

"Are you ready for ICH E6 R2?" – Practical Solutions for Outsourced Projects

Wednesday October 18th 2017
Normandy Farm 1401 Morris Rd Blue Bell, PA 19422

AGENDA

Welcome Reception Tuesday October 17th



Sponsored by

- 08.30 – 09.00** **Tea/Coffee/Registration**
- 09.00 – 09.15** **Welcome and Introduction - Review of workshop objectives**
Rikker Winther and Lan Bandara, PCMG representatives
- 09.15 – 10.00** **Implications of ICH E6 R2 for Outsourced Studies**
Mark Aubrey General Manager, Head of QA Mitsubishi

- Introduction to ICH E6 R2 guidelines
- Impact on oversight for outsourced projects

- 10.00 – 10:45** **Quality Risk Management in MedImmune (Early Phase Biologics)**
Grace Crawford – Head of Clinical Quality & Compliance, Alfred Chester, Dir. of Clinical Quality and Compliance MedImmune

- Quality Risk Management Overview
- ICH E6 R2 and Trial Level Risk Management Plans
 - Systematic Risk Assessment
 - Establishing Thresholds
- Operational Implementation

- 10.45 – 11.15** **Coffee Break**

11.15 – 12.15 **RBM, why it matters !!!!**
Paulius Ojeras, Director Vendor Management, and Kirill Soldatov,
Director Process Improvement, PSI-CRO

- Why bother at all?
- What is mandatory and what is nice to have?
- Practicable support for RBM implementation (forms etc.)
- Improvement on quality

12.15 – 13.45 **Lunch and Networking**

13:45 - 14.30 **Smaller company perspective on E6 R2**
Jacqueline Delfgaauw, DELFGAAUW LLC

- How do small companies (e.g. biotechs) cope with this new guideline?
 - Are they even aware?
 - Do they have the resources needed internally?
 - If they outsource how do they choose a CRO?
- Case report(s) to talk about past experience
- Practical tips for choosing right vendor

14.30 – 15:15 **Supplier Oversight learnings from an EMA inspection**
Susanne Erman-Bech (CQA Inspections Area Lead, Clinical Quality Assurance), Lundbeck

- Original approach to risk based oversight
- Observations and comments from the inspection
- Considerations for future oversight

15.15 – 15.45 **Open interactive session**

15.45 - 15.55 **Meeting Summary and Close**