Medical Devices
Regulation reforms in
India

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Joint Drugs Controller, CDSCO (HQ)
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Basic Concept

Drug __________To________________Device

- Harmonised regulation
- Best Practices fallowed in other Countries
Regulatory Reforms

Medical Devices Rules 2017

- Published on 31\textsuperscript{st} January 2017
- Effective from 01-01-2018

- Classification
- MD Grouping
- Essential Principle for manufacturing
- Product Standards
Regulatory Reforms

- Notified Bodies
  - Registration
- Medical Device Officer
  - Qualification
- MD Testing Officer
- Central MD Testing Laboratories
  - Established or designated
MD Rules ...Manufacturing

- Online application
- Class A & B... By State Government
  - Inspection by Notified body
- Class C & D....by Central Government
- Perpetual validity of license
- Suspension/Cancellation....on Websites
- Test License  by CLA
- Environmental conditions for manufacturing
MD Rules ...Import

- Only import license
- All classes of devices
- Perpetual validity of license
- GHTF countries in Rules – Rely on other countries
- If not approved in GHTF, Clinical Investigation
- Post approval changes...Major / Minor
- Recall provision
- Materiovigillanve
MD Rules ... Miscellaneous

- Labelling
  - Local Market
  - Export
- Unique Device Identification of MD
- Registration of Laboratories
- Export Certificate
- Rejection of application.....Misleading, Fake, Fabrication
- Debarment of application
### Requirements for approval of product

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<th>Regulatory Compliance</th>
<th>Class A</th>
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* Only for Electrical supply based devices
**Only for invasive or implantable devices
***Only for Investigational devices
Materiovigilance Programme of India (MvPI)

- Ministry of Health and Family Welfare, Government of India and National Health Systems Resource Centre (NHSRC) in collaboration with WHO Country office for India formally announced the commencement of NHSRC, as the **WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy.**
“Pharmacovigilance” is one of the core functions in the WHO global NRA benchmarking tool.

The WHO NRA re-benchmarking exercise, from 13-17 February 2017, was aimed at assessing the status of the India vaccine regulatory system.
Thank you