Aligning Quality Management Processes to Compliance Goals

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Joint Webinar

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THE MARKET LEADER IN PHARMACEUTICAL CONSULTING

Aligning Quality Management Processes to Meet Compliance Goals

Why is this important and why is this often deficient in Life Science Companies like those engaged in biotechnology, pharmaceuticals and medical devices?

Aligning Quality Management Processes to Meet Compliance Goals

In today's LEAN highly regulated and competitive world there's a new global expectation of pre-determined quality measures that need to be universally accessible. There is an expectation of more predictable mechanisms of delivery and interactions between user groups to help assure long-term sustainability of quality and product safety.

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The Current Climate / Reality of Systems Integration

- Companies have been applying various electronic solutions and management tools for over a decade.
- There is considerable variability in the approaches used.
- They do not necessarily integrate well with the other business process management networks to provide a truly reliable and efficient system that will provide the basis for sustainable compliance.

Some Shortfall Issues Often Connected with Conventional Quality Systems

- A disparate unconnected system of individual electronic / software solutions / applications often knitted together in a network or partial network.
- Situations where the approach is a combination of manual processes coupled together with some database solutions, but not fully integrated.
- Fully manual systems where everything is still a complete paper-based and labor intensive system.

Problem Statement

None of these approaches is ideal since they:

- Lack efficiency
- Are difficult to manage and maintain in a reliable operational state
- Lack robustness from compliance operational point of view.

… these result in circumstances that will not assure sustainable compliance.

Points to Consider

- The status quo is not an answer.
- The solution needs to meet your Quality System compliance requirements.
- The solution must integrate with your business platform to provide a comprehensive and universal functionality that provides value to your business.
- It must be user friendly and easy to administer and maintain.
- Ideally, the system can play a major role in driving the deployment of Quality Culture through the reinforcement of the quality system.

Some Industry Influences for System Design

- The consolidation of sectors of the industry channeling portfolio's of product candidates and products into fewer larger companies creating pressure on quality resources.
- The significant rise in product candidates that need to be managed through outsourced resources.
- The virtualization of companies, both start-up and larger commercial companies.
- Product partnerships where several companies have pieces of the overall puzzle but not the whole picture.
- The change in regulatory expectations that have evolved over the last decade.

Some Design Drivers for an Enterprise System Approach to Quality Management

- International Regulatory Authorities are placing a premium on compliance; ICH Q10 Quality Systems
- Risk and risk management is being required for every element from design to product distribution; ICH Q9 Risk Management
- Streamlined Lean Systems make good business sense and reduce error prone weaknesses.

Three Key Questions Connected with Use of Systems for Quality System Management

Question 1: How organizations can adopt an enterprise-wide approach to Quality and Compliance Management?

Question 2: What are the Best Practices to Manage Supplier, Internal and Customer quality processes?

Question 3: How can organizations obtain a 360° view of its Quality Management System?

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Question 1

How organizations can adopt an enterprise-wide approach to quality and compliance management?

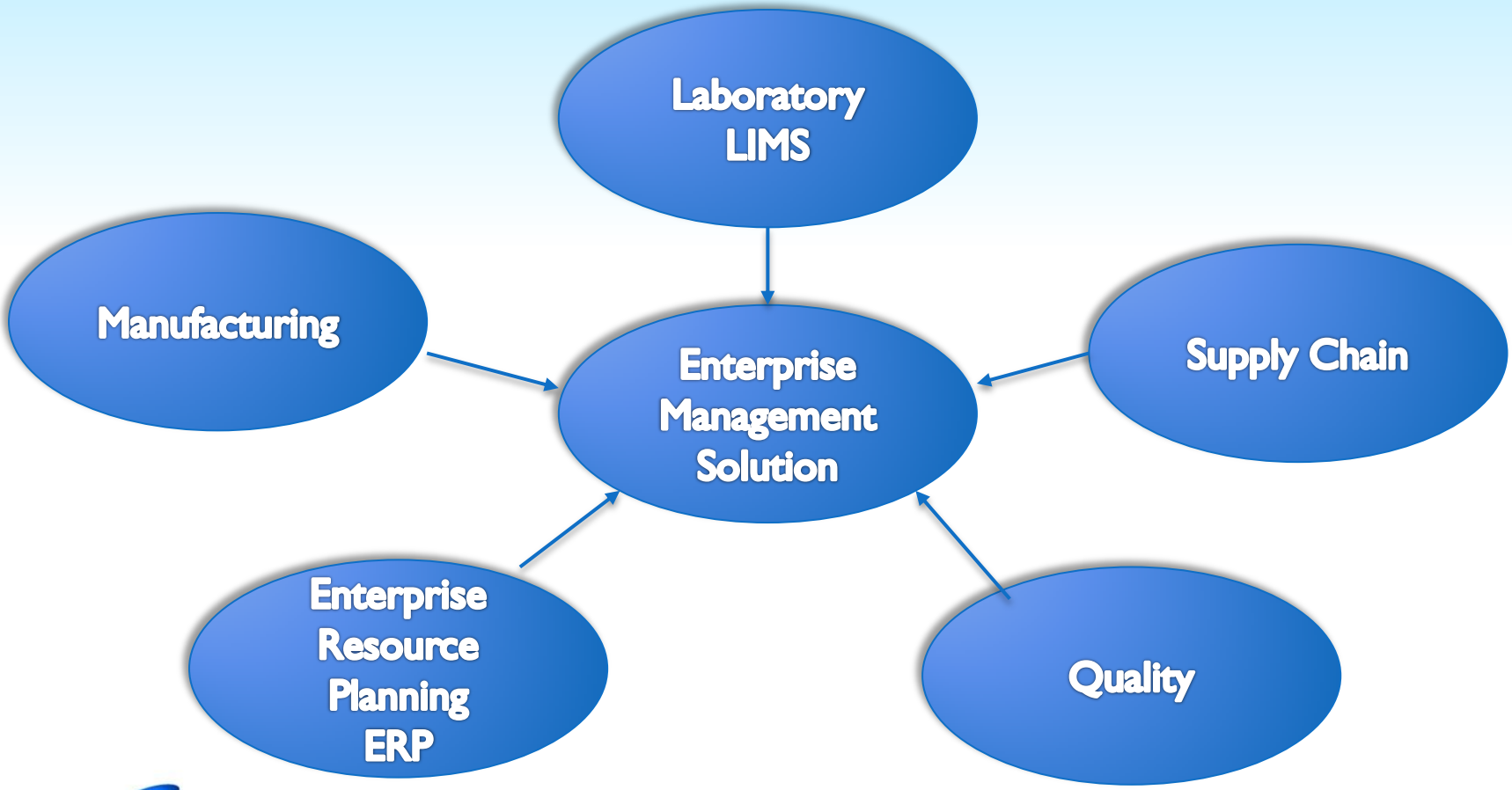
Use of Enterprise System in Life Science Industries

- Extensive application of enterprise systems in resource planning in production, engineering, sales, marketing and financial areas (MRP and ERP systems).
- Use of similar systems apply in the Management and Control of Supply Chain issues.

Major Shortfalls of Most of these Enterprise Solutions

- They fail to properly integrate the requirements for quality attributes and principles into their operating platforms.
- Quality is often seen to be an additional expense associated with the cost of manufacturing.

Interfacing Elements with Enterprise Network



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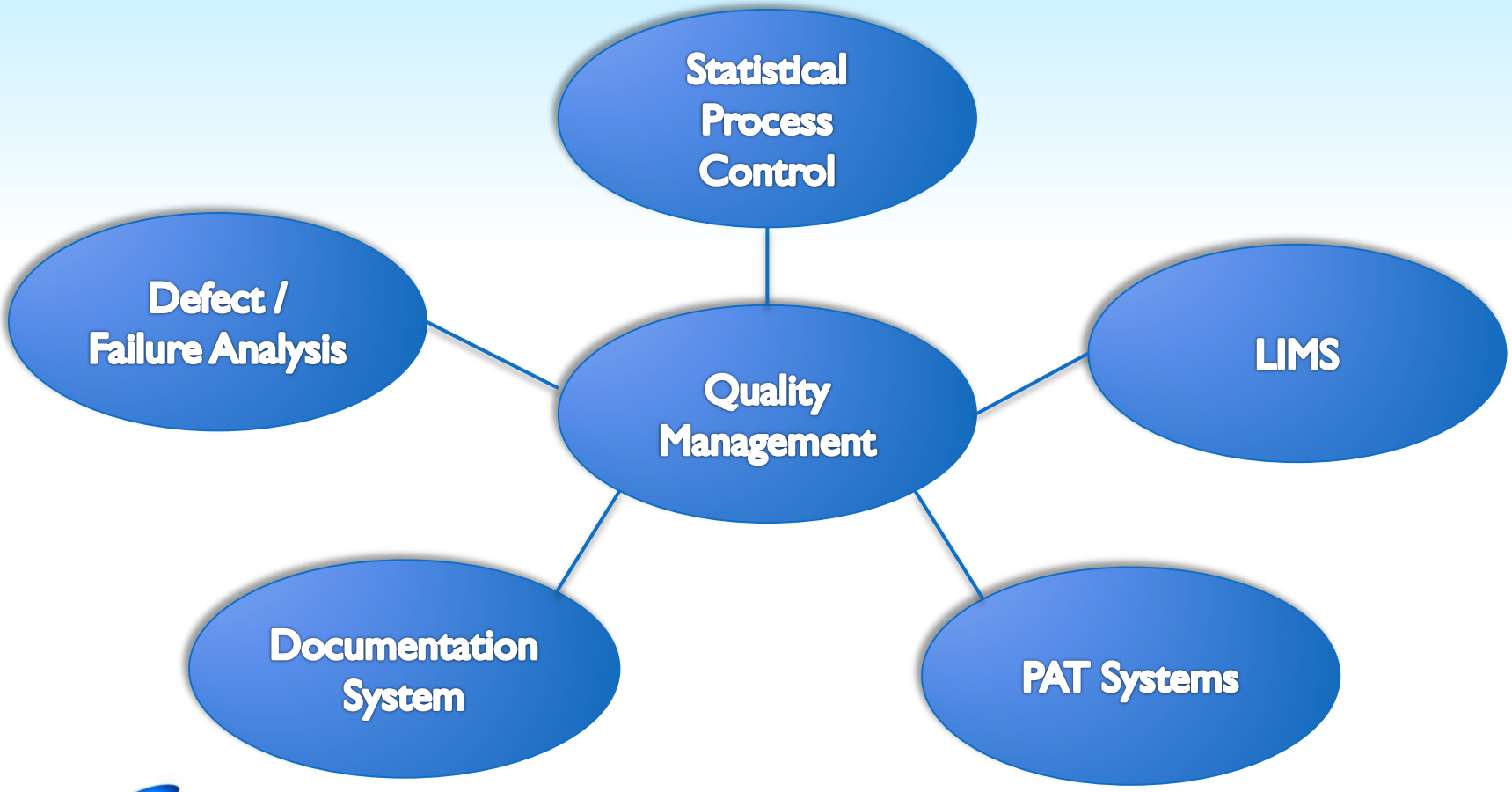
Some Systems That Provide Important Inputs for Quality Management



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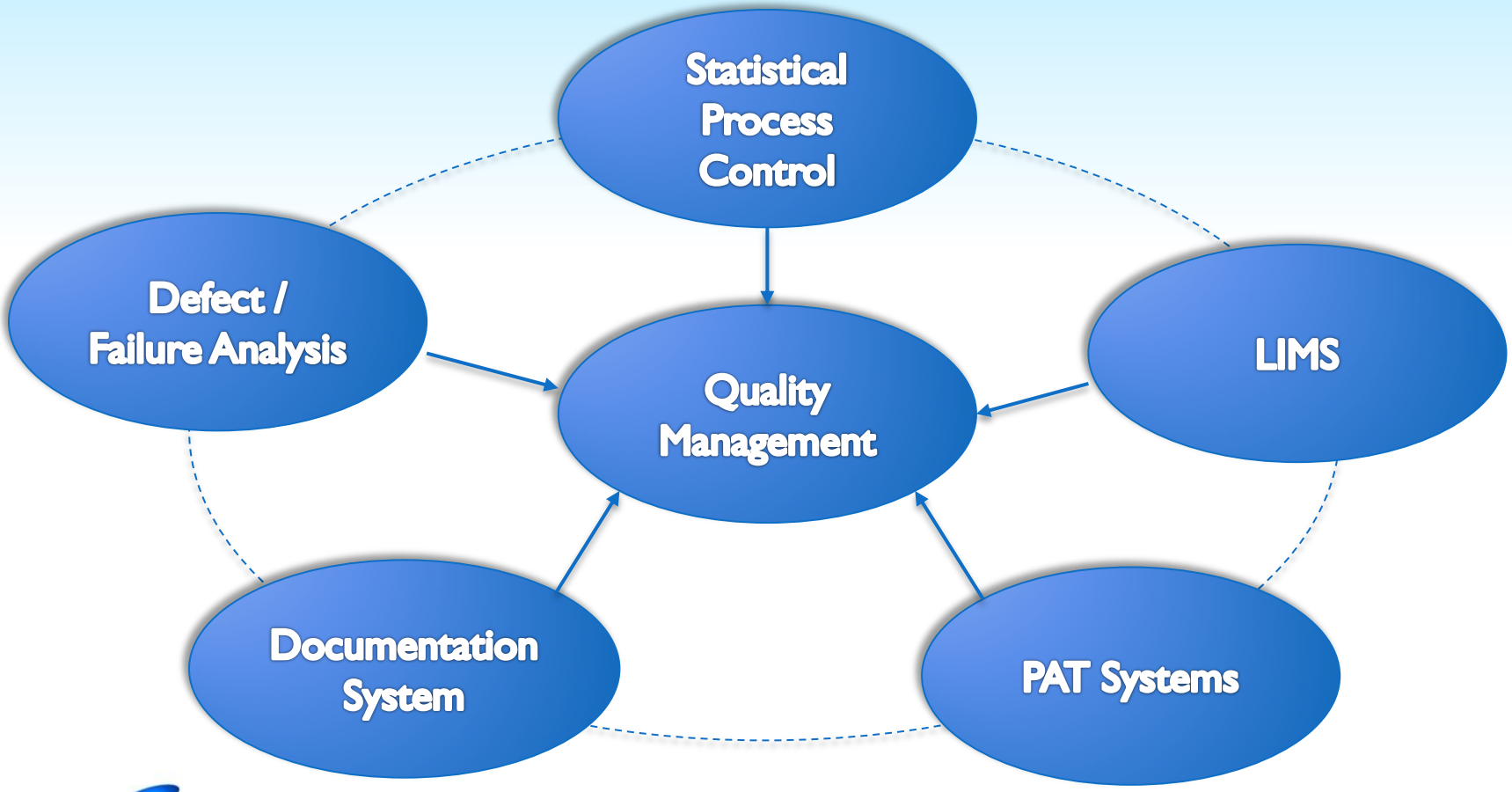
Their limitation is that they are often not effectively networked together to deliver quality management with peak performance.



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Potential Deficiencies

With all these types of applications there is a deficiency in their ability to:

- Collect and store data
- Share data – "talk" to other sub-systems through existing management software applications.
- This makes them rank as sub-performers in terms of meeting the level of flexibility needed for a lean, nimble, peak performer with expandable flexibility to meet modern industry demands.

Solutions for these types of shortfalls are at hand.

- New Quality Management Software that interfaces quality applications with business automation systems.
- This is achieved through linkage of quality system elements to the enterprise software system allowing a seamless exchange of data and information.

New Possibilities

- Can select MRP, ERP and SCM systems and link quality elements that meet particular needs.
- Linkage of quality elements to enterprise system is achieved through a standard interface framework.
- Provides companies with possibility to customize their quality requirements to deliver optimized manufacturing and business control.

Problems of Conventional Systems

- Often free-standing / stand-alone systems with limited network access.
- Data is localized or not available to all of network.
- Relies upon data-entry or data transfer / conversation.
- Process is often complex and prone to breakdown.
- Process can be slow and cumbersome – not user friendly.
- Process lacks swift mechanism for follow up and close-out once corrective actions are implemented.

Benefits of this Type of Integration

- Data entry and processing is streamlined which delivers a "Lean" system that is efficient, effective and compliant.
- Streamlining the system utilizes labor resources more effectively which reduces operating costs.
- Real-time access to manufacturing status / data and quality status necessary for effective production planning.
- Assists in an improvement in management effectiveness through quicker and more responsive use of data and process information through effective reporting portals.

Important Software System Elements Necessary for Effective Enterprise Management Integration of Quality for Compliance Management

- Should provide flexibility with scale-ability.
- Must mesh easily with the existing enterprise backbone.
- Should be cost effective to implement.
- Applications should be sufficiently detailed to provide all compliance requirements.
- For multi-site operations, should provide site-to-site integration.
- Is designed with an open architecture to easily interface with multiple database applications and server configurations.
- Provide appropriate security.
- Have support for upgrades as provided.

Question 2

What are the Best Practices to Manage Supplier, Internal and Customer Quality Processes?

Important Tools in the Development of a Best Practice Global Sourcing Strategy

- Process Map of the Process
- Supplier Quality Questionnaire
- Effective Risk Management Strategy
- A Communications Infrastructure
- Audit Program
- Quality Agreements
- Metrics/Analytics Program
  - Use of score cards

Supplier Sourcing Process Map

- Have a defined process map for your supplier process that's logical and considers cross-functional inputs.
- In developing this map understand the "Current State" as this will act as a reference point from which to develop the "Best Practice" "Desired State".
- Transition to the Desired State as the strengths and weaknesses are understood.

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Supplier Questionnaire Tool Composition

- This can vary depending upon the complexity, but should always include quality, cost and performance factors.
- For Quality:
  - Existence of GMP culture
    - Adherence to GMP's and ICH guidelines
  - Implementation of Quality System
    - Existence of policies, SOPs and records
  - Good Compliance Record
    - No citations by regulatory authorities

Supplier Questionnaire Tool Composition

For Process and Technological Capabilities:

- Appropriate facilities for production
- Capacity to deliver
- Strong technological capabilities
- Strong production controls
- Delivery performance record
- Clean environmental record

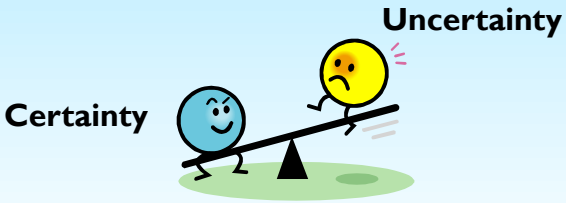
Supplier Questionnaire Tool Composition

For Personnel and Management Capabilities:

- Strong understanding of key performance indicators for supply chain.
- Strong technical management controls.
- Strong project management expertise.
- No de-barred individuals by FDA or other authority
- Strong in-house acquisition policy to maintain supply capabilities
- Appropriate group chemistry and business culture fit to foster long-term cooperative relationship.
  - Can-do spirit

Effective Risk Management Strategy

- 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 batch
    - Test failure – lost productivity



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Effective Risk Management Strategy

- Risk Management is a knowledge management program providing Decision Makers the power to make better Quality decisions.
- It involves identifying potential failure causing issues.
  - Ranking for criticality.
  - Mitigating the effects of these.
  - Where possible, eliminating these.
- Maintenance of sustainable compliance through oversight policy.
  - Determine areas needed.
  - Set out structure for levels required.
  - Execute oversight measures.
  - Review and make adjustments as necessary.

Risk-based Approach Flow Chart Described in ICH Q9 Provides Direction

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Determine Criticality Through Quantitative/Qualitative Models

Example: Compliance Record

Compliance Actions	Historical Database of Compliance Issues				
	No issues	Few issues	Occasional issues	Many issues	Significant issues
FDA violations requiring attention	**Low**	**Medium**	**High**	**High**	**High**
FDA objections voluntary action	**Low**	**Low**	**Medium**	**High**	**High**
Periodic internal audit findings	**Low**	**Low**	**Low**	**Medium**	**High**

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Supplier Management Success Strategies

- Align with main business goals and use fewer more performance based suppliers.
- Maintain up to the minutes databases of where suppliers are in relations to your needs.
  - So you understand where your process weak points are.
- Understand their capabilities and capacities and their potential failure points.
  - Risk Analysis
  - Focus on key strategies and manage the worst performers as a minor percent of effort.
- Use fewer "better" suppliers so you do not spend time on unnecessary management activities: audits, reports, etc.

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Supplier Management Success Strategies

- Do upfront work to minimize on-site audits.
  - Costly
  - Time-consuming
- Combine audits between sites where multiple sites involved.
  - Corporate approach rather than site.
- Focus suppliers to adopt your supplier needs and standards.
  - Monitor them using scorecards.
- Set up a supplier portal for purchasing transactions.
- Set up mechanism for verification of commitments.
- Persuade suppliers to embrace a cooperative quality approach where you agree on common requirements and then share data set to minimize duplication of effort.

Importance of Audit Management

Effective Audit Management Drives Continuous Improvement

Establishes Quality Requirements for Products and Process

Reduces the risk of non-compliance.

Therefore, it is important to integrate audit processing with the overall enterprise wide quality management approach.

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Key Points for Audit Program

- Identify high risk cases.
- Establish a uniform standard.
- Use standardized approach and format.
- Streamline review and report process.
- Establish uniform mechanism for remediation of deficiencies through any CAPA's activated.
- Assure timely follow-up and close-out of outstanding actions.

Important Considerations for Best Practices Connected with Internal Quality Processes

Key in this process are internal audits and assessments.

- These are mandated by
  - 21CFR820: Quality Audits
  - ISO 13485 8.2.2 Plan and Perform Quality Audit
- They are important because they assure companies that they are in compliance with Federal, State, Local regulations and company policies.
- They provide a "scorecard" for the success of the internal compliance initiative and its level of harmony with prevailing regulatory requirements.

Important Considerations for Best Practices Connected with Internal Quality Processes

- They engage internal stakeholders to identify best practices.
- They provide gap analysis data to feed into strategic planning.
- They provide on-going performance evaluations that enable continuous improvements and drive business decisions.
- Data analyses such as variance analysis, CAPA resolution trending, process capability and supply chain effectiveness are examples of data driving process strategies.
- Data sets which describe the internal customer service situation and customer expectations should be examined.
- Through Key Performance Indicators – and trended metrics generated from these, major QMS issues can be addressed with transparency and efficiently without bias.

Customer Quality Processes

They share many common points of importance to those for supplier and internal quality compliant management.

Key points:

- For customer feedback there are a variety of software systems that have been adopted from other industries.
- Many use a questionnaire type of feedback mechanism to gauge performance against expectations and feed that back into a database for processing.
- For Life Science companies perhaps the customer compliant system is the most critical, since it can have consequences for product recalls and adverse event reporting to regulatory agencies.

Customer Quality Highlights

- Use Dashboards and Scorecards to develop metrics that can be used to drive improvements.
- Integrated with Risk Mitigation Strategies these are best practices used to manage key impact drivers in relation to processes that affect customer satisfaction, which includes regulatory agencies, distribution networks, and primary / secondary users of the medical products.

Question 3

How Can Organizations Obtain a 360° view of its Quality Management Program?

What is the Goal -- Why do you want this?

- Deliver peak performance.
- Delivery user effectiveness.
- Delivery desirable customer experience.
- Maintain cost effective compliance.
- Reduce risk of failure due to the above.

It is about Managing Quality Compliance Risk.

So What is Risk?

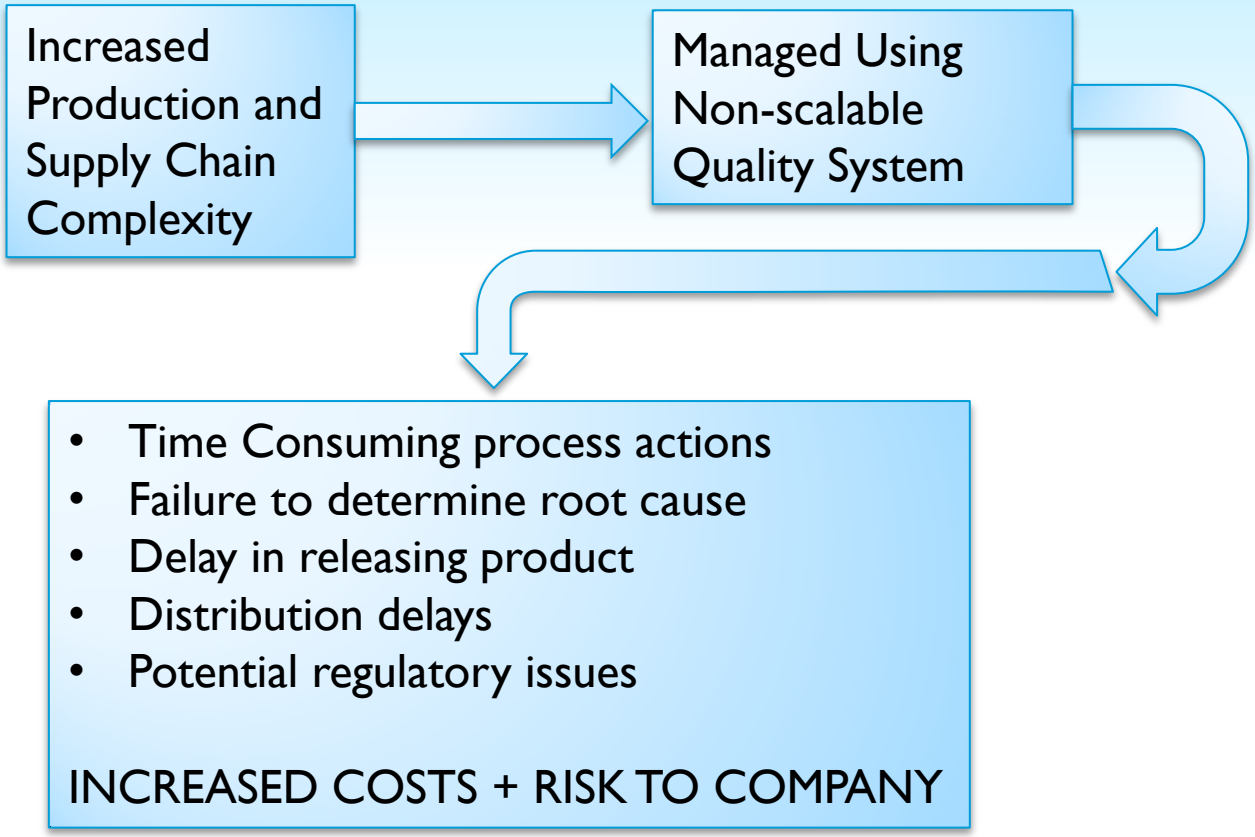
Re-cap

- Risk is the balance between certainty and uncertainty.
  - Product failure due to a manufacturing breakdown.
  - A batch rejection due to the failure to close-out an investigation or CAPA.
  - A recall due to a test failure.
  - Litigation due to an adulterated product.

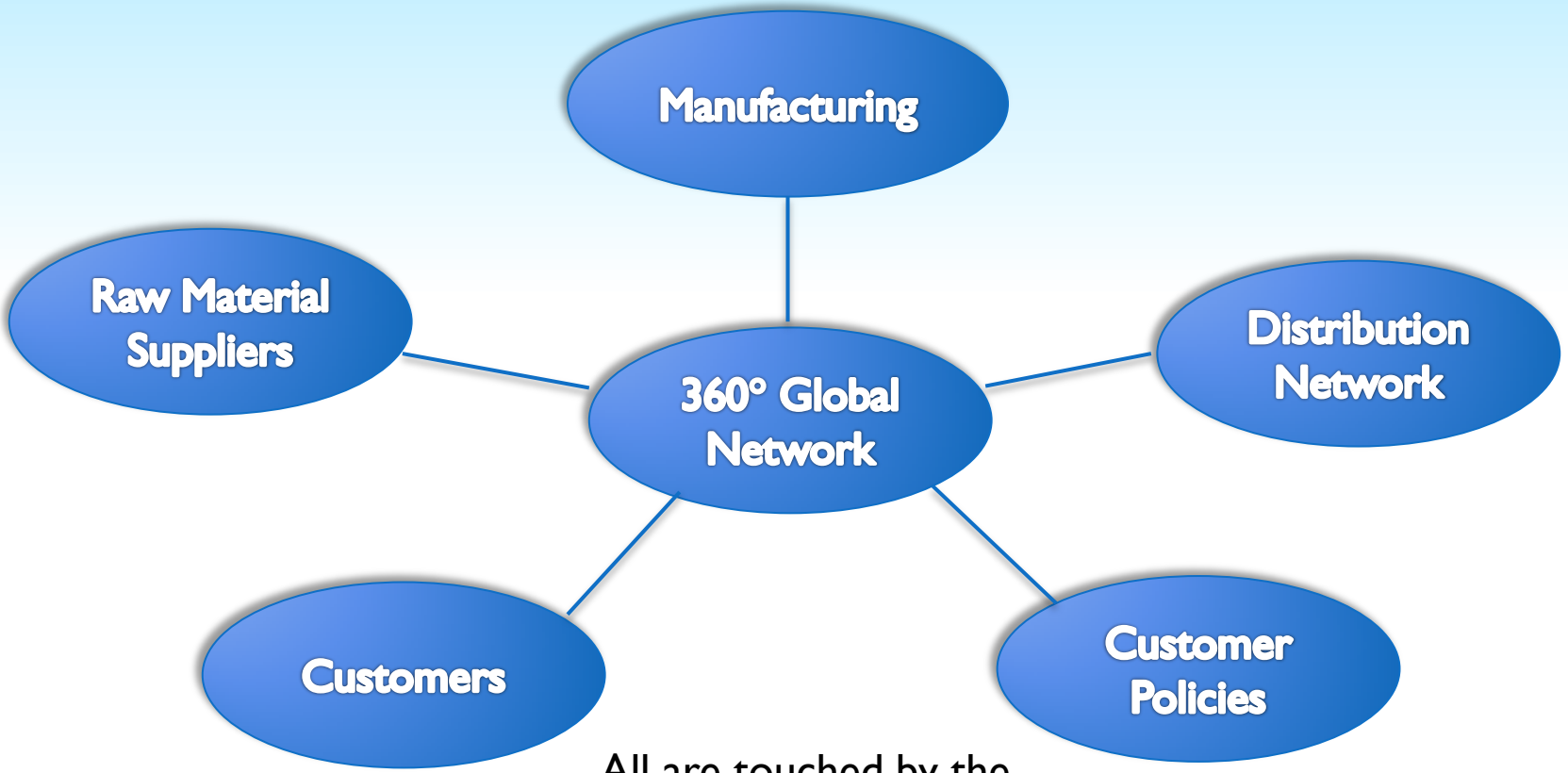
All these are Quality Management System related.

Risk Escalation

Example:



360° View of Quality Management Program



All are touched by the Company's Quality Management System

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Enterprise Solution Approach

- Provides organizations with a central processing network that can provide multiplexed information in a format that will permit good quality decision making in a timely fashion.
- Reports can be compiled to meet the need and cross-reference a variety of data types.
- Quick recognition dashboards can aid with decision-making and highlight important trends.
- Use of feedback questionnaires and numerical scorecards can be used to develop an accurate picture of operational performance.

Example of Supplier Scorecard

Scores to ± 10

Score Attribute	Ideal Score	Example Score
Documents received	1	0
Material quality OK	3	0
Delivery date Met	2	0
Material in good condition – packaging	1	1
Quantity delivered	3	2
TOTAL	10	3

*This lot would receive a poor rating. Every delivery is scored.

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Dashboards

One solution that provides management with an effective tool to handle these issues is through the use of a metrics driven data management dashboard.

Why?

- Provides real-time effective presentation of multiple related sets of information.
- Consolidates data in an easily recognizable format that is simple to interpret.
- Provides data in a trended format so strategic decision making is possible.

Through Dashboard metrics, the enterprise solution can provide useful information to effect the performance of the Quality Compliance program.

Some examples include:

- Deviations / investigations
  - Exception reporting
  - Root cause analysis
- CAPA's
- Breakdowns
- Maintenance issues – service performance
- Released batches
- Change control approvals
- Training
- Validation completed
- Technology transfer performed
- Analyses performed
  - First pass yield
  - Analyst performance
- Downtime due to contamination
- Environmental monitoring
  - Out of Specification
- Supplier issues
- Complaints
- Manufacturing process capability
- Lot-to-lot variability
- Design / defect analysis

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Conclusions

The case is overwhelming that Enterprise Management applied to Quality System decision making provides:

- A Lean strategy
- Flexibility
- Streamlined access to data
- Rapid decision making options
- Comprehensive coverage of all key options
- Speed
- Cost effectiveness
- Value

…All of which adds up to an increase in performance and the possibility of enhanced compliance.

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Conclusions

- What to look for from Best in Class performers
- They:
  - Have metrics/analytics and perform tracking of performance
  - Use real-time dashboards to monitor critical attributes and diminish supply chain disruptions
  - Perform industry benchmarking to maintain standards
  - Perform risk analytics to avoid/mitigate related issues
  - Leverage resources globally through standardized policies and practices to reduce duplication of effort or non-added value functions
  - Influence outcomes through use of LEAN 6 Sigma to improve performance

Conclusions

By assuming that all data exchanges are automated, you will assure a reduction in non-added value work, improve compliance related throughputs and promote transparency.

- Increases overall reliability
- Improves overall business performance

Example: electronic CAPA closeout. Transparency through data visibility promotes faster more effective resolution and compliance.

Questions?

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

For more information, visit:

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Or email: nsmart@smartconsultinggroup.com

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