CHRISTINA HEMMINGSEN

Global Regulatory Affairs Director

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Nordre Fasanvej 215, 2000, Frederiksberg, Denmark

ABOUT ME

- Strong regulatory strategic mindset
- Confident in leading the development and execution of project strategies
- Over 15 years of global regulatory experience across all phases of drug development
- Numerous regulatory interactions with global health authorities such as FDA, EMA, PMDA, Health Canada and CFDA
- Experience within multiple therapeutic areas and with various types of products (proteins, mAb's, small molecules and stem cells)
- Driven by professional challenges and close collaboration with cross-functional stakeholders

EDUCATION

University of Copenhagen, Denmark
Diploma in Regulatory Affairs

University of Copenhagen, Denmark
MSc. Biomedical Engineering

MSc. Thesis: "Prediction and Control of Blood Glucose Concentration in Patients with T1DM", at Department of Informatics and Mathematical Modeling, DTU in collaboration with Novo Nordisk

Experience

2023- Present
Ozack ApS I Copenhagen Denmark

Global Regulatory Affairs Director

Responsibilities

- Provide global regulatory expertise and strategic advice tailored to startups and SMEs in the pharmaceutical and biotech sectors. Efficient guidance through complex regulatory patways to accelerate innovation and compliance.
- Develop and execute on global regulatory plans in close collaboration with project teams, including leading regulatory project milestones such as:
  - FDA Scientific Advice
  - Central and National Scientific Advice in Europe
  - IND submissions, including opening of IND
  - PIP submission
  - Eligibility request for regulatory incentives
- Provide support on pharmaceutical development and project management.

2017 - 2022
Novo Nordisk A/S I Copenhagen Denmark

Global Regulatory Lead, Regulatory Specialist

Responsibilities

- Leading the global regulatory team towards the global MAA / NDA submission of Wegovy® in 2020.
- Preparing the regulatory strategy across different formulations and indications for semaglutide.
- Planning and execution of global HA meetings (incl. EOP2 and pre- NDA / pre-MAA).
- Regulatory representative in the due diligence team that lead to Novo Nordisk acquirement of Corvidia Therapeutics / Ziltivekimab.

2015 - 2017
Novo Nordisk A/S I Copenhagen Denmark

Senior Regulatory Professional

Responsibilities

- Regulatory Responsible for the comprehensive clinical programme that lead to the approval of Rybelsus®
- Driving regulatory strategy and health authority interactions for Rybelsus® in China

2015 -2015
Lundbeck A/S I Copenhagen Denmark

Regulatory Product Lead

Responsibilities

- Regulatory Lead for Brintellix®
- Regulatory strategy for MAA / NDA and variations in International Markets
- Promotional review

LANGUAGE

English	Full Professional
Danish	Proficiency

2012 - 2015
Novo Nordisk A/S I Copenhagen Denmark

Regulatory Affairs Clinical Professional

Responsibilities

- Point of contact for EMA and lead on the MAA submission for Saxenda®
- Driving regulatory interactions with EMA and CHMP (including oral explanation),
- Driving the development of the Company Core Data Sheet (CCDS)
- Driving MAA / NDA submissions outside of EU and US

2010 - 2012
Novo Nordisk A/S I Copenhagen Denmark

Regulatory Affairs Graduate

Responsibilities

- Responsible for promotional review and global life-cycle management activities for Levemir® and other insulins
- Development of target product profile, CCDS, and early clinical plans for anti-C5a (based in Princeton, US for 8 months)
- Medical Affairs Inflammation: Assessment of competitor labels/gap analysis and publication planning

2010 - 2010
University of Copenhagen I Denmark

Research Assistant

Responsibilities

- Assisted MD, PhD, DMSci Susanne Bro, chief physician at the Department of Nephrology on a cohort project, on CVD in pts with renal insufficiency. Provided support in the establishment of a clinical database, as well as in the application for approval and funding from the Danish Council for Strategic Research (Det Strategiske Forskningsråd).

2009 - 2010
Copenhagen Trial, Rigshospitalet, Panum Institute

Research Assistant

Responsibilities

- Assisted in Cochrane-reviews concerning anti-diabetic interventions (screening og studies for eligibility, extraction of data and review of publications (see "Publications"). The results from the meta analysis were presented at EASD 2010. The reviews were prepared in cooperation with doctors from Steno Diabetes Center and CTU.

Additional Information

Publications

- Hemmingsen B et al, Intensive glycaemic control for patients with type 2 diabetes: systematic review with meta-analysis and trial sequential analysis of randomised clinical trials. BMJ. 2011 Nov 24; 343:d6898. Doi: 10.1136/bmj.d6898

- Hemmingsen B et al, Targeting intensive glycaemic control versus targeting conventional glycaemic control for type 2 diabetes mellitus The Cochrane Collaboration, February 15, 2012. Doi: 1002/14651858.CD008143.pub