

**Job Title: Senior CMC Manager (Chemistry, Manufacturing and Controls) | 80-100%**

**Company: Synendos Therapeutics AG**

**Location: Basel, Switzerland**

**Job Summary:**

The Senior CMC Manager is responsible for leading all Chemistry, Manufacturing and Controls (CMC) activities at Synendos Therapeutics for the development of pharmaceutical products. This role will oversee the strategic planning, development and execution of CMC programs, ensuring compliance with regulatory requirements, and aligning priorities for optimal project execution. The ideal candidate will bring prior experience in drug substance and/or drug product manufacturing, process development, quality, and/or supply chain organizations.

Additionally, experience in formulation development, regulatory submissions and cross-functional project management is an advantage.

**Key Responsibilities:**

- Direct and coordinate the company's CMC activities for small molecule drug substances and drug products.
- Oversee GMP manufacturing activities, including process and analytical development, technology transfer, and scale-up.
- Prepare CMC development plan with full transparency of timelines, costs, risk analysis and mitigation.
- Lead CMC-related regulatory submission activities, e.g., IND, IMPD, ensuring compliance with FDA, EMA and other regulatory authorities.
- Ensure timely and compliant distribution of materials (supply chain management).
- Manage vendors (e.g., Contract Research, and Contract Development and Manufacturing Organizations (CROs/CDMOs)), ensuring quality, timelines and cost-effectiveness.
- Coordinate formulation development with internal and external stakeholders.
- Contribute to quality control and assurance measures in collaboration with Quality team.
- Lead CMC team and collaborate closely with internal stakeholders to ensure alignment of CMC strategies with corporate goals and objectives.
- Stay current with industry trends, regulatory changes and technological advancements in pharmaceutical manufacturing.

**Qualifications & Experience:**

- Ph.D. or Master's degree in Chemistry, Chemical Engineering, Pharmaceutical Sciences, or a related field.
- Minimum of 5 years of experience in CMC development within the pharmaceutical or biotech industry.
- Proven track record of involvement in CMC activities for small molecule products.
- Expertise in regulatory submissions and interactions with health authorities.

- Experience managing external CDMOs and CROs.
- In-depth knowledge of GMP, ICH guidelines and other regulatory requirements.
- Excellent project management and cross-functional collaboration skills.
- Strong problem-solving abilities and strategic thinking.
- Effective communication and stakeholder management skills.

#### **Why Join Us?**

- Opportunity to lead CMC activities for cutting-edge pharmaceutical innovations.
- Collaborative and dynamic work environment with growth opportunities.
- Competitive salary, benefits, and professional development support.

Interested candidates are encouraged to apply by submitting their resume and cover letter to [info@synendos.com](mailto:info@synendos.com)