Curriculum vitae **Hasse Herlevsen**

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SUMMARY

Master of Science in Pharmacy + Bachelor of Commerce + IMD top management education.
33 years in Big Pharma, Mid-size Pharma & Small Biotech: Quality, Development, Operations & Laboratories.
Latest 9 years as Vice President, Global Quality & Environment, Health & Safety.
Responsible for all Quality (GMP, GCP, GLP, GDP & QA for Pharmacovigilance)

I am an expert in strategic development of Quality - to improve quality systems and organizations to be more efficient. I am working both with pharma, biotech and medical devices. I give professional advice / second opinion about Quality cases.
I do rics evaluations: Identification of rics in relation to business and quality processes - leading to quantification and mitigation of rics.
I prepare for and host authority inspections. I have experience from 50+ inspections. I improve all major types of quality systems and combine them with LEAN. I do audits (GMP, GLP, GCP, IT, Medical Devices) and Due Diligences. I am working very much with Quality Metrics & Quality Management Reviews and Product Reviews. I also coordinate validation and implementation of IT-systems.

As a manager I involve stakeholders in creating a common big picture of what to do. I always work to bridge different views. I turn the big picture into an action plan. Then I start executing the plan together with the stakeholders. This ensures succes. I am efficient and realistic about how to achieve the targets - move quick from decision to action. I thrive with all kinds of start-ups. I have the ability to spot talent. I like sparring with people and help their personal development.

As a person I am very systematic and get things done on time. I am holistic thinking with focus on the long term goals. I have very good judgment skills and problem solving skills. I can perform clear analysis - I have the ability to read through large sets of data - and extract the key elements. I am working both on a strategic level and also like to do things myself.

ENTREPRENEUR

PERIOD	**2016 -**
POSITION	**Senior Consultant & Owner**
COMPANY	**rightQA.dk** **"-consultant with strategic view"** **Practical solutions - quality tasks and consulting** **We take responsibility and get things done**

WHAT WE CAN DO

We offer practical solutions that works!

- Audits & Due Diligences
- Authority inspections e.g. FDA & EU
- Professional advice / second opinion about Quality cases & Risk evaluations
- Quality agreements
- Solutions in the intersection between Quality, CMC and Regulatory
- Quality metrics
- Quality Management Reviews & Product Reviews
- Improve all types of Quality systems to be more efficient
- Coordination of validation and implementation of IT-systems
- Develop your Quality Organizations to be more efficient
- Effective LEAN in Quality - that works

EMPLOYMENTS

— we help people achieve healthy skin

PERIOD **2007 - 2016**

POSITION **Corporate Vice President - Global Quality & EHS**

COMPANY **LEO Pharma**

RESPONSIBILITIES

- Chief responsible for Quality in LEO globally:
  - GMP
  - GCP
  - GLP
  - GDP
  - Release of products and IMP
  - QA for Pharmavigilance
  - Environment, Health and Safety
  - Quality systems and IT systems
- Total 186 employees in 6 countries
- Budget of 20 mio. €

ACHIEVEMENTS

- Transformed global quality systems (Quality-manual, policies, SOP-system, deviations, recurring deviations, audits, change controls, customer complaints, GCP set-up, validations etc.) into more modern levels - with a pragmatic low cost attitude
- Implemented quality IT-systems (document handling system & system for quality processes) to become more effective and to support the business
- Introduced Quality Metric globally which gave much better management overview of the compliance status of the entire company
- Introduced LEAN in Quality globally which resulted in a more efficient quality organization
- Introduced Quality Management Reviews according to EU legislation. This gave top management a much better tool for high level decisions

- Built up an ISO system as Medical Devices were introduced in LEO. ISO certification achieved so LEO could go into the medical devices business
- A number of comprehensive reorganizations that resulted in a more agile and efficient Quality organization with stakeholder orientation
- Run a global company-wide compliance programme of 150 mio € during a number of years to upgrade facilities, systems and documentation to ensure that quality compliance was up to date
- Ensured the LEO Group globally was transformed from a critical compliance level to a compliance level with no major troubles with authorities
- Participated in several filings and succesful launches of new products - e.g.:
  - A product against actinic keratosis, Transformation of an acquired development company to a commercial company
  - A product against psoriasis, a foam produced at a CMO in Germany
  - An applicator product against psoriasis

LEO — we help people achieve healthy skin

PERIOD **2003 - 2007**

POSITION **Director of Quality for the LEO Group**

COMPANY **LEO Pharma**

RESPONSIBILITIES

- Responsible for Quality (GMP & GDP) in Denmark and globally for GCP, GLP & QA for Pharmacovigilance
- Quality systems and IT systems
- The global quality corporation in LEO Group

ACHIEVEMENTS

- Transformed a very conservative and fragmented quality organization into a global very connected quality organization
- Ensured that the company did not come into troubles with the authorities despite a low compliance level
- Built up quality systems to efficient support the business processes of the company
- Head of the GCP & GLP Department

Leukotech

PERIOD **2001 - 2003**

POSITION **Director of Technical Development & Quality**

COMPANY **Leukotech**

- ***a biotech start-up company with 10 employees***

RESPONSIBILITIES

Took care of all internal activities in the company:

- Cell culture
- Sterile Technology
- Protein purification
- Product development & formulation
- Chemical and microbiological analyses
- Quality
- Contract research & production

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ACHIEVEMENTS

Statement: *"It is amazing what you can achieve with only 8 staff in 2 years"*:

- Set up sterile cell culture production of 100 mg protein/day in hollow fiber technology with continous harvest
- Have put a clean room in successful operation with utilities and sterile procedures in a very short time
- Implemented a complete environmental monitoring program
- Established a highly productive Master Cell Bank
- Set-up of a full blown Down Stream Process of purification of the harvested protein with 4 filters, an- and cat-ion exchange, gel filtration chromatography and virus filtration
- Set up of a complete analysis programme: HBP-ELISA, IL-6 ELISA, SDS-PAGE (PHAST), IEF, Glucose & lactate determination, UV-measurement
- Developed a smart and cheap GMP-system in preparation for inspection to obtain a production license for bulk for clinical trials.
- Prepared a complete toxicological programme including GLP
- Examined the entire development process concerning regulatory and agency requirements

PERIOD **1983 - 2001**

POSITION **Various positions as department manager, group head, section head, chemist, scientist**

COMPANY **Novo Nordisk**

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RESPONSIBILITIES

- Management of a department of 69 employees
- Analytical chemistry:
  - GMP-analysis of finished products in development, stability studies, release of production and costumer compliance
  - GLP-analysis of animal studies
  - Broad range of laboratory techniques
  - 50 different methods of analysis
  - 75 pieces of laboratory equipment
  - Protein chemistry
- Insulin range - Growth Hormone - Heparin

ACHIEVEMENTS

Participated in a number of development projects which resulted in some of today succesfull products of Novo Nordisk:

- Task of new insulin analogues in phase 1, 2 and most 3.
- Different formulations of diabetes products
- Numerous quantity of regulatory documents for INDs (Investigational News Drugs) and NDAs (New Drug Applications) worked out
- Filings and successfully launches of new products

Significantly increased the quality level in laboratories:

- Took initiative to a lot af changes and new set-ups
- A lot of validations and qualifications implemented and carried out which significantly increased the compliance level
- Intensive experience with inspections from different authorities. The department is one of the mostly inspected departments at Novo Nordisk

EDUCATION

PERIOD	2010 - 2011
UNIVERSITY	IMD Business School, Lausanne, Switzerland
GRADE	Top management training programme 4 modules with market dives

PERIOD	1983 - 1986
UNIVERSITY	Copenhagen Business School
GRADE	Bachelor of Commerce (B.Com. = HD), Organization, Strategy and Planning

PERIOD	1977 - 1983
UNIVERSITY	Royal Danish University of Pharmacy
GRADE	Master of Science (M.Sc. in Pharmacy)
SOCIETIES	Master of the University Senate (= Konsistorium)

COURSES

See appendix

LANGUAGES

- Danish: Native proficiency
- English: Full professional proficiency
- Norwegian: Full professional proficiency
- Swedish: Professional working proficiency
- German: Professional working proficiency

PERSONAL DATA

- Born: 1958
- Married 24 years with Jette
- 2 kids: Ida 17 years & Mads 21 years
- Leisure: Travel all over the world with the family, Summer house, Family life, Good food

SELECTED COURSES

- 2014 Medical device regulations and standards, Qmed
- 2014 Medical devices Quality management system & responsibilities, Qmed
- 2014 Medical devices Product Maintenance, Qmed
- 2014 Quality Management Systems for devices - Top Management Responsibilities, Qmed
- 2012-2014 Intensive LEO Pharma Training Programme in LEAN with a lot of modules and visit to other companies
- 2011 Market Dive: Critical factors for success in the Brazilian dermatology market, IMD Business School, San Paolo
- 2009 Leadership Communication, International Consulting & Training Group, Siegfried W. Andersen
- 2002 Current Good Manufacturing Practices for Biotechnological Products, Leiden University, The Netherlands
- 2002 Advances in Cell Cultures for Clinic and Pharmaceutical Industry, Leiden University, The Netherlands
- In total nearly 100 courses in
    - Management, Strategy & Planning
    - Power & Influence
    - GMP & GCP & GLP
    - FDA inspections
    - Quality Auditing
    - ISO 9000 & ISO 9001
    - Analytical technologies e.g. HPLC
    - Economy & IT
    - Business English
    - Powerpoint, Excel & Words
    - Safety
    - External Affairs
    - Statistics & Metrology
    - Active Pharmaceutical Ingredients
    - Biotechnologie