



Risk Management for Life Sciences

Risk Management is taught using a blended approach of classroom and real-life work application. This approach to learning significantly increases training and skill-set retention, as well as allowing participants to apply what they have learned in a training setting.

PathWise facilitators have an extensive background in teaching Risk Management techniques in an FDA regulated environment.

Effective Risk Management is a critical process for those under increased regulatory scrutiny. In the past decade, ISO 13485/14971 and ICH Q9 have been recognized by the FDA as the standards to which all medical device and pharmaceutical companies should comply. Now, more than ever, life science companies need strong risk systems in place. Risk Management for Life Sciences will teach you how to improve your Risk Management performance to not only meet but exceed the FDA's increasingly stringent regulatory standards.

LEARNING OBJECTIVES:

- Understand where risk comes from and how to identify the sources
- Analyze potential problems and follow a proven process to mitigate, control, and document risk
- Build alarms into your analysis that shorten the time to risk containment and reduce damage controls
- Become proficient in tools such as FMEA, HACCP, FTA, SWOT, and Risk Mapping
- Outline a change process to reduce and prevent future risk occurrence

AUDIENCE

This course is recommended for the following life science professionals:

- Research and Design Engineers
- Risk Management professionals
- Quality Assurance professionals
- Regulatory and Compliance professionals

