

# ***RISK MANAGEMENT***

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## About – Bob Mehta

- Principal Consultant & Recruiter – Over 27 years of experience including 7+ years as a Principal Consultant/Recruiter at GMP ISO Expert Services.
  - 18 years experience at Allergan – Develops and Markets Sterile Ophthalmic Drugs, Medical Devices, and Biologics.
    - Started as a Sr. Lab Tech, promoted six times and the last position held was as the Sr. Worldwide QA Manager.
  - 2 years at Edwards Lifesciences, manufacturer of heart valves (Highest Risk Products) as the Sr. Regulatory Compliance Manager.
  - GMP ISO Experts provides service to International Pharma, Biotech, Combination Products, and Food/Dietary Supplement clients with gap analysis and remediation of Quality Systems (**CAPA, Complaints, Lab Compliance, Data Integrity, Process/Software Validation**), Supplier Management, Production/Process Controls, and For Cause/Supplier Audits **to meet FDA and global regulatory commitments.**



## About – Bob Mehta

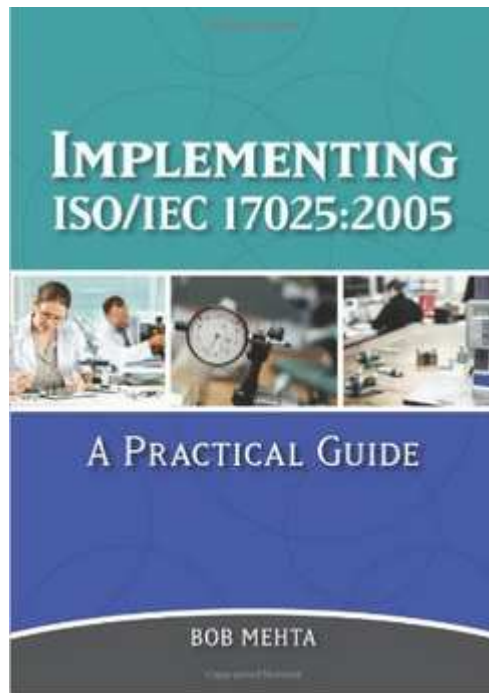
- Author of Articles – Published in Pharmaceutical Technology, MDDI, Nutraceutical World, and Quality Progress publications.
- Adjunct Professor at Cal State Dominguez Hills teaching courses for the Masters of Science in Quality Assurance program, Cal Poly Pomona teaching Six Sigma Blackbelt course, and instructor teaching American Society for Quality (ASQ) certification courses.
- Became a Fellow of ASQ in Nov 2014.
- **Check me out and/or send a request to add me to your network on LinkedIn:**  
<http://www.linkedin.com/in/bobmehta>



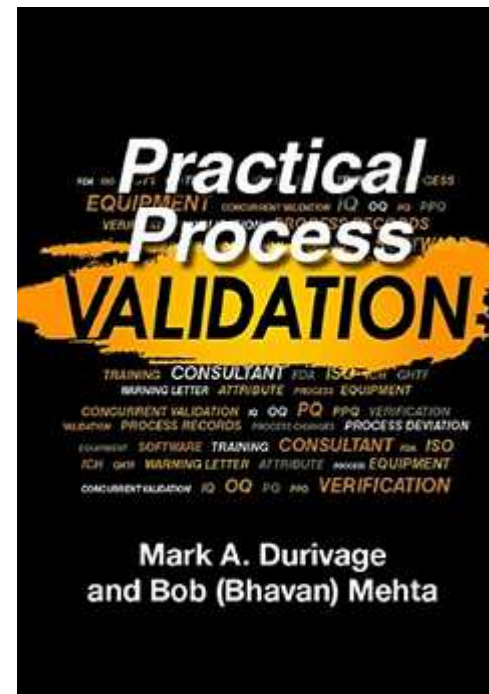
# About – Bob Mehta

Author of Books:

Released by ASQ Press in July 2016



★★★★★ 19 customer reviews





# Risk Management

## What is Risk Management?

- Risk management is the continuing process to identify, analyze, evaluate, and treat loss exposures and monitor risk control and financial resources to mitigate the adverse effects of loss.
- The identification, analysis, assessment, control, and avoidance, minimization, or elimination of unacceptable risks. An organization may use risk assumption, risk avoidance, risk retention, risk transfer, or any other strategy (or combination of strategies) in proper management of future events.

# Risk Management

## Risk Management



\* Actual comment from Judith Curry

How might this approach work in other areas?...





# Risk Management

## Risk Management Standard Requirements

- **ISO 31000:2009**
  - A generic risk management standard.
  - It is not specific to any sector or industry and can be applied to any type of risk.
  - It can be used by both public and private organizations and by groups, associations, and enterprises of all kinds.



# Risk Management

## Risk Management Standard Requirements

- **AS 9100 Rev. D & ISO 9001:2015 Term Used - Risk-Based Thinking**
  - An organization should be prepared to provide evidence of implementation related to the following:
    - Inputs (documented information) used for risk and opportunity determination.
    - How risks and opportunities are determined (e.g. meeting minutes, SWOT, strategic planning, etc.).
    - How determined risk and opportunities are addressed (e.g. action plans, on-job training, etc.).
    - Internal audits and performance evaluation activities taking into account the effective application of risk-based thinking.
    - Read Bob Mehta's article on the topic of risk management published in Quality Progress:  
<http://asq.org/quality-progress/2015/01/standards/dissecting-the-details.html>





# Risk Management

## Risk Management Tools

- **Information Gathering Techniques**
  - Brainstorming
  - Interviewing
  - Gemba walk
- **Qualitative Tools**
  - Failure Mode and Effect Analysis (FMEA)
  - Hazard Analysis and Critical Control Point (HACCP)
  - Fault Tree Analysis (FTA)



# Risk Management

## Risk Management Tools

### FMEA Steps for Product or Process

- **Step 1.** Identify product component or process step.
- **Step 2.** Identify the product or process failure mode; i.e., the manner in which the product or process could fail to meet process requirements.
- **Step 3.** Determine the cause of the failure mode.
- **Step 4.** Determine the effect the failure mode has on the product/process as perceived by the user.
- **Step 5.** Assign a numerical value to probability, detection, and severity.
- **Step 6.** Calculate the product of the three assigned values.
- **Step 7.** Follow up on recommended actions.



# Risk Management

## Risk Management Tools

### FMEA - Definitions

- FMEA is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to mitigate the failures.
  - **Risk Priority Number (RPN)** - Provides an alternate evaluation approach to Criticality Analysis. The risk priority number provides a qualitative numerical estimate of design risk. RPN is defined as the product of three independently assessed factors: Severity(S), Occurrence (O) and Detection (D).  **$RPN = (S) * (O) * (D)$** .
  - **Severity (S)** - Severity is a numerical subjective estimate of how severe the customer (next user) or end user will perceive the EFFECT of a failure.
  - **Occurrence (O)** - Occurrence or sometimes termed LIKELIHOOD, is a numerical subjective estimate of the LIKELIHOOD that the cause, if it occurs, will produce the failure mode and its particular effect.
  - **Detection (D)** - Detection is sometimes termed EFFECTIVENESS. It is a numerical subjective estimate of the effectiveness of the controls to prevent or detect the cause or failure mode before the failure reaches the customer. The assumption is that the cause has occurred.



# Risk Management

## Risk Management Training/Time

- To complete an industry specific case-study that includes system FMEA, design FMEA, process FMEA, service FMEA, software FMEA, create a Pareto Chart, and address potential failure modes that have a high RPN it takes a minimum of 6-8 hours.
- In the best interest of time and to address a request to select a general topic (not special topic for medical device, aerospace, pharmaceuticals, or automotive industries) for a group case study, you will be given a process map and Process FMEA (pFMEA) Spreadsheet with RPN Numbers calculated.



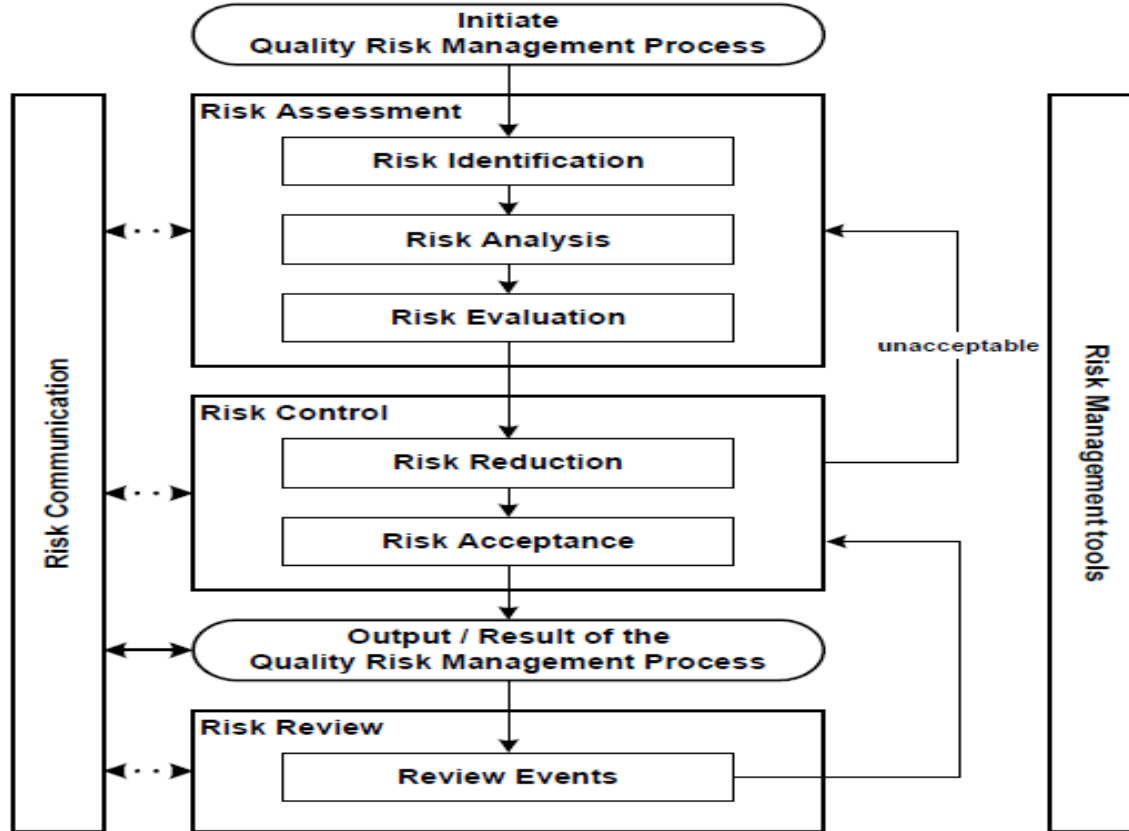
# Risk Management

## Risk Management Group Exercise – 30 minutes

- **Step 1** – Work on the case study with 4-6 individuals on your table. Select a spokesperson to share your results at the end of the group exercise.
- **Step 2** – Re-rank RPNs (from highest to lowest). Determine the Recommended Action(s) to address the potential failures that have a high RPN and document them on the blank FMEA Spreadsheet.
  - These actions could include specific inspection, testing or quality procedures; selection of different components or materials; limiting environmental stresses or operating range; redesign of the item to avoid the failure mode; monitoring mechanisms; performing preventative maintenance; and inclusion of back-up systems or redundancy.
- **Step 3** – Have a spokesperson share your team's results.

# Risk Management

## Typical Risk Management Process (ICH Q9)





# Risk Management

## Risk Management Case Study

- Due to time constraints, a simple case study was selected. In reality, there is much more involved when dealing with risk management.
- Each organization shall establish a formal Risk Management Program.
- A Risk Management Program includes SOP/s, Risk Management Plan/s, and template/s to standardize the process.
- Employee training is critical.
- The updating of the Risk Management File is an iterative process.



# Risk Management

## Risk Management - Conclusion

- Regulated industries require a formal risk-management program.
- ISO 9001:2015 and ISO 14001:2015 standards require organizations to use the term “Risk-based thinking”.
  - “Risk-based thinking” replaces what was called preventive action in the previous standards.
  - “Risk-based thinking” requires companies to evaluate risk when establishing processes, controls, and improvements in a Quality Management System.
  - Think about both positive and negative risks.





# GMP Training

**Thank you for your participation.**



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