a³ GCP consulting

Allan Johansen (DVM) - Training & Presentations selected*

Post-academia Certificates

- *'Lead QMS Auditor Course'* (ISO, IRCA course No. 145, run by QMI Scotland Limited, Bagsværd, Denmark), Dec. 1997
- *'Senior Management Development Program'* (Macquarie University, Sydney), Apr. & Jun. 2000
- *'ISO 9001:2000 Auditor Transition & Business Improvement Training Course'* (internal course run by QMI Scotland Limited, Basel, Switzerland), Dec. 2001
- *'Executive Development Program'* (internal company team workshop on leadership building - run by the London Business School), London, UK Aug. 2002 and Mar. 2005, plus Switzerland, Feb. 2003

Main Training Courses

- *Basic Competence in Clinical Research and GCP* (at the Brookwood International Academy of Healthcare Research, Guildford, UK), Jul. 1997
- *Practical GCP Compliance Auditing of Trials & Systems* (DIA, London, UK), Feb. 1998
- *Assertiveness Skills* (internal Roche course w/ external consultant), Aug. 2000
- *FDA Auditing of Computerized Systems & 21 CRF Part 11* (internal course run by EduQuest®, Basel, Switzerland), Feb. 2001
- *New Research Fraud Awareness Training* (internal course run by MedicaLegalInvestigations Ltd, Basel, Switzerland), May 2003
- *Data Monitoring Committees* (internal training course held by Roche expert / DSMB member, Dee Why, Australia), Dec. 2009
- *The Reid Technique of Interviewing and Interrogation* (internal course run by John E. Reid and Associates, Inc. Chicago, South San Francisco, USA), Dec. 2010
- *HIPAA Education Program* (e-self study module incl. post-test), Oct. 2013
- *Impact of reforms to the Privacy Act and the development of therapeutic goods* (ARCS Webinar by HWL Ebsworth Lawyers), Nov. 2013

Seminars / Conferences / Meetings attended

DIA (**D**rug **I**nformation **A**ssociation):

Annual Meetings – 1996 (US), 1999 (US), 2000 (US), 2002 (US), 2004^ (US), 2006^ (US), 2005 (US), 2007^ (Euro), 2008 (Euro), and 2010^ (US) ^) presentations given

Regional DIA Workshops / Meetings –

- *'Advanced GCP Workshop: New Techniques'* (USA), Sep. 1997
- *'GCP Audits and Surviving an FDA Inspection'* (Philadelphia, USA), May 1998
- *'Evolution of Drug Regulatory Process in Asia'* (Seoul, S.Korea), Sep. 2000
- *'Clinical Trials in Asia'* (Hong Kong), Nov. 2000
- *'Pharmaceutical Evolution in Asia 2002'* (Tokyo, Japan), Sep. 2002

- *'Asia Pacific Drug Development Symposium'* (Shanghai, China), Nov. 2002
- *'Safety is Global: Contemporary Pharmacovigilance and Medical Management Strategies'* (Singapore), Dec. 2008

ARCS Australia (**A**ssociation of **R**egulatory and **C**linical **S**cientists):
Annual Scientific Conferences – 2001, 2003, 2004, 2005, 2006, 2007^, 2008^, 2009, 2010^, and 2011^ ^) presentations given

FERCAP (**F**orum for **E**thical **R**eview **C**ommittees in the **A**sian and Western **P**acific Region):
Annual Conferences – 2006, 2008, 2009, and 2010

Other:

- *The 23rd 'Scandinavian Conference on Gastroenterology'* (abstract submitted & accepted - Reykjavik, Iceland), Jun. 1990
- *The 5th 'European Society of Clinical Microbiology and Infectious Diseases' Meeting* (Oslo, Norway), Sep. 1991
- *The Revised Declaration of Helsinki: Interpreting and Implementing Ethical Principles in Biomedical Research* (arranged by the WMA, Pretoria, South Africa), Mar. 2001
- *The 2nd Thai GCP Update* (arranged by the Thai FDA, Cha-Am, Thailand), Aug. 2001
- *Ethics in Human Research Conference* (Canberra, Australia), Apr. 2003
- *Research Ethics and Governance Stakeholder Meeting and Public Forum* (arranged by Queensland Health and ARCS, Brisbane, Australia), Nov. 2012
- *Impact of reforms to the Private Act and the development of therapeutic goods* (ARCS Webinar conducted by HWL Ebsworth Lawyers), Nov. 2013

Presentations/Training provided – internal

Investigator Meetings (half to one hour 'GCP Refresher'): Copenhagen, Denmark (f/Novo Nordisk, 1997); Hangzhou, China (f/Roche, 2001); Bangkok, Thailand (f/Roche, 2001); Singapore (f/Roche, 2001); Sydney, Australia (f/Roche, 2003); Manila, The Philippines (f/Roche, 2005); and Sydney, Australia (f/ global medical device company, 2014).

Numerous presentations and training in GCP / Clinical QA related subjects at quarterly 'Medical Meetings' at the Australian Roche Affiliate, semi-annual Global Monitoring Courses, annual Asia Pacific Pharma Development meetings - from 2000 through 2010, and other specific meetings / training sessions for Clinical Operations on compliance and audit findings / issues.

Presentations/Training provided – external

- '*Auditing Experience in P.R. China'* (ARCS, Sydney, Australia), Nov. 2000
- '*Laboratory Audits for Clinical Trials'* (Mahidol University, Bangkok, Thailand), Aug. 2001
- '*Audit Experience in China'* (Inter-Company Auditors' Meeting, Ashford, UK), Oct. 2001
- '*Medical Practices vs. Quality of Clinical Trials / GCP'* (2nd APEC Workshop, Tokyo, Japan), Sep. 2002
- '*Experience of Auditing Clinical Trials in China'* (EFGCP Annual Conference, Brussels, Belgium), Mar. 2004

- *'Clinical Quality and The Clinical Trial Centre Audit Process'* (SFDA Clinical Trial Inspection Systems Training Program, Phase I: On-the-Spot Pre-training, Shanghai, PR China), Mar. 2004
- '*The Experience of Auditing Clinical Trials in Asia – An Industry Perspective'* (DIA Annual US Meeting, Washington DC), Jun. 2004
- '*Examining Inspection and Audit Processes in Clinical Trials'* (Good Clinical Practices 2004, organized by IQPC, Singapore), Aug. 2004
- '*Do's & Don'ts: Practical Aspects of Site Audits'* (Singapore Good Clinical Practice Program (Advance Course) at the National University of Singapore), Aug. 2004
- '*Clinical Trial Auditing Practices and Major Findings'* and *'IEC Procedures and Non-Compliance Issues Identified in GCP Audits*' ("Eastern China International Seminar on Clinical Trials Inspections" – Regulation Research Meeting arranged by the SFDA Drug Safety Inspection Division, Shanghai, China), Aug. 2005
- '*To SDV or not SDV – what is the question?*' (ARCS Annual Scientific Congress, Sydney, Australia), Jun. 2006
- '*Clinical trials in Asia from an Industry QA Perspective: Partnering with AHCs, IECs & Regulatory Authorities to Archive Global GCP Standard*' (DIA Annual US Meeting, Philadelphia), Jun. 2006
- '*Contribution to Transparency and Accountability in Human Research – An Industry Perspective'* (FERCAP Annual Conference, Ayutthaya, Thailand), Nov. 2006
- *'Examining the Role of a DSMB throughout the Development of a Clinical Trial: From Patient Recruitment to Publication'* (DIA Annual Euro-meeting, Vienna, Austria), Mar. 2007
- '*Keeping up with the Change in the Asia Pacific Region – From a Clinical QA Perspective*' (ARCS Annual Scientific Congress, Sydney, Australia), Jun. 2007
- '*Knowledge Management – Record Management according to GCP' and 'Poor Compliance or Intentional Misconduct – Definition of Misconduct and Examples Thereof*' (two separate sessions at ARCS Annual Scientific Congress, Sydney, Australia), May 2008
- *'Ensuring GCP Compliance in Clinical Trials'* (GCP training session for Regulatory Authorities, Bangkok, Thailand), Aug. 2008
- '*What is a GCP Inspection? What is a GCP Audit?* and '*GCP Related Issues for IRB Management*' (two separate presentations, FERCAP Annual Conference pre-conference training, Bangkok, Thailand), Nov. 2008
- '*TDR clinical study audit findings: lessons learned'* (Internal WHO/TDR workshop chaired by Gunnar Danielson, Swedish/EMA GCP Inspector, Geneva, Switzerland), Mar. 2009
- '*Getting it Right! Avoid Audit Findings in Asia*' (ARCS Annual Scientific Congress, Sydney, Australia), May 2010
- '*Reviewing the Ethical Reviewers: What can we learn from this WHO-initiated Program?*' (DIA Annual US Meeting, Washington DC), Jun. 2010
- *'Learning from Others – Review of FDA Warning Letters Raising Issues on Monitoring'*** (WHO/TDR GCP Refresher Course, Bangkok, Thailand), Aug. 2010

- *'Misconduct and Fraud in Clinical Research'* (ARCS Annual Scientific Congress, Sydney, Australia), May 2011
- *'Warning Letters: Lessons Learned and Trends'* - **updated/extended/revisited including WLs issued to Clinical Investigators Jan. 2010 to Jan. 2012 (ARCS Webinar), Feb. 2012

For FERCAP – as facilitator & presenter:

- International Courses on '*Surveying and Evaluating Ethical Review Practices'* (Bangkok May 2004; Shanghai Aug. 2006; and Manila Jul. 2007)

For the WHO – as facilitator & presenter:

- *'Training Week / GCP Refresher course for WHO/TDR Monitors & Auditors'* (held at Thammasat University, Bangkok: Dec. 2005, Aug. 2008, Jul. 2009, and Aug. 2010)
- '*Diploma Course on Research & Development of Products to meet Public Health Needs*' – several presentations in the GCP section (Nagasaki University, Japan Nov. 2006, Oct. 2007, Nov. 2009, and Oct. 2011; Thammasat University, Bangkok Nov. 2008)

Training provided as Independent GCP Consultant:

- '*GCP Audit Training Course*' (full day class-room in addition to a two-days 'hands-on' investigator site audit - for clinical QA staff at major Taiwanese CRO), Taipei, Taiwan, Nov. 2011
- '*GCP Refresher Course*' (full day - for Investigator Site staff at a hospital's Clinical Trials Unit), Adelaide, Australia, Feb. 2013
- '*GCP Refresher Course*' (full day - for Sponsor staff at small Pharmaceutical Company), Melbourne, Australia, Feb. 2014
- *'Ethical Requirements in Clinical Research/ICH GCP Refresher Training'* (half hour + Q&A – part of an International Medical Device Company's Investigator Meeting), Sydney, Australia, Jul. 2014
- *'Advanced GCP Refresher Course'* (half day - for the Clinical Operation staff at the Australian affiliate of a 'top 20' International Pharmaceutical Company), Sydney, Australia, Jan. 2015

*****) 1997 and onwards, 2000 to 2011 from 140+ activities listed in the IRCA Training & Continuing Professional Development (CPD) Log.

[Updated Feb. 2015]