



JOB TITLE	PRINCIPAL SCIENTIST / ASSOCIATE SCIENTIFIC MANAGER 1	JOB CATEGORY	PROFESSIONAL
DEPARTMENT	R & D - DRUG PRODUCT (Formulation Development Lab)	JOB CODE	
LOCATION	BIOCON PARK	TRAVEL@WORK	OCCASIONAL
LEVEL	L5 - L6 - L7	POSITION TYPE	REGULAR
REPORTS TO		BU HEAD	
ROLE	INDIVIDUAL CONTRIBUTOR		

BIOCON BIOLOGICS

At Biocon Biologics, we are creating a model for the future of healthcare for all. We are a leading company in the biosimilars revolution where patients come first. Our

BACKGROUND AND EXPERIENCE REQUIRED

Masters in Biotechnology/Pharmacy/any other related field with 3 to 8 years of relevant industrial experience
 PhD in Biotechnology/Pharmaceuticals or any other related field with 0-3 years of relevant industrial experience
 Post-doctoral research in relevant field

PREFERRED SKILLS

The candidate should be well-versed in the area of drug product development. He/she should have experience in concepts of product stability, role of excipients in protein stability, knowledge of higher order structure and its role on product stability

The candidate should have knowledge on drug product formulation development. He/she should have knowledge on the concepts of developing a brand new formulation, evaluation of buffer systems, sugar excipients, role of surfactants such as polyols etc

The candidate should have basic knowledge of various container closure systems such as vials, pre-filled syringes, auto-injectors etc. that are prevalent in the market.

The candidate should have experience in running stability programs which include temperature, forced degradation studies, photo-stability studies etc

The candidate should have knowledge on product quality estimation techniques such as HPLC, CE-SDS etc. so that he/she should be able to understand the nuances of the data generated.

The candidate should have knowledge of particle characterization techniques and biophysical characterization techniques

The candidate should be well-versed in basic statistics and should have experience in using statistical software such as JMP, Minitab etc

The candidate should have basic knowledge of regulatory guidance from USFDA, EMA etc. and should have knowledge of ensuring development is done to meet the regulatory requirement

The candidate should have experience in developing drug product related data for Biosimilars.

JOB DESCRIPTION

ROLES & RESPONSIBILITIES (List in 'order of importance / time spent' as a '%')

Responsibility Area	Activities-	% Time spend
	List of activities performed within each responsibility area	
Technical	Extensively run/analyze data from all techniques involved in development of drug products for conducting various types of stability studies including process characterization studies	50
Technical	Handling of instrument calibration/maintenance, interfacing with Engineering and vendors for instrument maintenance	
Technical	Interpretation (including statistics) of data generated, preparing presentations for project meetings and presenting data to seniors	
Technical	Conduct process development activities including filter validation, extractables and leachables	
Documentation	Ensuring concurrent documentation of experimental data in the LNB, Data analysis and understanding trends in data generated, report writing and review, co-ordination with RQA	15
Cross-functional support	Extensive involvement in tech transfer activities to manufacturing/partners/CROs and following the performance of the manufacturing process	15
Non-technical	Involvement in vendor selection, evaluation, shipment activities to third parties, EHS activities and any ad-hoc trainings as required by the Company	10
Non-technical	Ability to manage a small team of scientists	10

COMPETENCIES

The candidate should have a go-getter attitude who are results oriented.

Prior experience in managing people technically and administrative will be a plus.

The candidate should have demonstrated ability of high level of integrity to ensure the documentation of the work done is given high level of importance.

The candidate should be a team-player who has demonstrated ability to work individually and in a team

Strong communication skills - written and oral