a³ GCP consulting
CURRICULUM VITAE FOR ALLAN K. JOHANSEN

PROFILE

A life-science qualified experienced clinical research professional with more than **18 years of Clinical Quality Assurance experience** - with the last 5 years as independent GCP auditor & consultant, 11½ as Head of the Asia Pacific Quality Assurance team at Roche in Australia, and 2 years as international clinical auditor for Novo Nordisk in Denmark;

Adding 7 years of prior experience in research, medical advisory and trial management roles, resulting in more than **26 years experience in the Pharmaceutical Industry**.

KEY EXPERIENCE & ACHIEVEMENTS

- Worked closely with Roche's Regional Clinical Operations' management to ensure consistently high quality standards, enabling the Asia-Pacific to become a top drug development region;
- Successfully conducted >230 audits* (approx 140 as lead) in 36 countries on 6 continents - including approx 140 audits in the Asia Pacific region (including Australia and NZ), in areas of Investigator Sites (phase II to IV - routine and for cause), CPUs ('Phase I Units' – qualification and in-process), CROs (qualification and in-process), pharmacovigilance (PhV), IRBs/IECs and Sponsor Affiliate Study Management, CSRs (deskbased),as well as hosting FDA foreign investigator site inspections, and preparing investigator sites for FDA and EMA inspections.
  Has since April 2011 conducted more than 40 audits as independent GCP auditor on behalf of American, Australian, British, Dutch, German and Swiss sponsor clients and QA partners;
- Presented numerous times at international conferences including APEC, ARCS, DIA, and EFGCP, internal workshops at WHO/TDR in Geneva and Bangkok, company Investigator's Meetings etc.**
- Facilitated and co-surveyed a series of Surveys of IECs in Asia Pacific on "Surveying and Evaluating Ethical Review Practices" under FERCAP (a WHO initiative);
- Led a series of audits on behalf of the WHO/TDR in mainly developing countries (Bangladesh, Ethiopia, Senegal, and Uganda) as well as Thailand and South Africa*, acting as *External WHO QA Adviser/Mentor/Lead Auditor;*
- Attached to Nagasaki University, Japan as *External Lecturer* at the annual "Diploma Course on Research & Development of Products to meet Public Needs" (supported by WHO/TDR).

COMPANY RECOGNITIONS

- Roche Australia Gold Excellence Award for Outstanding Performance and Business Excellence "*Surveys of Ethics Committees in A.P. - a WHO initiative*", 2009;
- Roche Global Pharma Development Gold Award for "*Excellence in Knowledge Sharing*", 2006.

EMPLOYMENT HISTORY - IN THE PHARMACEUTICAL INDUSTRY 1989 TO PRESENT:

a³ GCP Consulting (Australia) — April 2011 – present

Owner – Independent Consultant (Clinical QA) – GCP audits, training & consultancy in GCP compliance

Roche Products Pty Limited (Australia) — August 1999 – March 2011

HEAD CLINICAL QUALITY ASSURANCE ASIA PACIFIC

- Directed the operations of the **P**harma **D**evelopment **Q**uality **A**udits (PDQA) office in Dee Why, Australia;

- Recruited, trained, managed, provided leadership and conducted performance evaluations of the local PDQ team of eight (8) clinical QA professionals;
- Developed, reviewed and monitored the PDQ Asia Pacific budget;
- Developed, provided input to and implemented international clinical research quality assurance auditing systems, policies and procedures;
- As a member of the Roche Global PDQA Senior Leadership Team (SLT), assisted in the development and execution of Audit Master Plans, team leader for overseas PDQA auditors, and for 2 years deputy for Global Head of PDQA; in addition previously member of the global PDQ Quality Leadership Team (QLT);
- Conducted / lead and participated as co-auditor in international audits*;
- Acted as internal consultant on clinical QA matters, providing expertise and guidance to projects in Pharma Development;
- As expert on international Good Clinical Practice (GCP) requirements contributed to effective GCP implementation within Roche;
- Representing Roche PDQ presented at national and international conferences and trade association meetings**;
- Co-authored and submitted articles for publication (see below) to promote GCP and ethical standard implementation outside of Roche and to contribute to the company's quality image.

Novo Nordisk A/S (Denmark) April 1993 – July 1999
Clinical Quality Assurance, Health Care
INTERNATIONAL CLINICAL AUDITOR (JULY 1997 - JULY 1999)
Obtaining global experience auditing clinical trial centres

Medical Affairs Diabetes, Health Care Strategy Unit
INTERNATIONAL TRIAL MANAGER & MEDICAL ADVISOR

Regulatory Affairs, Health Care
REGULATORY OFFICER

Ferrosan A/S (Denmark) Dec. 1989 – March 1993
Research & Development Department, Søborg, Denmark
MEDICAL ADVISOR & CLINICAL RESEARCH ASSOCIATE
Developing OTC & natural remedies as well as managing phase IV studies

EMPLOYMENT HISTORY 1977 to 1989:

The Danish State Veterinary Service
Division of Food Control, Copenhagen & Ringsted, Denmark
VETERINARY OFFICER & IN-HOUSE EXPERT IN FOOD MICROBIOLOGY

Chr. Hansen's Biosystems A/S, Copenhagen / Hørsholm, Denmark
MICROBIOLOGIST & PROJECT MANAGER

The Danish Institute of Technology, Tåstrup, Denmark
MICROBIOLOGIST & ASSISTANT LABORATORY MANAGER

The Royal Danish Veterinary & Agricultural University (RAVU), Copenhagen, Denmark
ASSISTANT LECTURER

EDUCATION AND QUALIFICATIONS:

ISO 9001:1994 & 2000 certified **Lead QMS Auditor** – 1997 & 2000**

Royal Danish Veterinary & Agricultural University (RVAU), Copenhagen:

- Single Subject course in 'Tropical Deceases in Domestic Animals' - 1989
- Post-Graduate Degree in 'Food Microbiology & Hygiene' – June 1977
- **Doctor of Veterinary Medicine** (DVM – Masters) – graduating in Jan. 1976

PROFESSIONAL ASSOCIATIONS:

- **D**rug **I**nformation **A**ssociation (**DIA**)
  Member from 1993 to 2011 – numerous presentations at the Annual Meetings in the US and Europe**
- **A**ssociation of **R**egulatory and **C**linical **S**cientists to the Australian Pharmaceutical Industry Limited (**ARCS**) – active member of the Clinical Interest Area (IAC) Group
  Member from 2000 to 2015 – numerous presentations & workshops at the Annual Scientific Congress, Sydney**
- **F**orum for **E**thics **R**esearch **C**ommittees **A**sia **P**acific (**FERCAP**)
  Member since 2006 – presentations at pre-congress training sessions**

PUBLICATIONS (selected):

- Li, W. and Johansen, A. K.: *Updating package inserts: the barriers to timely implementation.* Regulatory Affairs Pharma, March 2011, 22;
- Hamadian, L. and Johansen, A.K.: *Countering conflicts of interest in ethical review*. GCPj, May 2009, 28-29;
- Hamadian, L. and Johansen, A.K.: *Reviewing the ethical reviewers*. GCPj, May 2008, 8-10 ;
- Revised and updated versions of the above in *"FERCAP@10"*. Edited by C.E.Torres & A.M.Navarro, 2011, 17-27;
- *"Good Clinical Practice: A Question & Answer Reference Guide" May 2014 (12th Edition), May 2015 (13th Edition) and May 2016 (14th Edition – under preparation)* (Barnett International, USA; edited by Michael Hamrell). As member of the Expert Advisory Panel from 2014 contributed with two sections on 'GCP and Clinical Research Standards' in Australia and New Zealand, respectively.

ADDITIONAL RELEVANT INFORMATION:

Languages Danish (native) and English: fluent at work & functional levels; German and Swedish: basic

Faculty Membership **EXTERNAL LECTURER**
Nagasaki University, Japan

References Available on request or refer to **"Recommendations"** in **LinkedIn® profile**

Contact Ph: +61(0)7 5478 9026; mailing address: 378 Highlands Road, Eudlo 4554 QLD, Australia.

Details on *) *Audit Experience* and **) *Training & Presentations* available on request or refer to **www.a3gcpconsulting.com.au** or by emailing **allanjohansen@bigpond.com**

[AKJ/Mar./2016]