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# Example of Drug Substance Job Description

Our growing company is looking to fill the role of drug substance. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

## Responsibilities for drug substance

* Represents Quality Assurance to guide various projects, process or procedure updates and technical meetings, as needed
* Responsible for review of executed DS batch records and CMO disposition pack and performance of SAP usage decisions for batch
* Responsible for training and mentoring other team members
* Responsible for review and approval of internal protocols, reports and regulatory filing updates as required
* Lead quality meetings with CMOs and represent QA on all other team meetings with CMOs
* Act as delegate for QA Drug Substance Manager as required
* Under general supervision will evaluate, select and apply standard engineering techniques and procedures
* Perform assignments that have clear and specific objectives and require investigation of limited number of variables
* Initiate and complete routine technical tasks
* Prompt and regular attendance to workplace

## Qualifications for drug substance

* Demonstrated ability to balance technical needs, resource requirements, and other business considerations across multiple assigned projects
* Experience with broad CMC issues encountered in drug development, and experience with regulatory filings (IND/NDA) are highly desirable
* Experience in operations involving highly potent compounds a plus
* Experience with directing the laboratory activities and development of junior staff members
* Ph.D., M.S
* Minimum of 10-12 years’ GMP related experience in biopharmaceutical / pharmaceutical or related industry