



QualityConnections

Bridging the Interfaces

Annual Conference

Marriott Royal Hotel, Bristol, 27–30 September 2011



The Research
Quality Association

SESSION 1

08.00 Conference registration

09.00 Opening address

Rachel Hodges, BARQA Chair

SHIPSHAPE AND BRISTOL FASHION

Chair: Rachel Hodges, BARQA Chair

09.15 The bridge of sighs

Colin Brown, Charles River Laboratories

- Accreditation (or?) monitoring inspections
- Comparison of ISO 17025 with GLP
- Meeting several GxPs in one group
- Impact of international differences within a multinational

09.45 The evolution of international GxP compliance – The bridge of dreams

Raymond Lowing

- Revision of GLP regulations: Do we move backwards or forwards?
- OECD: The MAD process, are we madly political or madly technical?
- How to increase harmonisation of interpretation between authorities
- Quality across regulations, the way forward and can it work?

10.30 Coffee

SESSION 2

QUALITY CONNECTIONS – GETTING THE MESSAGE ACROSS

Chair: Lynne Spencer, Eurofins Agroscience Services Ltd

11.00 Quality communication lessons from 'The Office'

Peter Cook, Human Dynamics

Do you love or loathe the BBC TV series 'The Office'? Irrespective of this, do you believe that the lessons are awfully funny and relevant as a much more 'sticky' way of learning about being your best? In this session, we will focus on the issue of quality communications, especially in respect of:

- Considering the impact of communications across cultures
- Dealing with difficult communications issues – when bad news is to be given for example

12.30 Lunch

STREAM ONE

SESSION 3

BRIDGING THE GAP

Chair: Janice Sarasola, Ondax Scientific

13.30 Ensuring compliance – potential risks for the small & medium sized enterprises venturing into the clinic for the first time

Sarah Fryer, Gregory Fryer Associates Ltd

- Understanding of clinical trial Sponsor responsibilities within a start-up Sponsor company
- Quality management systems for the start-up Sponsor company – what is appropriate?
- Potential risk to the small & medium enterprise if 'quality' is overlooked

14.00 GCP audits in veterinary and human clinical trials

Susan Makkink, Novartis Animal Health, Inc

- Know the differences between GCPs in veterinary vs. human clinical research
- Gain better understanding of GCP audits in clinical studies of veterinary medicinal products
- Identify the gaps between GCP audits of veterinary clinical research and human clinical trials
- Is there a gap between the quality of the research studies in animals and humans?

14.30 Improving research quality in African field trials sites

David Malone, IVCC, Liverpool School of Tropical Medicine

IVCC is a product development partnership with charitable objectives focused on the development of new vector control tools for use against malaria vectors in Africa.

This includes the development of novel insecticides and insecticide formulations that require field testing against African mosquitoes.

IVCC is providing support to vector control field trials sites by helping them to develop their in-house quality systems to improve trials data and guide the product development process.

15.00 Tea

SESSION 4

BRIDGING THE GAP

Chair: Angela Jennings, Syne Qua Non Ltd

15.30 Life after launch

David Sherwood, UCB Pharma, UK

- Quality assurance systems and regulatory affairs
- Medical affairs strategies and activities
- ABPI Code of Practice compliance monitoring
- Medical information activities
- Pharmacovigilance monitoring

16.00 Joined up QA, from cradle to grave

Joy Hughes, Audition RQA

- QA working in a number of different disciplines
- Presentation branches out to look at the process of drug and pesticide development and identify which QA skills are appropriate at each stage
- Are these skill sets mutually exclusive?
- Is management getting the best out of QA?
- What place does QA have in management structures that have become more and more discrete (the silo model)?
- How can management use all the many and various skill sets in QA synergistically to generate something that is greater than the sum of its parts?

16.30 BARQA AGM including presentation of awards