Regelgeving voor de medische hulpmiddelen industrie

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Good to know

A conflict of interest may exist as I work for IM Services BV which is a supplier to IVF clinics.

This presentation does not necessarily reflect the views of IM Services BV but is made on a personal basis.

Presentation content

- European legislation
- Technical File
- Quality Management System
- Production control
- Tests
- What’s next?

European legislation

- Medical Devices Directive [MDD 93/42/EEC] => Besluit Medische Hulpmiddelen [BMH] came into effect on 14 June 1993

- Successor : Medical Devices Regulation [MDR 2017/745 (EU)]
  - Entered into force on 25 May 2017
  - Transition period for application of MDR certification until 26 May 2020
  - Products manufactured under the MDD are allowed for sale and use until 27 May 2025

- Active Implantable Medical Devices Directive [AIMDD 90/385/EEC]

European legislation

- In Vitro Diagnostic Medical Devices Directive [IVDD – 98/79/EC]
- Successor : In Vitro Diagnostic Medical Devices Regulation [IVDR 2017/746]

‘*in vitro* diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, …., intended by the manufacturer to be used *in vitro* for the examination of specimens,…… derived from the human body, solely or principally for the purpose of providing information …….

European legislation

MDD highlights :

- **Safety and effectiviness**
- Different classes : I, Is, Im, IIa, IIb and III
- Classification based on Intended Use
  - Rule 2 All non-invasive devices intended for channeling or storing ……, cells or tissues, …… for the purpose of eventual …….. introduction into the body are classified as class IIa:
- Legal manufacturer/Authorized representative
- Post Marketing Surveillance [PMS]

European legislation

Notified Body

- Issue CE certificate
- Audits
- Review Technical File
- Specialization IVF/ART

Role of competent authority [IGZ]

- Registration of Class I devices,
- Recall and vigilance
- Accreditation of NB

Technical File

TF required for each <u>device family</u>

Content :

- Declaration of conformity
- Clinical evaluation [ISO 14155]
- Biocompatibility issues [ISO 10993]
- Sterilization validation [ISO 11135/37 and 11737]
- Risk management [ISO 14971]
- Labelling [ISO 15223]
- ……

Quality Management System

Standard QM System for manufacturers of medical devices is ISO 13485 : 2016

Risk based approach

> processes and products

Procedures for :

- Management Review
- Product realization
  - Purchasing
  - Production and services
- PMS, Recall, vigilance

Quality Management System

Management review : 1 x per year

Input

- External and internal audits
- Complaints
- PMS feedback
- Control and measuring of processes & products
- Corrective and preventive actions
- Quality objectives

Quality Management System

Purchasing

- Supplier qualification [ISO 13485 or ISO9001]
- Quality agreement :
  - specifications
  - change control
- Incoming goods inspection
- Batch CoA
- Audits
- Yearly supplier evaluation

Quality Management System

Production

- Assembly and packaging
- Sterilization

Quality issues :

- Traceability / FIFO
- Work instructions
- Qualified personnel
- Audits
- Labelling
- Packaging validation

Warehousing and transport

Production Control

- Component level
  - Bioburden level
  - Physical properties
  - Compatibility
- Assembly
  - Environmental control [cleanroom]
    - Particle count, T, Pa and %RH
    - Biocontamination control
  - Line clearance
  - Seal control
  - Visual inspection
- Final release for sterilization

Production Control

Sterilization

- Gamma irradiation and EtO sterilization
  - Process control
  - Release by QA sterilization plant
  - Regular re-validation
- Compatibility
  - Materials
  - Residu check
- Worst case approach

Tests

Mouse Embryo Assay [MEA]

- One-cell mouse embryo assay
- Duration depends on intended use
- Test method depends on product
- > 80% surviving blastocysts after 96/120 hrs

Limulus Amebocyte Lysate assay [LAL]

- Release value dependend on product and volume media

Tests

Sperm Motility Assay [SMA/HSSA]

- Human sperm
- SMI > 0.75

Bacteria and fungi

- Components
- Finished products

Cytotoxicity, sensitization, irritation

What’s next

Device lifecycle MDR :

- More stringent ex-ante control for high risk medical devices
- Clinical evaluation reports [CER]
- Post market clinical follow-up [PMCF]
- Periodic safety update report [PSUR]
- Post market surveillance [PMS]
- Summary of Safety and clinical performance [SSCP]

=> Risk – benefit evaluation

What's next

European Database for Medical Devices : EUDAMED

One central EU information system for :

- Vigilance reports
- Field safety notices [recall]
- PSURs for class III devices

and also for

- Registration of devices
- Unique Device Identification [UDI]
- Registration of manufacturers, Notified Body's, etc….
- Certificates issued or withdrawn
- Market surveillance by competent authority [IGZ]

Thank you for your attention!

Questions?