Next Steps and Closing Remarks

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Case Studies

API, Finished Product, Small and Large Molecules

- Case studies have been very interesting
  - for example:
    - Wide range of product types included
    - Linking product and process changes to clinical pharmacokinetics
    - Continuous processing and continuous quality verification
    - Some common approaches noted e.g. use of Quality Risk Management tools for initial identification of critical quality attributes and process parameters

Benefits of the workshop

- For regulators: awareness of real applications in the pipeline and a chance to share thoughts and issues from the perspective of an assessor or inspector

- For industry: opportunity to gauge the reaction of regulators to issues, which should be helpful in shaping future submissions and preparing for inspections

Opportunities for interaction

- Work-sharing project for variations to nationally authorised products when QbD and PAT is introduced in this way
- Dialogue with EMEA PAT Team on specific issues

Introductory remarks

- Each product will have its' own bespoke QbD development
  - ➢ from a conventional to an enhanced QbD approach
- Application of QbD is not static; it should be a dynamic process throughout the product life-cycle
- Patient should be at the centre of the design
- Useful to explain rationale between development strategy and the overall control strategy

Areas for further consideration

- Role of assessor and inspector in new paradigm

- Knowledge management
  - What is knowledge vs. data?
  - What data should be included in submission and made available at time of inspection?
  - How do you optimise use of 'prior knowledge'?

- Opportunities for more dialogue during development and post-approval phase
  - Meeting(s) prior to and during submission
  - 'Scientific dialogue'

Areas for further consideration

- Post- approval change management
  - Extension or introduction of a new design space
  - How to handle ‘non-critical’ attributes and parameters?
  - Role of Post-Approval Management Plan
- Continuous Process (Quality) Verification
  - Alternative to conventional process validation approach
- Models
  - Management and maintenance of predictive models

Areas for further consideration

- Quality risk management
  - ICH Q9 sets principles
  - Industry and regulators now gaining experience of use
  - Industry must ensure robust application
  - Regulators need to encourage it's use

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Areas for further consideration

- Biological/Biotech products
  - ➢ QdD and QRM approaches are equally applicable to biological/biotech products
  - ➢ Specific challenges
    - Information to be included in submission (Q11)
    - Process Validation/Evaluation requirements
    - Use of scale down models
    - Is RTRT achievable?

Next Steps

- Debriefing meeting between EFPIA and EMEA PAT Team to reflect on workshop and discuss outcomes

- Outputs of Workshop
  - Publication of presentations on EFPIA and EMEA websites
  - Publication of joint EFPIA/EMEA report
  - Consider developing Q&As for input into ICH Q IWG or publication by EMEA

- Further workshop(s) may be considered

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