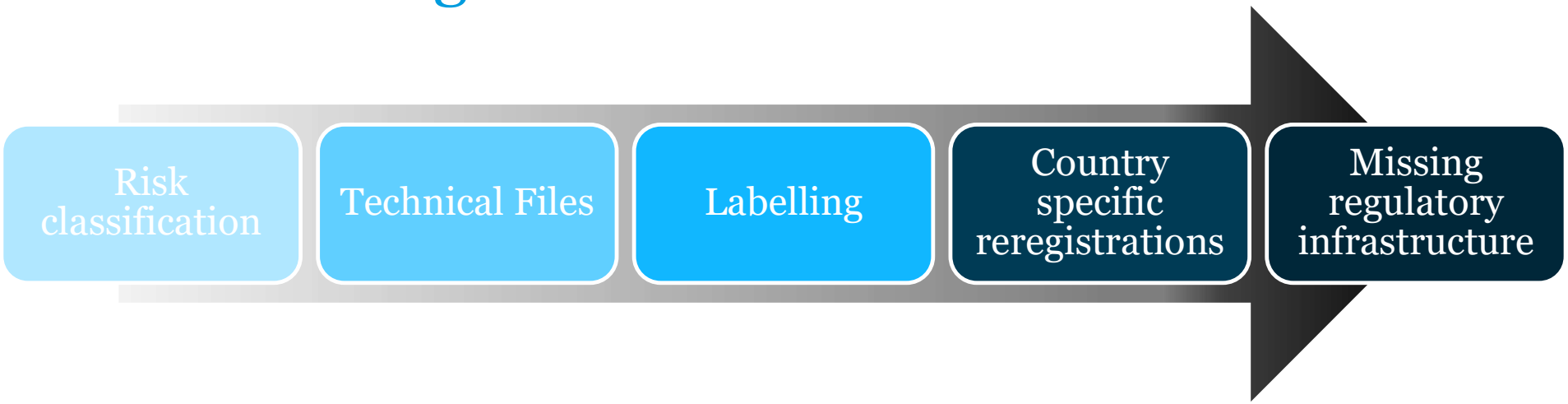
Abbott Core Diagnostics Overview

- Portfolio of Immunoassay, Clinical Chemistry & Hematology IVD devices, instruments & informatics systems
- First step in patient care decision making for hundreds of health conditions from heart attacks, to blood disorders to infectious diseases & cancers
- Seven manufacturing sites with a presence in Ireland, Germany, Italy & the US
- Several third-party manufacturing partners
- The percentage of portfolio requiring notified body certification increasing with IVD-R from 10% to 85%

IVD-R – Product Transition Activities

Product Certification	Global Registration	Change Implementation	Maintenance Phase
•Product Design Plan •IVD-R Compliant Technical Documentation & Labelling •Notified Body Submission	•IVD-R Certification & Declaration of conformity •Notification of Change to begin country registration •Legal Docs and country submission	•Predictability of timings across individual geographies •Supply Chain Management per country import requirements •Design Plan deliverables completed and cutover definition	•Surveillance audits and certification renewals •EUDAMED & SSP •Economic Operator •PMS & Vigilance reporting requirements

IVD-R Challenges



Risk classification	Technical Files	Labelling	Country specific reregistrations	Missing regulatory infrastructure
• Globally aligned and compatible • Simplifies data exchange between manufacturers and non-EU authorities	• Introduces new structure • Triggers review of existing data	• Needs to be revised • Minor tweaks but major change control impact	• Submit changes • Manage timing across all geographies and devices • Supply chain management triggering batch control	• Initial timelines published in 2017 • Ongoing legislative changes • Lack of predictablity • Additional requirements at national level

IVD-R Improvements

Transparency & Traceability

- Requires EOs to provide traceability of IVD devices
- Not a new requirement but expanded to downstream EOs
- EUDAMED

Clinical Evidence

- Updated over the entire product lifecycle
- Introduced scientific validity
- Aligns with latest technological advancements in medical science

Post Market Surveillance

- Increased safety
- Continuous on-market monitoring
- Not a new process but now tighter standardised
- Rules based on product criticality

Product Monitoring/PMS

Pre-Market Activities

PMS and PMPF planning as an extension of pre-market activities (e.g., performance evaluations).

Post-Market Activities

Collection and analysis of on-market data, including post-market product evaluation.

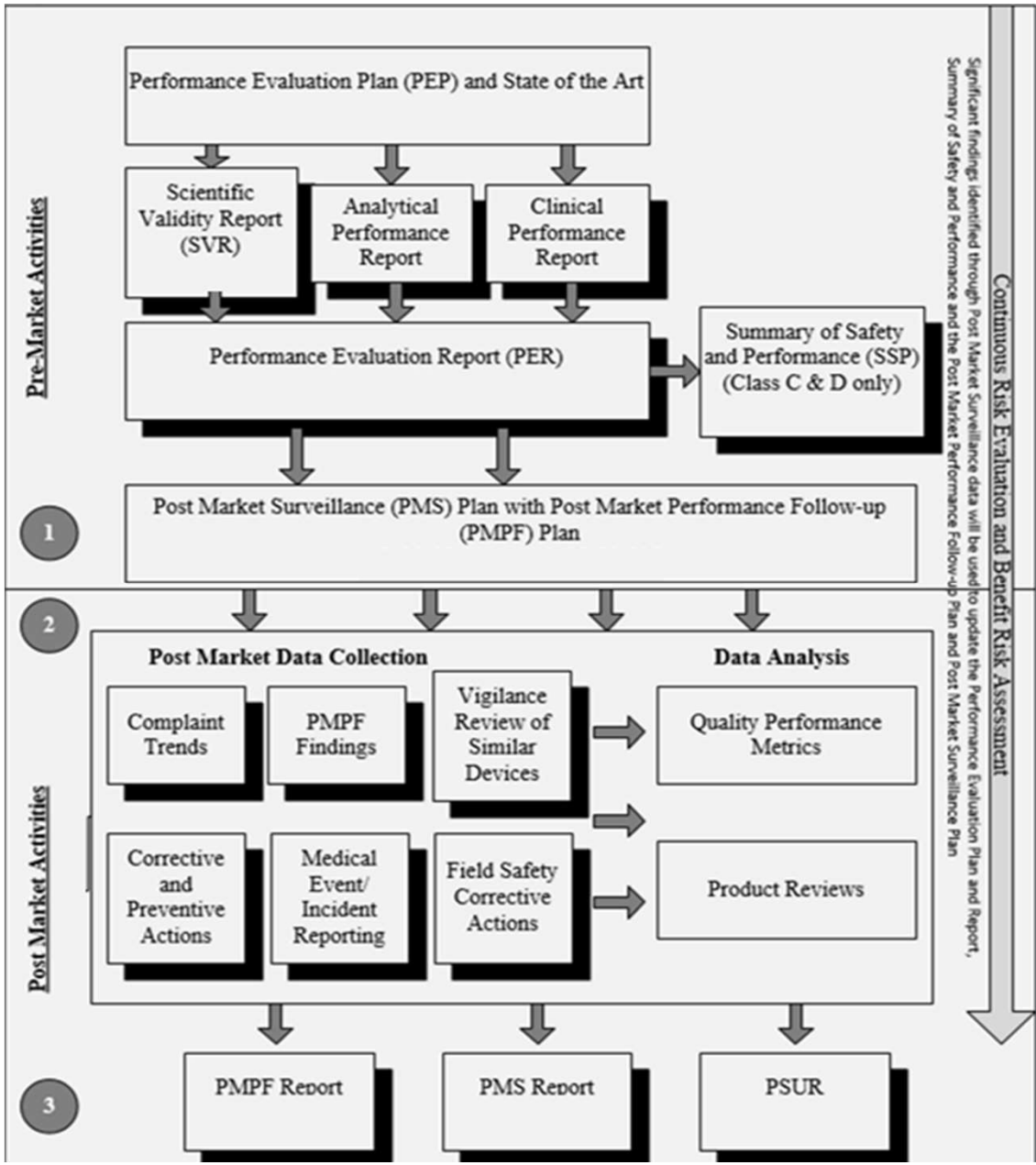
EQA

Post-market output/reports

according to the PMS and PMPF plans and internal reporting requirements (PMPF report, PMS report, PSUR).

Findings will lead to updates to Plans & Reports

Continuous Benefit-Risk Assessment



External Quality Assessments – General

External Quality Assessments – At Abbott

"PMS System methods of data collection may include"

- Corrective and Preventative Action (CAPA) taken for safety reasons
- Field Safety Corrective Actions, Field Safety Notices, and Field Actions
- Medical Events/ Serious Incidents
- Complaint Trend Reporting
- **Feedback Received for On-Market Devices** (e.g., EQA)
- PMPF Plan, which is a sub plan of the overall PMS Plan

External Quality Assessments – At Abbott

External Quality Assessments – At Abbott

The PMPF Template prompts for a "*proficiency testing review*" if manufacturing site participates in EQA.

It requires to evaluate the report and conclude the impact in State-of-the-Art Report based on the results.

The assessment conclusion is reflected in the PMPF Report which is made available to Notified Body.

An additional risk would finally trigger the update of the Summary of Safety Performance (SSP) that is published in EUDAMED.

External Quality Assessments – Challenges

Non-commutable reference materials can lead to discrepancies between test results from different laboratories, making it difficult to compare results and maintain consistent quality.

Internal resources required to cover logistic (e.g., such as shipping samples and coordinating schedules).

Costs associated with EQA programs can be a significant burden, especially for smaller IVD manufacturers.

Manufacturers benefit from EQA by receiving feedback on their test performance in real-world settings. This is in addition to own data retrieved on-market.

Summary

Abbott has introduced an IVD-R compliant processes.

Main challenge is the missing regulatory structure,

The PMS process is very complex .

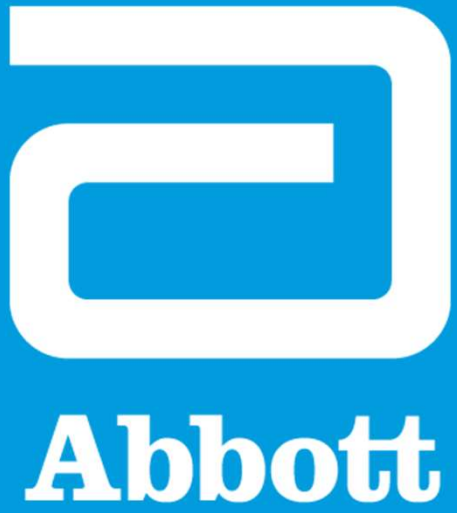
Challenging for global players with manufacturing sites spread across multiple geographies.

EQA plays a substantial role in supporting post-market surveillance.

Early warning system, supports assessments against competitors' devices, improves assays.

Some minor challenges remain.

Abbott has started the process and is refining it moving forward ("*PMS for PMS*").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