Day 1 Readout 16th May 2023

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Annex 1 Workshop Co-Chairs

17th May 2023

PDA Parenteral Drug Association

2023 Annex 1 Workshop Series (Singapore)

CONNECTING PEOPLE SCIENCE AND REGULATION®

P1: Insights from Regulators

- The implementation date for EMA is the 25th Aug! PIC/S countries will decide on the implementation date country by country
- Companies should be well underway in their Gap Analysis and remediation. Many requirements are not new, but are better explained in Annex 1
- Quality Risk Management (QRM) on Annex 1 non compliances are crucial. Example was given on the separation of Material/Personnel airlocks. New facilities – design in Annex 1!
- As operating companies, we should not be asking regulators what best practice for QRM looks like. We know our process, we know our risks, and we need to risk manage. The regulators job is to check we have done it impartially
- Aseptic Process Simulation – bad practice is not to be validated (e.g. power cuts). Possible interventions though should be simulated. Companies can mitigate power trips risk with UPS solutions. Same for Air Visualization Studies – these should mimic real life worst case

P2:PQS Principles and Annex 1 (Breakout session)

- Feedback from participants and companies – Annex 1 implementation is having an impact in terms of time and resource to implement. Gap analysis is underway but remediation by 25th August is proving a challenge – sometimes linked to due to constraints linked to suppliers availabilities to aid in remediation.
- QRM has been around for a while, but some companies still unsure on how to do a CCS in terms of standardized templates (Wait for P4!)
- QRM knowledge and experience gaps on both sides (operating company and regulators)
- Companies are getting a bit blinded by the challenges of implementation – companies need to step back, reflect and be creative in proposing solutions to Annex 1 requirements. Investment for some points is longer term solution – companies need to use QRM to propose more immediate remediations/mitigations
- For ATMPs RMM is advocated for implementation because of risk / benefit profile. Companies should be courageous. This is the inflection point!

P3:Premises / Barrier Systems (Breakout session)

- Smoke studies- no requirement to requalify at a certain frequency, only when there is a Change. However, do not present a 10-year-old video to Regulators! Regulators do view these videos, also to better understand your process
- We are not compelled to rotate 2 or more broad spectrum disinfectants. However about 65% of companies still rotate. Each organization needs to gather evidence to support the utility of this approach, or do not do it.
- Residues have to be removed. You disinfect on clean surfaces. Outstanding questions – how to validate disinfectant removal, how frequently do you remove them, how do you identify residues (visual?), frequency of sporicidal applications
- Stopper bowl – VHP is NOT a sterilant. Suboptimal design of introduction of bowls at present
- Introduction of stoppers can be suboptimal from a technology perspective (But we have stopper processors that can dock to isolators)
- Pharma is slow and resistant to adopt change – why? Where is our Courage

General Feedback

- Thanks to Regulators present in the room for the openness and sharing of your reflections
- Thanks to participants for being so respectful of others in breakout sessions (no phones!)
- Lots of questions on topics that are yet to be presented (please be patient)
- Thanks for facilitators in collating the feedbacks

Thank You