PQRI Workshop: Managing Excipient and API Impact on Continuous Manufacturing – May 17-18, 2022

PQRI Workshop Planning Committee – Chair: David R. Schoneker, IPEC-Americas

Product Quality Research Institute

Workshop Objective

To bring together both industry and regulatory experts to discuss the impact of excipients and APIs in Continuous Manufacturing (CM) of Pharmaceutical Products (Benefits & Challenges).

Key Take-aways

- Identify and evaluate excipient and API properties (possibly new) which could impact the continuous manufacturing process.
- Mitigate failure modes in Continuous Manufacturing related to excipients and APIs.
- How to design for excipient and API variability in Continuous Manufacturing.
- Apply experience from decades of Continuous Manufacture of Excipients, APIs and other industries.
- How to develop new excipients and grades designed for Continuous Manufacture.
- Implications for Continuous Manufacture of API Composites

Learning Objectives

Continuous Manufacturing and Excipient/API Impact

- Understand the current status of the ICH Q13 guideline and how ICH Q8/9/10/11 can be used to support and improve CM processes
- Identify Productivity considerations that exist in the Continuous Manufacture of Biologic Drug Substances
- How to bridge the gaps between batch and continuous manufacturing regarding the processes and material properties

Regulator and Industry input on API and Excipient impact on existing approved CM drugs – Risks and Mitigation?

- Hear about FDA and industry's experience on the impact of characteristics of API and excipients on Continuous Manufacturing
- Understand the quality and regulatory considerations in risk assessment and mitigation
- Learn about the industry's experience in developing and/or supplying excipients used for Continuous Manufacturing

Impact of Material Properties and Variability on Continuous Manufacturing

- Learn about the impact of Excipient variability: understanding intra- and inter-lot variability and the need for process robustness
- How modeling can assist in monitoring and development of the control strategy
- Understanding how QbD and design of experiments can benefit continuous manufacturing

Evaluation Techniques in Continuous Processing

- Understand the various PAT approaches and how they can improve the control of continuous manufacturing

Reducing Risks in Continuous Manufacturing

- Identify key process parameters and respective controls needed to maintain the state of the system within the design space.
- Identify and assess the role and impact of expected and unexpected variations and respective planned mitigation actions.
- Assess and evaluate the risks associated with the run time extension of manufacturing processes.
- Recognize potential failure modes of different unit operations and their relationship to input material's physical properties and respective mitigation strategies

Material Property Impact on CM Processes and Equipment

- Identify key material attributes of excipients and API that impact unit operations of continuous manufacturing
- Provide case studies highlighting the impact of excipient properties on unit operations
- Provide means for evaluating and selecting excipients to obtain desired final product made using Continuous Manufacturing
- Understand the significance of the standardization of material property characterization techniques

Information from Other Industries

- Learn how understanding what has worked in other industries can benefit Continuous Manufacturing for Pharmaceuticals

The Need for Novel Materials and Processes

- Learn what kinds of materials are needed and what types of excipients can be designed for purpose to enhance continuous manufacturing
- Hear about some novel excipient and co-processed API technologies being developed that could resolve some of the problems experienced with continuous manufacturing.
- Learn about the future of continuous manufacturing and development of innovative materials over the next 5 to 10 years

Breakout Sessions

Two Breakout Sessions will be held on the following topics to get participant input:

- Participant experience and challenges related to material property impact on CM processes
- What types of processing and characterization techniques and novel materials are needed to enhance CM going forward?

Registration

PQRI would like to acknowledge the Planning Committee members who have participated in developing the workshop program and we encourage anyone interested in continuous manufacturing to register for this workshop to learn from the experts and contribute your ideas

A pre-conference webinar will be held on March 30, 2022. Registration links will be available soon. PQRI may be developing a publication with the outcomes from the workshop proceedings.