CV - Lars Foldager, PhD

Summary

Throughout my career, I have been working with bioprocess development and manufacturing in the biotech and biopharmaceutical industry, including 25+ years in project management roles.

I have significant experience with all aspects of CMC Biologics Development, being overall responsible for the CMC Development (including mAbs, recombinant therapeutic vaccines and glycoproteins ~ 20-50 kDa) ranging from pre-clinical stage to Ph III/Filing Mode. I have headed cross-functional CMC Teams, defining and executing the CMC strategy, headed the outsourcing of CMC activities, including identification, evaluation and contract negotiation with Contract Development and Manufacturing Organizations (CDMOs).

I was overall responsible for all technical operations at the CDMOs, and have gained considerable knowledge of ICH Quality and CMC Regulatory requirements.

Previous experience includes commercial API bulk production of rhGH (human growth hormone), design through start-up and commissioning of a Fermentation Pilot Plant, bioprocess development, production support, scale up and Tech Transfer.

Professional experience

2002 - 2018: CMC Biologics Director / CMC Project Director, Lundbeck A/S
Responsibilities/experience including:

- Responsibility for CMC Development of biopharmaceuticals, including
  - Cell line development (CHO, *E.coli*)
  - Fermentation process development (fed batch, continuous), including scale up
  - Recovery & purification process development, including scale up
  - Formulation development (liquid, freeze-dried)
  - Analytical development and characterisation
  - Manufacturing of Clinical Trial Material (IMP)
  - Tech transfer of upstream & downstream processes and analytical methods
- Project Strategies and Project Scenario Planning, aiming for fully integrated plans
- Preparation for market supply, including
  - Process Risk Assessment exercise
  - Process Qualification & Process Validation - Drug substance and Drug Product
- Manage and overview CMC activities at CDMOs
- Write/review content of CMC regulatory documents, such as IBs, IMPDs, Comparability Reports and the CTD - Module 3 (Quality Section)
- Participate in formal meetings/Scientific Advices with Regulatory Authorities, such as FDA, EMA, PMDA (Japan) & BfArM (Germany)
- Participate in Due Diligence activities (as CMC expert)

2001 - 2002: Production Manager, hGH Bulk Production F&R, Novo Nordisk A/S

1986 - 2000: Scientist / Project Manager, Process Science Dept., Chr. Hansen A/S

Education

Ph.D., Institute of Biotechnology, Technical University of Denmark
M.Sc., Chemical Engineering, Technical University of Denmark

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