Implementation of Risk Based Approach in a Manufacturer to Meet ISO13485:2016

- **QMS Resources**
- **Supplier Controls,**
- **Training/Competence**
- **Validation,**
- **Complaints, CAPA**

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Risk Management ≠ Risk-Based Approach

There is no requirement in ISO 13485 to use formal risk management in the identification of risks at the level of the quality management system but risk management is required in relation to planning and implementing product realization.

Examples:

- QMS Resources
- Supplier controls,
- Competence
- Validation,
- Complaints / CAPA

Apply a Risk-Based Approach WITHIN your QMS Processes

- Ensuring the interval (how often you have it) of **management review** is proportionate to the risk that the QMS would not be suitable, adequate and effective
- Same situation with the **number and extent** of **internal audits**
- Same situation with the **number and extent** of **process control** points

In Supplier Controls - 7.4.3 Verification of Purchased Product

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Establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements.

How far should you go?

RISK of Product

Very frequent supplier audits! + 100% incoming inspection

100% Incoming inspection

Supplier audits

Sampling inspection

Remote supplier audits

Supplier Controls - Who is the Supplier?

The "usuals"

- Component suppliers
- Contract manufacturers
- Process Suppliers (e.g. Sterilization)
- OEMS (white labellers)
- Raw Materials Suppliers

These are also suppliers :

- Distributors
- 3PLs, freight forwarder, technical service, installation providers
- Certification companies
- Professional Services companies (consultants)

Failure to acknowledge that they are a supplier

Risk-Based Approach for Training and Competence

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Plan for a periodic review of the employee's capabilities to ensure the employee remains competent for their current responsibilities.

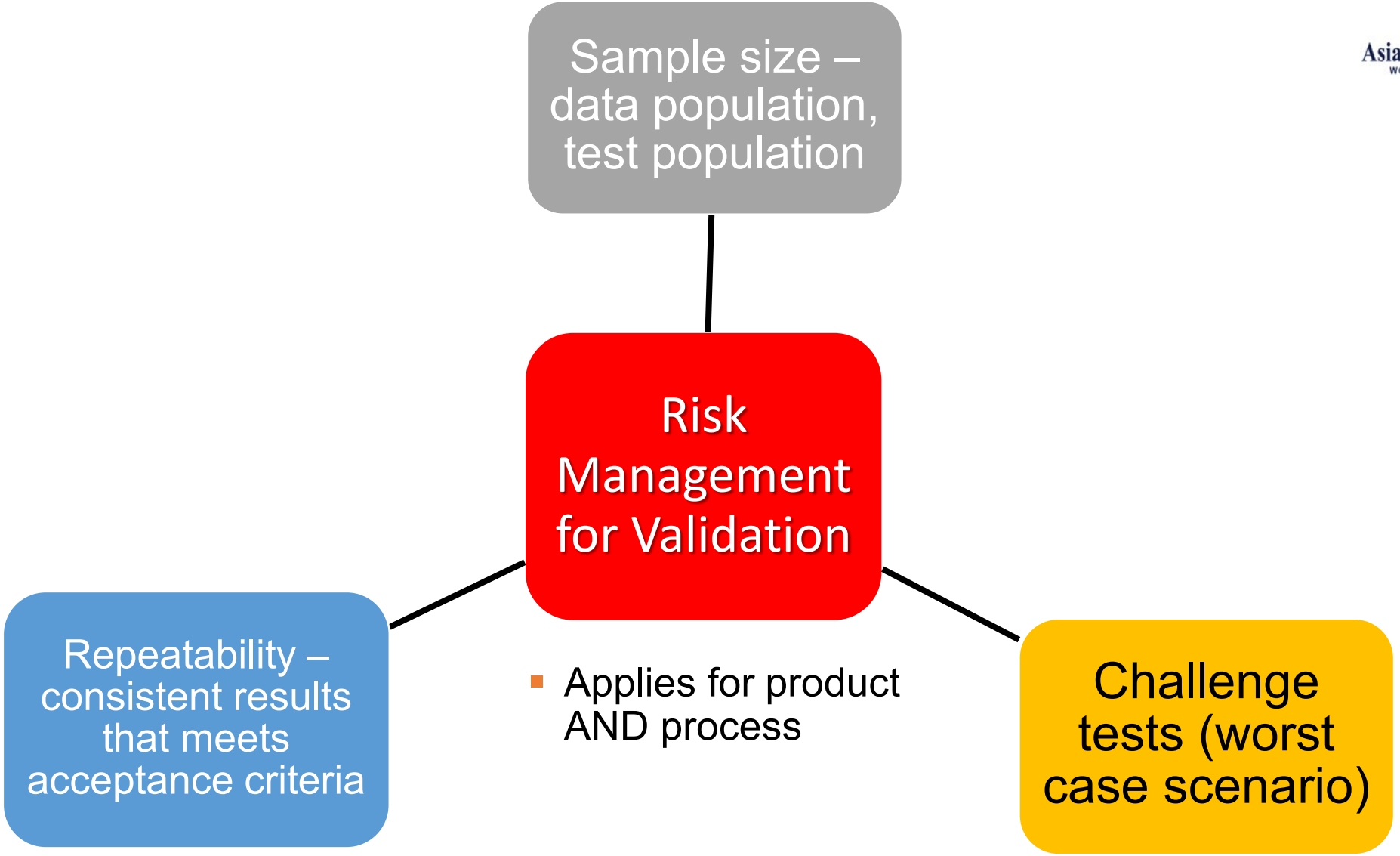
The risk of not performing a task or process adequately also has to be considered

RISK

- On-Job-Training
- Long-duration assessment
- Project-based assessment
- Test
- Classroom training (on-site, remote)
- Notification and confirmation
- 'Read n sign'

If this is a low risk activity, that means we can just **'Read n Sign' ?**

Processes have to be developed based on the competence required for the personnel intended to perform that process.



Risk Based Assessment for Failure Investigation (Complaints / CAPA)

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When Performing Investigation

- NO half-hearted investigations allowed!
- 5-whys, ishikawa, fault tree analysis (FTA) etc.
- Derive root cause – and ask “why” again!
- Investigation is meaningless without taking action
- Propose action plan after containment and correction

“Do or Do Not, there is No Try”

Set up a system

- When do we trigger an investigation?
- What is the extent of the investigation?
- If it is a new issue, is this a one-off? Or is this a new problem?

Software Verification, Validation Requirements

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- the extent of validation, including validation of software (4.1.6, 7.5.6, 7.6)
- procedures for the validation of the application of computer software used in the quality management system.
- shall be validated prior to initial use and, as appropriate, after changes to such software or its application.
- The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.
- Document these activities

- The most common mistake is the failure to plan and resource for it

Validation Assessments

- To validate or not to validate? This is the question….
- Actually a series of questions!
    1. what is the intended use?
    2. Is it used to drive quality or clinical processes, or make decisions?
    3. who developed it?

Software as a Medical Device

- **3.11 medical device:**

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

- investigation, replacement, modification, or support of the anatomy or of a physiological process;

- supporting or sustaining life;

- control of conception;

- disinfection of medical devices;

- providing information by means of in vitro examination of specimens derived from the human body

QMS Related Software

- Computer software can be used to implement, monitor, measure, or analyze the quality management system.

Clause 4.1.6

- The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5)
- Software systems used in support of the QMS should be backed up periodically and recovery of data should be planned for.

Software Examples that Directly Impact the State, Structure, or Compliance Of Your Quality Management System

- CAPA management, data analysis
- Complaint handling
- Internal audit scheduling/repository, for managing and recording internal audits; for managing actions arising from external audits;
- Calibration and Preventive Maintenance tracking software,
- CAD Software
- As an element of enterprise resource planning (ERP) platforms;
- For recording and managing nonconformities
- Product Lifecycle Management
- Software used for control of document and record (Computerized document control, Computerized record control),
- Software applications can be used for product design, testing, production, labelling, distribution, inventory control,
- Routine data analysis activities, for analysis of data on the performance of the quality management system.

Production and Service Software

- 6.3 Infrastructure

The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities;

b) process equipment (both hardware and software);

c) supporting services (such as transport, communication, or information systems).

- 7.6 Control of monitoring and measuring equipment

The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Software Used in Process Control

The requirements of ISO 13485 regarding the validation of the application of computer software used in process control apply, whether or not such software is purchased, developed, maintained, or modified for automated production or process control purposes.

- ERP software,
- excel that document test results,
- excel that calculates sample sizes,
- software/excel that has a formula/algorithm that determines pass/fail,
- Management information associated with automated production/inspection processes etc.
- software used for measuring product on a coordinate measuring machine
- software analysing the sterilization process parameters and determining whether the process meets the process requirements;
- software determining the regurgitation rate of a prosthetic heart valve, based on the dynamic measurement of the flow

What About Other People's Software?

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Software used in measurement, monitoring and analysis, whether purchased (Off-The-Shelf) or custom developed, should be validated for its intended use.

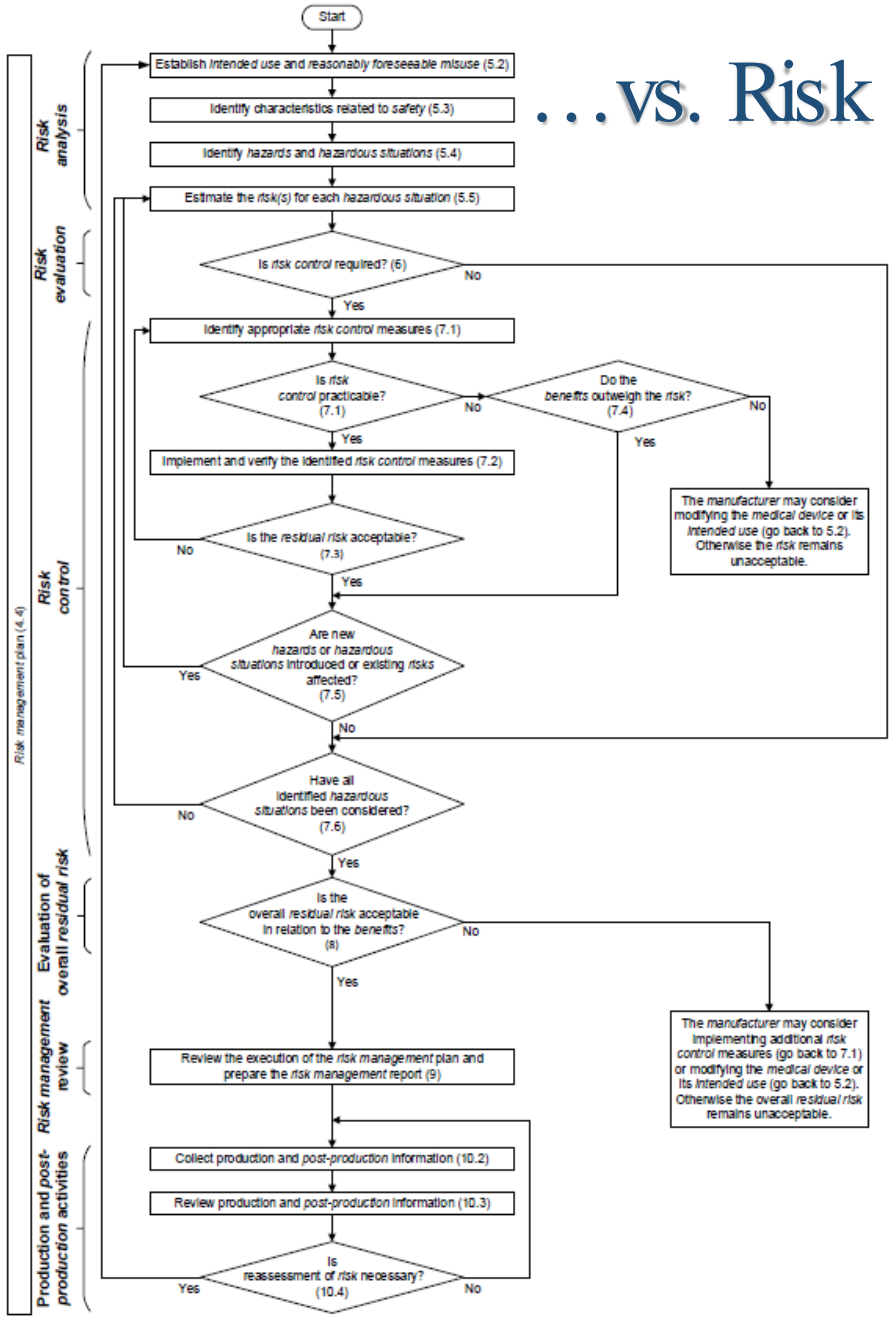
These Software are Not Normally Considered

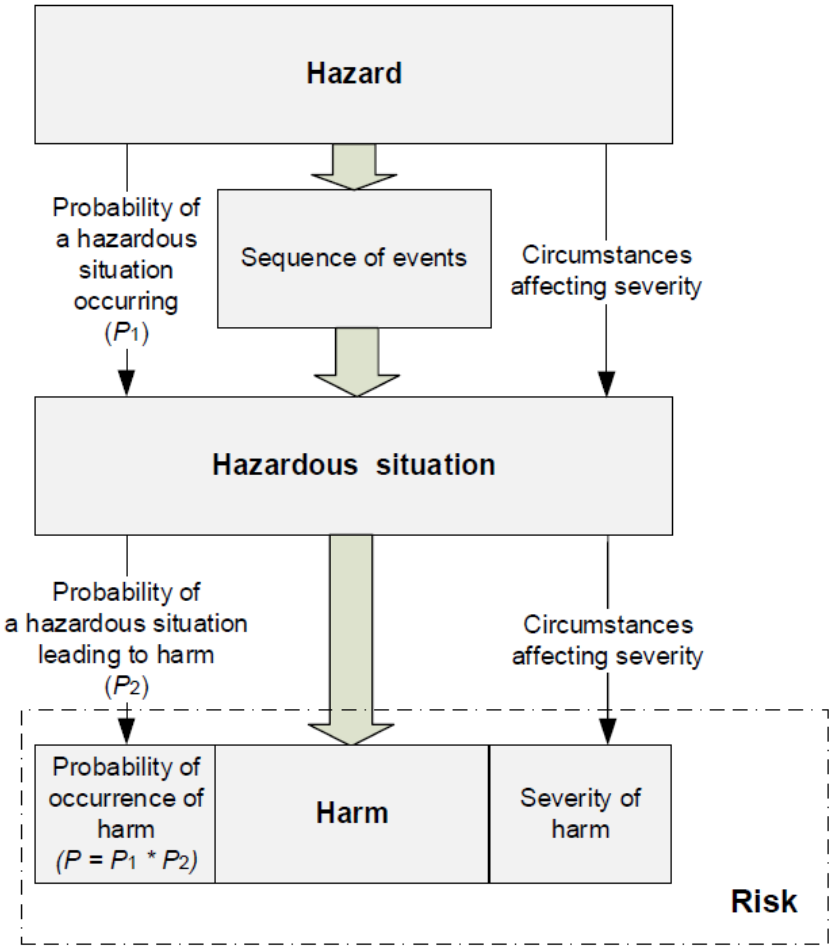
- Software used by your organization but is not related to the conformity to the quality management system or products requirements, or compliance with the applicable regulatory requirements for medical devices, e.g. software used for accounting.
- Software used for clerical works which do not have impact on quality, performance or safety of medical devices e.g., word processor software.

Common Misconceptions

1. FMEA the QMS(!!)
2. Adopt the FMEA to be like the risk analysis (component based, single fault condition etc.)
3. Risk management report is one paragraph
4. Cannot differentiate between risk management and risk-based approach

…vs. Risk Management in the Product





The most Unbelievable of all - FMEA the QMS(!!)

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The new editions of ISO 13485 (and ISO 9001) have a concept within them to apply a risk-based approach, or apply risk based thinking

- Some people have been interpreting this to apply risk analysis (process FMEA or other risk analysis tools) to the Quality Management System (QMS) processes.
  THIS IS NOT CORRECT.

Useful ISO Resources to Refer

- ISO https://www.iso.org/home.html
- A Practical Guide to ISO 13485 https://www.iso.org/publication/PUB100422.html
- ISO TC210 https://www.iso.org/committee/54892.html
- Committee special page https://committee.iso.org/home/tc210

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