
Director of CMC (UK)*(Small Molecule Drug Product)***Reporting to: Head of Chemistry****Location: UK-based, hybrid with flexibility to travel as required**

About AstronauTx

AstronauTx is a small, agile biotech developing therapeutics to treat neurological disorders by improving sleep architecture. We operate as a semi-virtual team, emphasising collaboration, creativity and rapid execution. Our culture values flexibility, hands-on problem-solving and individuals willing to roll up their sleeves to drive results in a fast-moving environment.

Position Summary

The Director of CMC will provide technical and strategic leadership across small molecule drug product development, ensuring GMP compliance and regulatory readiness as our lead programmes progress through early clinical development. The role will be responsible for formulation development and clinical supply through Phase 1 and into Phase 2, oversight of drug product CDMOs, drug product regulatory authoring, and liaison with our network of external drug substance and CMC consultants.

Key Responsibilities*Drug Product Strategy & Formulation Development*

- Provide technical leadership across small molecule drug product development
- Develop formulation strategies, including enhancement approaches where needed, to support product performance
- Provide input on pre-clinical formulation development to support toxicology and early candidate selection studies
- Define and execute drug product CMC development plans aligned with overall programme timelines
- Lead or contribute to formulation technology platform selection, balancing timeline, cost and phase-appropriate risk

Manufacturing & CDMO Oversight

- Act as the technical contact for drug product CDMOs, reviewing proposals, work plans and timelines
- Provide technical review of GMP batch records, deviations, change controls and CAPAs
- Contribute to drug product specifications and stability programmes with analytical partners

Regulatory & Documentation

- Author and review drug product sections of IMPDs and other CMC regulatory submissions
- Maintain up-to-date knowledge of applicable regulatory requirements (MHRA, EMA, FDA) and relevant ICH guidelines, and ensure their application across drug product activities
- Support responses to regulatory agency questions relating to CMC

Clinical Supply Support

- Provide CMC support for Phase 1 and Phase 2 clinical drug product supply, ensuring timely and compliant delivery
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- Coordinate with clinical operations to align drug product availability with study timelines
- Work with clinical supply partners on packaging and regional labelling requirements

External & Cross-Functional Collaboration

- Liaise closely with external drug substance and CMC consultants, CDMOs and third-party partners, ensuring alignment between drug substance and drug product development
- Work closely with Quality, Regulatory Affairs and Clinical Operations to support programme delivery
- Contribute CMC expertise to risk assessments, technical due diligence and development strategy discussions

Quality & Operational Excellence

- Support the Head of Chemistry on CMC priorities, budgets and timelines, flagging technical risks early
- Ensure robust documentation, data integrity and GMP compliance across drug product activities
- Help write and maintain CMC procedures (SOPs) as part of the company's quality system

Preferred Experience

- Degree in Chemistry, Pharmaceutical Sciences, Pharmaceutics or a related discipline
- Minimum of 10 years' experience in small molecule drug product development
- Experience defining and taking accountability for drug product strategy, ideally within or alongside a biotech, informed by a working knowledge of drug substance development
- Experience authoring, or making a significant contribution to, IMPDs and other CMC regulatory submissions
- Direct experience providing CMC support for Phase 1 drug products, including working with CDMOs and reviewing GMP batch documentation
- Ability to work effectively with external drug substance and CMC consultants and cross-functional stakeholders, with excellent communication skills

Desirable Experience

- Postgraduate qualification (MSc or PhD) in a relevant discipline
- Experience working within a small, fast-moving biotech environment
- Experience in pre-clinical formulation development
- Experience with enabling formulation technologies, including formulation enhancements for first-in-human dosing
- Experience conducting or contributing to developability/biopharmaceutics risk assessments
- Direct experience providing CMC support for Phase 2 clinical drug products

Why Join AstronauTx?

AstronauTx sits at a unique intersection of neuroscience, sleep biology and drug discovery, targeting a mechanism that is both scientifically compelling and largely untapped by the pharmaceutical industry. You will join a mission-driven team at a pivotal moment in the company's growth, with the chance to shape the CMC function as we move towards the clinic.

We offer a competitive salary, performance bonus and equity participation, alongside a comprehensive benefits package.

To Apply: Please submit your CV and a cover letter outlining your relevant CMC experience to careers@astronautx.bio