



# Properly Qualifying Your Vendor: How and Why

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# Learning Objectives

- Discuss what is Vendor Qualification
- Describe the need for a 503a compounding pharmacy to have a vendor qualification process
- Review the SOPs and processes needed to begin and utilize a vendor qualification program
- Provide example of vendor qualification activities

# What is Vendor Qualification?

- **Ensure your operations has a well-executed vendor oversight process and it is performed in accordance with regulatory expectations**
- **Ensure appropriate sourcing and contact negotiations with vendors**
- **Establish positive vendor relationships**
- **Pharmacy should create a Vendor Qualification SOP**

# Who could be qualified?

- **Environmental Monitoring Service Providers**
- **Software Provider**
- **API provider**
- **Courier service**
- **Microbiology Lab for sterility testing**
- **Equipment provider for pharmacy operations**
- **Clean room device providers**

# Why Qualify My Vendors?

- **Compounding pharmacies utilize vendors**
- **Compounding pharmacies trust our vendors**
- **Compounding pharmacies utilize the services of our trusted vendors**
- **So why do we need to qualify them?**

# Why Qualify My Vendors?

- **Who is responsible for quality operations at your pharmacy?**
- **Who is responsible for ensuring your pharmacy is in compliance?**
- **Who do regulatory agencies hold accountable for pharmacy operations?**
- **Where does the ultimate accountability of your operations lie?**

# Why Qualify My Vendors?

- **Due diligence**

- Ensure vendors/services providers do what they say they are doing
  - Review of the Vendor's SOPs
- Ensure vendors/service providers meet your regulatory requirements
- Ensure vendors/service providers meet your expectations. Can be service, price, responsiveness, and more

# Example Qualification: Environment Monitoring Qualification

- **Is equipment used in date and validated**
  - How is it validated
  - How do they ensure it is in date
  - What is providers testing policy
- **What is the providers training processes**
  - How are staff trained
  - Is it appropriate
  - Does it meet the pharmacies regulatory requirements
- **Has the vendor had false positives**
  - What has been corrective action
  - Do they have a CAPA process
  - Do they have a Quality Manual
- **Pharmacy should review these documents**



# Qualify current vendors

- **If creating a new qualification process, first need to qualify current suppliers**
  - Separate all vendors into categories
    - Critical
      - API Provider
    - Major
      - Courier service
    - Minor
      - Cleaning service provider

# Complete Vendor Qualification

- **Start with Critical category**
  - Vendors/providers will complete a questionnaire
    - Onsite visit may be needed/wanted – According to your Vendor Qualification SOP
  - Review results and document if provider is accepted (pass/fail criteria)
  - Document results
  - Schedule a requalification – According to your Vendor Qualification SOP

# Complete Vendor Qualification

- **Continue with Major and Minor category vendors**
  - Onsite visit may not be needed
  - What about Drug Wholesalers?
    - Further define in your SOP the process for qualifying this type of vendor
- **Document if provider is accepted**
- **Schedule requalification – SOP**

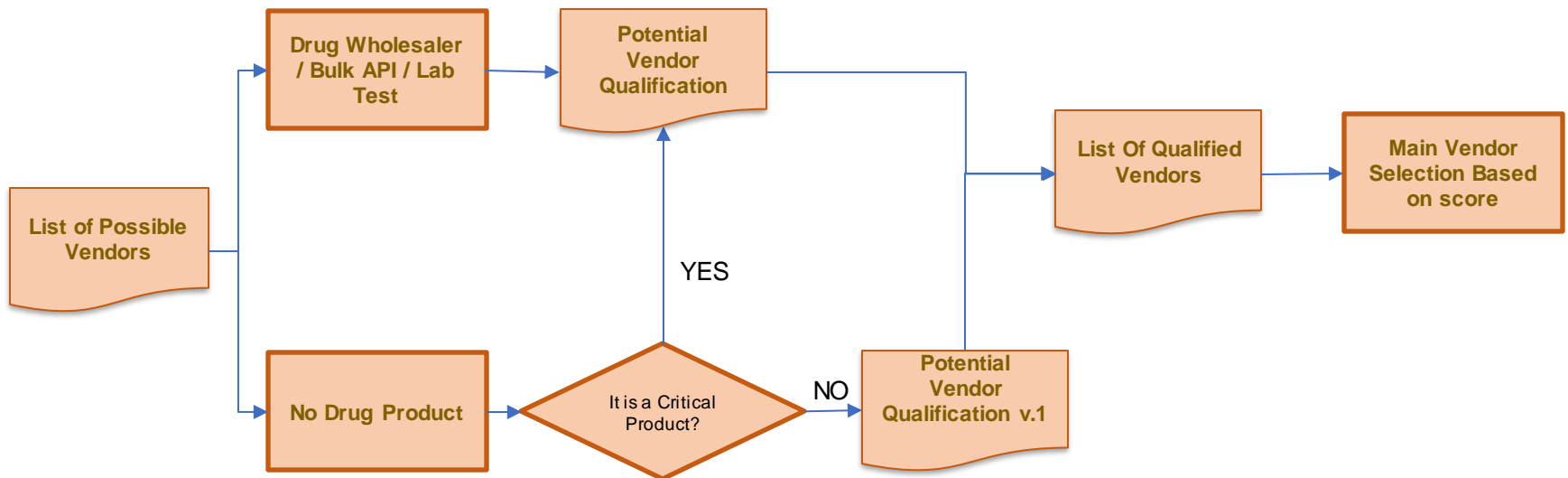
# Questionnaire

- **Questions focused on vendors processes and systems**
  - Quality Management
    - Does the organization complete with quality standards (GCP, GMP)? If so, ask for copies
    - Does the vendor have a documented quality system? If so, ask for SOPs
    - Are QA/QC responsibilities well defined? If so, ask for SOPs

# Questionnaire Categories

- **Create a list of questions for these categories**
  - Purchasing
  - Personnel
  - Facilities and equipment
  - Record retention
  - Computer systems
  - Complaints
  - Confidentially

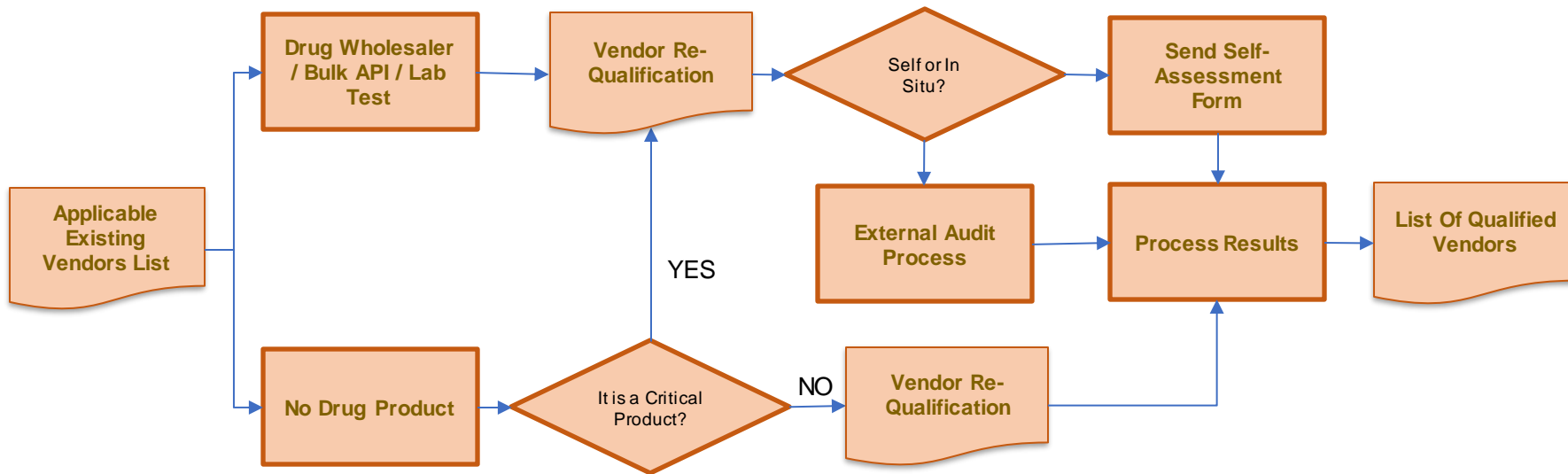
# Potential Vendor



# Requalification

- **“Inspect what you expect”**
- **Frequency should be defined by Pharmacy Vendor Qualification SOP**
  - Every 3 years
  - Sooner for critical vendors
- **May consider creating a requalification questionnaire**
- **May consider different vendors to visit onsite**

# Existing Vendor Requalification





# Create the Pharmacy Vendor Qualification SOP

- **Create an SOP based on these steps**
  - Create the process that works for you and then write the SOP
- **Review the SOP annually**
  - SOP on SOPs
- **Adjust based on process**
  - Who you visit
  - Who is critical, major, minor
  - SOP is a living document

# Thank you

Please contact me with any questions  
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