



BOSCON 2010

How Risk Affects Quality

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A new standard, ISO 31000, Risk management — Principles and guidelines on implementation states that organizations of all types and sizes face a range of risks that can affect the achievement of their objectives.

ISO 31000 tells us, among other things, that

- Risk management creates and protects value
- Risk management is an integral part of all organizational processes
- Risk management facilitates continual improvement of the organization..

BOSCON 2010 includes a strong focus on risk management and its importance in the various quality processes that we, as quality professionals, use.

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Presentations

- o New MDD: Impact on Manufacturers
- o Post Market Surveillance
- o Auditing Risk - Management Processes
- o GHTF SG3 draft guidance for CAPA
- o The Case for Verification, not Validation
- o Clinical Evaluation - A Notified Body's perspective
- o Certified Pharmaceutical GMP Professional Exam
- o Quality Tools to Reduce Microbiological Risk
- o Risk Management Using ICH Q9 and ISO 14971
- o Characteristics of Quality Leadership
- o Annual Product Review- or - Analysis of Data
- o Prepared for and Surviving Failure
- o Assurance Cases – The Risk Based DHF and Submission Connection
- o Risk Analysis by Using Software Quality Metrics
- o Accelerating Product Design with Simulation and Stochastic Optimization
- o Process Validation

- o Statistical Aspects of Process Validation
- o Getting the REAL Requirements for Quality Conformance
- o Improving Customer Experiences to Minimize Competitive Risk
- o From Product Quality to Organizational Quality
- o Continuous Improvement. What have I done to improve?
- o Performance Excellence: Effective Quality Systems
- o The TURTLE - Process Auditing
- o Please Don't Call Them CAPA's

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