Spotlight on ISO 13485 and Navigating Germany`s administrative bodies

Dr. Sandra Kreft

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Quality management system
DIN EN ISO 13485

design

development

manufacturing

of medical devices and their components

ISO 9001, EU Directive 93/42/EEC, medical product law

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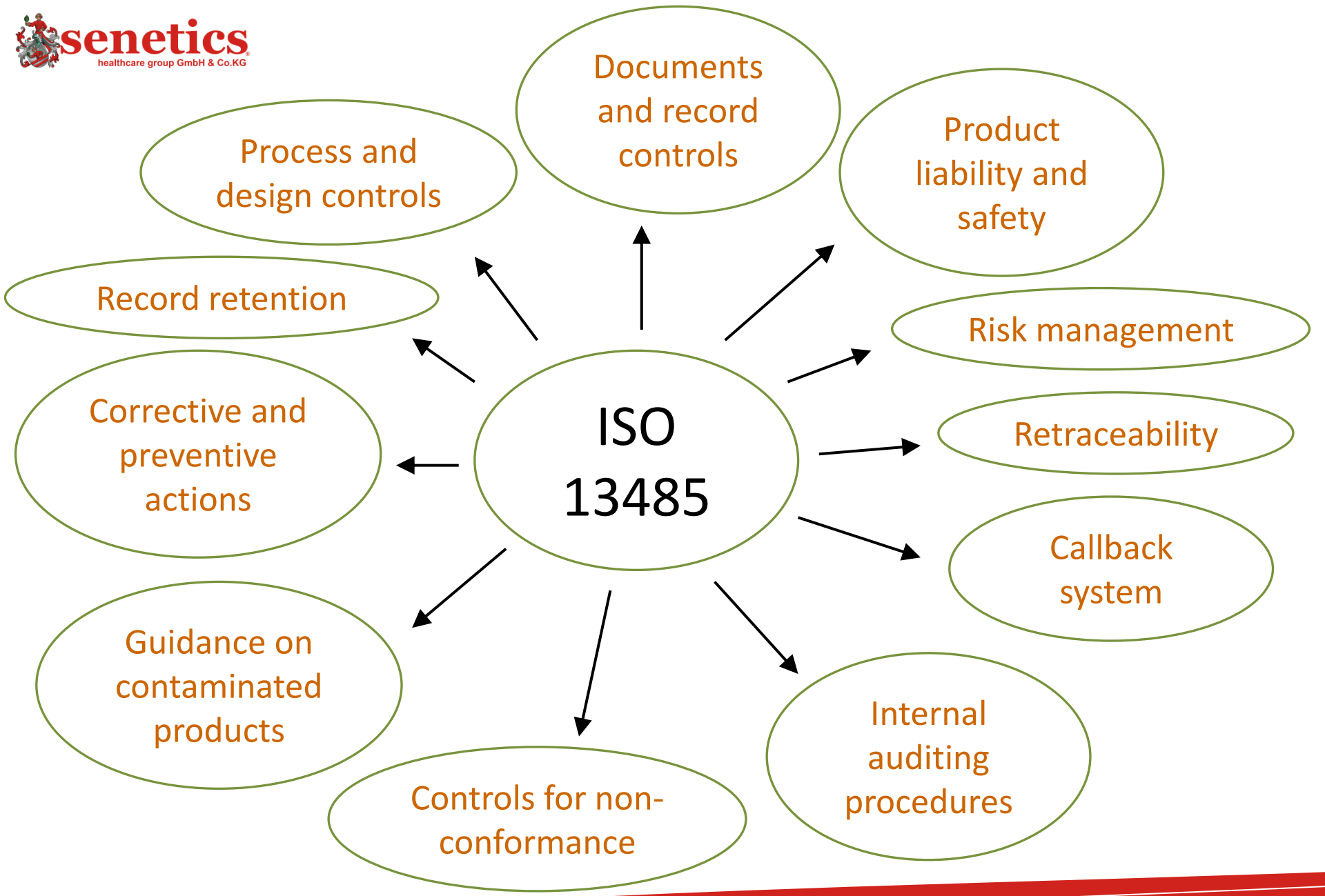

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Implementation of DIN EN ISO 13485

Preparation of quality handbook

Definition of processes

Definition of standard operating procedures (SOP)

Analysis of all definced processes/ SOPs in practise

Monitoring and traceability of all quality records

Perform internal periodic revisions on documents!

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DIN EN ISO 13485 certification

- Documents integrated in work life
- Search for suitable certification acency (TÜV, DEKRA, Medcert, DQS)
- Important: Comparision of several quotes

Preaudit (optional)	Audit 2nd year
Audit step 1	Audit 3rd year
Audit step 2	4th year: Re-Audit to obtain new certificate
Paper certificate	

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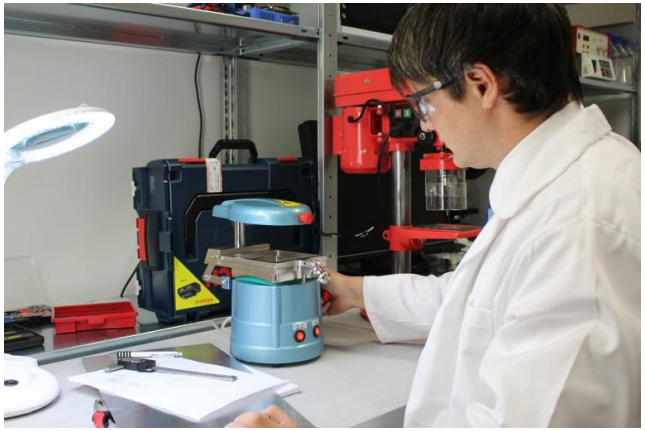
Tests & Validation

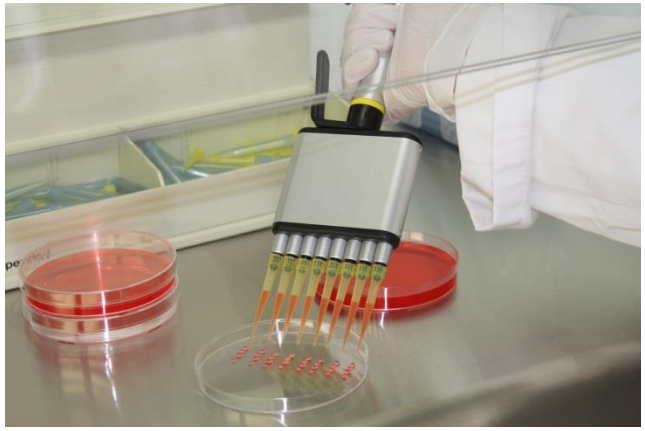
Technical testing

- Usability tests
- Process validation
- Electronical safety

Biological testing

- Bioburden (bacterial load)
- Sterilizing capacity
- Cytotoxicity





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CE Certification - requirements

Clinical evaluation and/or Clinical study

Analysis and evaluation of present clinical data to prove safety and efficacy

CE

Collect clinical data to prove safety and efficacy

NANDO Register of Notified Bodies in Germany:
http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=276

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Clinical studies of MP in Germany (DIN EN ISO 14155)

Principle Investigator

Study plan → Ethics committee
Higher federal authority

- Center for clinical studies (CCS/ZKS), often belonging to universities
- Local clinical research organisations (CRO)

→ offer support in preparation, conduction and analysis

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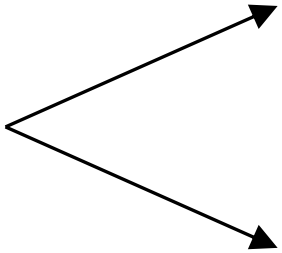
German authorities

BfArM
Federal Institute for Drugs and Medical Devices

Risk evaluation of medical devices

DIMDI
medicalknowledge
German Institute of Medical Documentation and Information



Market surveillance of medical devices

Ethics committee

- University (hospital)
- Federal Medical Association

Gemeinsamer Bundesausschuss

Federal Joint Committee

http://www.bfarm.de/EN/Home/home_node.html
https://www.dimdi.de/static/en/index.html
http://www.english.g-ba.de

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Checklist for suppliers and manufacturers

- ✓ Quality management and risk management
- ✓ Applicable laws and guidelines
- ✓ Testing and Validation
- ✓ Communication with notified bodies and authorities
  - ✓ Clinical evaluation and clinical studies
  - ✓ CE Certification and Reimbursement
- ✓ Placement on market and effective marketing
- ✓ Networking and contact to other distributors/suppliers

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Thank you for listening

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