CHALLENGES FOR CAPACITY BUILDING OF ASIAN REGULATORY AUTHORITIES - UTILIZATION OF PMDA-ATC FOR THE ASIAN REGION

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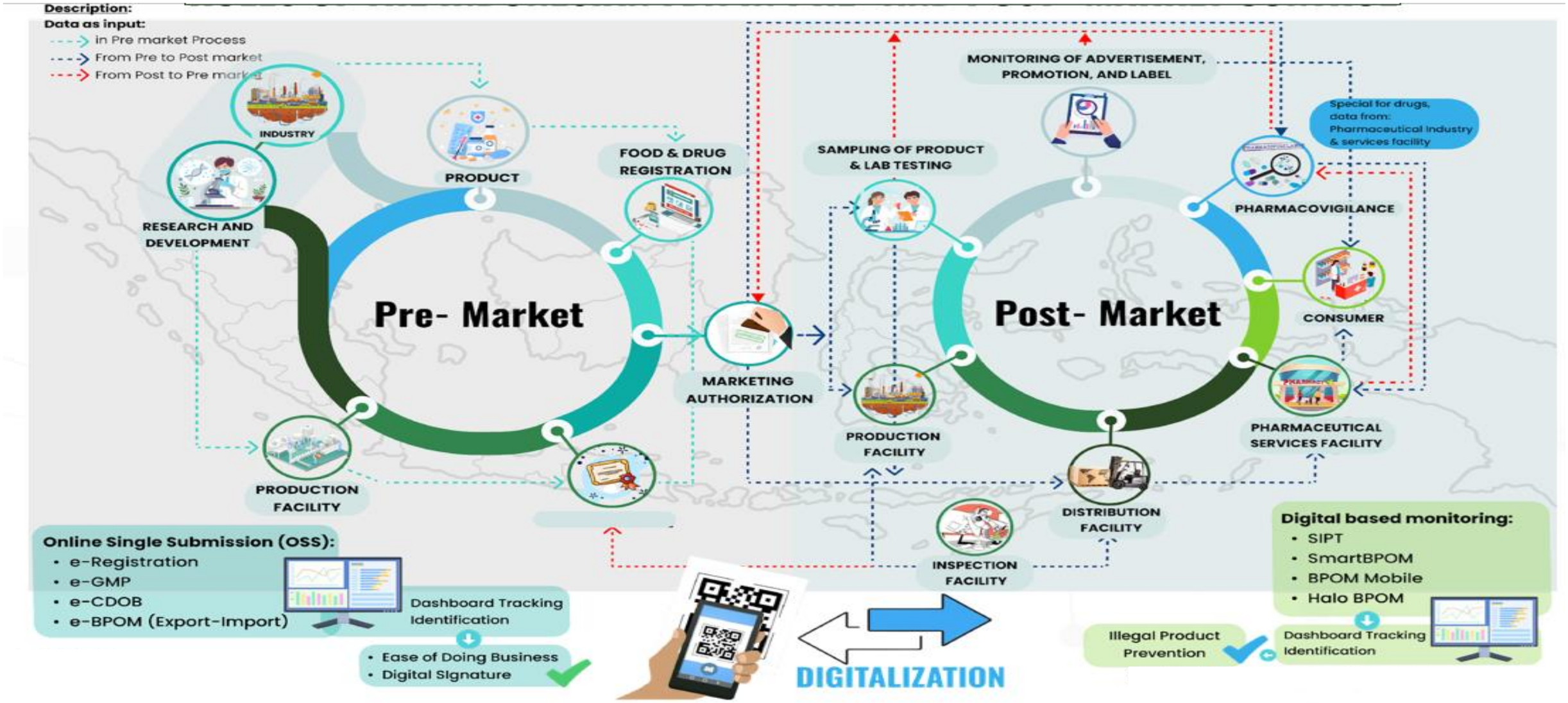
The Indonesian FDA

OUTLINE

1. Ensuring Safety, Quality and Efficacy: Regulatory Oversight of Medicines in Indonesia
2. Future Objectives of Capacity Building for Asian Regulators
3. Strategic Human Resource Development for Future Regulatory Objectives
4. Enhancing Human Resource Capacity through PMDA and Other Regulatory Authority Training Programs
5. Expectations for PMDA Asia Office: Strengthening Capacity and Regulatory Cooperation
6. Moving Forward Together: A Collaborative Approach

Ensuring Safety, Quality and Efficacy: Regulatory Oversight of Medicines in Indonesia



Acknowledgement WHO to The Indonesian FDA

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World Health Organization

Transitional WHO Listed Authority → WLA → Trust, Confidence, and Reliance

Maturity Level 3&4 for vaccine

Full spectrum of Vaccine Oversight

PREMARKET

- Vaccine Development & Establishment of Manufacturing Facilities
  - IND Regulatory System
  - GMP Certification
  - Clinical Trial Authorisation
  - GCP Inspection
- Marketing Authorisations (MA)
  - Vaccine Evaluation System for MA

POSTMARKET

- Post Market Surveillance and Control
  - Lot Release (Vaccines & Biologicals)
  - Pharmacovigilance
  - Label & Advertisement Control
  - Regulatory Inspections – GMP & GDP
  - Post Market Sampling & Testing

- ✔ Good Regulatory Practices (GRP)
- ✔ Good Laboratory Practices (GLP)
- ✔ Good Clinical Practices (GCP)
- ✔ Good Manufacturing Practices (GMP)
- ✔ Good Review Practices (GRev)
- ✔ Good Distribution Practices (GDP)
- ✔ Quality Management System (QMS)

ISO 9001:2015

Joint Assessment & Reliance

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Share best practices	Exchange knowledge on reliance	Contribute to the harmonization of regulatory standards
Promoting global excellence in medicines regulation	Enhance patient access to innovative treatments	Improve regulatory processes
Address healthcare challenges more effectively	Access to diverse expertise from different regulatory authorities	Public Confidence

World Health Organization

Dengvaxia in 2015

nOPV2 in 2020

Qdenga (Indonesian FDA as observer)

Perjeta, variation on MCB change, in 2024 (on going)

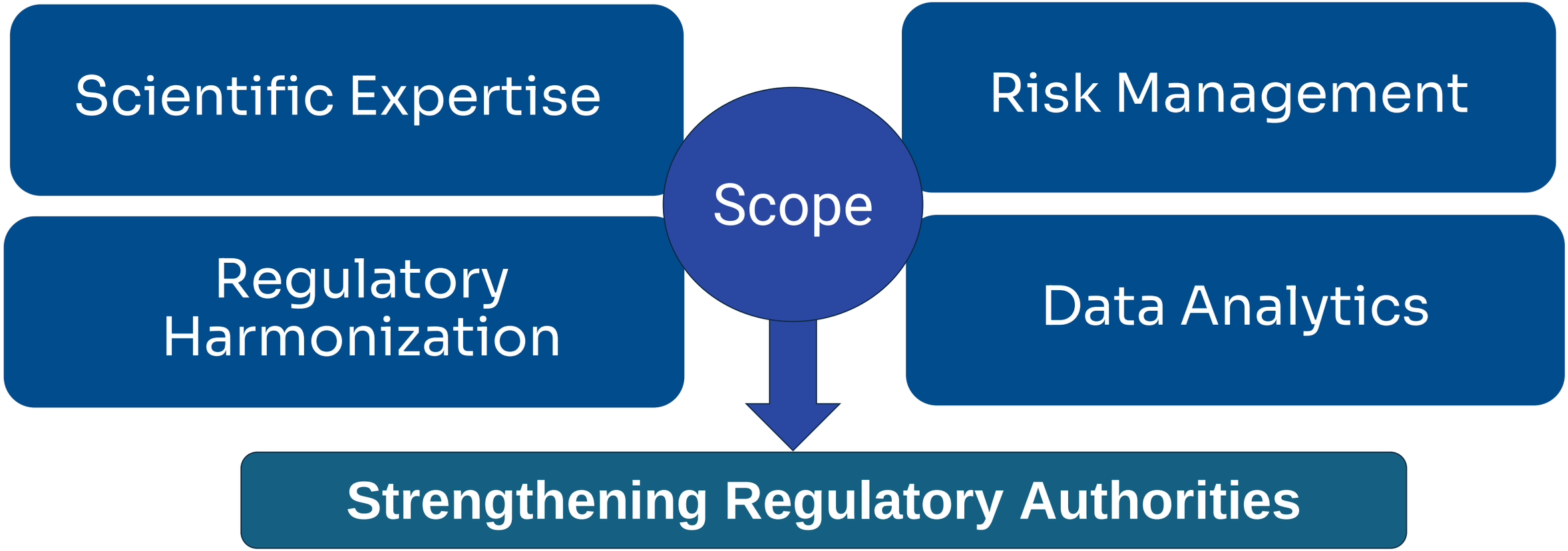
asean

Pyramax in 2018Ocrevus in 2023

Reliance Has been started since 2017 to use reference country's assessment report for decision making of marketing authorization of medicines and vaccines.

6 Reference countries:
US FDA, EMA, MHRA, Health Canada, TGA and PMDA

Future Objectives of Capacity Building for Asian Regulators



Strategic Human Resource Development for Future Regulatory Objectives

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LEARNING MANAGEMENT SYSTEM AND KNOWLEDGE MANAGEMENT SYSTEM

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Simphoni

Sistem Informasi Manajemen Pengetahuan dan Informasi Badan Pengawas Obat dan Makanan

Si Pandai
Sistem Pembelajaran Daring

SiPandai

Sistem Pembelajaran Daring

IDEAS

Integrated Development and Training Information System

Coaching and Mentoring Application

Enhancing Human Resource Capacity through PMDA and Other Regulatory Authority Training Programs

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pmda

สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

Other ASEAN Regulatory Authorities

NRAs to adapt and strengthen their capabilities.
The PMDA Asia Office plays a vital role in facilitating this evolution by fostering collaboration and providing essential capacity-building support.

PMDA Asia Training Center (PMDA ATC) 2016 – 2023

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Individual Impact

1. **Knowledge and Skill:** In-depth understanding of regulatory practices, especially in Risk Management Plan (RMP) development.
2. **Expanded Perspective:** Awareness of global regulatory trends and best practices.
3. **Improved Decision Making:** Equipped with evidence-based decision-making tools.

Organizational Impact

1. **Capacity Building:** Strengthened ability to evaluate and manage drug risks.
2. **Regulatory Harmonization:** Alignment with international standards.
3. **Knowledge Sharing**: Collaboration among regulatory professionals.
4. **Efficiency:** Adoption of best practices for regulatory processes.

Other Benefit

1. **Regulatory Enhancement:** Insights into international practices.
2. **Networking:** Collaboration with counterparts worldwide.
3. **Broadened Perspective:** Understanding global challenges.
4. **Cultural Exchange:** Building relationships with international colleagues.
5. **Access to Expertise:** Exposure to specialized knowledge.

A Collaborative Initiative : PMDA JAPAN - INDONESIAN FDA

PMDA-ATC & US FDA Pediatric Review Seminar, Japan, July, 2024

PMDA-ATC Pharmaceutical review Seminar, Japan, June, 2024

ASEAN-Japan Risk Management Plan (RMP) Symposium, Jakarta, 2023

PMDA-ATC Pharmaceuticals Review Seminar for JICA trainees “Regulatory Systems on Ensuring Access to Quality Medicines”, Tokyo and Toyama Japan, July 2023

PMDA-ATC Pharmaceuticals Review Seminar 2020, Jakarta

JAIF Project: the 2nd Risk Management Plan (RMP) on 25 – 26 May 2023

Enhanced Knowledge and Skills

- Deepened understanding of RMPs
- Technical expertise:
- Regulatory framework:

Improved Decision-Making

- Data-driven decisions
- Risk assessment

Strengthened Regulatory Oversight

- Enhanced surveillance
- Effective risk management

Facilitated Collaboration

- Global network
- Harmonization

Expectations for PMDA Asia Office: Strengthening Capacity and Regulatory Cooperation

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Training Programs

The PMDA Asia Office offers:

- a comprehensive range of training programs.
- interactive and practical Program methods

Technical Assistance

Technical assistance include guidance on:

- Developing regulatory frameworks,
- Implementing new regulations, and
- Strengthening post-market surveillance systems.

Knowledge Exchange

- Workshops,
- Conferences and
- Online platforms.

Expectations for PMDA Asia Office: Strengthening Capacity and Regulatory Cooperation

NO	EXPECTATIONS	ACTIVITIES
1	Enhanced Regional Cooperation	• Efficiency of Drug Review and Approval Process • Collaboration for New/Innovative Drugs • Utilizing PMDA Japan Assessment Reports
2	Strengthened Regulatory Systems	• Regulation and evaluation processes for different types of medicinal products: - Advance Therapy Medicinal Products (ATMPs) - Radiopharmaceutical Products: - Blood Products • Post-Approval Changes in PMDA Japan:**
3	Data Driven Decision Making	• Decision making process and PMDA review report for drug product • Joint Assessment and reliance mechanism in Japan
4	Sustainable Development	• Building Communication Networks Among Drug Authority Regulators
5	Improvement of accessibility new drugs in Indonesia	• Evaluation of Nonclinical and clinical data for Efficacy and safety aspect review • Method of Validation - Inhalation Product Quality and Dose (specific product)

Moving Forward Together: A Collaborative Approach

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Collaboration is Key:

- ✔ National Regulatory Authorities (NRAs) must collaborate to achieve shared goals.
- ✔ Joint training programs, like the PMDA-ATC, enhance individual regulators' skills and promote cooperation.

Looking Ahead:

- ✔ NRAs should engage in joint assessments to improve the regulatory environment.
- ✔ Investing in human resources and adopting a collaborative approach ensures a resilient and adaptive regulatory framework.

Thank You

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