"A View from the Trenches, Evolving Quality Systems in Contract Manufacturing of Listed Medicines"

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PharmOut

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SME Listed Medicines Manufacturer of :-

- Oral Liquids
- Topical Creams, Balms & Gels

and

- Health & Beauty Care

COMPLIMENTARY MEDICINES - CHALLENGES

- Significant product supply is by third party manufacture
- Large number of SKU's
- Shared equipment trains
- Constant product changes/iteration
- Ongoing price pressures continually driving sales/margin prices down
- Large number of Suppliers/Vendors who are not part of a "pharmaceutical supply chain

But listed is considered low risk

SPONSOR / MANUFACTURER RELATIONSHIP IN CM

- Many different customer sponsors
- Products under constant change
- Each customer with different requirements under their GMP agreements
- Varying levels of understanding of their compliance requirements
- Many trying to avoid as much cost as possible
- Many with little scientific understanding

LEGACY QMS

Many companies have legacy QMS which has been continually patches up to meet updated regulatory requirements

CM CONTRACT MANUFACTURING

- No sponsor loyalty
- Quality is simply a given

WHATS IMPORTANT TO A SPONSOR FROM A CONTRACT MANUFACTURER?

- Lowest possible cost
- DIFOT

EVOLVING QMS / QRM IN A CM ENVIRONMENT

- What do we want from our QMS / QRM?

- Compliance to ensure minimal risk exposure
- Continuous Improvement
- Management by level of Risk
- Efficiency so as to minimise the burdens of Cost

HOW DO WE AIM TO ACHIEVE THESE?

- Use QRM to prioritise and justify activities
- Streamlined efficient processes
- Robust production processes
- 'Grouping'

CLEANING VALIDATION

Requirements in CM

- Visually clean
- Conductivity

Traditional Way

- Review annually
- Set the validation schedule based on annual review and PQR

Problems

- Accounting for ongoing change in products & suppliers

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Evolving Prioritisation of Cleaning Validation

- Rate ingredients by a risk factor
- Each product generates a risk factor by equipment train for prioritisation of cleaning validation
- In-bed this into the QM systems

Process Validation

- Rate by number of active ingredients and consider if microdoses are present
- Use the same method for Process validation
- Solubility factors
- If any ingredients are scheduled etc above certain doses
- Equipment train
- In-bed this into the QM systems

Vendor Qualification

- Large number of vendors & SKU's
- The industry is allowed to use a paper audit but this is limited
- Suppliers who are either food or generic packaging companies
- Many sponsors insist on supply of their own materials or components but the manufacturer is still responsible for vendor qualification

RELEASE FOR SUPPLY - CHALLENGES

- Ensuring that the sponsor performs their obligations under the GMP Agreement
- Letting sponsors do stability? The validity of stability trials and test used
- Transport post supply, transport validation
- Label compliance

INVESTMENT IN TECHNOLOGY

- Continuous monitoring
- Cost benefit to invest when the SKU's constantly change?
- No guarantee of consistency of business

Continuous Improvement of the QMS/QRM?

Quality is a journey not and end

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Thank you!