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

Moderator: Bhavi Mittal, Sr. Scientist (Takeda)

INTRODUCTION TO EVENT

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
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.

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
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

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