
Research, Development, and Manufacturing

Typical Job Description for Research, Development, and Manufacturing



Individuals who work in the area of Research, Development, and Manufacturing are at the heart of the work in the Biotechnology/Biomedical industry. They work in the laboratories carrying out independent research, working closely with investigators to design, execute, and interpret experiments. Lab work may include such features as preparing culture plates and stock solutions, sectioning, participating in laboratory meetings, journal clubs, and animal care, among other responsibilities. In addition, research and development workers perform periodic instrument maintenance and calibration, investigate new technologies, maintain documentation, and order supplies.

The focus of workers in the manufacturing department is to ensure quality of production. They provide close and immediate technical support of biomedical recovery operations, including troubleshooting equipment problems, sterilization and process control. They pull samples of materials and supplies to ensure that product is manufactured to specification. They are responsible for such areas as equipment cleaning and preparation, solution preparation, fermentations, protein purification processes, cell harvesting, and documentation to meet all regulatory requirements. This work involves a strong emphasis on customer service interactions.

In both the research and development and the manufacturing aspects of the Biotechnology/Biomedical industry, safety is a vital part of the work. Both in terms of personal safety and the safety of co-workers, and in terms of the safety of the public-at-large, individuals take on the contentious responsibility for ensuring that the work environment is safe, that all materials are handled and disposed of in a safe manner, and that the commodities produced meet or exceed all safety and regulatory requirements.

SAMPLE JOB TITLES

- Assistant Materials Specialist
- Associate Systems Specialist
- Bioprocess Associate
- Bioprocess Technician
- Manufacturing Services Technician
- Materials Analyst
- Pharmaceutical Manufacturing Technician
- Pharmaceutical Materials Specialist
- Research Assistant/Research Associate

Routine Scenario: A Day in Research and Development

YOU ARRIVE at the beginning of your day and schedule out the activities for the day. Nearly everyone will be multi-tasking in an R&D environment. For example, while waiting for cells to grow, other activities may be accomplished. Thus two or three things may be done in parallel while performing tasks such as doing a cell culture. While watching the cell line, you make sure to feed cells at appropriate intervals, monitor cells to be sure they split at appropriate times, and implement appropriate quality control measures to ensure that cell lines are not contaminated. At the same time, you could be entering data into the notebook, doing general lab maintenance, or utilizing those cells or other cell lines in experiments. During the day you may have to do literature searches to see if other scientific personnel have done similar experiments. At the close of an experiment you ensure you have data that can be analyzed, and you review the data with a more senior person.



PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

A. Support clinical research

- A1. Maintain laboratory equipment
- A3. Operate equipment
- A4. Maintain biological stock cultures
- A5. Clean and prepare items for lab
- A6. Prepare biological and/or chemical materials
- A9. Communicate with co-workers to ensure quality laboratory work

B. Assist with research and development

- B1. Perform assays and experiments
- B2. Assist in method development
- B3. Investigate new technologies and methodologies
- B4. Perform data analysis
- B5. Handle and/or maintain biological stock cultures
- B6. Troubleshoot experiments and equipment
- B7. Communicate results

E. Perform documentation

- E1. Maintain lab notebook
- E2. Create documents
- E3. Document Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices
- E4. Write reports
- E5. Maintain equipment logbooks
- E6. Maintain chemical/biological stock records
- E7. Maintain training documentation

**Crisis Scenario:
Out of Compliance**

THE DATA GATHERED during the production process does not come back as expected or as set by quality control, which means the product is outside of tolerances. You must check the machinery and check to see if the correct process was followed. You check documentation to ensure all SOPs (Standard Operating Procedures) were followed. You then follow a systematic approach to safely check the machinery. A representative for the machinery may be called in to recalibrate. Each step along the way is documented and turned in to a senior person to determine what to do with the out-of-compliance lot. Basically, in this situation you provide documentation, follow SOPs for remediation, and refer to appropriate parties.

PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

C. Manufacture the product or provide the service

- C1. Set up equipment for the production process
- C2. Perform and monitor the process to make the product or provide the service
- C3. Inspect materials at all stages of process to determine quality or condition
- C6. Monitor, maintain, and troubleshoot equipment, tools and workstation
- C7. Communicate with co-workers and/or customers to ensure production or service meets requirements

D. Maintain a safe and productive work environment

- D3. Identify unsafe conditions and take corrective action
- D5. Coordinate with work team
- D7. Handle and dispose of hazardous materials
- D8. Maintain Security

E. Perform documentation

- E2. Create documents
- E3. Document Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices
- E4. Write reports
- E5. Maintain equipment logbooks

Long-Term Scenario: Chemical Spill Team

Being a part of a CST (Chemical Spill Team) requires basic understanding of how chemicals react and how safety equipment is used for dealing with chemicals, such as breathing apparatus or special clothing. You attend numerous special trainings so that if a spill arises, the reaction is a planned event and the spill is properly contained. The procedures are documented to ensure clarity, communicate required steps for safety, and train other employees in how to handle chemical spills. Depending on the nature of the chemical—liquid, gas, acid, solvent, or other forms—there are different methods for containing the spill. You meet regularly with the CST, obtain certifications, and practice regular drills with the spill team.

PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

D. Maintain a safe and productive work environment

- D1. Participate in employer-sponsored safety training
- D2. Participate in emergency drills and emergency response teams
- D3. Identify unsafe conditions and take corrective action
- D4. Suggest continuous improvements
- D5. Coordinate with work team
- D6. Provide orientation and training for other employees
- D7. Handle and dispose of hazardous materials
- D8. Maintain Security

E. Perform documentation

- E4. Write reports
- E7. Maintain training documentation

Concentration: Research, Development, and Manufacturing

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CRITICAL WORK FUNCTIONS	KEY ACTIVITIES								
A. Perform routine laboratory support work	A1 Maintain laboratory and equipment	A2 Order and stock supplies	A3 Operate equipment	A4 Maintain biological stock cultures	A5 Clean and prepare items for lab	A6 Prepare biological and/or chemical materials	A7 Send, receive and distribute biological and chemical materials	A8 Perform routine animal care duties	A9 Communicate with co-workers to ensure quality laboratory work
B. Assist with research and development	B1 Perform assays and experiments	B2 Assist in method development	B3 Investigate new technologies and methodologies	B4 Perform data analysis	B5 Handle and/or maintain biological stock cultures	B6 Troubleshoot experiments and equipment	B7 Communicate results		
C. Manufacture the product or provide the service	C1 Set up equipment for the production process	C2 Perform and monitor the process to make the product or provide the service	C3 Inspect materials at all stages of process to determine quality or condition	C4 Participate in the installation, modification, and upgrade of equipment	C5 Prepare final product for shipping or distribution	C6 Monitor, maintain, and troubleshoot equipment, tools and workstation	C7 Communicate with co-workers and/or customers to ensure production or service meets requirements	C8 Coordinate inventory	
D. Maintain a safe and productive work environment	D1 Participate in employer-sponsored safety training	D2 Participate in emergency drills and emergency response teams	D3 Identify unsafe conditions and take corrective action	D4 Suggest continuous improvements	D5 Coordinate with work team	D6 Provide orientation and training for other employees	D7 Handle and dispose of hazardous materials	D8 Maintain security	
E. Perform documentation	E1 Maintain lab notebook	E2 Create documents	E3 Document Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices	E4 Write reports	E5 Maintain equipment logbooks	E6 Maintain chemical/biological stock records	E7 Maintain training documentation		