Curriculum Vitae

Lone Cleveland Andersen

Job career

Career.
Present: GxP-specialist and Project Manager in GxP-Pharma Support A/S (and CEO of the consultant company).
I have 20 years solid experience in several pharmaceutical and biopharmaceutical production areas incl. 7 years from the regulatory international authorities; The Danish Health and Medicines Authority and EMA as Medicines Inspector.

As project manager, I have implemented ISO 9001, LEAN and many quality systems in different production sites. And I have upgraded quality systems and international production incl. consulting for the pharmaceutical industry worldwide.

I have a broad and regulatory GxP-experience from several international inspections of pharmaceutical and biopharmaceutical productions and quality systems. Further I have inspected blood banks and pharmacovigilance as a former Medicines Inspector and have experience in auditing laboratories according to ISO 17025. My regulatory work has given me profound and international knowledge of legal requirements in the pharmaceutical branch.

July 2014 GxP-Pharma Support A/S

- GxP specialist and Project Manager
- Establishment of GxP-Pharma Support A/S; owner and CEO
- Assigned specialist of training in EU- GMP/GDP topics at Pharmakon (external training)

2012 – 2014 Danish Health & Medicines Authority, inspection department

- Medicines inspector for GMP, GDP and blood banks
- Auditor for 3 laboratories; chemical, microbiology/biology and radioactive laboratories according to DS/EN ISO 17025 standard
- Responsible for the disciplines IT, GDP, narcotic drugs and veterinary drugs incl. legalization and education/training in the disciplines.
- Responsible for GMP seminars in DHMA inspector team
- Interpretation of and training in the new GDP guideline (2013)
- Quality system: Elaboration of templates, reports and internal SOP's.
- Participation in recruitment procedure
- Sparring partner in quality for top management
- Sparring partner for the GDP team
- Training of new GMP-/GDP-inspectors in relation to GDP legislation
- Assigned specialist of training in EU-GMDP subjects at Pharmakon (external training)

2007 – 2012 Danish Medicines Agency, inspection department

- Medicines inspector for GMP, GDP, pharmacovigilance, blood banks and relief organizations
- Auditor for inspection departments according to DS/EN ISO 17020 standard
- Auditor for 3 laboratories; chemical, microbiology/biology and radioactive laboratories according to DS/EN ISO 17025 standard
- Responsible for the disciplines pharmacovigilance vet., veterinary drugs, Centralized Authorized Products (CAP)
- Responsible for GMP seminars in the DHMA inspector team
- Responsible for departmental seminars
- Participation in EMA working group and meetings re. Pharmacovigilance vet.
- Participation in establishment of Pharmacovigilance training course for EU inspectors
- Responsible for handling sampling and CAP to analysis at EDQM
- Sparring partner in quality for top management
- Sparring partner for several quality project
- Assigned specialist of training in EU- GMP/GDP topics at Pharmakon (external training)

2005 - 2007 Novo Nordisk A/S, Project Manager, Local Manufacturing & Sourcing

- Development of new Business Support Organisation incl. development of an IT strategy
- Development of competencies related to Business Strategy and establishment of relevant and related training and competencies
- Quality Support to Affiliate production in Koriyama, Japan
- GMP training of production staff in Affiliate in Koriyama, Japan
- Quality Coordinator; planning, participation and follow up internal and external audits and inspections from the authorities
- Coordinator for Quality Management Reviews (DS/EN ISO 9001)
- Project management of several quality projects; ISOTrain an electronic GMP training registration system and different LEAN projects
- Implementation of LEAN incl. tools and training

2001 – 2005 Novo Nordisk A/S: Project Manager, Contract & Licence Manufacture

- Project manager for establishment of a licence production in Belarus; packaging of vials
- Project manager for establishment of a licence production in Cuba; aseptic processing, filling and packaging
- Quality Support to Affiliate Production in Koriyama, Japan
- Establishment of an ERFA group in specific Japanese authorities regulations; aseptic and sterile processing and production
- Quality Responsible for GMP og ISO 9001 in the organization
- Coordinator for Quality Management Reviews (DS/EN ISO 9001)
- Quality Coordinator; planning, participation and follow up internal and external audits and inspections from the authorities.
- Establishment of qualifying courses in GMP, GDP og ISO 9001
- Establishment of GMP-training matrix for different employees

1999 – 2001 Novo Nordisk A/S: Quality Coordinator, API bulk insulin production

- Support to API bulk production, in-process laboratory, Review of batch-documentation and approval of production, elaboration of SOP's, handling deviations and CAPA, handling changes, perform validations, register in IT systems
- Responsible for implementing the ICH guideline in force regarding API requirements (the existing EU GMP vol. 4, part II)
- GAP analysis and action plan for implementation of API requirements and follow up
- Optimizing and harmonization of batch documentation in 6 production areas
- Training of productions staff and academics in API requirements according to legislation and ICH Guideline
- Participation in internal audits as GMP specialist
- Coordinating internal audits in the organization

1998 – 1999 Novo Nordisk A/S: Team leader in aseptic insulin production (finished goods)

- Team leader for cleaning staff and assistant in environmental monitoring
- Quality Support in aseptic production og utilities; review of batch documentation and approval og production, handling customer complaints, elaboration of SOP's, handling changes, deviations and CAPA, perform validation etc.
- Surveillance and trending of data from the aseptic environment
- GMP training of production staff in aseptic processing og environmental monitoring
- Participation in internal audits and inspections from the authorities.
- Project manager for implementing HC*LIMS, an IT system for analytical results
- Project manager for implementing ISO 9001/9002:1994 in a Site with 7 production departments
- Establishment of Quality Management Review (DS/EN ISO 9001)

1994 – 1998 Novo Nordisk A/S: GMP coordinator in insulin packaging department

- Project manager; implementing ISO 9001 in a Site with 7 production departments
- Project management; establish ISO kick-off meetings, ISO steering committee and a project organization
- Participation in multidisciplinary workshops for harmonization of overall cross functional Novo Nordisk quality policies and procedures according to ISO 9001
- International ISO training of staff from affiliates in South Africa and Japan
- Responsible for reference samples
- Responsible for GMP quality meetings in packaging, assembly and stock
- Participation in internal audits and inspections from the authorities.
- Optimization of documentation and quality systems according to ISO og GMP requirements
- Elaboration and standardization of Annual Product Review
- Harmonization of batch documentation

- Establishment of Cross functional quality and erfa-meetings in several productions sites
- Quality support to packaging, assembly and warehouses; responsible for review of batch documentation, elaboration of SOP's, handling deviations and CAPA, handling changes and customer complaints etc.
- GMP training of production staff
- Overall cross functional training in ISO 9001 topics

1994 – 1994 Head Dispenser, Asnaes Pharmacy

- Counter expedition in main pharmacy and affiliate, 4 month

(**1993 - 1994** Maternal leave 9 month; daughter born in April 1993)

Main Education:

- 2010: Lead Assessor, ISO 17025, DANAK
- 1999: Project manager, Novo Nordisk A/S
- 1997: Certified ISO 9001 Lead Auditor, BSI Training Service
- 1993: M.Sc. Pharm. Copenhagen Pharmacy University

Lectures:	**Title / organizer**
September 2013:	New GDP guideline, Pharmakon
April & May 2013:	New GDP guideline; interpretation and training of inspectors in DHMA
March 2008:	EU GMP, Pharmakon
April 2008	Qualification and validation of equipment, Pharmakon

Erfa-groups:

2001 – 2003:	Chairman for Japan-ERFA group, Novo Nordisk A/S

Trusts:

2006 -	Chairman of the Board for Nomas A/S
1997 – 2014:	Chairman of the Board Nr. Hvalsoe Village

Private information:

Born:	15.09.1962
Civil status:	Married since 1988
Children:	2 grown up daughters
Interests:	Gardening, travels, camping and outdoor life, orienteering