



Position Title:	Director, Analytical Development
Department:	Pharm Sci & Tech Ops (PSTO)
Hiring Manager:	Head of PSTO
Date Opened:	March 2021

We are a team of experts from multiple disciplines who have come together driven to bring hope with life-changing therapies to patients and their families.

Position Overview:

We are currently seeking a driven, thoughtful contributor to lead our Analytical Development function for all development stages. This role will help establish both near and long-term strategy while managing all activities through our outsourcing model for our development programs.

Responsibilities:

- Oversee technology transfer and validation of analytical methods to support starting material, intermediate, drug substance and drug product testing at CMOs/CTOs
- Identify and characterize drug impurities and degradation products
- Perform analytical method development for drug substance, and drug product
- Characterize and maintain reference materials
- Oversee and review in-process and release testing for drug substances and drug products at CMOs/CTOs
- Summarize batch analysis data and track impurities for DS and DP
- Design and monitor stability studies and trend stability and release data using statistical methods
- Review analytical documents and development reports
- Collaborate with QA, CMC team and CMOs towards timely generation and approval of documents
- Write technical reports and documents in support of regulatory filing
- Prepare CMC documents for INDs/IMPDs and NDAs/MAAs

Qualifications:

- MS or Ph.D. in chemistry or pharmaceutical sciences
- 10+ years in analytical development
- Strong organizational abilities and communication skills
- Self-directed and motivated
- Collaborative and team work
- Experience with CROs and CMOs
- Expert knowledge in regulatory, ICH and cGMP requirements

- Proven track record in applying analytical techniques to solve challenging problems