SUPPLY CHAIN MANAGEMENT:

A GUIDE TO SUPPLY CHAIN 4.0 AND BUILDING RESILIENCY

Honeywell

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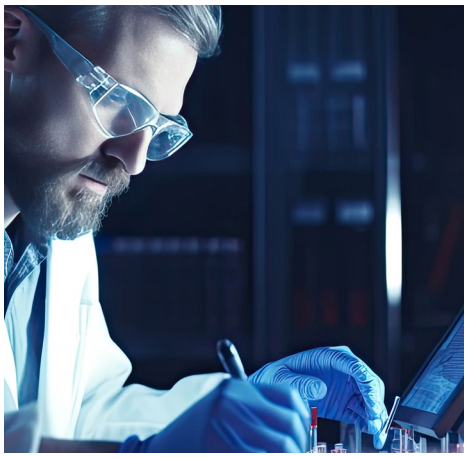
MANAGEMENT SUMMARY

1

The COVID-19 pandemic has brought on unique, eye-opening challenges for manufacturers, forcing companies to reevaluate their supply chain management for the unpredictable.

Now is the time to leverage technology to achieve and maintain a resilient supplier chain. In addition, industries need to understand the impact of current suppliers, trends and reducing complexity.

This white paper provides an overview of a strategic, tactical, risk-based approach to Supply Chain 4.0.



ACCORDING TO THE AMERICAN PRODUCTION AND INVENTORY CONTROL SOCIETY, 15TH EDITION:

- The supply chain is the global network that delivers products and services from raw materials to end customers through an engineered flow of information, physical distribution and cash.
- Supply chain management is the design, planning, execution, control and monitoring of supply chain activities to create net value, build a competitive infrastructure, leverage worldwide planning, synchronizing supply with demand, and measure performance globally.

"I THINK FRUGALITY DRIVES INNOVATION, JUST LIKE OTHER CONSTRAINTS DO. ONE OF THE ONLY WAYS TO GET OUT OF A TIGHT BOX IS TO INVENT YOUR WAY OUT."

– JEFF BEZOS, FOUNDER OF AMAZON AND A SUPPLY CHAIN INNOVATOR

REGULATIONS

Device manufacturers bear the overall responsibility for the safety and effectiveness of finished devices.

Therefore, not meeting the Food and Drug Administration (FDA) regulations can cause enforcement actions, including recalls. The FDA has the authority to inspect component manufacturers, but they rely on the finished device manufacturer to ensure it meets specifications.

Regulation Links

Purchasing controls 21CFR820.50

ISO 9001 Auditing Practices Group. "Guidance on Remote Audits." ISO and IAF, April 16, 2020.

INDUSTRY CHALLENGES

2

The COVID-19 pandemic has drastically affected the business environment, forcing companies to rethink their supplier management process and supply chain responsiveness.

Industries continue to face challenges, such as end to-end collaboration, managing risk, single sourcing products, visualization, benchmarking and standardization. In addition, the increased prices and regulatory challenges have led biotechnology, pharmaceuticals and medical device industries to outsource manufacturing and packaging services, therefore increasing the risk and complexity of the supply chain (thousands of part numbers, hundreds of suppliers and multiple global locations). By failing to establish a robust supplier management program, companies expose themselves to significant compliance issues (voluntary or mandated recall), service deficiencies, financial consequences and damaged reputation.

A recent recall involving a convenient kit cost the company $96 million, and another recall involving software errors caused 55 injuries and one death, according to Becker's Hospital Review.

"What was shocking with covid-19 was this disjointed supply and demand. Borders were shutting down, which made it impossible to make and route shipments in an optimal way. To be prepared for that, you need to have some contingency plans, and they need to be financially supported, so things don't break down at the next shock."

– ANDREA MINCA, 2020

On behalf of interos, in 2020, vanson bourne market firm **conducted market research** on 450 u.S. Senior decision-makers in their company's risk, planning, it, procurement and operations.

WHAT IS SUPPLY CHAIN 4.0?

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The ongoing suitability of components and services to customers depends on the quality of the product or services received by suppliers. Managing Supply Chain 4.0 is a way to be proactive with all value chain partners and their extended supplier network.

Companies struggle to synchronize and integrate data into their supplier process(es). When visibility increases, it provides an opportunity to build collaborative relationships with suppliers and supports innovation, speed-to-market and competitive differentiation.

Supply Chain 4.0 provides real-time data and transparency to enhance collaboration with suppliers and customize the supply chain to meet business requirements (Hitachi Group, 2020). This vision of a complete partner ecosystem will establish real-time communication and data sharing to identify issues early and proactively prevent quality issues from entering the supply chain. There is no "one-size-fits-all approach" to Supply Chain 4.0, but digitalization can:

- Provide end-to-end collaboration
- Enable the implementation of best practices
- Shorten cycle time
- Provide benchmarking
- Standardize processes

HOW TO MANAGE SUPPLIERS

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DEFINE A SUPPLIER PROCESS

Before you can manage the supply chain, ensure procedures are documented and include:

Risk definitions and terms:

- Suppliers shall be classified based on the inherent risk related to safety and quality presented
- How is risk management integrated into the supply chain?
  - How will suppliers be classified?
  - What are the controls for each classification?
  - What are the quantifiable metrics for each classification?
  - What risk assessment tools will be utilized?
- A documented metric that aligns with a corporate vision and strategy and provides an opportunity for continual improvement
- The systematic, independent documentation process for determining the extent and criteria for audits
- The frequency and how suppliers are qualified and requalified

  Example:
  - High-risk suppliers shall have an on-site/remote audit every two years and a paper audit annually
  - Medium-risk suppliers shall have an on-site/remote audit every three years and a paper audit annually
  - Low-risk suppliers shall have an on-site/remote audit or paper audit at least every four years
- Decision tree for when an on-site (or remote) audit is required
- Define, document, and review the responsibilities of the supplier

WHAT IS IN YOUR INVENTORY?

Supply interruption is felt globally and can negatively impact patient lives, with an estimated 72 percent of active pharmaceutical ingredients (API) manufacturers supplying the United States market are located overseas, and 13 percent from China, according to a 2019 report from the FDA's Center for Drug Evaluation and Research.

Safeguarding and understanding the vulnerability of your supply chain starts with an in-depth inventory review of products and services involving the quality management system (QMS).

- Inventory all components/ goods/services which could affect the finished device
  - Include a review of the bill of materials (BOM) and device master records (DMRs)
- Next to each component/good/ service, provide supplier information
- Determine if there are any pending critical audits for performance issues or upcoming projects
- Organize existing documentation to include quality agreements, surveys, post-market reviews and past audits
  - Quality agreements should contain at minimum:
- Appropriate written responsibilities for cGMP activities
- Purpose/scope
- Product/service(s)
- Contact information
- Terms and expirations
- Quality control, change control, change management
- Dispute resolution
- Regulatory compliance
- Reporting support

SUPPLIER RISK MANAGEMENT

A supplier risk management program provides visibility to suppliers and products. The benefits of using risk management for your suppliers include:

- Driving direct and measurable value
- Meeting compliance
- Strengthening supplier relations
- Visibility and avoiding preventable risk

Risk efforts should be implemented on all suppliers relating to the QMS to help determine vulnerabilities. Risk efforts should include understanding not just Tier 1 suppliers but Tier 2 and Tier 3. It is critical to utilize cross-functional teams to help identify risk (IT, QA (Quality Assurance), RA (Regulatory Authorities), Engineering, Logistics, etc.), remember risk can be potential, actual or perceived.

- Tier 1 suppliers are customer facing, high volume, high spend, with limited alternative suppliers
- Tier 2 suppliers are where Tier 1 suppliers get their materials
- Tier 3 suppliers commoditized supplies occasionally used supplies

> According to ISO 9001:2015, 0.1 General, "Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise."

ANSI/AAMI/ISO 14971: 2019 Medical devices- Application of risk management to medical devices provides the general requirements for risk management system:

- Identify hazards and hazardous situations (risk analysis)
- Estimate and evaluate the associated risk (risk evaluation)
- Control risk (risk control)
- Monitor the effectiveness (production and post-production activities)

The table below shows examples of risk factors to evaluate and determine which supplier to prioritize.

RELATED RISK	IMPACT: LOW-0, MINOR-3, MODERATE-7, HIGH-10
COMPLEXITY	Based on the impact of risk due to complexity
GEOGRAPHY	What region and what is the infrastructure, threats, and economic
SENSITIVITY	Based on the difficulty of maintaining the conditioned environment
PURCHASING VOLUME/INVENTORY	Based on the impact on customers
FINANCIAL	Based on the financial risk of business along with the impact of sales
PRODUCT USE	Based on the amount used throughout the product line
INTERNAL AND EXTERNAL AVAILABLE INVENTORY	Based on if supply and demand can be met, lack of availability

A key component of proactive risk management is a collaboration between your supply managers and your suppliers.

RANKING CRITERIA TO DETERMINE THE SUPPLIER IMPACT		
POTENTIAL RISK CATEGORY	DESCRIPTION	RANKING
CRITICAL POTENTIAL RISK	• Directly affects people's/animal's lives • Can seriously threaten people's/animal's health • Can cause significant environmental damage	**5**
HIGH POTENTIAL RISK	• Can cause noncompliance with regulations • Significantly affects the vital attributes of the product or service, such as functionality, performance and reliability • It involves the interests of external parties, such as business partners, suppliers and competitors • Can significantly impact the organization's public image	**4**
MODERATE POTENTIAL RISK	• Reduced level of vital attributes, such as functionality, performance and reliability	**3**
LOW POTENTIAL RISK	• Insignificant shortcomings on nonvital product attributes • Flaws that are related to individual Preferences	**2**
NO POTENTIAL RISK	• No negative impact	**1**

HIGH RISK – MAJOR/CRITICAL

- Potential for product contamination, complete product failure or severe chains disruption
- Potential violation of customs/ regulatory requirements or blatant disregard of technical/ quality agreement
- Multiple systemic or chronic deviations from the requirements
- Conformity is required within three months or according to an agreement

MEDIUM RISK – MINOR/MAJOR

- Required procedures do not exist or exist but are not implemented or followed
- Lack of awareness or attention to cGMP requirements
- Lack of IT and other technical resources appropriate to the size of the business
- Deficient management systems for handling customer service, production planning and inbound/outbound planning
- A substantial number of instances of partial fulfillment of requirements
- The system is not achieving defined objectives
- Compliance is required within six months or according to an agreement

LOW RISK – MINOR

- Regulatory, ISO, contractual, and internal requirements met in principle, but not in the current system need additional focus and other improvements
- Compliance is required within six months or per agreement

A helpful tool when evaluating risk is by a visualization chart/diagram/graph using the standard red, yellow and green colors. An example of a four-tier classification system for risk impact:

		RISK IMPACT			
		Negligible (1)	**Moderate (2)**	**Marginal (3)**	**Critical (4)**
ABILITY TO MITIGATE RISK	**High Ability (1)**				
	Moderate Ability (2)				
	Low Ability (3)				
	No Ability (4)				

Once risks are categorized, then key performance indicators (KPIs) should be developed, not limited to:

- Financial risk
- Market risk
- Operational risk
- Compliance risk

Upper and lower acceptable values are defined with triggers and actions.

Example: If three shipments from a supplier have nonconformities, then the inspection will increase to high.

PROCESS INPUTS	RISK MANAGEMENT
TANGIBLE **INTANGIBLE**	• Risk Model • Risk Plan • Feedback Loop • Reporting Structure

Supplier performance monitoring includes both tangible and intangible items and may include:

Tangible

- Quality
- On-time delivery
- In-full delivery
- Audits
- Survey
- Certificates, resume, licenses
- First article review
- Scorecards
- Testing data
- Inspections, nonconformances
- Recalls
- Service complaints

Intangible

- Supplier partnership
- Continuous improvement
- Responsiveness to questions and concerns
- Customer service
- Open and forthcoming
- Post-market reviews

Supplier audits, remote and on-site, are based on compliance, performance and improvement and are performed on:

- Key or high-volume suppliers
- A downward trend in performance
- High-risk suppliers
- Testing data
- Management reviews and feedback

AUDIT PROCESS

An approved supplier list (ASL) should be updated continuously and communicated with all facilities. The ASL should include:

- Company name
- Address
- Scope of supplier
- Contact information
- Status of approval
- Monitoring requirements and activities
- Supplier classification

SUPPLY CHAIN 4.0 ENABLES RESILIENCY

5

The complexity of the global supply chain is an area of significant risk. Even though companies understand the vulnerabilities and the importance of mitigation actions, it is still difficult to know until they can accurately quantify the monetary impact. Therefore, companies need to capitalize on opportunities and minimize risk.

Supply Chain 4.0 embodies preparation and resilience by continuously monitoring overall efficiency to meet product requirements, production demands and maintaining an effective QMS. Supplier management includes the activities taken to improve supplier capabilities and performance for products and services. Supplier qualification is a critical process to a successful outcome. Companies must build control and quality into the assessment and selection of suppliers. There is a balance between supplier control, manufacturer control and acceptance activities; it is essential to set expectations for suppliers and maintain open communication.

An automated supplier management solution allows for consistency throughout the purchasing process and integration of QMSs to help mitigate risk, increase productivity, reduce cost and yield improvement in product quality.

According to APQC's 2019 Supply Chain Survey, the top obstacles for improving the supply chain process are regulations, lack of support and technology. Companies are not able to control regulations but can influence the availability of support and technology. By harmonizing the supplier process, using a seamless data exchange and real-time visibility at all levels, industries can track, collaborate and manage suppliers. In addition, maintaining a consistent supplier process with standardized templates, audits and conditions will help reduce variations and identify the areas of highest supplier risk across the organization.

For more information
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