Innokas Medical | Healthtech Excellence Since 1994

Agile co-creation and manufacturing of next generation medical devices - how to ensure the practical application of the regulatory requirements are met throughout the device whole life cycle

Tiina Kotipalo Innokas Medical Oy

Innokas Medical is 100% owned by Paree Group

PAREE GROUP

serres

Serres is the progressive leader is smart fluid management solutions around suction. Through our solutions, we help healthcare professionals succeed in their daily work. Our offering enhances every step from suction to disposal making the whole process safer and smarter. Supporting over 40,000 operations each day, the Serres solutions help healthcare professionals to focus where it matters.

www.serres.com

vieser

Vieser is the leading Nordic manufacturer of drain systems for buildings. Vieser engages in long-term and customer-focused design of products for a range of different applications in wet rooms, with three product families: floor drains, covers and water traps.

www.vieser.fi

Innokas Medical

Innokas Medical is a Finnish health technology company founded in Oulu in 1994. Innokas offers its customers professional medical technology solutions by mastering the agile path from idea to high-quality design and product development, regulatory approvals and cost-efficient manufacturing of medical devices. Innokas is ISO – certified and FDA registered company.

www.innokasmedical.fi

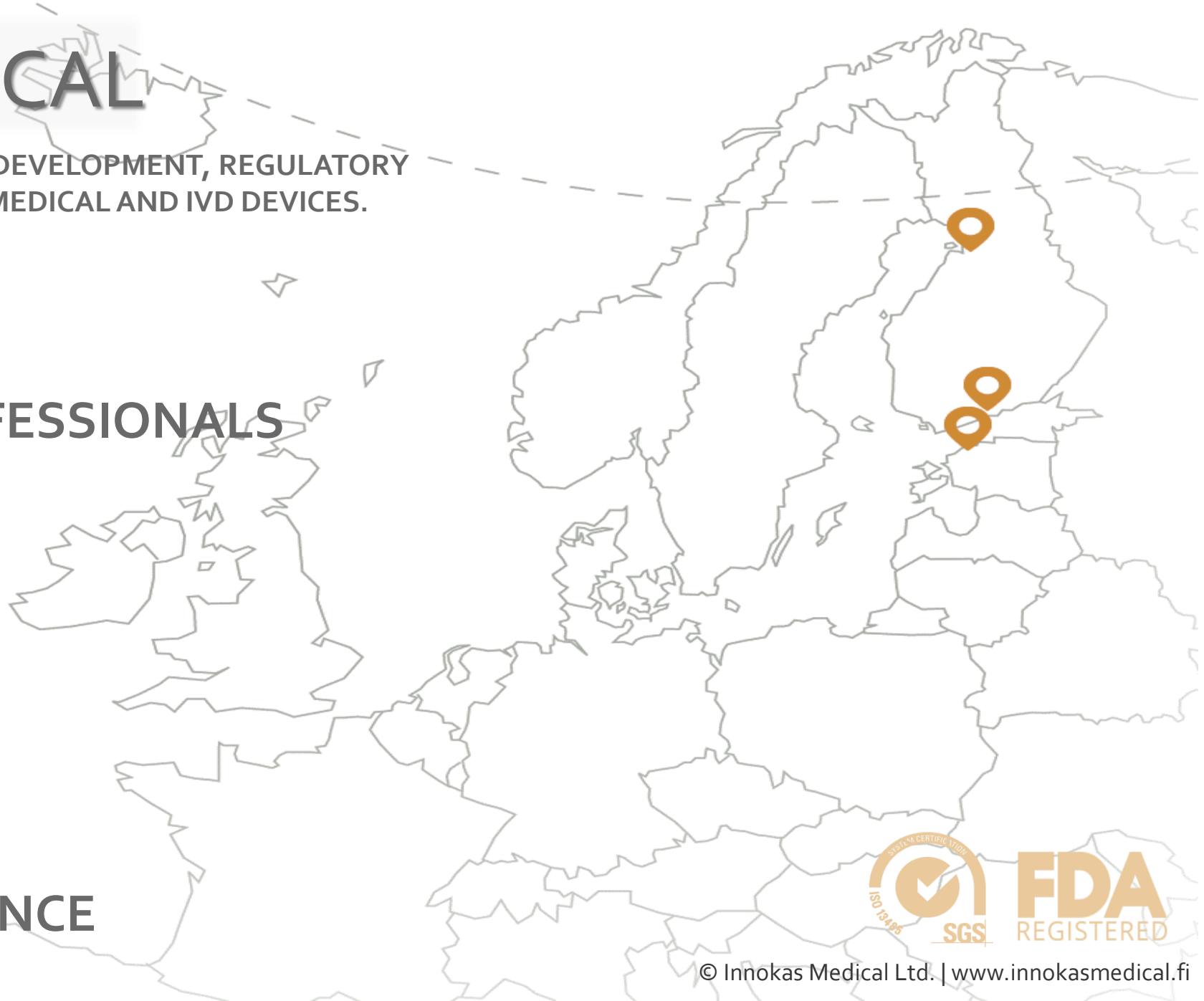
Cubist

We are an IT consultancy company developing intelligent solutions for the healthcare of tomorrow. We help our customers with a broad range of software development services. We do front end, back end, sensor integration, embedded software, data science, AI, machine learning, regulatory advice and project management.

www.cubist.eu

INNOKAS MEDICAL

SPECIALIZED IN DESIGN AND PRODUCT DEVELOPMENT, REGULATORY APPROVALS AND MANUFACTURING OF MEDICAL AND IVD DEVICES.



220

HEALTHTECH PROFESSIONALS

31M€

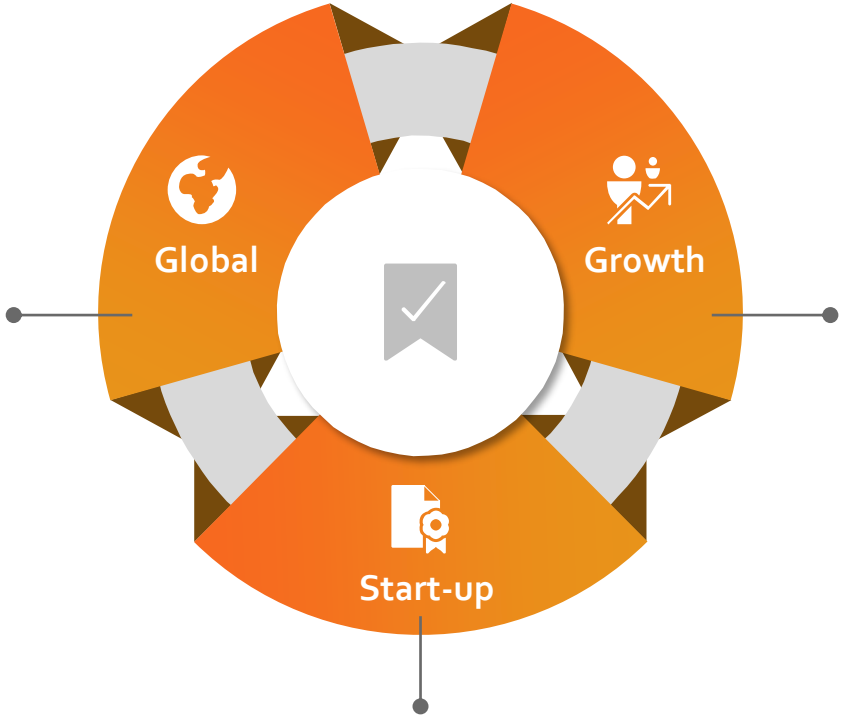
REVENUE

25

YEARS OF EXPERIENCE

INNOKAS IS TRUSTED BY

INNOVATIVE HEALTHTECH BRANDS.



AIDIAN
Elekta
CareFusion
GE Healthcare
PHILIPS
icare FINLAND
OPTOMED
VAJAT Direct Conversion X-ray Imaging
C-RAD
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serres
Medanets DIGITAL CARE & HUMAN TOUCH
MONIDOR
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alcosystems
sooma
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SYNOSTE
otivio
MOODMETRIC
GRAINSENSE
RSP systems NON-INVASIVE TECHNOLOGY
MODE
COALA
GlucoSet CONTINUOUS GLUCOSE MONITORING

OUR STRENGTH

Co-creation partnerships in medical technology - over the entire product life cycle.

Idea Elaboration

Design & Development

Regulatory Approvals

Design Transfer

Manufacturing Operations

Life Cycle Management

COVID-19 impacts on regulations

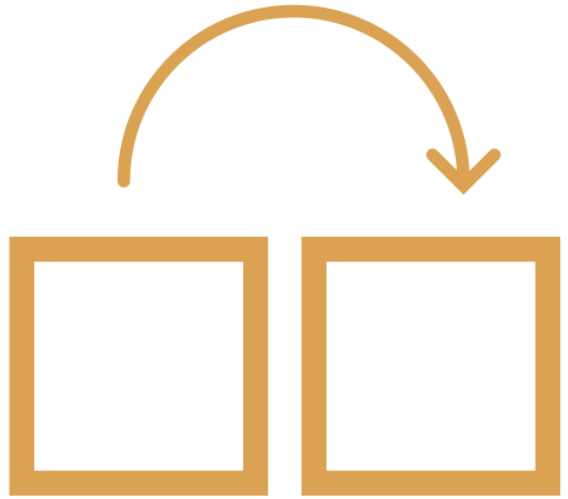
- European Comission **postponing the Date of Application (DoA) of the Medical Device Regulation** (MDR) for one year
  - See next slide
- Shortages in parts and some logistics problems
- Changes in demand of devices
- EU competent authorities, Notified Bodies and test laboratories very busy
- Some export restrictions in different countries
- Some temporary easing of regulations and approval processes by different authorities in EU
- FDA, Health Canada and other authorities easing regulations temporarily as well
- Onsite audits → Remote audits
- Many standards now available for free (e.g. PPE, ventilators, etc.)

Postponing the DoA of MDR for one year

- New MDR Date of Application 26.5.2021
- Timelines linked to DoA postponed as well
- AIMDD and MDD remain applicable for an extra year
  - Registration
  - Reporting and Post Market Surveillance postponed
  - All Class I self-certified devices continue in MDD
  - Up-classified devices continue MDD
  - it is still possible to start clinical studies under the current Directives before May 26, 2021, and continue them after that date
  - MDD certificate renewal possible
- Things that are not changing
  - The last date of expiry for MDD issued certificates (26-May-2024)
  - The last date to sell medical devices that were placed on the market before expiry (ex. warehouse inventory) is still 26-May-2025 and has not changed.
  - Dates for Unique Device Identifier (UDI) and direct part marking
  - In-Vitro Diagnostic Regulation (IVDR) remains unchanged and is still applicable as of 26-May-2022.
- MDD Harmonized standards updated
- Lots of new MDR guidance published by MDCG

Forced transition to MDR

- Significant change in device
- Significant change to the certified QMS
- Change of a critical supplier
- Notified Body change
  - Due e.g. NB not designated for MDR
  - NB based in UK, Switzerland or Turkey
  - NB stops being NB
  - No agreement with current NB

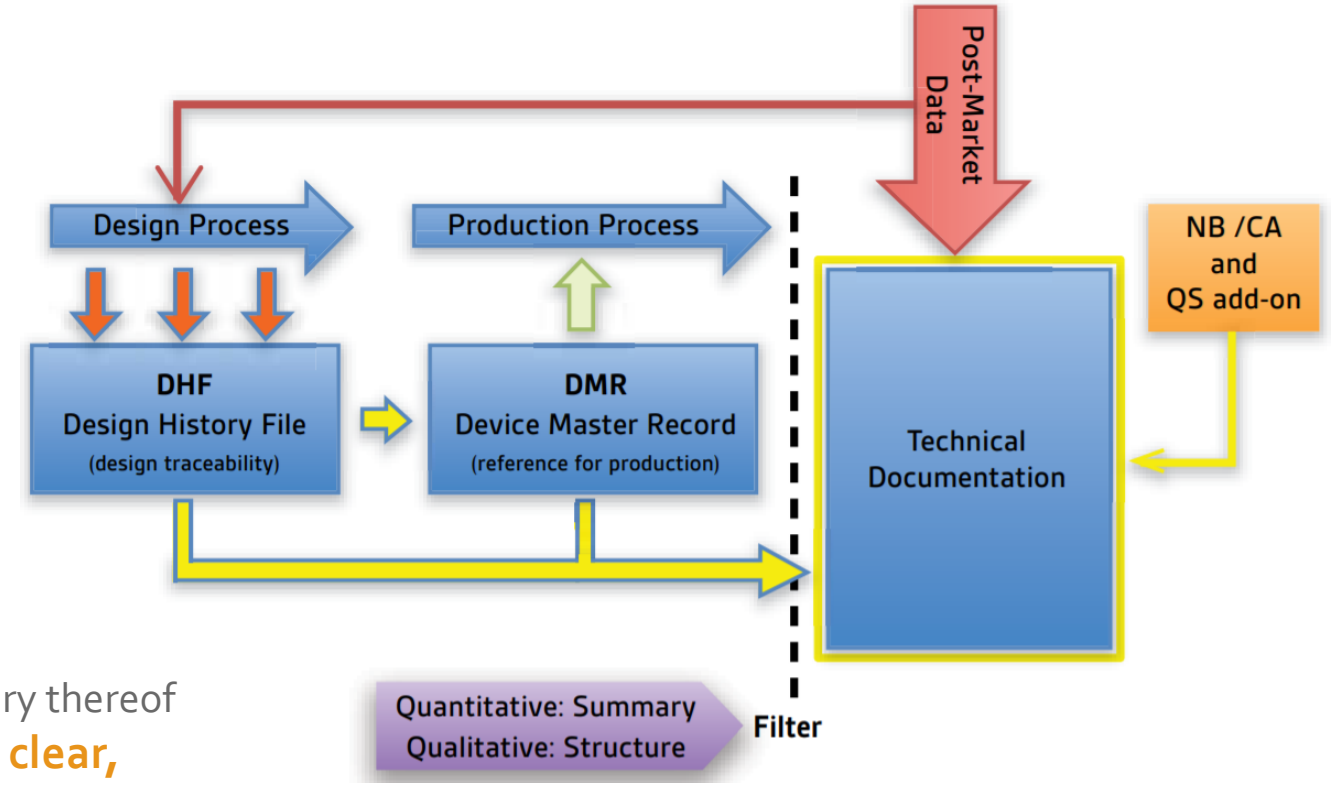


Keep going as planned and do not postpone MDR activities!

CE Certification of Medical Devices – Technical Documentation

NB audit | Technical Documentation

- DHF
- DMR
- STED
- Risk Management
- Post Market Data
- Declaration of Conformity
- etc…

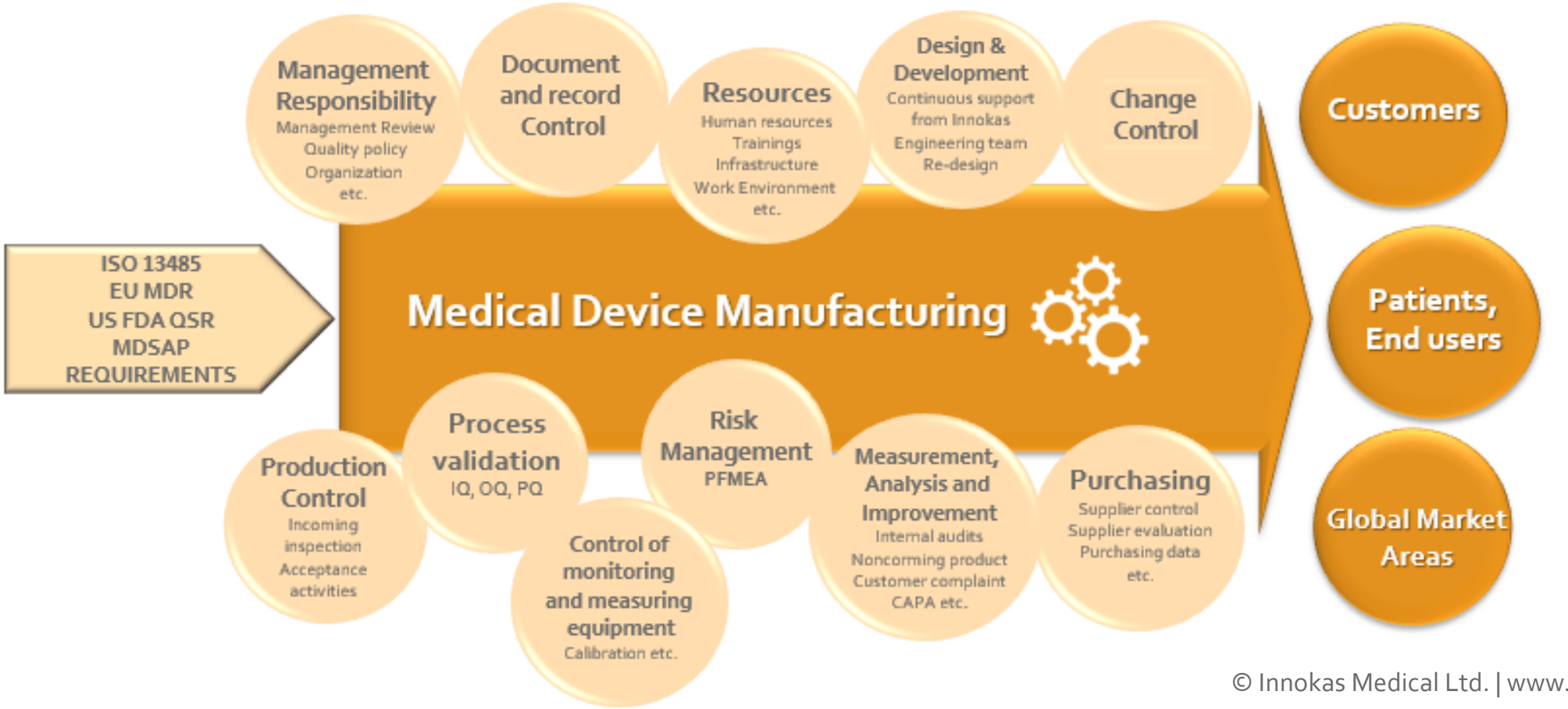


The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in **a clear, organised, readily searchable and unambiguous manner** and shall include in particular the elements listed in Annex II

CE Certification of Medical Devices – Quality Management System

NB audit | Quality Management System

- ISO 13485 certificate
- New MDR requirements



Medical and IVD Device Regulatory Process - in practice 1/2

The quality should be built into company's internal processes. Through the fine-tuned, high-quality processes we can ensure that all the regulatory requirements are met during each phase from idea to production and post-production activities.

Idea of a Medical Device

Requirements

Identify **clinical intended use**

Define users, use environment, patients, medical device qualification and classification

Find out regulative requirements and general safety and performance requirements

Quality Management System ISO 13485

Requirements

Establish Quality Management System to ensure that the requirements are met throughout the life-cycle of the medical device.

- *Quality Manual*
- *Risk Management*
- *SOPs*
- *Document templates and forms*
- *Management reviews*
- *Internal audits*
- *CAPA procedure*
- *Post Market Surveillance etc...*

Design and Development

Requirements

Design process according to ISO 13485 QMS, MDR and FDA requirements

Harmonized standards and **Common Specification**

Risk Management according to ISO 14971

Usability Engineering according to IEC 62366

Software Design according to IEC 62304

IEC 60601-1 & **collateral and particular standards**

Technical Documentation, UDI

Clinical Evaluation

Requirements

A systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

Approvals for different market areas

Requirements

Technical Documentation

DHF

Manufacturing processes

Registrations

Applications:

CE marking

FDA 510(k)

Canada MDL

etc...

Medical and IVD Device Regulatory Process - in practice 2/2

The quality should be built into company's internal processes. Through the fine-tuned, high-quality processes we can ensure that all the regulatory requirements are met during each phase from idea to production and post-production activities.

Design Transfer

Requirements

Ensure that the device can be manufactured consistently in good quality

Manufacturing documentation

Production line ramp-up

Working instructions

Receiving inspections

Trainings

Supplier controls

DHR templates

Production Process Validation

Requirements

Installation Qualification; equipment installation approvals, work instructions, reports, trainings etc.

Operational Qualification; ensuring that manufactured products fulfil the requirements

Performance Qualification; ensuring manufacturing process will consistently produce acceptable products

Production according to ISO 13485 and FDA GMP Requirements

Requirements

Manufacturing processes according to ISO 13485, FDA GMP and other regional specific requirements

Risk management (PFMEA)

Documents and Records (DHR)

Receiving inspections
Manufacturing equipment maintenance and calibrations
Final testing

Change management

Internal audits, CAPA

Post-Production Activities

Requirements

Customer feedback procedure

Design Change Control

Manufacturing Change management

Service

Vigilance
Post market surveillance

VALUE ADDING PARTNER

Offers co-creation partnerships in medical technology - over the entire product life cycle.

Idea Elaboration

Design & Development

Regulatory Approvals

Design Transfer

Manufacturing Operations

Life Cycle Management

Thank You!

www.innokasmedical.fi

ISO 13485 SYSTEM CERTIFICATION SGS

FDA REGISTERED

Improving people's lives by crafting healthtech ideas to reality.

Innokas Medical