

PRESENTATION

Senior Quality Advisor with more than 25 years' experience from the Pharmaceutical and Medical Device Industry, with focus the last sixteen years on quality assurance, e.g. internal and external audits, quality advice to R&D functions and global projects.

Significant experience from hosting regulatory inspections, including FDA. In addition, a long experience in training of personnel and students in quality management systems and particularly in the quality aspects of laboratory work.

Extensive knowledge in GLP, GMP, GCP and ISO-13485 and other related standards.

Problem solving and leadership skills, customer focused, result oriented, open-minded and flexible. Lived and worked in different countries and speak several languages fluently.

PROFESSIONAL EXPERIENCE LIFE SCIENCE

2017-present Idogen AB, Lund, Sweden QA Manager • QMS ATMP GMP Production

2013-present PKxpert AB, Stockholm, Sweden • Senior Quality Advisor

- GLP QA – GLP TK/PK study phases, internal audits & quality management system, including SOPs
- Quality advice small and mid-size Pharmaceutical, Health Care and Technology companies
- Quality training (GxP, ISO 13485)
- CRO/Supplier audits

2013-2017 Baxter Inc., Lund, Sweden

Quality Specialist and Site Audit Coordinator

- QMS ISO-13485; 21 CFR Part 820; GMP & GDP
- Internal, corporate and supplier audits
- CAPA

2011 – 2013 Semcon Caran AB, Lund, Sweden

Senior Consultant

- Quality advisor small and mid-size Pharmaceutical, Health Care and Technology companies
- Audits of CROs and suppliers
- QA/RA in Global Medical Technology Company
- Courses at Malmö University in Quality and Validation

2001 – 2011

AstraZeneca R&D Lund, Sweden

Senior Research Quality Advisor

- Managed all GLP quality assurance activities at the Lund site
- Conducted internal audits, and external audits of CROs, suppliers and vendors
- Hosted authority inspections
- Training of personnel
- Provided quality advice to R&D functions, global projects and networks
- Participated in due diligence teams

2000 – 2001

Bioglan AB, Malmö, Sweden

Head of the Quality Control Laboratory

- Developed and managed the quality system to GMP regulations
- Core member of the Bioglan Leadership Team
- Managed personnel, budget and investments
- Responsible for safety, health & environment

1987 – 2000

Ferring Pharmaceuticals, Malmö, Sweden

Head of Bioanalysis

- Developed and managed the quality system to GLP/GCP regulations
- Managed personnel, budget and investments
- Responsible for safety, health & environment
- Developed and validated radioimmunoassay for analysis of biological samples from clinical and non-clinical studies

1985 – 1987

Department of Biotechnology, Lund University, Sweden

Senior Research Technician

- Developed immuno-chemical assays
- Developed separation techniques

1972 – 1984

General Hospital, Molde, Norway

Team Leader: Clinical chemistry, hematology, in-vivo diagnostic tests with gamma-ray imaging, radioimmunoassays and different types of electrophoreses.

1970 – 1972

Medical Laboratories, Ignatius Hospital, Breda, the Netherlands

Laboratory Technician – Clinical chemistry, hematology, hormone analyses

ACADEMIC DEGREES

B.SC Clinical Chemistry – University of Applied Sciences, Breda, the Netherlands

COURSES & TRAINING

2010	Team building – Lean Sigma – Continuous improvement
2014	Medical Device QA/RA, China, South Korea, Japan, Canada
2010, 2008, 2007, 1996, 1992	GCP regulations and related topics, such as conduct of clinical trials
2009, 2005, 2004, 2003, 2002	Computerized systems – Validation, Electronic Records/Electronic Signatures, LIMS
2008, 2003	Auditing – QMS auditing (ISO 9000)
2018, 2017, 2016, 2015, 2008, 2004, 2001, 2000, 1999, 1998, 1994, 1992	GLP regulations and related topics, such as methods validation
2008, 2004, 2001, 2000, 1997, 1996, 1995, 1991	Project management and leadership capabilities
2007, 2006, 2003, 2002	Communication – Presentation technique – Interview technique
2012, 2002	Quality Management System
2017, 2016, 2015, 2014, 2013, 2001, 2000, 1999, 1997, 1996	GMP regulations and related topics, such as cleaning validation
2017, 2016, 2015, 2014, 2013	Good Distribution Practice
1999	Medical English, University of Lund
1993	Certificate of Proficiency in English, University of Cambridge – Local Examinations Syndicate – International Examinations
1985	Pharmacology, University of Lund

MEMBERSHIPS

RQA – Research Quality Association

SARQA – Swedish Association of Regulated Quality Assurance