TRAINING
INTRA or INTER-COMPANY

MD RISK MANAGEMENT
Concepts & Method

Réf : 2601B_L_Gen

Pedagogical objectives:

- Know the vocabulary and requirements for Risk Management [RM] according to Regulation (EU) 2017/745 and ISO 14971:2019.
- Know the components of the RM documentation
- Acquire autonomy in establishing up product risk analyses
- Know how to manage product risks over the entire life cycle

Modalities of implementation:

Presential allowing face-to-face discussions about,

- Creating a Risk Management documentation
- The steps involved in estimating the occurrence of damage
- A possible link to real data from post-market surveillance
- Setting up a damage table
- Maintaining consistency between the Risk Management documentation and all the technical documentation of the device

Assessment of the objectives achievement*:

- Before: Positioning questionnaire
- During: Implementation of exercises
- Right after: Learning acquisition questionnaire
- Distant: Usage evaluation questionnaire

In practice:

DATES:	To be defined
DURATION:	1,5 days - 10h30
TIMETABLE:	14h30-18h00 / 9h00-12h30 & 14h00-17h30
LANGUAGE:	Training given in English
LOCATION:	Client location -OR- PARIS 20ème
PRICE:	On quotation
ACCESSIBILITY:	Access possible for people with reduced mobility. Adaptation according to disability, please contact us
CONTACT:	administration@bpath.eu

** Previous satisfaction rate: 91%*

Targeted audience:

Medical Devices professionals:

- Beginners, false/non-beginners who need to update their knowledge
- Managers or members of departments responsible for Quality, Regulatory Affairs, Product Development, Manufacturing Processes, Clinical Affairs

Prerequisites:

- None

Program:

- Definitions **Day 1**
- Expectations in terms of risk management
- The risk management documentation
- Risk analysis:
  - Risk identification
- Risk analysis: **Day 2**
  - Estimation, evaluation
  - Control, Verification
- Benefits & Benefits/Risks
- Risk management report
- Consistency with the technical documentation

Pedagogical method:

- Presentation - Exercises - Teaching materials
- Illustration based on examples
- Direct exchanges with participants

Monitoring:

Attendance sheets, assessments and a certificate at the end of the course to confirm what has been learned.

Instructor:

Richard Minfelde, PhD. After more than 15 years of R&D/industrialization in orthopedic and spinal devices, he created Bpath in 2012 to meet the needs of non-active DM manufacturers and project developers in regulatory and technical fields. He supports Clients in producing technical data in response to new regulatory requirements, within which risk management plays a central role.