

# Risk Assessment of Outsourcing Pharmaceutical Packaging

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# Why Outsource?

- Technical requirements
- Capacity requirements
- Speed of Setting up
- Location - market requirements
- Costs!



# What to Outsource?

- Primary packaging operations
- Secondary packaging operations
- Primary & secondary packaging
- May include
  - pack design
  - artwork
  - sourcing of materials



# How to Outsource

- **Assess internal (own) resources**
  - personnel
  - facility
  - equipment
  - capacity
- **Assess external resource availability**
  - personnel
  - facility
  - equipment
  - capacity



# How to Outsource

- **Assess ability to manage contractors**
  - technical support
  - product/technology transfer
  - auditing & monitoring
- **Consider associated risks**
  - doing it in-house Vs
  - outsourcing



# What should be considered?

- technical knowledge requirements
- product(s) characteristics
- facility & equipment
- cGMP - ability to comply!
- location - logistics considerations
- capacity - availability
- personnel requirements
- regulatory requirements



# What should be considered?

- assess internal resources
- do we have suitable facility/equipment?
- do we have sufficient capacity?
  - people
  - facility & equipment
  - infrastructure, e.g.QC/QA, warehouse, etc.
- do we have technical expertise?
- any limitations,e.g. regulatory, market,etc.
- costs!



# What should be considered?

- assess external resources, can you find a company with required:
  - technical expertise
  - capacity - facility & equipment
  - resources - people, infrastructure
- are they located where you want them?
- regulatory consideration
- local market considerations
- costs!



# Risk Assessment

## Risks - in-house!

- insufficient knowledge (technology!)
- poor /lack of local market requirements
- insufficient capacity
- may require capital investments
  - costs
  - lead time, design, build, install, validate
- overall unit cost may be too high!



# Risk Assessment

## Advantages - in-house

- under own control
- can implement operations in line with own policies and procedures
- limited management issues
- staff development



# Risk Assessment

## Risks - outsourcing

- confidentiality issues
- technical knowledge
- resource availability
- capacity - (in line with your timelines!)
- other products in the facility
- other customers!
- communication & management issues



# Risk Assessment

## Advantages - outsourcing

- technical knowledge for specialist products
- local market advantages, e.g regulatory
- resource availability
- logistical advantages (e.g. close to market or region)
- potentially lower costs!



# Developing Requirements

- What is it you want to outsource?
  - Primary packaging
  - secondary packaging
  - both
  - sourcing of materials
- what standards do you expect?
  - regulatory
  - local market
  - own company



# Developing Requirements

- Document your expectations on
  - quality standards
  - volumes/spread over say 12 months
  - regions to be covered
  - stock control
  - support availability, tech transfer, validation
  - audits
  - right to visit
  - dealing with complaints



# Developing Requirements (Setting priorities)

High = must have

- meeting cGMP standards
- validation
- regulatory approval
- capacity
- cost?!!



# Developing Requirements (Setting priorities)

Medium = would like to have but will accept alternatives

- sourcing materials from your approved suppliers
- use of dedicated facilities
- stock holding

• Low = nice to have



# Decision Making

Assess risk, considering

- requirements
  - in-house advantages
  - in-house disadvantages
  - outsource advantages
  - outsourcing disadvantages
  - priorities
- First level decision



# Decision Making

If decision was to outsource, then;

- identify potential candidates
- conduct due diligence audits
- prepare short list
- second risk assessment
- use knowledge from audits
- assess against the requirements and priorities



# Risk Management

- detailed contract with the contractor
  - business
  - quality & technical
- prepare technical transfer documentation
- provide technical support (product data)
- agree roles & responsibilities
- prepare mitigation plans for each risk
- monitor progress, including the first launch



# Summary

- outsourcing packaging can be a good short or long term solution
- ensure you know and have documented your requirements
- have a robust selection process
- always challenge against in-house option
- must have sufficient resource to transfer technical knowledge, implement & validate



# Summary

- must have sufficient resource to continue support, monitor and audit
- a good detailed technical agreement will minimise problems
- if cost is the main driver, then ensure you include cost of technical transfer and support required!

