Regulatory Framework for Control of Refurbished Medical Devices

Submitted by: GE Healthcare
Regulatory Framework for Control of Refurbished Medical Devices

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CURICULUM VITAE

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Presently, Director, Regulatory Affairs, ASEAN, GE Healthcare & Co-Chair, Asian Harmonization Working Party Work Group 1 on harmonizing pre-market registration requirements across Asia and Middle East

Prior, 7.5 years in Health Science Authority Singapore, last appointment as Deputy Director, Licensing & Surveillance, Medical Device Branch

• Part of Team that implemented Medical Device Regulations, and introduced ASEAN CSDT & GDP, in Singapore;
• Co-Chair ACCSQ MDPWG;
• Chair, AHWP Technical Committee; and
• Member of Global Harmonization Task Force Study Group 1
Agenda

- Ensuring Safety of Medical Device Manufacturers
  - Quality Management System
  - Use of International Standards to Ensure Safety & Performance
- Ensuring Safety of Refurbished Medical Device

Medical Devices: Spare Parts for Ourselves
*GHTF* Definition of a Manufacturer

Any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies)

*Global Harmonization Task Force*
GHTF Definition of a Manufacturer

**Design and/or manufacture** may include:-

- Specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilisation, installation, or remanufacturing; and/or

- Assembly, packaging, processing and/or labelling of one or more finished products

GHTF Definition of a Manufacturer

Any person who assembles or adapts a device(s) that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is **not** the **manufacturer**, provided the assembly or adaptation **does not change the intended** use of the device(s)
GHTF Definition of a Manufacturer

Any person who changes the intended use of, or modifies, a finished medical device in a way that may affect safety or performance, without acting on behalf of the original manufacturer and who makes it available for use under his own name should be considered the manufacturer of the modified medical device.

Ensuring Safety of New Devices

(non-exhaustive)
EC Certificate

- EC Certificate
- Approval full Quality Assurance System
- Annex II section 3 Directive 93/42/EEC concerning medical devices
- Manufacturer
- GE Hangwei Medical Systems
- Device category
- CT Scanners – MRI systems
- G-Med certifies that, on the basis of the results contained in the file referenced J018084-R, the quality system – for design, manufacturing, and final inspection – of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II section 3.
What’s Does it Mean?

As an example

- What are the meanings behind the wordings of the certificate?
- Notified Body (CE XXXX) issues a certificate. It means that:
  - manufacturer has maintained a QMS that meets the ISO 13485:2003 standard; and
  - meets EU Medical Device Directive (93/42/EEC)
EU Harmonized Standards (Ionizing Radiation Devices) (New)

EN 60601-1-3:2008
Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance -
Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-3:2008

EU Harmonized Standards (Ionizing Radiation Devices) (Old)

EN 60601-1-3:1994
Medical electrical equipment -- Part 1: General requirements for safety -- 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-1-3:1994
Refurbishment

Principles of **Good Refurbishment Practices (GRP)**

*Refurbishment Definition*

“a **systematic** process that ensures safety and effectiveness of the medical equipment **without** significantly changing the equipment’s or system’s performance, safety specifications and/or changing **intended use as in its original registration**.”
Principles of Good Refurbishment Practices (GRP)

Any upgrades processed during GRP refurbishment shall be performed in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that equipment or system.

Same Elements of Regulatory Control for MDs

- Quality Management System (QMS)
- Post-market Surveillance
- Technical Documentation
- Declaration of Conformity
- Registration of manufacturers, distributors and their devices
Certificate: **EN ISO 13485:2003**

- Hereby certifies that the Organization
- GE Medical Systems (China)
- Has established and applies a quality management system for medical devices for the following **scope**
  - Refurbishment and Service of CT, MR, X Ray Products
- Proof has been that the requirements specified in
  - **EN ISO 13485:2003**
- are fulfilled. The quality management system is subject to yearly surveillance.
Conclusion

- **Ensuring Safety of New / Refurbished Medical Device**
  
  *Manufacturers / Refurbishers*
  
  - Audit of Quality Management System
  - Use of International Standards to Ensure Safety & Performance

  One yardstick for safety, quality & performance – “no double standard”
Thank You

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Conclusion

Global Harmonization Task Force
- What is GHTF & their current regulations?

Harmonization
- What is / what is not harmonization?

Tools of Harmonization – Common Dossiers, Grouping
- Tools to be used for registration
- Tools to be used for designing a regulatory framework that is least burdensome
**Conclusion**

**Tools of Harmonization – Common Dossiers, Grouping**

- Use of international Standards / local standards
- Outsourced / 3rd party manufacturing sites
- Clarity in grouping rules (affects registration fees)
- Grouping affects **multi-economy use** of CSDT
- Inclusion of accessories codes into CSDT (affects import and supply of accessories)
- Import and supply of spare parts / expendables (affects local supply)

**Recommendations**

- Aware of need to map against other regulatory elements and guidance documents for setting up a harmonized regulatory framework (e.g. registration of manufacturers and listing of medical device, definition of MD, classification of MD, definition of manufacturers, authorized representatives)
Asia Network Design & Optimization (AsNDO)

...to here
Overcome Current SC Challenges

1. Shortening product life cycles
2. Lengthening global supply chains
3. Increasing product complexity
4. Rising logistics expenses
Classification of Medical Devices

- Risk based classification
- Device classification depends on intended use and indications for use
- Devices are classified into 3 classes, based on the level of control needed to assure the safety and effectiveness of the device:
  - **Class I** (Low risk) – General controls
    - With exemptions
    - Without exemptions
  - **Class II** (Moderate risk) – General controls and special controls
    - With exemptions
    - Without exemptions
  - **Class III** (High risk) – General controls and premarket approval

Premarket Requirements

- Classification determines type of premarket submission required for market clearance
- Class I and II devices typically require premarket notification (510k), unless exempt by regulation
- Class III devices require submission of premarket approval (PMA)
Premarket Requirements

Class I

- General controls sufficient to provide reasonable assurance of safety and effectiveness

  - General controls:
    - Establishment registration
    - Medical device listing
    - Labelling requirements
    - Premarket notification (510k) submission (unless exempted by regulations)
    - Manufacture under GMP requirements

(Note: All classes are subject to general controls)

Premarket Requirements

Class II

- General controls insufficient to provide reasonable assurance of safety and effectiveness. In addition to general controls, special controls are necessary

- Special controls:
  - Special labelling requirements
  - Mandatory performance standards
  - Post market surveillance
Premarket requirements

Class III

- General controls and special controls insufficient to provide reasonable assurance of safety and effectiveness
- Premarket approval (PMA) is required: scientific review to ensure safety and effectiveness

Premarket requirements

Premarket notification (510k)

- Premarket application to demonstrate that device is as safe and effective i.e. substantially equivalent to a legally marketed device (i.e. predicate device)

- A device is substantially equivalent to a predicate device if it
  - Has the same intended use and technological characteristics as the predicate device
    OR
  - Has the same intended use as the predicate device and different technological characteristics that do not raise new questions of safety and effectiveness
Premarket Approval (PMA)

- Scientific review to evaluate the safety and effectiveness of Class III devices.
- Sufficient valid scientific evidence to assure that the device is safe and effective for its intended use must be submitted.
- An approved PMA is, in effect, a private license granting the applicant permission to market the device.

Review of a PMA is a 4 step review process consisting of:

- Administrative and limited scientific review by FDA staff to determine completeness (filing review).
- In depth scientific and regulatory review by appropriate FDA scientific and compliance personnel (in depth review).
- Review and recommendation by the appropriate advisory committee (panel review).
- An FDA good manufacturing practices (GMP) inspection.
Quality System Requirements

- Quality system requirements are set out in the Quality System Regulation
- FDA does not require a manufacturer to register a quality system (a requirement of ISO and EN quality systems)
- FDA inspects quality system requirements in the course of regular inspections of a manufacturer’s facilities
- Foreign manufacturers are also subject to FDA inspections

Postmarket Requirements

- Requirements are set out in the Safe Medical Devices Act and FDA Modernisation Act:
  - Manufacturers must submit medical device reports for device which caused death or serious injury, or, if the malfunction were to recur, would have cause death or serious injury
  - User facilities must report device related deaths and serious injuries and submit a summary of all reports to FDA on an annual basis
  - Manufacturers must have in place distribution records and other methods for tracking permanent implants or life sustaining/supporting devices used outside a facility
  - Manufacturers and importers must report to FDA any removals and corrections of a device from the market
### Wide Range of Device Types – Different from Drugs

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### GHTF* Definition of a Medical Device

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro reagent or calibrator*, software, material or other similar or related article:-

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
   - investigation, replacement, modification, or support of the anatomy or of a physiological process,
   - supporting or sustaining life,
   - control of conception,
   - disinfection of medical devices,
   - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

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GHTF Definition of a Medical Device

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

The definition of a device for in-vitro examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an in-vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes.

Facts About MD & the Industry

• Wide range of device types
• Many different areas of clinical use
• Accessories (sometimes disposable) critical to device use
• Import of spare parts / expendables
• Globalization and global manufacturing sites
• Physician’s influence on clinical outcome
• Risk sharing during device use
Globalized manufacturing sites

USA
- Monitor B888
- Monitor C124
- Milwaukee, USA

Finland
- Monitor A812
- Monitor B82
- Helsinki, Finland

Mexico
- Monitor V2B8
- Mexico
- Mexico City, Mexico

China
- Accessories manufacturing
- Wuxi, China

Certificate of Registration

- LNE certificate for the production of medical devices
- GE Medical Systems Information Technologies GmbH
- Wöringerstrasse 5
- 7911 FRISBURY GERMANY

Design and configuration of medical equipment and accessories
Design of imaging information systems

Not conforme aux exigences des normes internationales

For the Certification of

LNE (Laboratoire National d’Essais)
ISO 13485 Certificate

- LNE certifies…
- GE Medical Systems
- For the activities
- Design and configuration of cardiology equipment…
- Performed on the location of
- GE Medical Systems
- Complies with the requirements of the international standards
- This certificate is issued according to the rules of G-Med certification
- G-Med Notified Body for Medical Devices

Conformity Assessment Bodies (CABs)
GHTF Definition of CABs

GHTF Definition of Conformity Assessment Body (CAB):

a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorised to undertake specified conformity assessment activities by a Regulatory Authority (RA) that will ensure performance of the CAB is monitored and if necessary withdraw designation.

Conformity Assessment of QMS & Device

Conformity Assessment of Manufacturer’s QMS

• Audits of the QMS
• Audits of the Post Market Surveillance process

Conformity Assessment of the Device Safety and Performance

• Review of device product technical documentation in dossier

✓ Review of Declaration of Conformity
Accreditation of Conformity Assessment Bodies

For example: Assessment of Technical Competence

- Product knowledge
- Clinical experience
- Regulatory knowledge
- Auditing experience