July 31st, 2024
11:00

Dr. Luisa Lundin
,NorthX Biologics, Sweden

BACKGROUND

Dr. Luisa Lundin is currently the Alliance Manager at NorthX Biologics, a CDMO specializing in advanced biologics. Prior to her current role, Dr. Lundin worked as a Scientific Support Specialist for the entire EMA region at a global medical technology company. She holds a PhD in Microbiology from the University of Copenhagen, where she specialized in the dynamics of stressed microbial communities in biotechnological settings. She has co-authored over 20 scientific publications during her academic career. Dr. Lundin's extensive career is built on a foundation of strong theoretical knowledge and practical lab experience, enhanced by insights gained from the manufacturing and pharmaceutical industries. She has gained experience in both research and industrial settings across various countries in Europe and the USA. A passionate advocate for a holistic approach to science, Dr. Lundin believes strongly in building bridges between different fields and expertise to ensure scientific advancements translate into practical benefits. She is an active member of ATMP Sweden, a network that promotes collaboration and communication to accelerate effective ATMP-based patient solutions.

Research to Reality: Bridging the Clinical Manufacturing Gap

Abstract

The transition from innovative research ideas to market-ready therapeutics involves complex scientific, regulatory, and logistical challenges. A collaborative environment where researchers, industry professionals, and regulatory experts can exchange knowledge and develop strategies is essential for efficiently and effectively bringing innovative therapies to patients. Identifying and addressing the critical steps in process development, quality control, and regulatory compliance is crucial for researchers as they develop strategic plans for advancing their discoveries into clinical applications. Bridging the gap between academia and the manufacturing world is necessary to address the practical aspects of scaling up from laboratory research to GMP-compliant production. Supported by real-world examples from the industry, this discussion will explore the fundamental elements of GMP manufacturing from the perspective of a Contract Development and Manufacturing Organization (CDMO). Key topics will include translating research protocols into GMP standards, navigating regulatory hurdles, ensuring compliance, developing robust quality control and assurance frameworks, and utilizing innovation hubs for process optimization. These topics will be illustrated with case studies of successful transitions from concept to GMP manufacturing.

Academia C²TN
SEMINÁRIOS · Workshops · Ações de formação · Mesas redondas
C²TN | TÉCNICO LISBOA