

Tools and Strategies for De-risking Rapid Drug Substance and Drug Product Development

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*Part of the Crystal Pharmatech Webinar Series:
"Selecting the Right API Form and Formulation"
2020-2021*

Outline

- Commonalities of Early Development Objectives for Big Pharma and Little Pharma
- Form/Formation/Formulation: The practice of integrated development in Pharma and CRO environments
- The importance of Form and Managing the Form Selection process: ex Impact of Enantiotropy
- BCS and developability: Particle size and Mitigating new forms
- Process Induced Transformation and the presence of amorphous phase material
- Monitoring crystallization process changes and their impact through characterization and chemical analysis
- Accelerating stability determinations for DS and DP

Summary

- Form, Formation and Formulation have overlapping interactions that can influence product quality
- A combination of experimental and developability assessment tools can be applied to mitigate risks, identify decision points early, and define resource allocation
- “Tiny Pharma” can apply integrated development concepts by leveraging their CRO’s/consultant’s technical skills to focus down or steer development options through efficient pathways and avoid backtracking
- Proactive data acquisition during early development of API and formulation helps avoid surprises and creates a knowledge base to solve subsequent issues and improve the value of your asset.

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