CV - Mads Friis Sørensen

Employment, Company and Position
Jan 2007 – present

- **Pharmac, Founder and Senior GMP Consultant,** Elsdyrvej 18, 4623 Ll. Skensved, Denmark

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

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

Audit and assessment of quality management systems in relation medical device manufacturing.

Special competences:

- **Function as Qualified Person**
  QP release of marketed products and clinical trial material.

- **Function as QA IT Compliance Responsible**
  Assuring compliance in relation to computer system validation and data integrity handling

- **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 ISO, GMP/GDP audits and Self Inspections**
  ISO, 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

- **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/GDP training**
  Training is performed as a part of the customers internal requirement for on-going GMP/GDP training. Speaker at external courses with focus on general GMP/GDP, equipment qualification and quality risk management in accordance with ICH Q9. Present in collaboration with Pharmakon a/s

- **Handling of CMC documentation**
  Preparation and review of CMC documentation, including Drug Master Files, IND's and IMPD's in CTD format

- **Implementation of Quality Risk Management principles in Quality Management Systems**

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

The services are performed 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 plus relevant annexes and 21 CFR Part 11, 210, 211.

Senior Gxp Consultant, Pharmac, Main Experience

2021	-	present	QA Specialist, 4 companies, sterile pharmaceutical manufacturing (CMO-model)
2017	-	2018	Qualified Person, Import of unlicensed medicines
2017	-	Present	Qualified Person, Repackaging, Import, Veterinary products
2017	-	2020	Qualified Person, sterile and non-sterile pharmaceutical manufacturing (CMO-model)
2016	-	Present	QA Specialist, sterile pharmaceutical manufacturing (CMO-model)
2016	-	2016	Qualified Person, Biological API Manufacturing
2015	-	2018	QA Manager, sterile biological pharmaceutical manufacturing (CMO-model)
2014	-	2014	Qualified Person, Import of unlicensed medicines
2014	-	2015	Qualified Person, non-sterile pharmaceutical manufacturing (CMO-model)
2013	-	2014	Qualified Person, sterile and non-sterile pharmaceutical manufacturing
2012	-	2015	QA/QC Specialist, Manufacturing of Cosmetics
2011	-	2018	Qualified Person, non-sterile pharmaceutical manufacturing
2010	-	2013	QA Manager, non-sterile API manufacturing
2009	-	2010	Qualified Person, Parallel Import
2008	-	2012	Qualified Person, non-sterile pharmaceutical manufacturing

In the period from 2007 to present I have held more than 60 audits of API and drug product manufacturers (sterile and non-sterile) and distributors in EU, Asia and USA.
In parallel I have done project based consultancy work within CMC, Quality Assurance and Quality Control for several pharmaceutical companies including implementation of quality risk management in pharmaceutical quality systems.

Courses:

Courses – Title and Company	**Date**
GMP latest news, Pharmakon	March 2022
Basic GMP, Key2Compliance	February 2022
European Clinical Trial Regulation ((Eu, No 536/2014), Advarra LLC	September 2021
Risikostyring I GMP og GDP, Pharmakon, Instructor	September 2021
Clean Rooms & HVAC System, Clean Rooms & HVAC System	December 2020
Supply Chain Oversight, ECA 2-days Online Training	October 2020
14th QP Forum, European QP Association	November 2019
Quality Risk Management, Pharmakon. Instructor	November 2019
General Data Protection Regulation, The Back Office	June 2019
GMP. Sidste nyt (legislation update) Eudralex Vol. 4, Pharmakon	November 2018
Quality Risk Management, Pharmakon. Instructor	May - November 2018
Good Supply Chain Practices, IFF	April 2018
Annex 1 – manufacturer of sterile medicinal products, IFF	April 2018
Instructor, MIND (QA, GC, GXP) , University of Copenhagen. Quality Control	December 2017
How to write an ASMF, Pharmalex Denmark	July 2017
Process Validation, Pharmakon	August 2016
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 QA Forum 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

Former employment

- 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
  - Equipment Responsible

- 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
  - Equipment Responsible

- 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
  - GC and HPLC

- 1993 – 1994 **Technical University, "Københavns Teknikum"**
  Teacher, qualification course in chemistry and mathematics