



**QUALITY
CONSORTIUM**
THE AVOCA GROUP

The Heldrick Hotel &
Conference Center
New Brunswick, NJ



6th Annual AQC Fall Member Meeting

Wednesday, October 25, 2017

8:30am – 9:00am

Registration and Continental Breakfast

9:00am – 10:00am

Session 1: Welcome and Review of Ongoing AQC Initiatives

- Patricia Leuchten, CEO, The Avoca Group
- Crissy MacDonald, Executive Director, Client Delivery, The Avoca Group
- Steve Whittaker, Executive Director, Avoca Quality Consortium

10:00am – 10:30am

Session 2: Case Study: Inovio Development of an Industry Leading Clinical Quality Risk Management System (CQRMS)

- Patricia Green-Amsler, CCRC, CCRA, Senior Director, Clinical Compliance, Inovio Pharmaceuticals
- Linda Peterson, Associate Director, Clinical Operations and Global Integration, Inovio Pharmaceuticals
- Karen Roycroft, Director of Clinical Quality Assurance, Inovio Pharmaceuticals

10:30am – 11:00am

Networking Break

11:00am – 12:00pm

Session 3: Inspection Readiness – Taking the Knowledge Center to the Next Level

11:00am – 11:25pm INTERACTIVE SESSION

- Steve Whittaker, Executive Director, Avoca Quality Consortium
- Karin Daun, Senior Consultant, The Avoca Group
- Ann Taylor, Director, Clinical Development Quality, Pfizer

11:25am – 12:00pm INSPECTION READINESS ACTIVITY

Table Moderators

- Priya Annamalai, Manager, R&D Quality, Inspection Management, AbbVie
- Alfred Chester, Director, Clinical Quality Compliance, Medimmune
- Grace Crawford, Vice President, Clinical Quality & Compliance, MedImmune
- Katie Delaney, DHA, Associate Director, Clinical Compliance, BeiGene
- Ana Santos, Director, Project, Alliance & Process Quality, Corporate Quality, INC Research/inVentiv Health
- Fred Tantoy, PhD, RN, Director, Clinical QA, Achaogen
- Ann Taylor, Director, Clinical Development Quality, Pfizer

12:00pm – 12:30pm

Session 4: Key Findings - Avoca Industry Research on Risk Practices in Clinical Research

- Dennis Salotti, Vice President, Operations, The Avoca Group

12:30pm – 1:45pm

Lunch

Moderated Roundtable Discussions (Optional)

Facilitator: Caryn Laermer, Director, Avoca Quality Consortium

Does ICH E6 (R2) have you spooked? Results from CRO/Sponsor Surveys

- *Jeff Rogers, Vice President, Partnerships, Comprehend Systems*

Unmasking the impact of M&A on QMS: Practical Risk Management

- *Todd Kisner, Vice President, Corporate Quality and Regulatory Compliance, Bioclinica*

Audit Trail Reviews – A Ghoulish Prospect

- *Jennifer N. True, Quality Director, Early Phase Clinical Development and Clinical Laboratories Medicines Quality Organization, Eli Lilly and Company*

Data Unification: An essential first step in transforming into next generation clinical trials processes. Tricks to be cautious of before dreaming of treats!

- *Kalyan Gopalakrishnan, Executive Vice President, Strategic Projects, Navitas Life Sciences*

1:45pm – 1:55pm

Post-lunch Energizer

- Steve Whittaker, Executive Director, Avoca Quality Consortium

1:55pm – 3:15pm

Session 5: Collaboration of AQC/ACRP - Investigative Site Quality Management Framework, Inspection Readiness, and Predictive Metrics

1:55pm – 2:25pm ACRP AVOCA PARTNERSHIP

- Beth Harper, Workforce Innovation Officer, ACRP
- Patty Leuchten, CEO, The Avoca Group
- Crissy MacDonald, Executive Director, Client Delivery, The Avoca Group

2:25pm – 3:15pm TABLE ACTIVITY AND PANEL

Overall Moderator:

- Steve Whittaker, Executive Director, Avoca Quality Consortium

Table Moderators:

- Avoca Staff and Leadership Advisory Board members

Panel Members:

- Beth Harper, Workforce Innovation Officer, ACRP
- Sharon Hanlon, MSN, Group Director, Clinical Trial Engagement & Contract Management, Bristol-Myers Squibb
- Rhonda Henry, Vice President, Site Networks and Patient Centricity, Sites and Patient Access, PPD
- David Vulcano, Associate Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

3:15pm – 3:45pm

Networking Break

3:45pm – 4:15pm

Session 6: Clinical Trials of the Future

- Connie Moreadith, Senior Consultant, The Avoca Group

4:15pm – 4:50pm

Session 7: Strategies and Focus for 2018

- Patricia Leuchten, CEO, The Avoca Group
- Crissy MacDonald, Executive Director, Client Delivery, The Avoca Group
- Steve Whittaker, Executive Director, Avoca Quality Consortium

4:50pm – 5:00pm

Close of Event