Employment, Company and Position

Jan 2007 – present

Pharmac, Founder and Senior GMP Consultant
See www.pharmac.dk.

Summary
General consultancy for the pharmaceutical industry within the area's of Quality Assurance, Quality Control, Analytical Development and CMC.

Services are performed for both commercial manufacturing sites and companies working within development and production of clinical trial material.

Special competences:

- **Function as Qualified Person**
  QP release of marketed products and clinical trial material (non sterile). Function as QP for parallel import companies and for companies importing from third countries
- **Setup and maintain Quality Systems**
  Building up quality systems for companies applying for their first manufacturing authorisation. Review and maintenance of existing quality systems in accordance with updates in legislation and industry standards
- **Handling of Deviations including CAPA, Change Controls and OOS**
  Preparation and approval of deviations and change controls both within Quality Control, Production and Quality Systems
- **Performing GMP/GDP audits and Self Inspections**
  GMP and GDP audits are performed in accordance with the customers supplier evaluation programs. GMP audits include manufacturers of packaging material, raw materials, Active Pharmaceutical Ingredients, laboratories, pharmaceutical manufacturing facilities, warehouses and facilities for packaging/blinding of clinical trial material. Self inspections are performed in specific departments and as process inspections
- **Setting up stability programs**
  Preparation and review of stability protocols and reports in accordance with ICH Q1. Evaluation of data and preparation of stability assessments and stability statements for drug substances and drug products
- **Analytical method validation**
  Preparation and review of validation protocols and reports in accordance with ICH Q2
- **Performing GMP training**
  Training is performed as a part of the customers internal requirement for on-going GMP training. Speaker at external courses with focus on general GMP, equipment qualification and quality risk management in accordance with ICH Q9. In cooperation with Danish Technological Institute
- **Handling of CMC documentation**
  Preparation and review of CMC documentation, including Drug Master Files, IND's and IMPD's in CTD format
- **Interpretation of Eudralex Vol. 4 Annex 13 "Investigational Medicinal Products"**
  Working within development and production of clinical trial material for phase I, II and III clinical trials using annex 13 to set the standard for documentation at each development step

Performed as requested in compliance with API and Drug Product requirements according to Europe and

US legislation as outlined in ICH Q7, Eudralex Vol. 4 Part I, II, III and 21 CFR part 11, 210, 211

Apr 2006 – Jan 2007

Forward Pharma

CMC Consultant, private basis

- Contact to CRO´s for manufacturing of API and Drug Product for clinical trial study
- Coordination of CMC activities
- CMC documentation

Jun 2006 – April 2007

NeuroSearch A/S, Analytical Development

CMC Coordinator
CMC coordinator, identifying CRO´s for production of GMP material for clinical trials, setting up kick-off meeting and performing contract writing and negotiations.

Main responsibilities:

- Management of CMC group within specific projects
- Contact person and coordinator for internal and external CMC activities for manufacturing of API and Drug Product for clinical trial studies
- Preparing CMC documentation
- Audit of API supplier

Mar 2006 – Jun 2006

NeuroSearch A/S, Analytical Development (temporary position)

Head of Analytical Development
Head of Analytical Development (in total 6 employees), working with stability and development of analytical methods for API and Drug Product.
Analytical backup for research and development department.

Main responsibilities:

- GMP Compliance
- Laboratory management
- Planning of the daily work in cooperation with the department chemist and project managers
- Responsible analytical chemist within development projects

2005 – 2006

Dansk Droge (Axellus A/S)

Manager – AD & QC
Reference to CEO.
Manager for 3 laboratories (in total 21 employees), covering control and release of raw materials and finished pharmaceutical formulation, stability testing and development of analytical methods. Part of the Management Group.

Main responsibilities:

- GMP Compliance
- Setting up and approval of specifications and release methods for raw materials such as minerals, vitamins and API´s for herbal medicine in accordance with HACCP and GMP rules
- Stability programs for drug products and food products in accordance with regulations and customer demands
- Ensuring that analytical work was performed in accordance with quality standards
- Ensure that QC delivered high quality analyses in accordance with production plans and sales strategies
- Continuously improve analytical methods and techniques in order to maintain a high scientific level in the laboratories
- Management related work such as budget, personnel etc.
- Inspection/audit

2003 – 2005

Dansk Droge (Axellus A/S)

Quality Manager
Qualified Person (QP). Reference to CEO.
Manager for Quality Control and Quality Assurance (in total 20 employees). Part of the Management Group.

Main responsibilities:

- Responsible for Dansk Droge's entire quality system, covering regulations both within pharmaceutical products and food supplements
- Qualified Person. Release of finished product formulation within pharmaceutical product and food supplements in accordance with regulatory and customer demands
- Contact person towards the Danish Medicines Agency, The Danish Veterinary and Food Administration and customers
- Updating and maintenance of quality systems
- Inspection/audit
- QC related work as outlined above

1999 – 2003

NeuroSearch A/S, Analytical Development

Research Scientist
Analytical chemist working in a development laboratory, with main focus on characterization of new API´s.

Main responsibilities:

- GMP Compliance
- LC/MS used for identification of impurities
- Development of HPLC-methods used for determination of assay and impurity profiles in API´s
- Responsible analytical chemist within development projects
- CMC documentation
- Stability. Evaluation and preparation of stability reports and stability statements

1997 – 1999

FeF Chemicals A/S (subsidiary, Novo Nordisk A/S), Quality Control

Analytical Development & QC Chemist
Analytical chemist working in a combined development and QC laboratory, with method optimization and validation together with in-process control and release of products (excipients).

Main responsibilities:

- GMP Compliance
- Equipment qualification and method validation
- GC and HPLC

1994 – 1997

H. Lundbeck A/S, Quality Control

QC Chemist at Lundbecks API production site
Analytical chemist working in a QC laboratory, performing in-process control and release of raw materials, intermediates and final API´s.

Main responsibilities:

- GMP Compliance
- Daily planning of laboratory work in coordination with production.
- GC and HPLC

1993 – 1994

Technical University, "Københavns Teknikum"

Teacher, qualification course in chemistry and mathematics

Courses – Title and Company	**Date**
3rd Annual Clinical Trials Supply Nordics 2016, Clinical Trials Arena	June 2016
GMP. Sidste nyt (legislation update) Eudralex Vol. 4, Pharmakon	November 2015
Cleaning Validation – Strategy, techniques and regulations, Key2Compliance	May 2015
Nordic QAforum 2014. Kompetens Instituttet Norden AB	Nov 2014
Beyond GMP. Key2Compliance	June 2014
GDP – Sidste nyt – ny vejledning (New legislation), Pharmakon	Sept 2013
GMP Compliance Auditing Key2Compliance/Pharmaceutical Compliance Associates	Nov 2012
GLP/GMP (Participant and speaker. In cooperation with Danish Technological Institute)	Mar/Sep 2012
QP Dilemma/Challenges. GMP-Update, Pharmakon	Mar 2011
GDP – Workshop, Pharmakon	Mar 2011
GDP – Good Distribution Practice, Pharmakon	Oct 2009
Workshop on Change Control Karen Ginsbury, Pharmaceutical Consulting Israel	Feb 2009
GMP Trends David Begg Associates	Jan 2009
GMP for Quality Control and Laboratory Operations Key2Compliance/Pharmaceutical Compliance Associates	October 2009
Recommendations on how to apply ICH Q8/Q9/Q10 during auditing Key2Compliance/ Novo Nordisk A/S	Sep 2008
cGMP: Interpretation and Application Key2Compliance/Pharmaceutical Compliance Associates	May 2008
GMP and FDA compliant Quality and Documentation Systems, European Compliance Academy (ECA)	Oct 2007
ICH Quality Guidelines 1 – 10, Pharmakon	Oct 2007
Introduction to LCMS, MSC ApS	Feb 2007
GMP, Saks Quality	Apr 2006
Basic Management, IDA – Denmark	Sep 2005-Jan 2006

Food Supplements and Herbal Medicine, Pharmakon	Sep 2004
GMP for Laboratories, Laborantskolen & Pharmakon	May 2003
Structure Elucidation by LC/MS, Agilent Technologies	Mar 2002
Setting Specifications for Drug Substances and Drug Products The Center for Professional Advancement	Oct 2001
FDA 21 CFR Part 11 – Electronic Records & Signatures Agilent Technologies	Jun 2000
OECD GLP Guideline The Role and Responsibility of The Study Director QA, NeuroSearch	Feb 2000
Interpretation of CID Mass Spectra 16th Montreux LC/MS Symposium	Nov 1999
LC-MS, MS-Consult/Agilent Technologies	Nov 1999
Analytical Methods Validation for FDA Compliance The Center for Professional Advancement	Jan 1998
GMP-training, PharmaNet, Inc.	Nov 1996
Kombikursus – Microsoft Office, Eric Mainz A/S	Oct 1996
GMP og bulkproduktion/produktionshygiejne Danmarks Apotekerforening	Sept, Oct 1995
FDA cGMP awareness, GMP – Pharmaceutical Quality Assurance	Oct 1995
HP5890 Kapillargaschromatografi, Hewlett-Packard	Dec 1994
Gaschromatografi, Introduktion, Hewlett-Packard	Feb 1994

Education:
MSc in Engineering (Chemistry) from the Technical University of Denmark, 1993