ISPE Tech Transfer: From Process Development to Product Manufacturing (June 18, 2015)

Moderator: Bhavi Mittal, Sr. Scientist (Takeda)

INTRODUCTION TO EVENT

ISPE Connecting a World of Pharmaceutical Knowledge

ACKNOWLEDGEMENTS

Meeting Managers:
- **Jonathan Ly,** Barry-Wehmiller Design Group
- **Howard Sneider,** CRB Consulting Engineers
- **Zeke Johnston,** AMAG Pharmaceuticals
- **Norline Crossdale-Walker,** Genzyme

ISPE Boston, Education Planning Committee
- **Amy Poole**
- **Erin Young**
- **Charlotte Castillo**
- **Mike Levesque**

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Background and Motivation

- Technical transfer is a major component of pharmaceutical manufacturing operations.

- Historically, technical transfer was sustained and maintained within a company's existing infrastructure and was part of its culture.

- However, with the emergence of outsourcing as a successful business model, the knowledge and experience that used to reside within a company for tech transfer was increasingly fragmented (and sometimes lost!).

- Therefore, more than ever, it is important to understand, re-develop, and adopt good technical/business practices that can help in sustaining the tech transfer expertise in the outsourcing model.

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Our Goal

- For those looking to gain experience, we hope you leave with increased awareness of critical technical and business points for tech transfer

- For those who already have extensive experience in the sponsor – vendor world, we hope to provide you with a few new ideas to make that experience more successful

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Our Speakers

- **Joe Cobb, CPIP,** Director, Pharmaceutical Development, Metrics Contract Services/Mayne Pharma US

- **Gary Mills,** Associate Director, Drug Product Development, Momenta Pharmaceuticals, Inc.

- **Claudia Buser**, Director, Cell Banking Development, Genzyme/Sanofi

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Preparation for Today

- Speakers were identified by a steering group to highlight the viewpoints of sponsor companies and CDMO companies

- Speakers were requested to share their experiences on sponsor – vendor relationships

- Today's discussion is based around what speakers see as critical issues for successful sponsor – vendor relationships **in the context of tech transfer**

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