

Risk

Assessment, Control & Management

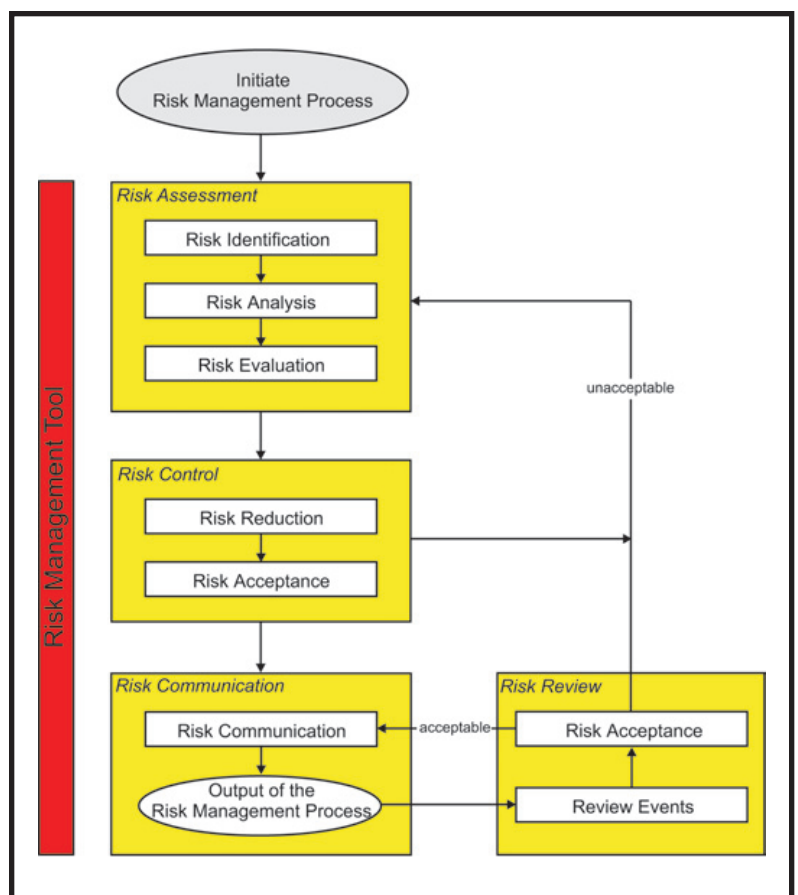
The FDA ICH Q9 Quality Risk Management (QRM) guidance suggests that facilities develop a QRM program. This program encourages the manufacturer to analyze their processes and operations to identify elements of potential risk that will put the quality of their product and their business at risk. Developing a QRM program can be a challenging task without the proper tools and planning. CRB has the expertise to assist you with your risk assessment.

CRB utilizes proprietary software that facilitates and enhances the risk assessment process for biopharmaceutical applications. We have embraced the FDA Q9 Quality Risk Management guidance and have developed a systematic methodology for the implementation of QRM Programs. Effective QRM facilitates improved and more informed decisions, enhancing the manufacturer's ability to deal with risks that can have serious implications on their process and/or business.

The CRB team brings lessons learned in operations, facility and process design to facilitating risk assessment reviews. Our team has been involved in the review of billion dollar capital projects in the biopharmaceutical industry. These projects include processes and the associated utilities and support areas for biotechnology processes, bulk drug processes, and potent compound processes of all sizes and varying degrees of safety hazards and operability.

Our clients appreciate our systematic approach to Risk Assessment Analysis as it provides the appropriate balance between:

- The necessary review to thoroughly identify real or potential safety and/or
- Process issues while understanding their operations' productivity requirements.



RISK ASSESSMENT, CONTROL & MANAGEMENT

Risk Assessments & QRM can be used and implemented at various levels and at different points during the evolution of your company. Examples of applications where CRB can help you develop Risk Assessments and QRM include:

- Business/Corporate/Financial Risk
- Hazard/Safety Assessments
- Quality Assurance, Quality Control
 - Documentation, Training, Auditing/Inspection
 - Change Control
 - Stability Testing, Release Specification Verification
- Regulatory Operations
- Process and Product Development
 - Establish Specifications, CCPs, Manufacturing Controls
- Materials Management
 - Evaluation of Vendors
 - Evaluation of Raw Materials, Stability, Source, Testing, Storage, Distribution
- Production and Process
 - Basis of Validation
 - Cleaning & Sanitization
 - Impurity Profiles and Clearance
 - Analytical & Biological Testing Requirements
 - Monitoring Requirements
 - Packaging Requirements
- Facilities, Equipment and Utilities
 - Design of Facility & Equipment
 - Materials of Construction
 - Containment
 - “Appropriate” Utilities and Environment
 - Calibration and Preventative Maintenance



The Platforms that are generally accepted provide a thorough documentation of the risks associated with the processes and business plans.

- HAACP
- FTA
- FMEA
- HAZOP
- Development of Process and Product “What-If” Scenarios
- Customized Process Hazards Analysis “What-If’s”

