

Sterility Assurance & Quality Risk Management Conference





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Some Thoughts (My Thoughts Only)

- Risk management is basically taking what you know and making the best decision you can at that time
- More formal definitions/interpretations:
 - A systematic process of identifying, assessing, and mitigating threats or uncertainties that can affect your organization
 - A risk management program is taking what you know and anticipating what could go wrong/not as expected and predetermining your actions in a well thought out manner to avoid snap decisions or knee jerk reactions that could make the situation worse



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- We have been doing this for ages without necessarily realizing we have been doing it.
 - When the cavemen ventured out of the cave every morning and looked around to see if it was safe
 - When you stood at the bottom of a rock wall and decided whether to climb it or not
 - Pulling up to an intersection and looking both ways and deciding whether to accelerate or wait for “that” car pass
 - Deciding on and buying your first car or house.....

- Whether we realize it or not, risk management has been a part of our lives since we were born



So Why Do It??

- Good business practice
- Every drug product has inherent risk – including aseptic drug products
 - Microbiological, chemical, process related, packaging, etc.
- Also, because we are required to, one reference....
 - Section 711 of FDASIA and the CARES Act amended section 501 of the FD&C Act (21 U.S.C. 351) to clarify that, for purposes of section 501(a)(2)(B), the term current good manufacturing practice includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of *raw materials, materials used in the manufacturing of drugs, and finished drug products.*



Some Definitions (My Thoughts Only)

- **Quality:**
 - a product or process that meets predefined expected parameters possibly for: attribute, character and property
 - Something that you can trust is going to have the expected.....
- **Risk:**
 - Situation or product/process that has the chance or possibility of danger, loss or injury
 - The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51:2014)
 - Change of some event or action happening that you do not want to happen
- **Management:**
 - The process of organizing and coordinating people, resources and tasks to achieve a desired outcome or goal efficiently and effectively
 - Dealing with either people, situations or events to get a desired result in the best way possible



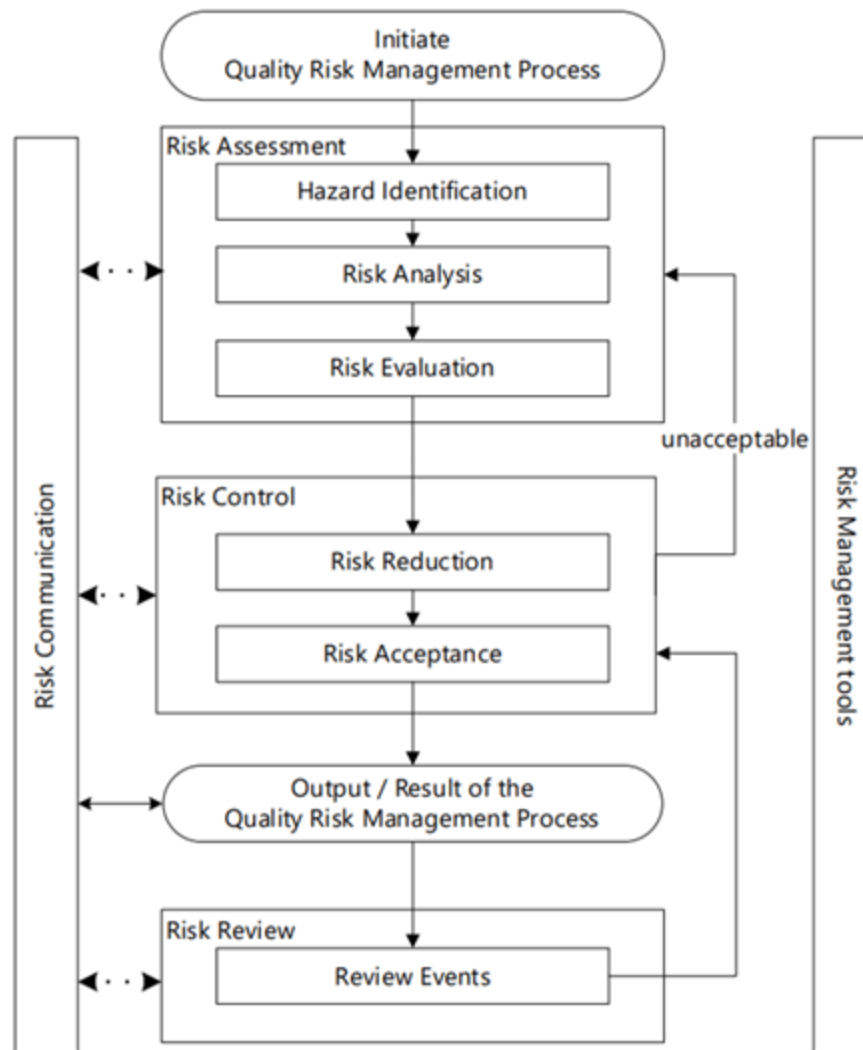
Some Definitions (My Thoughts Only) (cont..)

- Deviation:
 - The act of departing from the expected course or accepted standard
 - An event or result that does not meet predetermined expectations
- Investigation:
 - the careful, detailed examination or systematic search for facts about something hidden, complex, or unknown, often with the goal of understanding how something happened, discovering its cause, or identifying those responsible
 - A structured and methodical activity to gain accurate information into the topic of interest



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- Who has responsibility for risk management – we all do
 - Multi-functional groups taking responsibility for their specific areas of expertise to provide their insight into issues that may arise
 - This is not just a quality department thing or paperwork to be filled out
- It is a predefined/established program and process that is worked on and developed by all interested parties
 - Management, production, maintenance, quality control, quality assurance, laboratory, etc.



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- This is a living program, not just a document or contract signed off on and put in a drawer
- It is pre-defined (as best as possible) to maintain as much objectivity as possible
- It is implemented and at all levels
- Training is provided to allow those using it to know what actions to take
- Re-evaluation is a requirement for improvements and updates



Combo Products

- How do combo products fit into this equation
- This applies to combo products as well however for the device portion of the drug product, they are covered and assessed against the device side of things.
- ISO 14971
 - This standard requires manufacturers to develop a Risk Management Plan, conduct risk analysis and evaluation, implement risk controls, review residual risk, and maintain a Risk Management File with ongoing production and post-production information. Compliance is a global regulatory requirement and signals a manufacturer's commitment to safety.



Parts Of The Process

- Initiating
 - Defining problems or risks including any bias or assumptions about identifying risks
 - Once identified, assemble data associated on the potential risk/hazard/harm/impact
 - Identify a lead for this specific risk
 - Make sure to include deadlines, deliverables and some decision tree
- Risk assessment – overall risk
 - What could go wrong (example: filling equipment-missing PMs (how many times)-detectability of rouging in the filling needles-product complaints for particulates)
 - What is the likelihood it will go wrong
 - What is the detectability if it does go wrong
 - What is the impact



Parts Of The Process (cont.)

- Risk control
 - Now that you have identified a risk, is it one that needs to be controlled
 - What can we do to eliminate/reduce to acceptable level
 - Do you already have a plan in place to mitigate that risk (eliminate/reduce to acceptable level) – evaluate OBJECTIVELY



Some Methods – right out of FDA Q9 Guidance

- I am sure you have heard of most if not all of these methods:
 - Flowcharts, data sheets for identification
 - Failure Mode Effects Analysis (FMEA)
 - Failure Mode, Effects and Criticality Analysis (FMECA)
 - Fault Tree Analysis (FTA)
 - Hazard Analysis and Critical Control Point (HACCP)
 - Cause and Effect Analysis (Ishikawa fishbone)
 - Etc.



Risk Formality

- Uncertainty
 - How much do you know about the issue or lack of knowledge about the issue
 - The less you know, the more formal
- Importance
 - How important is the decision you are making on this issue
 - The higher the importance, the more formal
- Complexity
 - How complex is the process/activity to the issue
 - The higher the complexity, the more formal



Communication

- This has its own slide as communication is extremely important
- If you identify a major risk but tell no one, it is not managed

- “For want of a nail...”



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- One noted citation for this idiom is: Poet George Herbert recorded it in 1633 as "For want of a naile the shoe is lost, for want of a shoe the horse is lost, for want of a horse the rider is lost."



Risk Management - Pulling All This Together

- Risk Identification (product and process related)
 - Risk methodology tools
 - Risk formality
 - Risk communication
-
- All these together should allow and equip you to effectively manage risk to your product/process



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- Thank you very much for your time...