Harmonising Medical Device Regulations to Benefit Patients

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Lets align on interpretation

Patient Benefit

- Does what it is supposed to do (Intended Use)
- Does what it is supposed to do, effectively (Performance)
- Does not cause harm (Safety)
- Is made with proper processes, equipment and components (Quality)
- Is an advanced technology with enhanced Safety/Performance/Quality (Innovative Access)

Lets align on interpretation

“In order to strengthen the regulatory capacity for oversight of medical products globally, WHO encourages international cooperation among regulatory authorities in all its forms, including convergence, harmonization, information- and work-sharing, reliance and recognition”
-WHO

HARMONISATION

The action or process of making something consistent or compatible; the act or state of agreeing or conforming

CONVERGENCE

the regulatory bodies across participating countries adopt a unified system for marketing approvals of drugs, biologics, and devices to ensure the highest standards of quality, reporting and advertising

RELIANCE

leveraging the output of others whenever possible while placing a greater focus at the national level on value-added regulatory activities that cannot be undertaken by other authorities, such as in-country vigilance activities and oversight of local manufacturing and distribution

Harmonisation and Convergence Opportunities

1. Categorisation and Classification
2. Document Requirements and Definition
3. Standards and Certification Recognition (and Reliance)
4. Site Inspections
5. Trial/Evaluation of Products

Categorisation and Classification

- Drug Product vs Device vs Combination or Borderline Product vs Cosmetic vs Disinfectant
- Risk Classification of Medical Devices

Document Requirements and Definitions

- Manufacturing Licence, GMP Certificate, ISO 13485 certificate

- Declaration of Conformity (DOC), Certificate of Analysis (COA), COC (Certificate of Compliance/Conformance)

Standards and Certificate Recognition (and Reliance)

- International Standards – ISO

- Registration certificates from recognised jurisdictions (incl. CE Certificate, Health Canada, TGA, Japan)

Manufacturing Site Inspections

- Inspection Reports from recognised jurisdictions and entities

(incl. WHO, Notified Body)

- Additional costs, resources etc.

- Consider Virtual Inspections (Limited Scope)

Trial/Evaluation of Products

- Recognition mechanisms for reports and evaluations done with “similar” testing criteria

Regulations should *always* benefit patients

Intended Use

Performance

Safety

Quality

Access to Innovation