Example of Drug Product Development Job Description

Our innovative and growing company is looking to fill the role of drug product development. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for drug product development

- Qualify methodologies as appropriate per ICH Q2 (R1) requirements for routine use, drive the rationale for the level of qualification required
- Oversee and manage the transition of methods and data analysis to a high throughput/automation platform
- Liaise with analytical development team to ensure performance data are shared, and methods can be optimized
- Report, track and trend analytical data, and serve as the subject matter expert on project teams
- Generate high quality documentation to support regulatory filings
- Work with the Drug Product Development teams (OSD & Parenterals), the Strategic Business Support team and the appropriate Value Stream leadership team to conduct a 'gap analysis' annually of the scientific capabilities versus the requirements to support the portfolio
- Coordinate and lead tech transfer meetings, attend process development sub-team meetings as necessary, and manage information flow and decisions
- Responsible for (as appropriate) leading, facilitating, or coordinating all activities pertaining to tech transfer, which includes initial process/facility fit, process transfer, manufacturing readiness, production and testing, and tech transfer/project closeout
- Manage the tech transfer project schedule with external manufacturing partners and integrate this with other scheduling functions, so the schedule is visible and usable by relevant stakeholders

Qualifications for drug product development

- Experience in GMPs, formulation development and writing of regulatory submissions
- Identify the mechanisms governing drug product process and product performance and scale up using underlying physical and chemical principles properties of materials
- Evaluate critical to scale parameters and equipment parameters that can affect performance at a larger scale (e.g, blend times, shear rates, compaction/compression forces)
- Process and scale-up modelling of pharmaceutical processes to prepare oral, parenteral, solid and liquid dosage forms
- Experience in managing drug product process and device development from Phase 1 to post-approval
- Demonstrates technical proficiency, creativity, collaboration with others, and independent thought