

Developing a “Roll Out Plan”

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A partnership

- The following content is an expression of equal partnership in the aims and goals of adopting the IPAC-RS GMP guideline
- Bepak is a certified supplier for sanofi-aventis Holmes Chapel. Preparing this presentation was just one of the many ways we work together
- And so you're stuck with us both!!!

Outline

- The Product & the why – with case study examples
- So what should we do? – rolling it out
- What to do next
- What to do with Challenge
- Auditing
- In Summary
- Questions

The Product and the why

- Any product along the supply chain is not a product without partnerships along that supply chain
- The quality of the product received by the patient is the result of the total supply chain stream
- Contributors in that supply chain need to know and understand their impact on that product quality
- The extent of that impact defines the required level of familiarisation of the IPAC-RS guideline.

A MDI is composed of many parts!!



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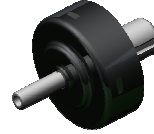
Example of OINDP Device Components and Sub Components

Inhaler Type (N)	Primary Packaging (N-1)	Sub-Component (N-2)
Metered Dose Inhaler (MDI)	Canister	Material of construction (aluminium, stainless steel, etc.) and coatings (e.g. Polymers)
	Metering Valve	Metal components (e.g. Spring), polymers (e.g. Metering chamber), elastomers (e.g. gaskets and seals).
	Actuator/Mouthpiece	Polymers

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Case Study - Understanding criticality

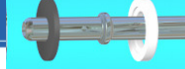


- Product Complaints
 - Patient reported that a valve would not function
 - Reported to N-1 by N
- N-1 investigation discovered stem hole out of position
- Root Cause:
 - Build up of waste material on machine at N-2
 - The dimension was not classified as critical
 - Low level checking
 - Skip Lot acceptance – checks not done on every batch
- The product is used with an overcap on the ferrule. Due to the slight change in hole position on the stem, the overcap ended up covering the stem hole
- Thus all testing through the lifecycle was satisfactory as function testing is performed without the overcap.

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Case Study – Importance of good change control



- N-1 Supplier requested N opinion on a metal component that exhibited some fissures/cracks on metal flange of a valve stem
- Potential that this could cause leakage in end product
- Investigation identified that the N-1 had recently changed to an alternative supplier of steel (N-2). But N were not aware.
- N-2 new supplier steel grade was the same but had a slightly greater proportion of certain minerals which affected its processing performance when converted into the stem shape
- Initial evaluation request ensured issue was captured and solved
- Highlighted the importance of having a robust change control process and good dialogue to ensure appropriate assessments are made ahead of change.
- Also to include N-2 expertise in the dialogue to ensure whole supply chain is involved during potential changes.

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So – what should we do?

- Assess suppliers to evaluate if the guideline applies to their activity
- Assess the impact of what your supplier does on your customer's needs
- Identify present Quality systems in place at the supplier. Do they know of the guideline? Are they on a 'path of knowledge'?
- Perform in house assessment of requirements of the product versus clauses in the guideline
- Consider a Risk Management approach
- Perhaps make a matrix???

The Matrix (there is no spoon!!)

	Change Control (7.2.3.1)	Control of extractables (8.2.4.4)	Component batch documentation (7.5.3)	Component Cleaning (9.2)
N-2 A Raw Material – Polymer	■	■	■	■
N-2 B Spring	■	■	■	■
N-1 C Can	■	■	■	■
N-2 D Gaskets	■	■	■	■
N-2 E Ferrule	■	■	■	■

Two examples of difference

- Change Control is important to everybody
- Extractables – applicable for rubber supplier but not for ferrule supplier.

Rolling it out.

- How much resource can you commit? Be realistic. Can we gain from other company's rolling this out at the same supplier?
- How are we going engage our suppliers and change mindsets if it is needed?
- Emphasis on the evolution of the guideline is key for suppliers who are already fully ISO certified.

Rolling it Out

- At all key business meetings with relevant suppliers, take a copy of the guideline and promote it
- Explain the guide, it's reasons for being and indicate your intentions to use it
- Provide details of how to obtain a copy (unless you can afford to give copies away!!)
- Spread the word!!

What to do next?

- Customer and supplier discussion the requirements of the product versus clauses in the guideline
- Recommendation to perform gap analysis of suppliers Q systems against the guideline
- Assess criticality of gaps and what needs to occur to bridge them.
- Use the guideline as the tool to aid bridging those gaps
- Agree expectations and timelines
- Utilise ongoing business meetings, audits etc as a means of monitoring progress as part of your regular supplier management program.
- *There is no broad brush approach to take as it depends on the needs, levels of knowledge and criticality.*

What to do with Challenge?

- What if the supplier cannot meet all of the guideline requirements?
- Utilise a risk management approach to assess critical aspects of the supply – the 'must have' rather than the 'nice to have'
- Understand the potential barriers and work together to agree a rational approach moving forward
- The importance of dialogue and understanding reasons is key for both parties.

Auditing

- When arranging audits indicate the guideline as a reference document for the audit and include in introductory meeting
- Audits are a useful tool to help with a gap analysis of the supplier Q system
- Supplier can use the guideline to aid in preparation for the audit
- Quote sections of the guideline in audit reports where necessary to enhance knowledge.

In Summary

- Define your own timelines and work with your suppliers. There is no fixed rule, we all have different resources, risks and criticalities
- Once the ball is rolling, keep the momentum. If you back off, they may back off too
- GMPs and quality standards are continuously evolving. If changes are implemented in the guideline ensure that your suppliers are aware
- Simply – just use the guideline.

- “By failing to prepare, you’re preparing to fail” – Benjamin Franklin (1706 – 1790)

● Questions