

Case Study

Navigating the Edge: Managing 100% Outsourced Manufacturing Risk

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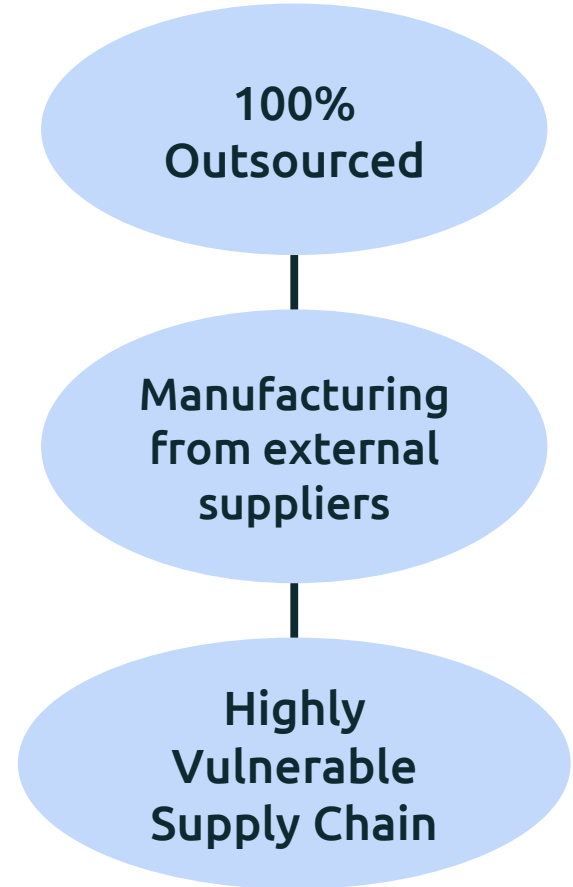
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Introduction

Pharmaceutical Company



Reasons to Outsource

Contract Manufacturing Organization (CMOs)



**R&D
Evolutions**



- Biologics
- Cell and gene therapies
- Personalized medicine



**Advanced
Facilities**



- Quality Control Systems
- Automated Manufacturing processes
- Comprehensive regulatory compliance



01

Key Risks Identified

We own the responsibility even if we don't own the machines

Risks Identified

01

Lack of Confidentiality

Third Party suppliers can gain access to **restricted company data**, and can utilize it for their own gain, increasing vulnerability to cyber attacks

02

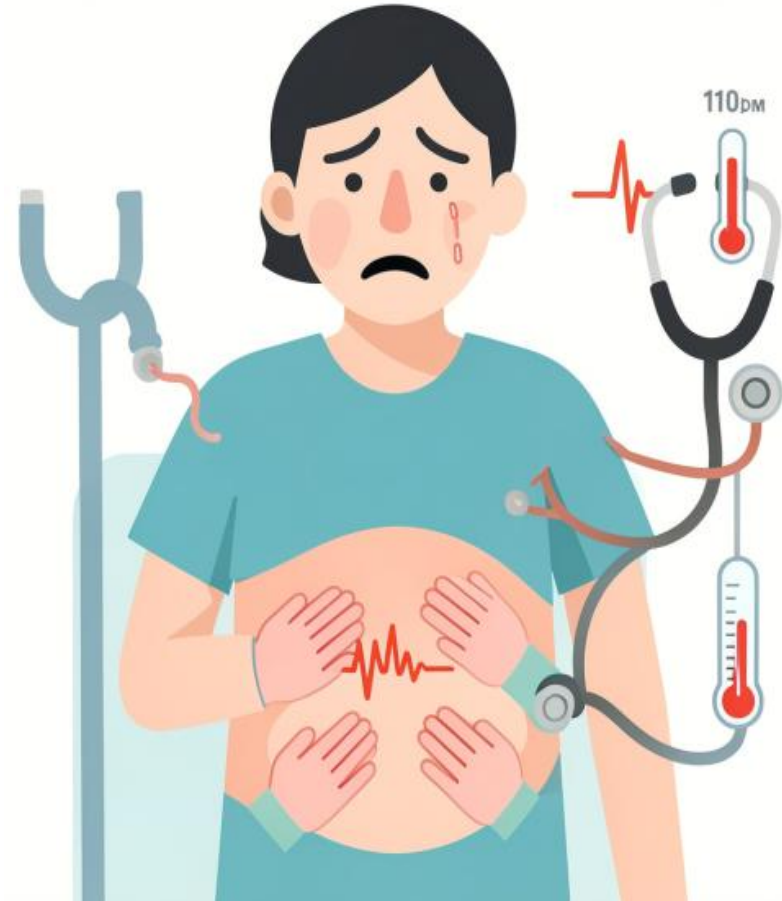
Loss of Quality

A vendor that lacks quality control can expose a **company to risks, failed inspection, and even product recall**

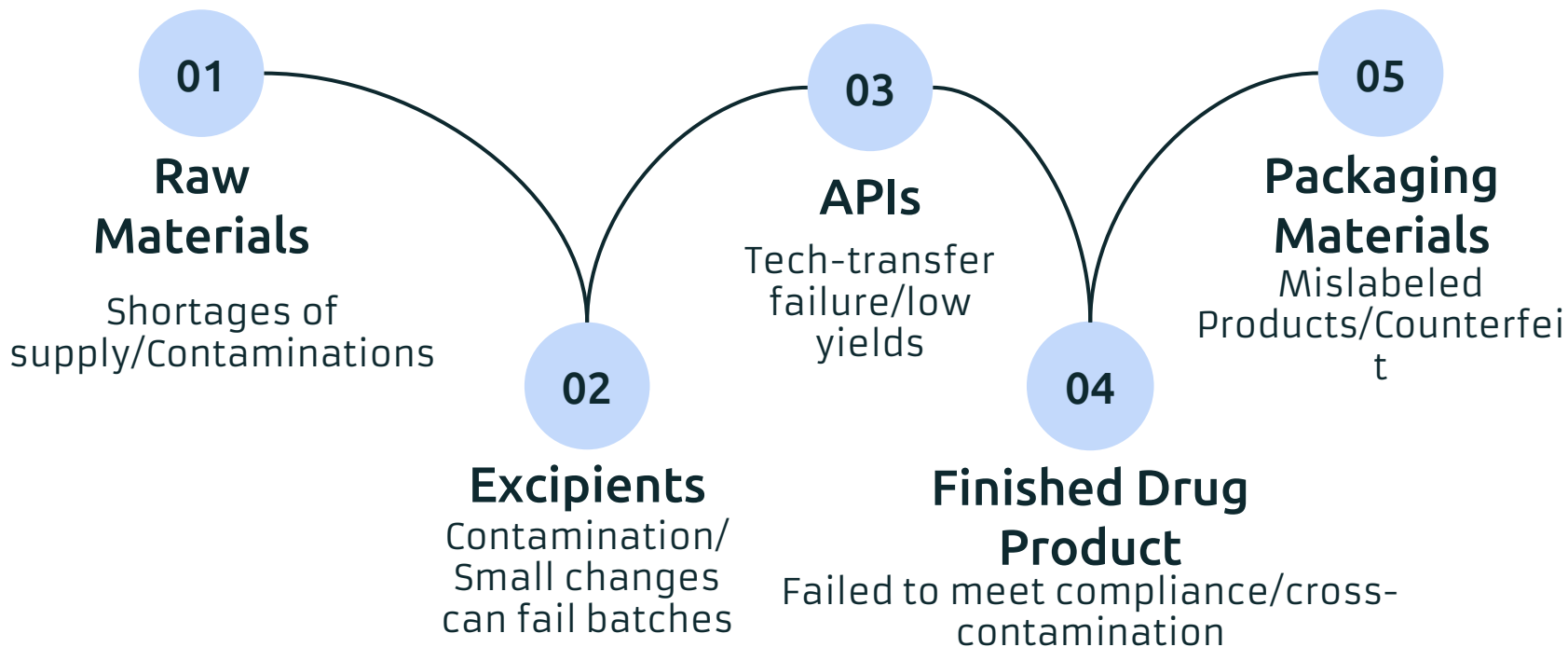
03

Communication Gaps

Delays, misinterpretations, and even **inconsistent handoff** between both sides can lead to massive errors



Risk Across the Pipeline



02

Risk Assessment Approach

Identify, Measure and Prioritize = Proaction



Key Questions to Ask

1. What could go wrong with suppliers?
2. How likely is failure?
3. How severe would punishments be?





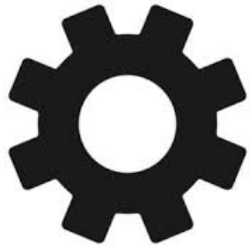
Research

1. FDA Warning Letters
2. Company History - Regulatory History
3. Experience
4. Equipment and staff quality
5. Operations Capacity

Supplier Risk Assessment (SRA)

Operational Reliability

- Delivery Time History
- Production Delays
- Capacity Limits



Financial Stability

- Supplier financial history
- What are the spending their budget on



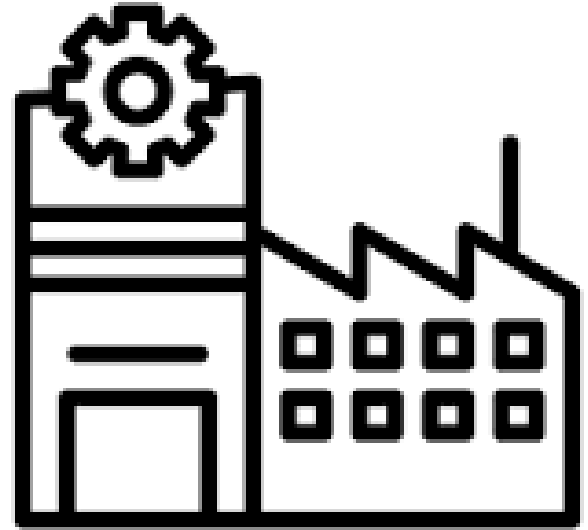
Geographical Risk

- Location, how far away
- Exposure to Political, Natural, Trade disasters



Quality Risk Assessment (QRA)

- Manufacturing Process Risk
 - Stability
 - Control (Contamination)
- Production Quality consistency
- Compliance with Regulations
- Testing systems
- Human error and Training



Time-to-Recovery (TTR) Analysis

If the supplier shuts down?

- How long would it take them to
 - Fix production issues + Restart operations + Resume delivery
- Availability of alternative
 - backup suppliers + Tested and Vetted
- Regulatory Restart Time
- Emergency Inventory



03

Mitigation Strategies Implemented





01

Mitigation Strategies

Supplier Diversification

- Source from multiple suppliers across different regions
- Avoid geographic concentration risk
- Minimizes the impact of localized disruptions

02

Strategic Safety Stock

- Maintain safety stock for essential products
- Stockpile key raw materials
- Ensures short-term continuity during disruptions.

03

Investment in Visibility & Technology

- Track supplier performance in real time
- Monitor potential disruptions early
- Improve demand forecasting

Executing Mitigation Strategies

I. Supplier Onboarding & Qualification

- a. Identify and vet alternative suppliers
- b. Conduct regulatory approvals and quality testing
- c. Establish contracts and production capabilities

→ Ensures backup suppliers are ready before disruptions occur

2. Phased Rollout Timeline

- a. Short-term: Build safety stock, update contracts
- b. Mid-term: Qualify secondary suppliers
- c. Long-term: Implement digital monitoring systems

→ Short-term wins and long-term resilience

3. Technology Integration

- a. Implement supply chain visibility platforms
- b. Integrate supplier data into centralized dashboards
- c. Train teams to use real-time monitoring tools

→ Enables proactive decisions using accurate data



04

Outcome

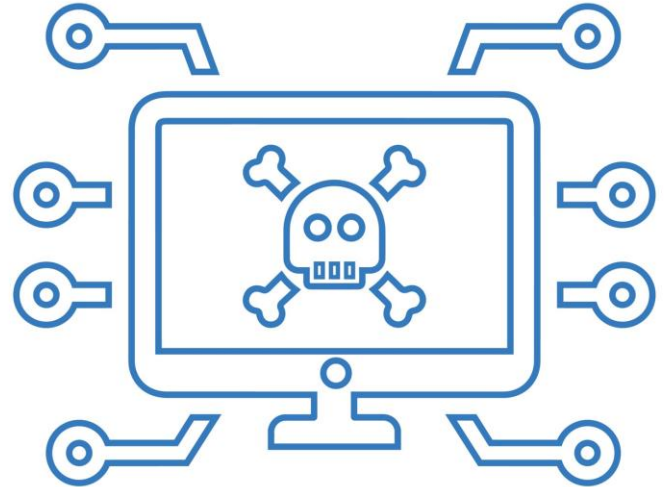
Expected Outcomes of Confidentiality Risk Mitigation and Supplier Diversification

01

Reduced possibility
of confidential data
leaked

Reduced sharing of IP
through controlled
supplier segmentation
and limited data
sharing

02



Expected Outcomes of Quality Risk Mitigation and Strategic Safety Stock



01

More oversight into outsourced quality management initiatives, and implementation of standardized processes

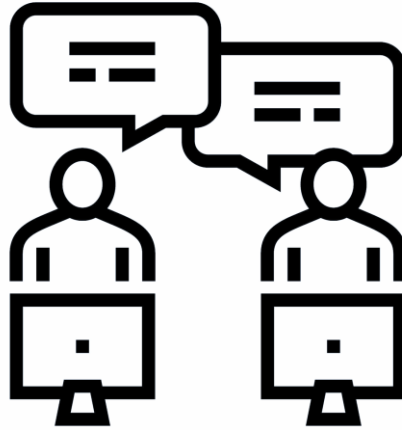
Reduction in stockouts from quality failures through maintaining a inspected safety stock

02

Outcomes of Communication Fallouts Mitigation and investment in visibility systems

01

Improved visibility and a restructured, streamlined communication system



02

Faster issue recognition through real time supplier performance data