Tina Meinertz
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Principal Advisor Pharma Development

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Competences

- More than 30 years of experience from the pharmaceutical industry hereof 14 years' experience from RA CMC
- RA CMC experience with CMC strategies for injectables and solid dosage form development and marketing authorizations wordwide (EU/US/JP/CA/Australia/China)
- Seven years of managerial experience within RA CMC
- Experience with writing of CTA/INDs for clinical trial applications for Phase I-III
- Experience with Q&A phases for CTA/IND/NDA/BLA/MAA approvals
- RA CMC experience with CMC strategies for LCM changes
- 10 years of experience with product development (injectables and solid dosage forms) for early development and MAA/BLA
- Experience from clinical development including GCP training.

Key results (Regulatory CMC)

Successful review of BLA/MAA resulting in approval of Skytrofa (Nonapegsomatropin) in EU/US.
Successful review of BLAs/MAAs resulting in approval of Refixia®(Nonacogbetapegol) and Esperoct® (turoctocogalfapegol)
Development of challenging regulatory strategies and risk analysis for meeting packages and responses submitted during review of BLAs/MAAs and substantial supplements.
Successful submission and approval of several substantial amendments worldwide for NovoEight®, NovoSeven® and NovoThirteen®
Successful submission and approval of INDs/CTAs for projects in phase I and phase II.
Timely and successful NDA submission and approval of PrandiMet® in China and Israel
Hands on experience with Decentralised and Centralised regulatory procedures in EU

Software/Standards

- ICH Q1 to Q12 covering regulatory requirements for NCE and Biologics (Medicademy Module 6 and 10).
- The Regulatory law frame in EU (Module 1 and 2 Medicademy)
- The Regulatory Environment in JP (Module 4 Medicademy)
- 21 CFR including guidelines for INDs/NDAs, BLAs and Supplements
- GCP certified - Brookwood International Academy of Healthcare Research

Extensive knowledge in:

- Veeva (Document handling and regulatory approvals)
- Microsoft 365

Personal Characteristics

With her many years of experience (+30) in the pharmaceutical industry within product development and regulatory affairs Tina has a very strong basis for settling strategies to the benefit of the projects within the regulatory framework.

Tina is a team player, goal and result oriented, dedicated with a high personal commitment to reach agreed timelines.

She has a positive attitude with changes and eager to acquire new competencies.

Furthermore, she has a good cultural understanding from collaboration with colleagues worldwide and very positive employee satisfaction evaluations from the teams managed over the years.

References

Medicologic A/S (present)
Principal Advisor Pharma development

Ascendis Pharma A/S

Director Regulatory CMC Head of the RA CMC team with direct reports in DK and US respectively. Responsible for providing effective support to the organization to ensure the best development programs for all current projects (Biologics and NCE's) as RA CMC expert at Ascendis Pharma

ALK Abello

Manager RA CMC Injectables, Drops & Devices
Head of the RA CMC team with 10 direct reports based in DK.
Overall responsible for regulatory CMC activities for ALK's Injectables, Drops & Devices product portfolio marketed in EU and China regulated under the Allergen extract legislation and the adrenaline product Jext®, which is a combination product regulated in EU as a medical device and combination product.
Responsible for regulatory strategies for major strategic LCM projects affecting drugs substance and drug products processes and manufacturing sites across the injectables product portfolio.

Novo Nordisk

Department Manager RA CMC & Device Biopharm (2015-2019)
Global Regulatory Lead (2014-2015)
Senior Regulatory Professional (2013-2014)
Regulatory professional (2009-2013)
Surveillance Coordinator (2006-2009)
Clinical Supply Chain Outsourcing Manager (2004-2006)
Clinical Development scientist (2001-2002)
Research Scientist, Product Development (1992-2001)

Responsibilities available upon request

Pharmexa

Research Scientist, Biologics development
Formulation and development of protein-based vaccines for preclinical as well as clinical studies. Evaluation and decision on primary packaging materials used for the parenteral products developed. Writing of development report for IND submission
Primary contact person to the external CMOs responsible for manufacturing of the parenteral products developed for clinical use.
Support downstream protein chemists with knowledge of stabilization of proteins by freeze drying.