

Raw Material Variability Discussion – PPAR 2013 @ BMS

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Amgen

Raw Material Variation Poses Risk to Process and Product in (Bio)pharmaceutical Manufacturing

- Drug Substance

- Media and Buffers
- Disposables
- Resins and Filters
- Chemicals and Excipients



- Drug Product

- Buffers
- Chemicals and Excipients
- Primary Containers (syringes, vials, cappers, stoppers)



Understanding and Managing Supply Chain is Critical

Discussion Points

- Raw Material characterization
 - How much is being done up front?
 - How much PAT is being used for RM Characterization?
 - How to capture raw material variability across product lifecycle?
- Continued Verification and On-going trending
 - How much on going trending? Evaluate correlations to the product performance?
 - Multivariate monitoring to capture learning for RM variation post-commercialization
- How about controlling RM Variability?
 - Procedural controls? Specs?
 - Feedforward/feedback control?
 - Relationships with the suppliers to reduce variation?
 - Any prescreening (e.g., PAT-based/chemometrics based)?

PPAR Collaboration opportunity for electronic data transfer standards for Raw Materials

- An agreed upon pharma/biopharma standard would be helpful to lower the activation energy required with the suppliers (also a standard will reduce TCO)
- Proposal:
 - Form a working group from PPAR
 - Review Amgen's method for general applicability and gather comments to generalize across bio/pharma industry requirements
 - Approach ASTM E55 committee to draft the standard for publication (Preliminary approach via Duncan Low was positive)