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# Example of Drug Substance Job Description

Our company is growing rapidly and is searching for experienced candidates for the position of drug substance. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

## Responsibilities for drug substance

* Gain an understanding of how to develop scalable isolation processes for intermediates and active pharmaceutical ingredients
* Learn to utilize analytical techniques such as HPLC, UPLC, and UPLC-MS to evaluate reaction performance and identify impurities
* Apply laboratory automation techniques toward expediently solving fundamental chemistry problems
* Preparation of a summer-end presentation and report
* Manages and trains Upstream Manufacturing personnel involved in cGMP fermentation, harvest and chromatography load preparation
* Leads and mentors Upstream staff
* Directs and participates in manufacturing activities including scheduling, document production and review, and assures of cGMP compliance
* Oversee Upstream and Downstream MS&T laboratories to support biological drug substance processes at Devens, Massachusetts and contract manufacturing organizations
* Oversee Manufacturing Technology functions supporting commercial manufacturing at Devens site
* In collaboration with Biologics Process Development, responsible for large-scale technical-transfer activities for late-stage clinical and commercial manufacturing processes, including establishment and support of process control strategies, specification windows, and comparability packages that lead to successful validation and commercialization

## Qualifications for drug substance

* Excellent organizational and communication skills demonstrated ability to manage projects and foster relationships within a matrix organization and with external partners
* Extensive DS development experience in biopharmaceutical or biotech industry
* Have knowledge in regulatory guidelines and regulatory document preparation
* The candidate must be well organized and have excellent oral and written communication skills, and be able to communicate and connect with all levels of the organization
* Demonstrated ability to function in a collaborative/team oriented environment
* Prepare, coordinate and facilitate high-quality Portfolio Reviews at Bio DS LT (incl