Rx-360

The International Pharmaceutical Supply Chain Consortium

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Supplier Quality Working Group

Supplier Quality - Rx-360 - The International Pharmaceutical Supply Chain Consortium

- Members from pharmaceutical companies and leading suppliers to the pharmaceutical industry.
- Share perspectives and work collaboratively to achieve greater efficiencies to better serve patients in the long-term.

See: http://www.rx-360.org/

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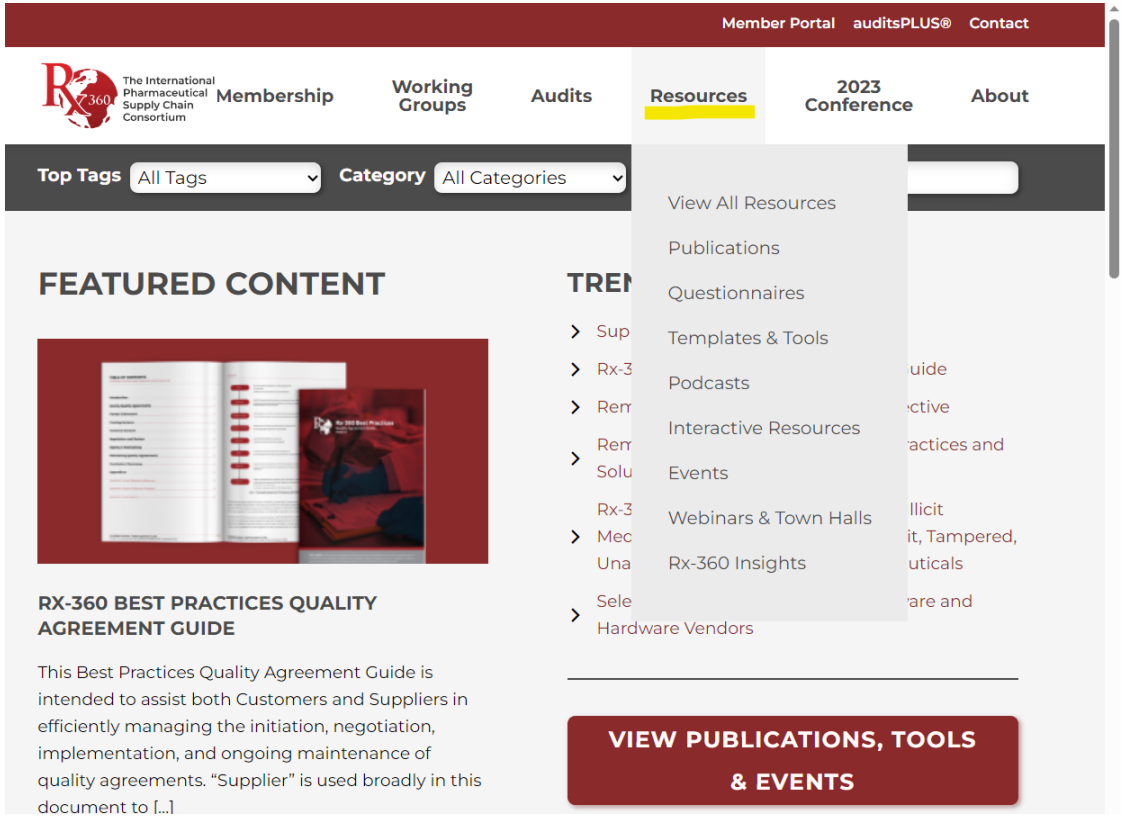
Supplier Quality Resource Overview

Resources - Rx-360 - The International Pharmaceutical Supply Chain Consortium



1. Managing critical vendors
2. Quality Elements for Suppliers of Products or Services to GMP Regulated Companies
3. RX-360 BEST PRACTICES QUALITY AGREEMENT GUIDE
4. NATURAL DISASTER CONTINGENCY PLANNING VERSION 2.0

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Managing Critical Vendors

PURPOSE

- Management of a critical vendor under scrutiny and how to minimize the impact on supply chains.

SCOPE

- Critical vendors that supply manufacturers (customers) of regulated products. Focused on regulatory areas but can be applied to other areas of quality concern.

HOW TO IDENTIFY CRITICAL VENDORS

- Criticality of the materials and/or services to the business
- Availability of the material and/or service
- Number of products/material supplied
- Financial impact

Managing Critical Vendors

PROACTIVE EVALUATION OF CRITICAL VENDORS

- Due Diligence & Audits/ Tour of the supplier's site facility
- Technical capabilities and capacity
- Environment, Health & Safety
- Regulatory & Financials
- KPI's & Trend Monitoring
- Regulatory Notice & Monitoring

IDENTIFYING & EVALUATING NON-COMPLIANCE ISSUES

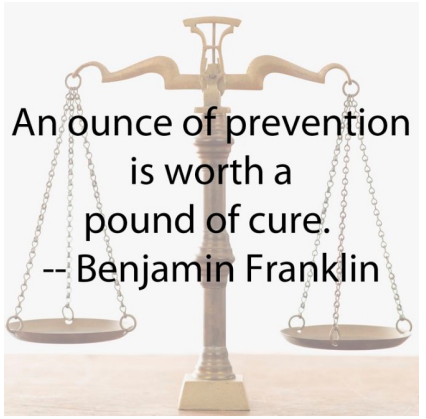
- Discovery of event
- Event Investigation/ actions

RISK MITIGATION AND CONTROL

- Collaboration
- Remediation Activities
- Exit Strategy
- Follow-up and Verification (CAPA)

Managing Critical Vendors

CONCLUSION



- Identifying critical vendors at the **earlier stages** of the supplier qualification process will ensure that they are subjected to appropriate controls and monitoring levels.

- The **level of visibility** to supplier operations is essential for an early detection of potential quality and compliance concerns:
  - increasing the frequency of **onsite audits** or onsite **technical visits** and
  - review of **quality Key Performance** Indictors (KPIs) on a regular basis.

- **Open and clear communication** between parties to help prevent issues before they arise.

Quality Elements for Suppliers of Products or Services to GMP Regulated Companies

PURPOSE

- Basic GMP elements expected of suppliers
- Risks involved regarding the intended use vs. actual use of products/ services

SCOPE

- Suppliers of products/ services that have an impact on GMP processes (regulated medical products manufacturing) within the pharmaceutical supply chain

PRINCIPLES

- GMP compliance increases opportunities in the marketplace and provides an advantage over competitors.
- QMS in place, such as ISO 9001 or other relevant system(s).
- Absence of such systems, the ten (10) key principles should be considered and implemented.

Quality Elements for Suppliers of Products or Services to GMP Regulated Companies

THE TEN KEY PRINCIPLES OF GMPS

1. Document Manufacturing Processes
2. Investigate Deviations
3. Follow Good Documentation Practices
4. Validate Processes/Qualify Facilities and Equipment
5. Set-up, cleaning and Maintenance of Facilities and Equipment
6. Assurance of Job Competencies and Training
7. Adopt Good Hygiene and Housekeeping Practices
8. Establish a Quality Management Program
9. Develop a Proper Supplier Management Program
10. Audit for Compliance

Quality Elements for Suppliers of Products or Services to GMP Regulated Companies

RISK EVALUATION

- The understanding and application of GMPs is essential for not only manufacturers of regulated medical products but for all suppliers of products or services throughout the supply chain.

CONCLUSION

- Developing a plan to implement the “Principles of GMP” is probably one of the most important things a supplier to the regulated medical industry can do.
- The implementation of the “Principles of GMPs” will also more closely align the supplier with their customers which can lead to improved relationships and less observed deficiencies during customer audits, and possibly a reduction in complaints as well.

Questions?

Jennifer Goodman

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- Avantor
- Member of Rx-360 Supplier Quality Working Group

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Natural Disaster Contingency Planning

NATURAL DISASTER CONTINGENCY PLANNING VERSION 2.0

PURPOSE

- To adequately prepare, and expeditiously manage disaster situations to minimize business, customer, and patient impacts.

SCOPE

- Applicable to any life sciences business, including corporate functions and manufacturing or distribution centers.

PRE-ESTABLISHED PLANS

- Phased business recovery plans including:
  - Disaster Response Plan
  - Business Continuity Plan
- Risk, Severity, and Industry Type will determine complexity

Natural Disaster Contingency Planning

RISK EVALUATION

- Evaluate potential for a specific natural disaster to occur.
- Evaluate risk to business once disaster strikes.

PREPARE PLANS (DISASTER RECOVERY & BUSINESS CONTINUITY)

- Disaster Recovery:
  - Prepare the contingency plan command center
  - Personnel disaster response efforts
  - Facility disaster response efforts,
  - Product and service disaster response
- Business Continuity:
  - Conduct business impact analysis
  - Identify critical functions
  - Organize business continuity team
  - Conduct training

Natural Disaster Contingency Planning

EXECUTION OF PLANS

- Immediately activate prepared plans and Disaster Command Center
- Disaster Response Kit
- Communications
- Initiate BCP in parallel

POST-MORTEM

- Periodically test the plan
- Debrief to assess events
- Assessment of response and lessons learned
- Update plans as necessary

CONCLUSION

- Understand the disasters which can affect an organization
- Understand how this may impact the business.
- Prepare both disaster response plan and business continuity plan.

Best Practices Quality Agreement Guide

RX-360 BEST PRACTICES QUALITY AGREEMENT GUIDE

SCOPE

- Mutually agree to establish a Quality Agreement
- Evaluate Risk
- Determine the appropriate Quality Standard(s)

STRUCTURE

- Identify the appropriate template or structure for use in the context of the **product** and **parties**
- Organize the document for logical flow, including numbered sections, aligned headers, and roles and responsibilities in columnar form

FRAMING CONTENT

- Edit templates so content is comprehensive, relevant, focused on scope
- Ensure timelines, when warranted, are **explicitly defined**

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Best Practices Quality Agreement Guide

TECHNICAL CONTENT

- Identify and include appropriate relevant quality terms and/or definitions
- Ensure applicable legal terms are provided

NEGOTIATE

- Using standard templates will save time
- Proposed changes should be explained / redlined
- **Quality** should negotiate with **Quality**

REVIEW

- Language should be **simple and unambiguous**
- Ensure that legal and quality perspectives are considered in the final review

Best Practices Quality Agreement Guide

SIGNATURE

- Dedicate authorized signatory and ensure signatory process conforms to contract and records protocols
- Confirm that both sides and the applicable jurisdictions recognize counterparts and digital/electronic signatures

MAINTAIN

- Utilize a central electronic repository and notification of target dates through EDMS/LMS systems
- Utilize appendix system if anticipate ongoing or frequent updates; consider a dedicated email to limit amendments to contact lists
- Include post-signature tasks in internal procedure

CONCLUSION

- Assists both Customers and Suppliers in efficiently managing:
  - initiation,
  - negotiation,
  - implementation, and
  - ongoing maintenance of quality agreements.
- Intended as a **reference guide** for **best practices** and should be used to streamline processes and provide simplified solutions for common tasks associated with Quality Agreements.

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Questions?

THANK YOU