

Building an Effective Supplier Control Program:

A review of key program elements & their implementation.

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Building an Effective Supplier Control Program

A review of key program elements & their implementation:

- 1. Determination of risk;*
- 2. Selection & classification of suppliers;*
- 3. Supplier performance & monitoring;*
- 4. Ensuring responsive action;*
- 5. Clarity of who is responsible for what; and*
- 6. Supplier development*

But 1st: What's the business motivation?

- Good business
 - Drives quality back to the source
 - Reduces variation & uncertainty
 - Reduces waste hence cost

And

- Regulatory agencies like it ...

Guidance - Devices

- CFR 820 Quality System Regulation
 - Subpart E--Purchasing Controls
- ISO 13485 Quality System Standard: 7.4 Purchasing
- GHTF SG3 (WD) N17R7 Bonn (2/8/08)
 - Guidance on the control of products and services obtained from suppliers

For completeness - Drugs

- 21CFR211.84
 - Testing and approval or rejection of components, drug product containers, and closures
- ICHQ7A: GMP for API
- USP<1078>: GMP for Bulk Pharmaceutical Excipients

1. Determination of risk

Proportional & Balanced:

- Supplier Controls proportionate to the severity and risk identified in the risk management program.
 - Risk analyses via Design Controls.
 - Identification of critical components.
- “If you don’t get the proper assurances through Purchasing Controls, then have to balance them through other activities.” (e.g. incoming acceptance activities)

Need to ensure that the balance of controls are commensurate with the risks.

Determination of risk

Quality & Supply Risks:

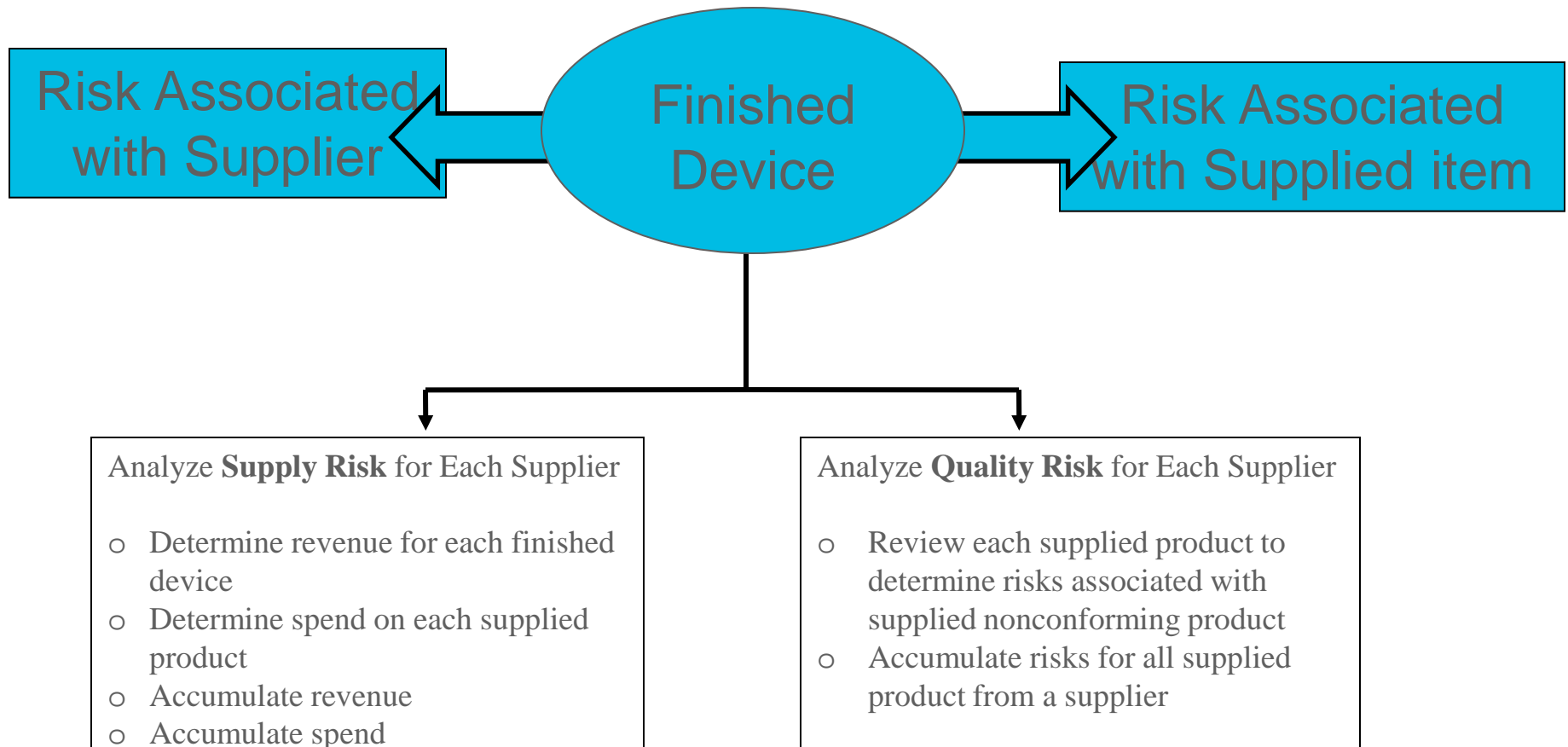
- Ensure Supplier Risk Assessment considers **both**:
 - Quality risk
 - Finished Device Quality implications
 - Supply risk
 - Including implications of supplier going out of business

AND

- Allow for dynamics of time – establish minimum periodic review frequency:
 - Significant change in business conditions,
 - When product/process change accumulates

Determination of risk

Fan out from the Finished Device



Determination of risk

Quality Risk encompasses **risks** to the quality of the finished device **across the device product lifecycle** including risk to the patient/user

Quality Risk Level	Patient / User Impact
Critical	Potential for causing or resulting in hazardous or unsafe conditions for individuals using or maintaining the finished product including permanent injury or death .
Major	Potential for causing or resulting in hazardous or unsafe conditions for individuals using or maintaining the finished product including major injury to the user or patient requiring medical intervention to treat injury; may also result in finished product failure.
Minor	Potential for minor injury to user or patient not requiring medical intervention to treat injury. Also may result in reduction in finished product's usability.
Negligible	No potential for user or patient injury . Generally regarded as nuisance issue for user or patient and is not likely to result in a complaint.

Determination of risk

Lessons Learned:

- Ensure that Process Risk is considered (pFMEA)
 - A 3 dimension scale (S + L + D) is useful with supplier
[Not to confuse with the final Product Risk scale (S + L)]
- Quantify Risks - Useful to use RPN method
- Start with estimated performance then ensure on-going review of actual performance
- Include supplier “business” risk
- Consider *cross-over* risk from supplier of multiple parts

2. Selection & classification of suppliers;

Supplier Evaluation:

- Evaluation techniques include:
 - Questionnaires
 - Self surveys
 - Audits
- Assess elements of supplier's quality system based on established risks of supplier-provided parts
- Supplier's grading based upon evaluation results and assigned an evaluation **status**.
 - Approved, conditional, not approved

Selection & classification of suppliers;

Supplier Certification:

- Useful to classify Suppliers based on:
 - QUALITY Risk and SUPPLY Risk.
- **Supply Risk** includes consideration of:
 - Annual spend with the supplier and
 - Potential impact due to disruption of supply.

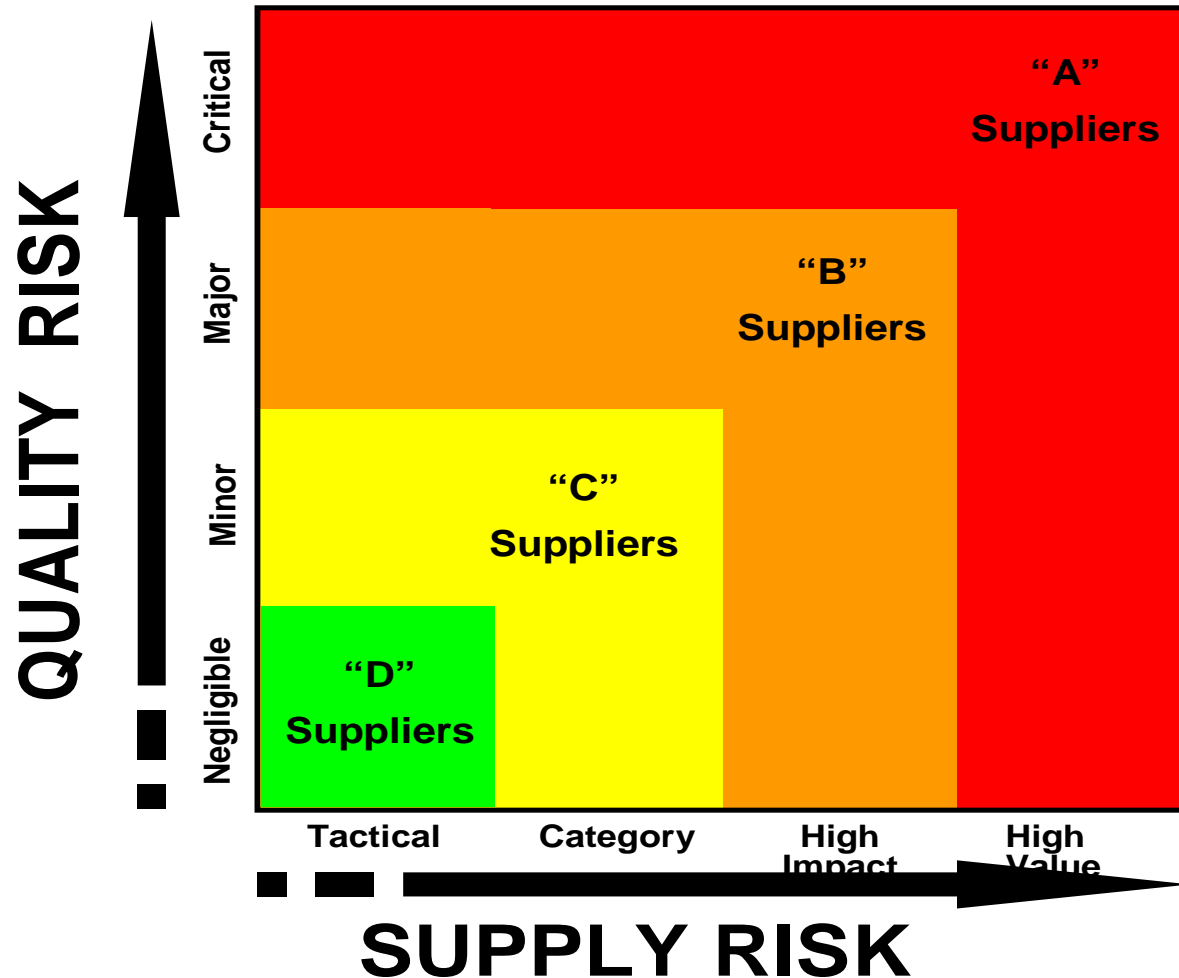
Disruption of supply considers the risk for all items received from the supplier and determines the **most severe impact** which could **result from supply disruption**.

Selection & classification of suppliers

- **Class A:** The highest level of supply and or quality risk. Suppliers that are in this classification are “**strategic**” with “**critical**” quality risk.
- **Class B:** The second level of supply and or quality risk. Suppliers that fall into this classification are “**key**” with a “**major**” quality risk.
- **Class C:** The third level of supply and or quality risk. Suppliers that are in this classification are “**category**” with a “**minor**” quality risk.
- **Class D:** The lowest level of supply and or quality risk. Suppliers that are in this classification are “**tactical**” with a “**negligible**” quality risk.

Selection & classification of suppliers

RISK & Supplier Classification



Selection & classification of suppliers



Complexity

- **Purchase Order** acceptable where **risk is low**.
- **Detailed contract/agreement** with quality and regulatory provisions where **risk is higher**.
- Where supplied parts include **sub-tier suppliers**, provisions to identify controls at sub-tier level.

Selection & classification of suppliers

Lessons Learned

- Some suppliers VERY protective of proprietary knowledge
 - Respect & work with but be prepared to find alternates
- If unwilling to enter into a contract/agreement, identify compensatory supplemental controls

3. Supplier performance & monitoring

Metrics, monitoring and feedback processes:

- Performance metrics:
 - On-time delivery, Lot acceptance, Audit findings, SCAR
 - Internal 1st pass yield, non-conformities
- Ongoing Supplier monitoring with a frequency and depth matching the identified level of risk.
 - Include periodic review of critical product/process data.
 - Trends and significant performance issues

Supplier performance & monitoring

Performance & Monitoring Matrix Based on Quality Risk

Requirements	Product Quality Risk			
	Critical	Major	Minor	Negligible
Product Evaluations	Qualification + First Article Inspection	Qualification + First Article Inspection	First Article Inspection	First Article Inspection
Supplier Process Evaluations	MSA/Gage R&R; OQ and possibly PQ; Control and Capability studies	MSA/Gage R&R; OQ and possibly PQ; Control and Capability studies	MSA/Gage R&R and PQ required for any special processes	PQ required for any special processes
Supplier Process Controls	Control Plans and process monitoring	Control Plans and process monitoring	Inspection	Inspection

Sample sizes for product qualifications and process evaluations are based on pre-determined **Confidence and Reliability levels**

Supplier performance & monitoring

Control Plans:

- Documented description of the systems & methods for controlling part-&-process quality by focusing on key characteristics

“Critical To Quality” (CTQ) parts/processes

Supplier performance & monitoring

Sole Source Suppliers:

- When a sole source supplier provides a product/part, apply supplemental controls to further mitigate risk:
 - Elevate Quality and/or Supply Risk to a higher risk level.
 - Increase Monitoring controls :
 - *Product Acceptance Activities* (e.g., increased inspection sampling)
 - *Supplier Performance and Monitoring* (e.g., augmented frequency of reviews).

Supplier performance & monitoring

Performance Metrics – example: **Supplier Quality Score**

- Establish Minimal performance for Quality and Delivery
 - 90% LAR and
 - 90% On-Time Delivery

Supplier Quality Score:

- **Lot Acceptance Rate (LAR)** for all products received during the time measured.
- **On-Time Delivery Score** for all deliveries received during the time measured :
 - Good: ≤ 5 days early and ≤ 2 days late
 - Bad: > 2 days late or > 5 days early

Supplier performance & monitoring

Performance investigations:

- Triggered when performance metrics do not meet predetermined levels.

“Trigger” limits based on the supplier’s classification.

- If a **Class A** supplier does not meet its quality or delivery requirement for **one month** an investigation is initiated;
- If a **Class B** supplier it may be after **2 consecutive months**

Supplier performance & monitoring

Performance Feedback:

- Provided at different levels & frequency based on the supplier's classification with more formalized methods occurring for the higher classification suppliers.
- Elevated & specific when 'trigger' limits tripped & when later satisfied

Supplier performance & monitoring

Lessons Learned

- Some suppliers motivated to make uninformed changes due to other customers – e.g. RoHS compliant soldering processes.
 - “Trust but verify”
- Some suppliers technically strong but weak in P&PC
- Some suppliers have no Medical Device experience
- Allow for both **escalation & de-escalation** response actions
- Supply base is Global
- *Different* does not equal *wrong*

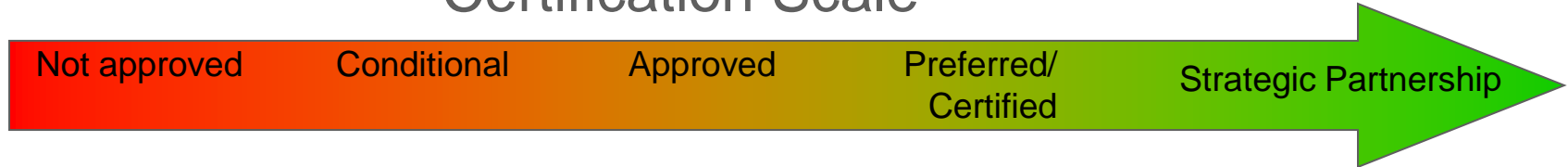
4. Ensuring responsive action

Establish expectations:

- Define performance activities (via Partnership meetings)
 - Certification
 - Auditing
 - SCAR
 - Control plans
 - Performance review
- Training (esp. medical device)
 - Process controls & risk assessment
 - Continuous improvement methods & plans
 - Change management
- Advantages of moving along the certification scale

Ensuring responsive action

Certification Scale



Certification:

- Supplier Certification:
 - Result of supplier demonstrating they can consistently meet quality requirements.

Minimum requirements for Certification:

- Must be an **Approved Supplier**
- Adequate process controls demonstrated (e.g. control plan)
- On-going product monitoring
- Demonstrated capability
- Motivation
 - Provisions for de-certification
 - Marketing advantage for supplier

Ensuring responsive action

Auditing:

- When findings are issued, drive response within a set time
- Responses to include:
 - Actions to correct and prevent recurrence of the finding
 - Planned completion date for each action
 - Effectiveness verification criteria & action and completion date
- Supplier responses reviewed for acceptance (renegotiated if not) and tracked to completion (& verified).

Ensuring responsive action

SCAR System:

- Procedures for supplier corrective and preventive actions responding to
 - non-conformance, customer complaints, field actions, supplier evaluation deficiencies
- Share expectations with supplier (training)
 - Defining when Supplier CAPA (SCAR) is are required
 - Methods for evaluating the suitability of SCAR responses
 - Collaborative management of change
 - Records/evidence demonstrating that effectiveness checks were performed & successful
 - Steps to take if effectiveness checks fail

Ensuring responsive action

Control plans:

- A living document, developed and revised to reflect addition/deletion of controls and measures with time
- Maintained and used throughout the product life cycle
 - Describes systems & actions for controlling (& monitoring) parts and processes
 - Describes monitoring of Key characteristics
 - Describes “special process” identification and monitoring
- Separate control plans for the two distinct phases of product life cycle:
 - Pre-production
 - Production

Ensuring responsive action

Lessons Learned

- Share expectations
- Satisfy supplier's expectations of purchaser
- “Work” control plans together
- Give supplier a goal (& associated reward)

5. Clarity of who is responsible for what

Quality Agreement:

- Addendum to the Purchasing Contract or Purchase Agreement
- Defines the roles and responsibilities with respect to the quality controls and deliverables to meet quality requirements
- Identifies performance review contributions

Clarity of who is responsible for what

Sub-tier Control:

- Clarify **supplier** is **responsible** for their sub-tier suppliers
 - This includes management of control plans when risk assessment identifies product/process of sub-tier supplier
 - Trust but verify
- Clarify **purchaser** is **accountable** for device

Clarity of who is responsible for what

Shared Performance Review		
Metric / Information	Purchaser Provides	Supplier Provides
Product Performance Results	X	
Field Corrective Action Update	X	
Product CAPA	X	
Process CAPA (including supply chain)		X
Non-conformance Review and associated CAPA		X
Process First Pass Yield & Defect Analysis		X
Source & Receiving Inspection Results	X	
Quality System Certification / Regulated Audit Status <ul style="list-style-type: none"> • External Audits • Nonconformities • Status of QS certifications • Test Lab / Agency status (if applicable) 		X
Design Change Control Update (includes material)	X	
Process Change Control Update		X
Business Process Specification Maintenance	X	
Updates to the Contact Matrix	X	X

Clarity of who is responsible for what

Lessons Learned

- Establish **predetermined & agreed acceptance criteria** of completion
- Don't stop at direct suppliers – dive into sub-tiers
- Don't stop at parts suppliers – apply to service providers
- Be responsive to geographical & cultural differences
- Trust but verify
 - Verify that permanent changes are permanent
 - Verify material supplied is material specified
 - Sub-tier suppliers are managed

6. Supplier development

Development Plan:

- Working closely to implement supplier controls assuring product quality and delivery requirements are met.
 - Through risk management activities, incorporate descriptions of approaches used to identify, prioritize and monitor supplier development activities
- Working closely to help drive improvement
 - Part
 - Process
 - Performance
- Develop Development Plan to ‘walk’ the certification scale

Supplier development

Lessons Learned

- Open & regular communication
- Share pain and share successes
- Encourage informed, improvement-based change
- Not all 'supplier issues' have Supplier as root cause
- Some suppliers do not have Medical Device experience
 - What's 'good enough?'

Summary

Established clear & shared expectations

Quantify & measure

But

It's more than the numbers ...



CONCLUSION ...

- Quality & Supply Risk Assessment
- Evaluation & classification of suppliers
- Clear expectation (specification & performance)
- Mutual responsiveness
- Clarity in of who's responsible for what
- Monitor & measure & develop

... Trust but verify