

2016 AQC Fall Member Meeting Agenda

November 3, 2016

8:30-9:00 am

Registration and Continental Breakfast

9:00-9:45 am

Session 1
Welcome and Review of Ongoing AQC Initiatives

Patricia Leuchten, President and CEO, The Avoca Group
 Lakshmi Sundar, Vice President, Strategy and Marketing, The Avoca Group
 Steve Whittaker, Executive Director, Avoca Quality Consortium

9:45-10:15 am

Session 2
Case Study: Harnessing AQC Tools to Gain a Jump Start on Drug Development Processes

Bruno Gagnon, BPharm, MSc, Executive Consultant, Clinical Operations

10:15-10:40 am

Networking Break

10:40-11:30 am

Session 3
Patient Centric Perspectives and Implications for Protocols

Denise Calaprice, PhD, Senior Consultant, The Avoca Group

11:30-12:15 pm

Session 4
A Case Study in Using Diligent for Technical Service Provider Prequalification: Demonstrating how Shared Approaches to Non-Competitive Processes Improve Quality and Efficiency

Janis Hall, Senior Consultant, The Avoca Group
 Tim McGarty, Global Category Manager, Digital Development, eCOA, PR&R, Novartis
 Dennis Salotti, Vice President, Operations, The Avoca Group

12:15-1:15 pm

Networking Lunch Sessions

- 1) *Do Quality Systems Need to be Agile? Looking at Agility, Benefits and Risks* David Lerner, PA Consulting
- 2) *Diligent, How to Operationalize a Centralized Approach to Prequalification* Scott A. Harris, Sanofi
- 3) *Effective Oversight Governance for Small Companies* Bruno Gagnon, BPharm, MSc, Executive Consultant
- 4) *ICH E6 Addendum – Section 5.0, Quality Management; are you ready?* Jonathan Rowe, PhD, MS, MA, Pfizer
- 5) *Novel Approaches for Communication of Clinical Trial Status and Results to Patients* Paddy Wall, Longboat Clinical

1:15-2:00 pm

Session 5
Case Study: Practical Applications of AQC Tools

Marie Anne Stager, Executive Director, Head of Clinical Development Operations, Seattle Genetics

2:00-2:45 pm

Session 6
AQC Portal Redesign

Debbie Briffa, Consultant, The Avoca Group
 Lakshmi Sundar, Vice President, Strategy and Marketing, The Avoca Group
 Per Kreipke, Technology Lead, The Avoca Group

2:45-3:15 pm

Networking Break

3:15-4:15 pm

Session 7
Inspection Readiness Work Stream – Knowledge Management: Readiness and Preparedness

Karin Daun, Senior Consultant, The Avoca Group
 Steve Whittaker, Executive Director, Avoca Quality Consortium

4:15-4:45 pm

Session 8
Strategies and Focus for 2017

Lakshmi Sundar, Vice President, Strategy and Marketing, The Avoca Group
 Steve Whittaker, Executive Director, Avoca Quality Consortium

4:45-5:00 pm

Close of Event