GMP Auditing Practices & Risk Management in Supply Chain Management

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THE MARKET LEADER IN PHARMACEUTICAL CONSULTING

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Supply Chain Management & Risk

Regulatory authorities have raised the bar with new requirements

- *"Pharmaceutical cGMPs for the 21st Century: A Risk based Approach"*
- *ICH Q8 Pharmaceutical Development*
- *ICH Q9 Quality Risk Management*
- *ICH Q10 Pharmaceutical Quality Systems.*

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Supply Chain Management & Risk

It's now part of the Regulatory expectation that decisions and better decision making have a Risk Management component as part of their Forward Strategy for Quality.

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Supply Chain Management & Risk

It's important to know the
Regulatory landscape & risk factors
associated with your system
that will require mitigation.

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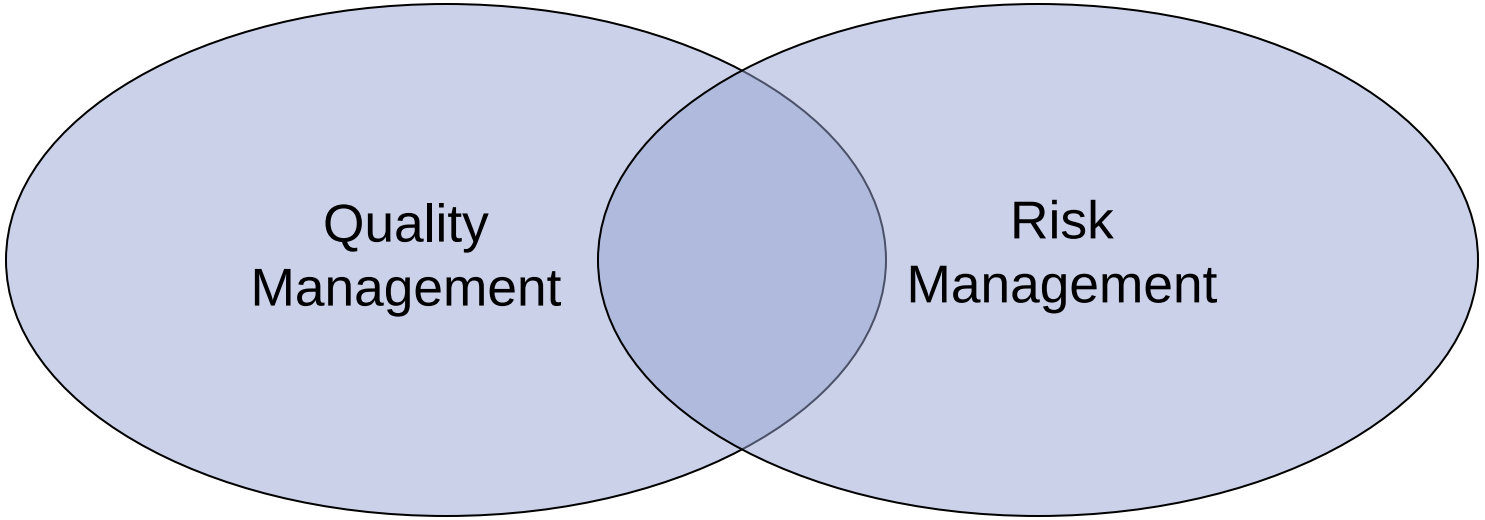
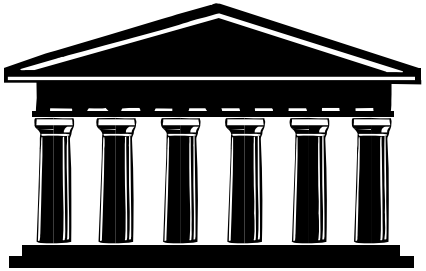
Relationship between Quality & Risk



Quality Management

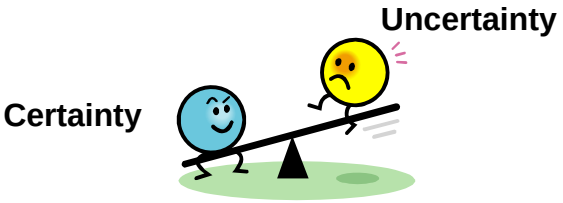
- Is the process of designing and operating a product or service operation effectively and efficiently.
- Through these pillars (Customer Requirements, Performance Criteria, Design Criteria and Process Criteria) in the “House of Quality” the following goals are satisfied:
  - Effectiveness: involves meeting or exceeding customer expectations
  - Efficiency: involves meeting the goal without wasting resources
  - Compliance: involves satisfying prevailing regulatory requirements
  - Financial: meeting product quality specifications targets to generate revenue

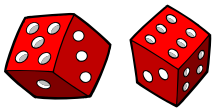


House of Quality

Risk

- What is it?
  - Certainty and uncertainty
  - The probability of something occurring
  - The potential consequences of the result of something occurring.
    - Equipment breakdown
    - Specification failure – wasted lot/batch
    - Test failure – lost production





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Risk Management

Involves the process of identifying potential failure causing issues

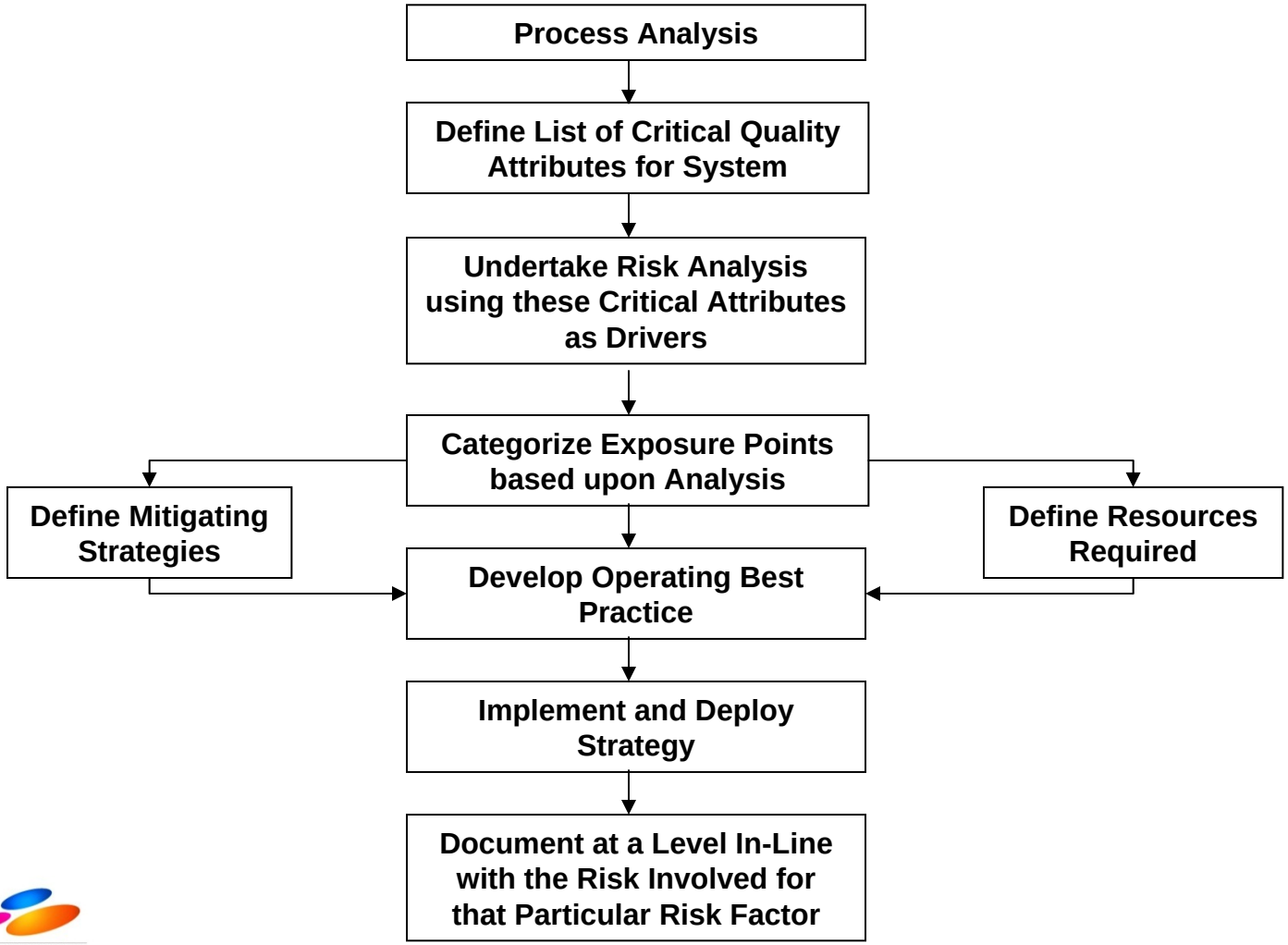
- Ranking for criticality
- Mitigating the effects of these
- Where possible eliminating these

Risk Management

Core elements involved in this activity include:

- Being proactive to assess probability and potential consequences
- Taking preventive actions to reduce probability of potential consequences
- Using tools to predict or anticipate likely problems
- Taking swift pre-determined measures to minimize problems if they occur..

Risk Based Approach Flow Chart



Consider Raw Material Suppliers

- For supplier management processes this involves accessing data generated in development and applying it towards manufacturing processes
  - Specifications
  - Expiration dating
  - Quantities
  - Conditions

Raw Material Suppliers

Some key points:

Supplier strategies should include:

- Selection criteria
- Specifications control

To demonstrate a high level of appreciation of the material attributes.

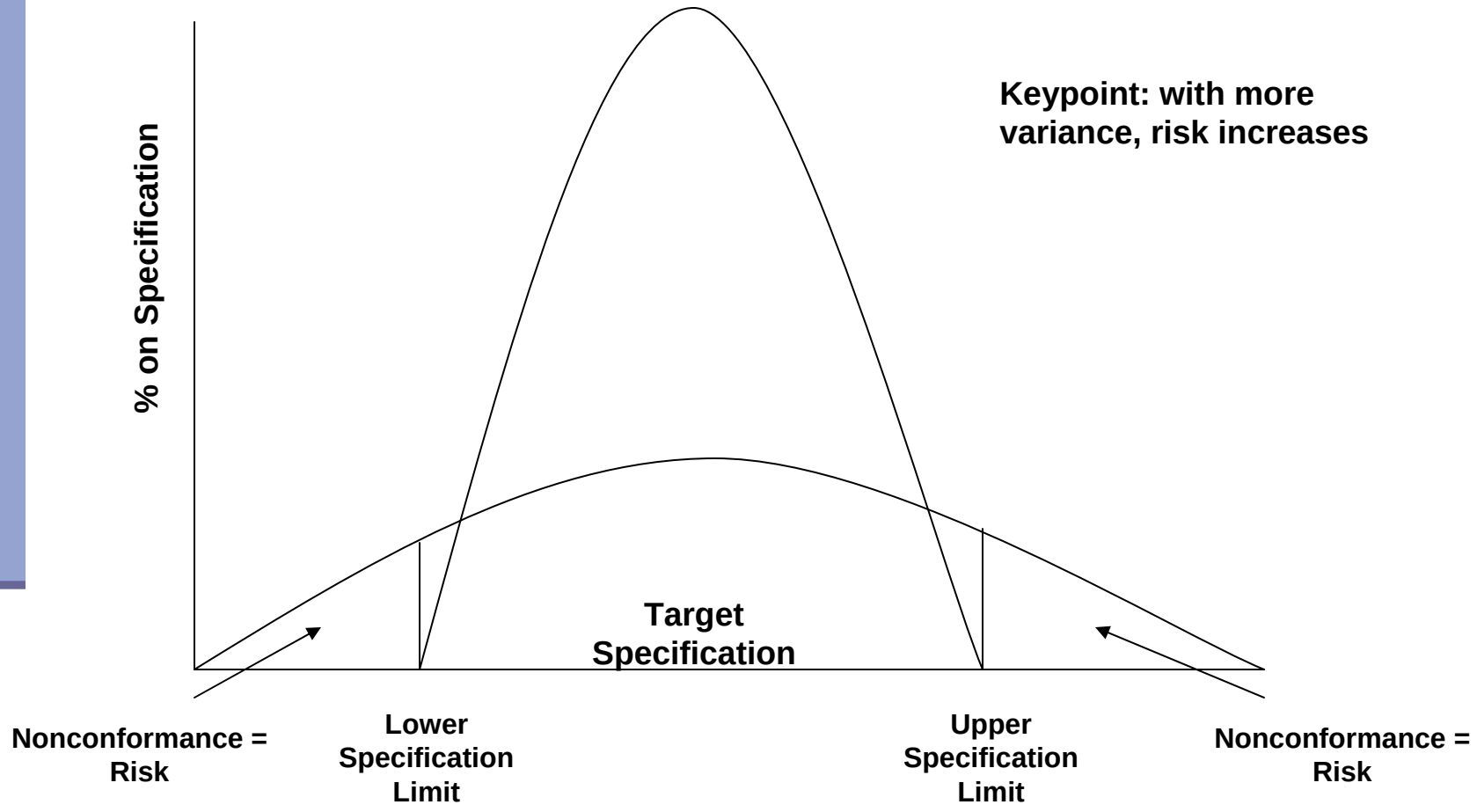
Risk Factor Identification

This needs to be developed for each process, supplier and material.

Some examples include:

- How the material is produced
  - Synthesis, natural product
- The country of origin
  - Potential for virus contamination
  - Potential for heavy metals contamination
- Specification Variability associated with the material
  - Seasonal crops that are imported

How to Reduce Risk through Quantitative Analysis of Specification Variability



Questionnaire Tool Composition

This can vary depending upon the complexity but should always include cost, quality and performance factors.

Financial Consideration:

- Cost of material from supplier
- Financial stability of vendor

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Questionnaire Tool Composition

Quality Consideration:

- Existence of GMP culture
  - Adherence to GMPs & ICH guidance
- Implementation of Quality System
  - Existence of records
- Good Compliance Record
  - No citations by regulatory authorities

Questionnaire Tool Composition

Process & Technological Capabilities:

- Delivery performance record
- Capacity to deliver
- Strong technological capabilities
- Strong production controls
- Strong compliance and environmental record

Questionnaire Tool Composition

Personnel & Management Capabilities

- Strong understanding of Supply Chain needs
- Strong technical management controls
- No de-barred individuals by FDA or other authority
- Strong acquisition policy in place
- Group chemistry and business culture fit to foster long term relationship.

Criticality Factors

- The objective is to reduce risk and manage total value for your company.
- Need to understand what factors are introducing risk into the equation.
- The balance between uncertainty and certainty should be managed according to its impact on the manufacturing process.

Criticality Factors

Quantify based on a numerical scale.

- 1-4 Low
- 5-8 Medium
- 8-10 High

Note:
Preferred vendors should be in the 8-10 range.

Numerical Ranking of Supplier Performance Attributes

Attribute	High	Medium	Low
Quality	8		
Cost		6	
Process / Delivery			3
Management Service Capability			3

Relative Weightings for Attributes

Divide each value by the total number

- In this example :
  - Quality 0.40
  - Cost 0.30
  - Process/Delivery 0.15
  - Management Service capability 0.15

Now we can compare different suppliers

What's Important

- You now have a mechanism to rate your material suppliers based upon a criticality matrix which takes account of risk.
- Each component is numerically weighted in terms of its importance to the process.

The Audit

- Review Organizational Structure
- Tour the facilities:
  - Warehouse
  - Process Area
  - Laboratories
  - Records area

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The Audit

- Review Documents
  - Review Management Controls
  - Review the Quality Policy/Plan
  - Review Quality System
- Review Control of Documents and Records, for example:
  - Change Control
  - Deviations/Investigations/CAPA
  - Complaints

The Audit

- Review Human Resource management
  - Training/competency
- Infrastructure
  - Facilities procedures
    - Manufacturing
    - Warehouse
    - Laboratories
    - Environmental
  - Equipment procedures
    - Operational
    - Cleaning
    - Validation
    - Calibration/maintenance

The Audit

- Review Production Records
  - Dedicated equipment/not dedicated
  - Dedicated comprehensive batch documents
    - Authentic Master Batch Records
  - Validation of processes
    - Evidence of verification of process capability

The Audit

- Review purchasing process
  - Vendor qualification process
  - Verification of purchased product through traceability exercise
- Review Warehouse Operations
  - Control of material
  - Non-conforming products isolation and disposal

Audit Reports

Some important points:

- Detail any reasons why suppliers don’t meet expectations per your qualification process
- Detail any remediation plans proposed to the supplier for performance improvement
- For inspection issues being remediated, a statement that the action being taken is acceptable to restore compliance.

Establish Supplier Profiles

Some important points:

- Integrate your specification requirements with the capability of the supplier.
- Use the data from the questionnaire tool to shape the type of vendor that you want as a partner.
- Make sure this tool gathers all the necessary information to make that choice.
- Compare against operating experience.

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Establish Supplier Profiles

- Use numerical analysis to separate poor performers from qualifiable candidates.
- Create an audit plan to address deficiencies.
- Create new best practices profile from the results.
- Update information on database from successive audit reports to continuously monitor performance and justify continued use.
- From this establish “Preferred Vendors” list.

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Questions?

Thank you for this opportunity to share our ideas with you.

For more information, visit:

www.smartconsultinggroup.com

Or email: nsmart@smartconsultinggroup.com

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