Johner Institut

Seminar Person Responsible for Regulatory Compliance

Learning Content

- Technical expertise, legal basis MDR and IVDR (Article 15), Guidance MDCG 2019-7
- Individual tasks of the Person Responsible for Regulatory Compliance:
  - Conformity of the produced devices and technical documentation
  - Post-Market Surveillance
  - Reporting serious incidents, recalls, and trends
- Possibilities of implementing a job description
- Sharing of responsibility among several people
- Advantages and disadvantages of an internal PRRC versus an external one
- Liability of the PRRC (internally and externally)
- Comparison with pharmaceutical industry
- Medical Devices Implementation Act (MPDG) and its penal and fine provisions
- Dealing with disputes

Schedule

Time	Content
09:00 am - 09:30 am	Introduction and expectations
09:30 am - 10:25 am	Legal basis, technical expertise and tasks of the PRRC
15 min break	
10:40 am - 12:00 pm	Tasks of the PRRC
10 min break	
12:10 pm - 01:00 pm	Tasks of the PRRC
40 min lunch break	
01:40 pm - 03:15 pm	Tasks of the PRRC, division of responsibility, liability, job description, proven solutions from the pharmaceutical industry
15 min break	
03:30 pm - 04:45 pm	Advantages and disadvantages of an internal or external PRRC, dealing with disputes, penalty and fine regulations
04:45 pm - 05:00 pm	Time for further questions

You can find more information and the registration option here