2016 MIT-CMAC CM Symposium: Regulatory and Quality Session

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Disclosures

- The speaker is solely responsible for the content of this presentation
- The views presented here do not necessarily represent the views of GSK

Regulatory and Quality Session Outline

- Introduction , Moheb Nasr, GSK
- Regulatory and Quality Considerations – Industry Perspective , Markus Krumme, Novartis
- Regulatory and Quality Considerations – US FDA Perspective , Larry Lee
- Regulatory and Quality Considerations – EMA Perspective , David Cockburn
- Regulatory and Quality Considerations – PMDA Perspective , Yoshihiro Matsuda,
- Panel Discussion

Introductory Remarks

- CM provides a unique innovation opportunity
- CM is a true and complete representation of Quality by Design (QbD)
- Good support from regulators, especially within ICH regions
  - More work is needed to assure global alignment
- Current regulations/guidelines do not prevent implementation of CM
  - Further clarification on some aspects needed
- We must remain focused and committed to assure success

Manufacturer Responsibilities

- Embrace the opportunity
- Utilize of modern science, engineering and control approaches
- Develop and justify the control strategy
- Assure regulatory Compliance
- Encourage enhanced dialogue with regulators

Regulators Responsibilities

- Encourage and embrace innovation
  - Work collaboratively with industry and academic institutes
  - Review and update some outdated regulatory guidances and practices
- Assure adequacy of proposed control strategy (fitness for purpose) and evolution of regulation
- Allow operational flexibility, without compromising quality
  - Manufacturer commitment to enhanced science and engineering should be encouraged and rewarded
  - Facilitate continual improvement and lifecycle management
- Utilize a pragmatic risk-based approach
  - Differentiate between risk to quality and “residual risk”