Johner Institut

Seminar Medical Device Consultant MPDG

Learning Content

- Introduction and comparison of the old and new legal systems
    - Old legal system:
        - EU: MDD, AIMDD, IVDD
        - DE: MPG, MPV, MBetreibV, MPSV
    - New legal system:
        - EU: MDR, IVDR
        - DE: MPAnpGV, MPDG, MBetreibV, MPDGGebV, MPAMI
- Relationship of laws, directives, regulations, standards, general (safety and performance) requirements
- Changes in the requirements to the new legal system
    - Classification of medical devices
    - Conformity assessment procedure
    - Requirements for the economic operators
    - Person Responsible for Regulatory Compliance (PRRC) (Art. 15 MDR/IVDR)
- General introduction to the MPDG
- §83 MPDG: Medical Device Consultant
    - Expertise of Medical Device Consultants
    - Requirements for the qualification
    - Tasks and duties of the Medical Device Consultant
- Market surveillance and monitoring after placing on the market
    - Cooperation with the PRRC

Schedule

Time	Content
09:00 am - 09:30 am	Introduction and meeting of the participants
09:30 am - 11:00 am	Regulatory basics
15 min break	
11:15 am - 12:45 pm	Medical Device Consultant according to MPDG and monitoring after placing on the market
12:45 pm - 01:00 pm	Final test and end of the seminar

You can find more information and the registration option here