About
Company

KVALITO Consulting Group is a strategic partner and international network for quality and compliance service for regulated industries. Headquartered in Basel, Switzerland, we have subsidiaries in Germany, Czech Republic, Ireland and Malaysia. With our enthusiasm for progressive technologies and our indepth knowledge of industry best practices and regulations, we drive effective and efficient project delivery to keep our industry-leading clients ahead of the competition.

www.kvalito.ch

KVALITO

KVALITO TRAINING

Upskill your teams and thrive

RISK MANAGEMENT

Contact Us

Phone: 03-27281182

Email: training@kvalito.ch

Websites: https://kvalito.ch/training/

Who should attend:

- **Quality Assurance**
- **Quality Control**
- **Operations**
- **Manufacturing**
- **Qualification/Validation**
- **Regulatory Affairs**
- **Clinical Trials**
- **Engineering Automation**
- **Pharmacovigilance**

Trainer Profile

Karunakar Budema is a senior life science consultant with KVALITO AG based in Basel, Switzerland. Karunakar worked in Leading Life sciences, Automobile and Communications companies in various roles across the globe. He is CISA Certified with more than 22 years of Information Technology Experience in Project Management, and Quality Management areas in the Pharma Domain. Good Understanding of 21 CFR Part 11 compliance, GAMP 5, Risk Management, Computer Systems Validation and Data Integrity. Karunakar executed several pieces of training as an internal trainer in Computer System Validation, Data Integrity, Automation Testing and Project Management.

Why Choose Us

- 100% Claimable
- Certified Trainers and Industry Experts
- Customized Training Programmes

"Empowering Pharmaceutical and Health Professionals: Mastering Risk Assessment for Quality and Compliance"

Our AGENDA

How will I benefit?

- Gain a comprehensive understanding of risk management in the context of **quality systems and regulatory compliance**
- Acquire **knowledge and skills** to effectively participate in quality and compliance-related risk assessments
- **Improve product quality, regulatory compliance, and reduce legal liability** through structured risk evaluation

What will I learn?

- Introduction to **regulatory requirements and their impact** on risk management
- **Methodology and best practices** for conducting risk assessments
- Differentiating between CSV (Computer System Validation) and CSA (Computerized System Assurance)
- **Understanding failure consequences and their implications** in risk management
- **Implementation strategies** for integrating risk management into quality systems

What is included?

- Essential knowledge to conduct quality and compliance-related risk assessments
- A general understanding of quality systems, processes, and the Risk Assessment process
- The foundation to conduct structured risk evaluations for effective decision-making