MEDICAL DEVICE REGULATIONS FOR
REGULATORS, MANUFACTURERS, AND USERS

WHO 3rd Global Forum on Medical Devices

Geneva, CH

May 10, 2017
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe.

DITTA covers the following industry sectors:
1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. and Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle.
ACTIVITIES WITH INTERNATIONAL ORGANIZATIONS

• **At UN level:**
  • DITTA invited to UNAIDS Smart Cities in NY in June to present on innovative technologies
  • DITTA published a statement on importance of technologies linked to discussions on SDGs for UN General Assembly in New York

• **With World Bank:**
  • Partnership agreement between DITTA and WB signed in May in Geneva

• **With WHO:**
  • DITTA is a member of the GMNCD Group since last year
  • DITTA provided comments during 2 consultations on priority medical devices in cancer
  • DITTA provided comments during 2 consultations on Global Regulatory Framework
  • DITTA speakers at CIPRaM in Spain in Oct. on Radiation Safety and Bonn Agreement

• **With IAEA:**
  • DITTA representation in Training course on Brachytherapy (Vienna – Oct)

• **Activities linked to IMDRF:**
  • DITTA proposed work item on Int’l Standards adopted by IMDRF
  • DITTA workshop on Medical Software in March
  • DITTA workshop on Int’l Standards in Sept.

Follow us on Twitter! @DITTA_online
SPEAKERS:
MEDICAL DEVICE REGULATIONS FOR REGULATORS, MANUFACTURERS, AND USERS

Josee Hansen (Senior Advisor, Department of Essential Medicines and Health Products, World Health Organization) - *Regulatory framework from a regulator’s perspective and how regulators can put in place a regulatory framework.*

Mary Overland (Dir. Regulatory Intelligence and External Affairs, GE Healthcare) – *Data generated during the medical device life cycle, where and by who it is used.*

Regulatory framework for medical devices: WHO perspective for regulators

Josée Hansen

10 May 2017
WHA Resolution 67.20

Regulatory system strengthening for medical products

Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

WHA 67.20 medical devices

... to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;
A WHO Model Regulatory Framework for medical devices including IVD’s with global input and reflecting a modular approach in regulating medical devices

- **How** to begin regulating?
- **What** to regulate: harmonized definitions and guiding principles
- **How** to regulate: stepwise development and implementation
- **When** to regulate: priorities and transitional period
Recent publications

http://applications.emro.who.int/dsat/emropub_2016_EN_18962.pdf?ua=1

Common approach for regulating medical devices

- Need to regulate medical devices and create market oversight
- Definition, risk classes, essential principles of quality and performance
- Stepwise approach: two or three steps
- Convergence, harmonization, collaboration
"Health technologies" refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. (WHA 60.29.)
Regulating medical devices - challenges

- Less developed regulatory systems than for vaccines and medicines, particularly in LIMC’s
- Lack of awareness
- Characteristics of medical devices as a product group
- Regulating in an existing market
- Lack of specialized knowledge and resources to draft and implement medical devices regulations
- Lack of resources
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices

WHO Medical device technical series
Two steps approach

- Basic level controls and enforcement
  - Legal framework
  - Market oversight
  - Reporting system

- Expanded level controls and enforcement
  - Regulatory controls depending on the priorities of the country
### Basic level controls and enforcement

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## LEGAL FRAMEWORK

### Expanded level controls and enforcement

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Good regulatory practices

- Critical elements for regulating medical devices
  - Political commitment
  - Legal framework
  - Implementation plan
  - Competent authority with enforcement power
  - Involvement of stakeholders
  - Transparent and impartial

- Importance of convergence, harmonization, reliance and recognition
Good regulatory practices

Working document QAS/16 686
October 2016
Draft for comment
Prepared by EMP/RSS

WHO/DRAFT/ October 2016
ENGLISH ONLY

Good regulatory practices:
guidelines for national regulatory authorities for medical
products

http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf?ua=1
Convergence and harmonization

- Convergence and harmonization
  - Definition of a medical device
  - Classification of medical devices
  - Essential principles of safety and performance
  - QMS
  - Standards
  - ...

- Confidence building and Information sharing

- Reliance and recognition
(Regulatory) convergence

A voluntary process whereby the regulatory requirements in different countries or regions become more similar or “aligned” over time. The process results from the gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures, or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.
(Regulatory) harmonization

The *process* by which *technical guidelines* are developed in order to *be uniform across participating authorities* in multiple countries.
Reliance

The act whereby the NRA in one jurisdiction may take into account and give significant weight to – i.e., totally or partially rely upon – evaluations performed by another NRA or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.
Recognition

The *routine acceptance* by the NRA in one jurisdiction *of the regulatory decision of another NRA* or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. *Recognition may be unilateral or multilateral*, and may be the subject of a mutual recognition agreement.
Conditions for reliance and recognitions

- The legal framework basis that allows the regulatory authority to apply the principles of “reliance” and “recognition”

- A clear understanding of the regulatory system that applies within the country where the medical device is manufactured.

- Certain regulatory activities are inherently only within the competence of the national authority.
Reliance and recognition

Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

Source: Swissmedic
Thank you very much
Earlier publications

2001


2003

http://apps.who.int/iris/bitstream/10665/42744/1/9241546182.pdf

2011

### Expanded level controls and enforcement

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DATA GENERATED DURING THE MEDICAL DEVICE LIFE CYCLE

WHO 3rd Global Forum on Medical Devices
10 May 2017

Mary Overland
Director Regulatory Intelligence and External Affairs, GE Healthcare

DITTA BOD member
Presentation Overview

• Intended audience – Regulators/users in early phases of implementing a regulators framework for medical devices.

• Manufactures create and submit data as part of their quality and regulatory systems
  • Where in the product life cycle is this data created
  • Accessing the data
**MEDICAL DEVICE PRODUCE LIFE CYCLE**

**Type of Data**
- Product Specifications
- Design History File/Technical File/Design Dossier

**Where Stored**
- Auditors/Premarket Submissions

**Accessed By**
- Labeling & collateral materials
- Auditors/Premarket Submissions
- Quality System Auditors – Regulators or 3rd party quality system auditors
- Premarket/Licensing Regulatory reviewers
- Users – Operators Manuals
- Public websites – product literature; hi level specifications

**DESIGN**

**Defined, Tested, Verified/Validated:**
- User performance requirements
- Technology – standards, regulations, environmental
- Risk analysis/mitigation (device classification)
- Safety, efficacy, reliability
- Shelf life, stability, packaging

**Documentation:**
- Drawing and specifications
- BOM – bill of materials
- Labeling

- Quality System Auditors – Regulators or 3rd party quality system auditors
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- **DESIGN**
- **MANUFACTURE**
- **COMMERCIAL RELEASE**
- **POSTMARKET SURVEILLANCE**
- **END OF LIFE**
# Medical Device Produce Life Cycle

## Manufacture

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### Quality Plan
- Specifications/BOM – drawings, composition, component, & software.
- Production specifications – equipment, methods and procedures, & environment.
- Quality Assurance – procedures, acceptance criteria, equipment & tools.
- Packaging and labeling specifications.
- Installation, maintenance, and servicing.
- Dates of manufacture.
- Quantity made/released for distribution.
- QC Acceptance records.
- Primary and production unit, batch, lot ID/label.
- UDI or UPC ID or control numbers.

### Quality System Auditors
- Regulators or 3rd party quality system auditors (notified bodies)
- Premarket/Licensing Regulatory reviewers – Quality Plan for High risk

### Users
- Operators Manuals; Certificate of Conformance
- Public websites – product literature; hi level specifications
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• Submission requirements:
  o Declaration of Conformity to essential requirements of all applicable Directives
  o High Risk Devices – Design Dossier, Quality Plan, Clinical Data.
  o Device description, Intended Use, etc.
  o Labeling (Warnings)
  o Advertising & Promotional Materials
  o Fees
• Certificate of Origin
• Compliance to transportation restrictions (dangerous goods, hazardous materials environmental)

• Premarket/Licensing Regulatory reviewers.
• *MDSAP/Auditors – license verifications

• License/registrations-market access “granted” – 510k, PMA, CE Mark, etc.
• Labeling - Advertising
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**MEDICAL DEVICE PRODUCE LIFE CYCLE**

DITTA

GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

[Logos of various organizations]
POSTMARKET SURVEILLANCE

Type of Data
- Clinical/Adverse Events/Field Safety

Where Stored
- Compliant System/CAPA Files

Accessed By
- Auditors/Regulatory Premarket Reviewers

Accessed By
- Public Records

Clinical Studies for high risk devices - registries
- Adverse Events/vigilance - trending
- Risk Assessment, root cause analysis, corrective/preventive action(s).
- Notifications/Safety Alerts – to regulators, users, patients.
- Field Safety Corrective Action/Recall

Quality System Auditors
- Premarket/Licensing Regulatory – consider performance history when evaluating new license applications
- NCAR – regulator shared AER database

FSCAs, Recalls, AERs, Safety Alerts
# Medical Device Produce Life Cycle

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### MEDICAL DEVICE PRODUCE LIFE CYCLE

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- **Product expiry date**
- **Devices no longer marketed by OEM.**
- **Service and Repair challenges:**
  - Technical support – fewer technicians trained on older devices
  - Supply chain – suppliers discontinue parts
- **Restrictions on transport of used equipment and parts.**
- **Refurbished Medical Devices**
  - “NEMA/MITA 1” - Good Refurbishment Practices for Medical Imaging Equipment
  - IEC PAS 63077: Good Refurbishment Practices for Medical Imaging Equipment
- **Premarket/Licensing Regulatory reviewers.**
- **MDSAP/Auditors – license verifications**
- **End of Life Notification – advises of timeframe to cease parts and service.**
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