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Regulatory and Quality Considerations for Continuous Manufacturing

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Regulatory and Quality Considerations for Continuous Manufacturing

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Regulatory and Quality Considerations for Continuous Manufacturing

- **Current draft intended <u>for discussion only</u> and will be revised prior to publication**
- **Outline of current draft:**
  - **Current regulatory environment**
  - **Regulatory considerations**
  - **Quality and GMP considerations**
  - **Regulatory and quality considerations for bridging existing batch manufacturing to continuous manufacturing**
  - **Gaps and Challenges**
  - **Glossary and definitions**
  - **References**

Key Messages (1)

- Continuous manufacturing provides multiple opportunities for improvements in pharmaceutical manufacturing
- The current regulatory environment supports advancing regulatory science and innovation, including CM
- Traditional concepts need to be further explored or modified, to advance the implementation of continuous processes (e.g. material traceability, residence time distribution)
- The regulatory expectations for assurance of quality and reliable and predictive processing, are the same for batch and continuous processing
  - A control strategy developed for a batch process, may not be appropriate when the same operations are operated in continuous mode
- Continuous manufacturing provides additional opportunities to design the appropriate controls into the system, rather than current industry practice on relying mostly on testing materials at the end of the process

Key Messages (2)

- The flexibility of cGMPs supports new manufacturing technologies including continuous manufacturing
- Risk analysis techniques and/or modeling tools should be employed to fully understand the process, the impact on product quality, and to develop the appropriate controls
- Continuous Quality Verification is well suited to the validation of continuous manufacturing processes
- Regulatory expectations for cleaning and cleaning validation are the same
  - For continuous manufacturing processes, some adjustments may be necessary

Proposed Discussion Points (1)

- Appropriate definition of state of control to assure quality?
- What are the expectations for testing/control of in process materials in CM?
- Are different assumptions appropriate for cleaning validation of CM equipment?
- Applicability of current regulatory guidances to scale-up and control issues?
  - Impact of regional requirements?
  - Are FDA SUPAC guidances applicable to CM?
- How and when should batch/lot size be defined?
- Should flexible batch sizes be allowed?

Proposed Discussion Points (2)

- How to meet current ICH stability requirements?
- Consideration for sampling location, frequency, volume and representative sampling?
- Lifecycle management (e.g. model maintenance, continuous process verification, equipment maintenance)?
- Are there different approaches in managing CM under PQS?

Next Steps

- Current paper will be revised based on:
  - Comments received before today
  - Symposium discussion and recommendations
  - Additional comments to be forwarded NLT June 6, 2014
- Feel free to send your comments and suggestions (moheb.m.nasr@gsk.com)