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# Outsourcing: Choosing your service provider



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Knowledge and safety are paramount  
“Your product, your responsibility”



# Outsourcing

## What does 'good' look like?

- The contract giver knows what they need
- The **risk** of outsourcing compared to the risk of **not** outsourcing
- All options considered by the right people
- Options evaluated with audits - before the decision.
- The agreement provides for:
  - Explicit responsibilities
  - Regular audit
  - Reporting
  - Control measures
  - Reporting the expected and unexpected.
- Audits identify critical control points and issues, and these are resolved.

Know your supply chain. Focus on patient safety & product quality

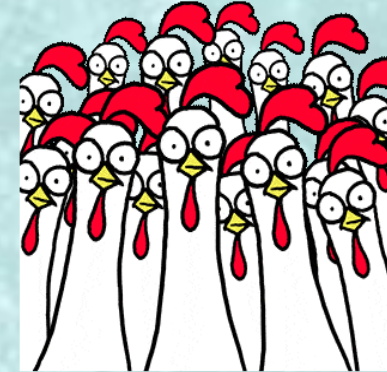
# Outsourcing – choosing your service provider



Identify what exactly you need to be outsourcing & why



Do we have the capability?



Involve the right people



Cost benefit analysis



Pre-audit checks & agreements



Make the right decision

# Outsourcing storage:

**Scope** – full access,  
nothing hidden

Workflow – logical,  
accommodating of  
your product

Attitude – exhibiting  
the right behaviours

Management –  
seniority,  
knowledgeable,  
focus on continuous  
improvement.



# Outsourcing transport:



- Who am I contracting?
- Security of product
- Use of sub-contractors
- Cross-docking
- Using agency staff.

# Outsourcing transport:

- Contingency
- Route risk assessment
- Cross contamination



Remember - Global supply chains are longer than ever.

# Outsourcing personnel:

## Key staff e.g. Contract RP

Why are you outsourcing this key role?

### The conundrum:

I engage a contract RP because I don't have enough knowledge

**BUT**

How can I do this if I don't have enough knowledge myself?



## Ancillary staff e.g. Dual roles

'A wholesale operation within a wholesale operation'

### Essential:

- Primary employer defined in QTA
- Clearly set out in each QMS
- Defined in employment contract
- Training responsibilities defined
- Audit expectations clear.

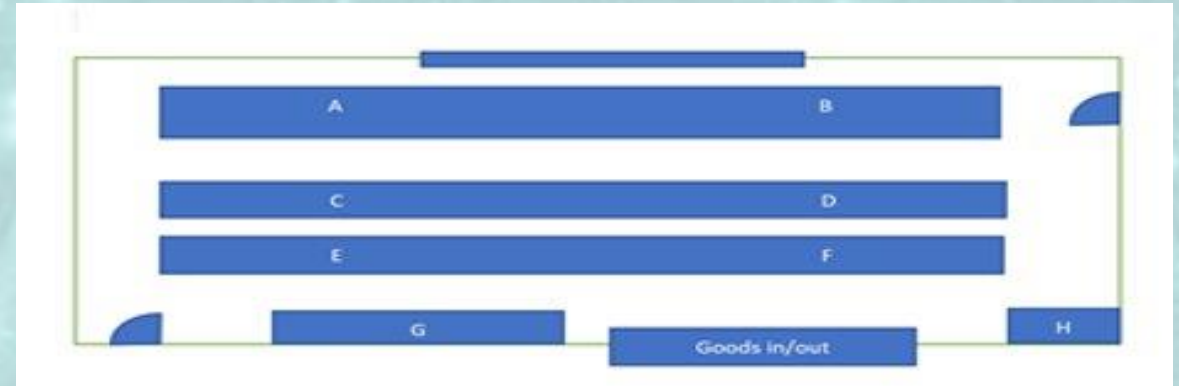
See our website article: **'Choosing a Responsible Person'**  
to understand more about outsourcing personnel.



# Outsourcing other activities:



HVAC System-Regularly maintained/contracts reviewed/contingency for breakdowns?



Warehouse Mapping - Is it conducted by an external company? Do you review the scope, methodology and conclusions?

Freight Forwarders- Do you know what documentation is needed to be retained for audit purposes? What activities do they do on your behalf?



# Summary

## ***Written agreement***

Are agreements suitable for each party?

Watch out for arrangements changing over time

Regular review and improvement

Consider continuity/contingency plans (weather, staff, breakdowns)

## ***Other considerations***

Carry out audit prior to and following an outsourced approval

Ensure your wholesale licence is reflective of all licenced activities

Change control & KPI's/QMS changes

Involve the right people/staff training

## ***Review chosen company/Individual***

Reputation- have they been recommended?

Authorised for intended purpose

Experienced/knowledge of activity/medicinal product

**Know your supply chain- focus on patient safety and product quality**



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