

## Curriculum Vitae

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## Job Experience:

March 2022-

### Sr Consultant, Owner, Salamon RA-CMC

Consultancy work within Regulatory Affairs CMC in the pharmaceutical/biotech area

May 2021 – Dec 2021

### Associate Director, RA CMC, Genmab A/S

Biotech product (antibody (mAb)-based cancer therapeutic product)

- Providing input to strategies regarding Module 3 content (US, EU, Japan)
- Coordinating the writing and reviewing process between Genmab, CMOs and partners
- Regulatory review of documents
- Handling Q&As to IMPD amendments, including input to response strategies and response writing

Jan 2017 – Apr 2021

### Principal Regulatory Professional, RA CMC, ALK-Abelló A/S

Biological products (immunotherapy and diagnosis of allergy; biological source materials; pollen, house dust mites, animal hair and dander, venoms)

- Preparing regulatory strategies and providing input to life cycle management activities; CMC-changes, new markets, withdrawals
- Writing and reviewing regulatory CMC documents (CTD M1, M2, M3)
- Updating old dossiers to current regulatory standard for legacy products
- Handling Q&A for MAs and variation applications; coordinating, preparing strategies, and writing response documents
- Experience with National approvals (EU, CH, Korea, China) and MRP, incl repeat use-procedure
- Defining and implementing internal process for national eCTD-submissions in EU, incl SOP writing, and training of colleagues in HQ and affiliates
- Working with several processes and systems (change handling, regulatory status, QA-batch release, document tracking etc)

Sep 2006 – Dec 2016 (except Feb 2010 – Feb 2011)

Sr. Regulatory Professional, RA CMC, Novo Nordisk A/S

Recombinant biotech products (insulin- and GLP1 analogues)

- Review and compiling of CMC documents (CTD M2 and M3) for MAA/NDA and CTA/IND for worldwide submissions
- Working with life cycle management (variations) world wide
- Regulatory evaluation of change requests and non-conformities
- Providing input to production, laboratories, and QA regarding regulatory requirements for documentation of changes
- Handling Q&As for MAA/NDAs and change applications
- Providing input to implementation of quality procedures in regulatory affairs dept.
- Teaching personnel in production/QC/QA in regulatory compliance
- Working with several processes and systems (change handling, regulatory status, QA-batch release, document tracking etc)

Feb 2010 – Feb 2011

Process Supporter, Manufacturing Development, Novo Nordisk A/S

- Purification process optimization / laboratory scale testing
- Writing regulatory CMC documents for CTAs and NDAs
- Preparation of non-conformities and change requests
- Updating SOPs and Master Production Instructions

Jan 2001 – Aug 2006

Analytical Chemist QC, Novo Nordisk A/S

- cGMP
- Release and stability testing, chemical and biological method
- Qualification of equipment and Validation of analytical methods
- Writing of SOPs, non-conformities and change requests
- Supervision of technicians
- Writing of regulatory documents (analytical procedures)

Aug 1992 – Dec 2000

Scientific employee, University Hospital (Rigshospitalet), Copenhagen

- Developing chemical and molecular methods for diagnosing hereditary and metabolic storage disorders

- Cell culturing (mammalian cells) and enzyme activity measures
- Preparation of information material to clinical staff
- Supervision of technicians

Aug 1989 – Apr 1991

Master Thesis, De Danske Sukkerfabrikker, Copenhagen

Title: Somatic embryogenesis in *Daucus carota* (carrot)

- Cell culturing, DNA extraction, HPLC-analysis

**Selected Courses:**

2018 Regulatory Affairs Module 12 (Drug/Device Combination), *Atrium*

2018 Regulatory challenges in markets outside ICH, *Atrium*

2017 Allergy course, *ALK-Abelló*

2014 Managing the project, Level 2, *Factor3*

2012-2013 Pharmaceutical Process Academy, *Novo Nordisk*

2011 Regulatory Affairs Module 10 (Biopharmaceuticals – Quality Development and Documentation), *Medicademy*

2008 CMC Regulatory Compliance for Biopharmaceuticals and Biologics, *CfPIE*

2007 Marketing Authorisations for Pharmaceuticals, *Pharmacon*

2004 Protein Purification and Characterisation, *Kielberg Consult*

2002 Biotechnological Production Processes, *Novo Nordisk*

2001 cGMP for QC Laboratories, *John Lee*

**IT:** Microsoft Office, Veeva Vault (Submissions and Quality)

**Language:** Danish (mother tongue), English (fluent in writing and speaking), German (basic knowledge)

**Education:**

1983-1991 Cand. Scient. (MSc) in biology, University of Copenhagen

1982-1983 Medical studies, University of Copenhagen