

Supply Chain and Supplier Auditing



Who Am I?

- ▶ Biomedical scientist.
- ▶ 20+ years experience in the pharmaceutical industry.
- ▶ Practicing QA Manager, QP, RP.
- ▶ Qualified Pharmaceutical Lead Auditor.
- ▶ Routinely plan, manage and execute supplier audit programs for small, medium and large organisations.



Why Conduct Supplier Audits?

As part of a vendor selection and onboarding process.

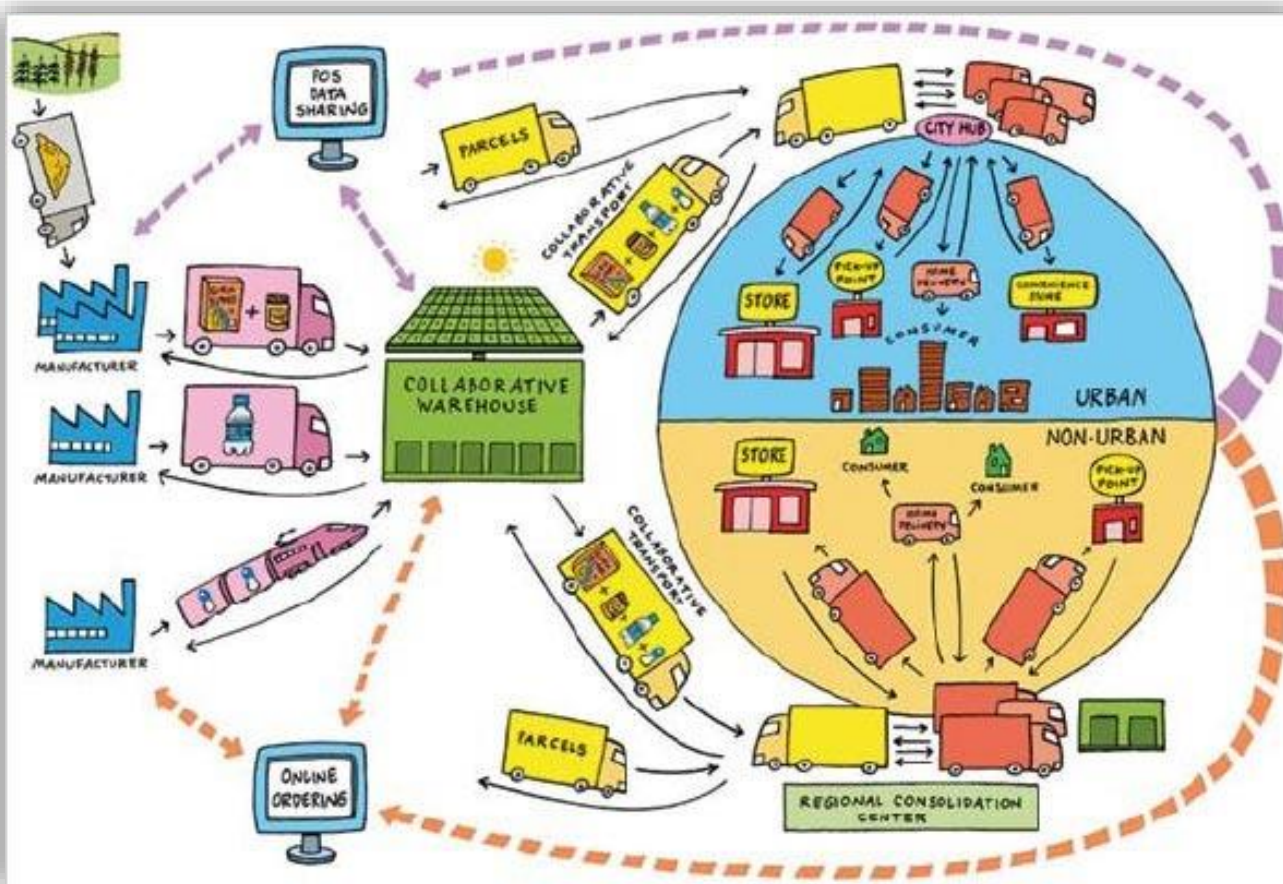
Periodic review of vendors as part of a company's internal control framework and prior to contracts being renewed.

Investigation into allegations of misconduct by the third-party.

Benefits of Supplier Audits

- ▶ Verify standards.
- ▶ Ensure that a functional QMS has been established.
- ▶ Identify risks.
- ▶ Active communication between customers and supplier.
- ▶ Strengthen long-term healthy business relationships.
- ▶ Development of suppliers can be documented and compared.
- ▶ Supplier risks and quality related costs can be reduced.
- ▶ Ensure quality throughout supply chain.

Complex Supply Chains



Risk Based Approach

Aim should not be to audit every vendor engaged by the organisation but to conduct a thorough audit with greater frequency for targeted, high-risk vendors.

Cost-effective.

Enhance the quality of the organisation's operation.

Risk Based Approach

- ▶ Operational risks.
 - ▶ Complexity of product.
 - ▶ Location of vendor.
 - ▶ Complaints, non-conformances, recalls.
 - ▶ Supplier KPIs.
 - ▶ Are they your only vendor?
- ▶ Regulatory risks.
 - ▶ Previous audit history with your company.
 - ▶ Previous inspection history from other bodies.
- ▶ Reputational risks.
 - ▶ Proactivity between audits.
 - ▶ Visibility of the product.
- ▶ Financial risks.
 - ▶ Single source?
 - ▶ Cost of product.

New Supplier Onboarding

Pre-Audit

- ▶ Research.
- ▶ Prepare.
- ▶ Focus.
- ▶ Target.
- ▶ Careful selection of auditor – not all are equal.
- ▶ What's your standard?

During Audit

- ▶ Build rapport.
- ▶ Fact find with kindness.
- ▶ Open, collaborative.
- ▶ Desired vs actual.
- ▶ What's the risk?
- ▶ Do you want to work with them?

Onsite Audit

General impression
of the production.

Plant equipment,
machinery and
manufacturing.

Internal and external
communication.

Quality
Management.

Testing instruments
and equipment.

Inspection.

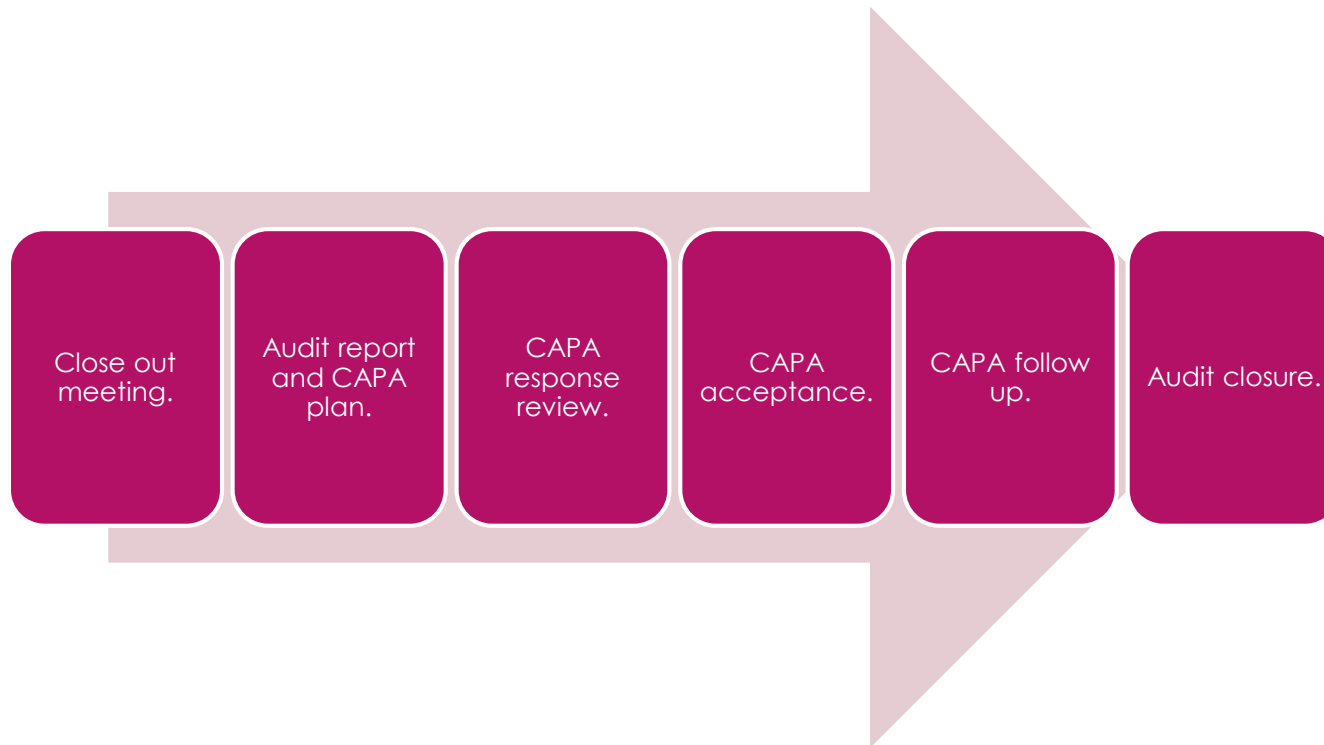
Employee
qualification.

Delivery reliability.

A story...



Managing Follow Up Actions



Rinse and Repeat?

Periodic evaluation

Timeliness of response
tells you a lot

Right to Audit

A right of audit clause within third party vendor contracts is a valuable asset in a company's compliance programme as it is increasingly common for customers, especially for government and large multinational customers, to mandate and exercise it in their supplier contracts.

Conclusions

- ▶ Rigorous and thorough vendor audits send strong, compelling compliance messages throughout the organisation and to the company's third party vendors demonstrating that the company values transparent and compliant behaviour.
- ▶ Taking a risk based approach focusses activity.
- ▶ Place value on the process, on the auditor, on the outcomes.
- ▶ Vendors should, in turn, be less inclined to engage intentionally in unethical conduct if they know that an audit may be conducted at any time.
- ▶ Vendor audits are, therefore, often an effective way to demonstrate and evidence a company's careful oversight of supply chain management from a compliance perspective.
- ▶ Companies should be prepared for their customers, especially government agencies and large multi-nationals, to want to exercise their right to audit clause within their contracts.

Any Questions?

thank
you



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