KVALITO
TRAINING

Upskill your teams and thrive

RISK MANAGEMENT

Who should attend:

- Quality Assurance
- Quality Control
- Operations
- Manufacturing
- Qualification/Validation
- Regulatory Affairs
- Clinical trials
- Engineering Automation
- Pharmacovigilance personnel

ABOUT US

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 in-depth 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

Training grant claimable under HRDF SBL KHAS scheme

AGENDA

The focus of pharmaceutical companies and Health authorities is moving from CSV to CSA,. Risk management of systems and solutions is taking top priority in terms of safety and efficacy. Within a Quality System (QS), it is essential to be able to make decisions based on facts and good science. Having a well-understood and integrated Risk Assessment process can improve product quality and regulatory / GxP compliance and reduce legal liability. This training equips you with an overview of how to conduct quality and compliance-related risk assessments. You will leave with a general understanding of quality systems, processes and the Risk Assessment process; the basis from which to conduct a structured risk evaluation.

Duration: 4 hrs

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.