The Indonesian Association of Medical & Laboratory Devices Enterprise (GAKESLAB Indonesia)

Good Regulatory Practices in Indonesia

and Stakeholders' perspective

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AFFILIATED ORGANIZATIONS

- Secretary General, GAKESLAB Indonesia (the Indonesian Association of Medical and Laboratory Device Enterprise)
- Vice Head of Pharmaceutical & Medical Device Permanent Committee, Indonesia Chamber of Commerce
- Head of MD Industrial Competence Committee- IKKESINDO (Association of Indonesia Healthcare Consultant)

PROFESIONAL EXPERIENCE

- Healthcare professional (1993-1997)
- Working in prominent MNCs and local pharmaceutical industries (1998-2005)
- Cardiology and Diabetic Franchise Head, Johnson& Johnson Indonesia (2005-2010)
- Founder and CEO of Mursmedic Group (2010-now) – distributor & manufacturer of medical device/ household product , with affiliation in 5 major ASEAN countries

OTHER CREDENTIALS

- Contributors for various media on medical device topics
- *Host* of "Chat Room" program in Viga TV (specializing to discuss various issues around Medical Device business and industry

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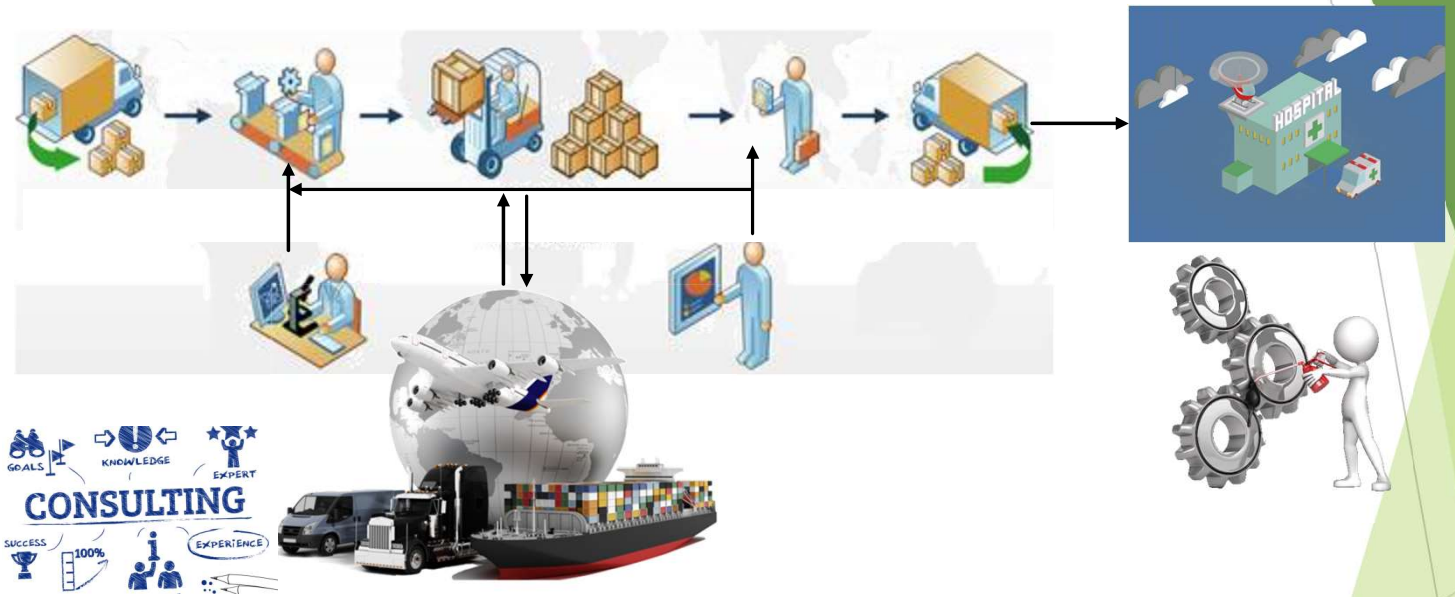
About GAKESLAB Indonesia
(established on 1977)

https://www.youtube.com/watch?v=lva6fTq236s



End to end MD industries association (from R&D to after sales service)

Almost 1,100 members and 21 provincial commities

Broad network locally dan internationally

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Good Regulatory Practices

Where is Indonesia?

Before Covid-19

Adopted ASEAN Medical Device Directives since 2017

- Implement license of establishment for MD (MD Production & Distribution License)
- Implement ASEAN CSDT
- GMP and GDP which is consistent with ISO 13485
- GMP certification is not yet a pre-requisite for MD license application

During Covid-19

Relaxation period

- Waiver of license of establishment & registration certificate for imported Covid-19 products (importation is granted with BNPB recommendation)
- Accelerated license of establishment approval
- Accelerated product license approval process

After Covid-19

Relaxation period

- Registration of production facility is moved under Ministry of Industry
- GMP and GDPMD will soon become pre-requisite for MD license application
- Pre-market system is guided by ASEAN CSDT as before Covid-19

How "convergent" is Indonesia vs. the rest of the world?

Indonesia MD Regulatory Framework

Establishment

- Business licenses via One Single Submission- Risk Based Approach (OSS-RBA) system
- Standard Certification (Issued by Ministry of Industry) for manufacturing
- Distribution license issued by MoH for distribution
- GMP & GDPMD certification by Indonesia MoH

Pre-market

- Registration at Indonesia MoH
  - ✓ ASEAN CSDT is referred
  - ✓ MDD/ MDR/ PMA FDA format will be compatible
  - ✓ ISO 14155 is recognized for MD clinical trials

Quality management system

- ISO 13485 is adopted for GMPMD and GDPMD audit

Post-market

- Reporting system for product distribution via e-report & Mobile Alkes App
- Field action is mainly performed by regulator

- ❑ Indonesia is among the most mature countries in ASEAN on regulatory framework
- ❑ Except for some local requirement (next slide), Indonesia is ready to move towards regulatory convergence as international standards have been recognized & adopted

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Some "non-convergent" requirement

1

Inclusion of products as MD

Some products such as hospital furniture, toothbrush, feminine napkins & adult diapers are MD in Indonesia

2

Exclusions of products from MD

Some products, such as artificial tear is classified as MD by AMDD definition but classified as drug in Indonesia

3

GMP/GDPMD certification

ISO 13485 and ISO 9001 will be advantage for certification process but not directly accepted as formal certification

4

Additional quality requirement for procurement

Some division at MoH and other ministries still ask for additional quality requirement such as PQS WHO certification even for registered products

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Experience with Indonesia's Current Processes & Standard

1. Pre-market requirement still follows ASEAN CSDT guidelines, however success criteria set by local lab for testing (that will construct the dossier) is still reported to be inconsistent

2.
   - Indonesia's clinical trial guidelines and process acknowledge ISO 14155 , however some drug's clinical trial concept is still adopted
   - Existence of CRO which specialized in MD is still very rare

3. Indonesia's MD system relies on pre-market much more than post market. Post market system is mostly initiated by MoH. The proactive process such as field safety corrective action (FSCA) by industries and adverse event/ quality complaint report by users are not effectively executed, so it may weaken the implementation of quality management system and slow down the development of local product quality.

Indonesia has strong ground to move towards regulatory convergence but needs to catch up in some areas to balance the entire MD system, so the convergence will benefit the system

Will Regulatory Convergence be an advantage for Indonesia?

1 Increase opportunity for exportation
Products which are developed, manufactured and registered under the convergent system will be accepted easier when exported

2 Eliminate cost duplication
Regulatory convergence will reduce soaring up cost due to activities duplication as the cost will eventually go to the patients

3 Facilitate information sharing
Countries which have convergent system will be easy to share database & information when quality issues happened

4 Convergence is incentive for foreign investment
Regulatory convergence facilitate easy pre-market process & increase product acceptance by market

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What to avoid when moving towards *regulatory convergence* for Indonesia

1. Regulatory convergence should not disadvantage be designed in a way that will disadvantage local MD manufacturer vs. global/ local manufacturer as Indonesia is moving towards MD resiliency

2. Regulatory Convergence should not become barrier to MD innovation. There must be agile scientific body(ies) in reviewing MD technology development and/ or local design to recommend amendment of regulatory framework from time to time

3. Regulatory Convergence should not the MD cost when not interpreted well (i.e., when redundancy in pre-market review or excessive requirement is wrongly understood as regulatory convergence)

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Take Home Message

1. Regulatory system is required to guide the MD system, however as MD industries must be more agile post Covid-19 era, regulatory convergence should facilitate faster regulatory support for innovation
2. Each country esp. in this region (including Indonesia) must set their basic regulatory system well (both pre & post market) while moving towards regulatory convergence
3. Implementation of regulatory convergence must consistently involve academia and industries, in order to avoid contra-productive result, which may slow down countries MD system

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Thank you
Terima kasih

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