

Manufacturing Technician (Downstream)

| REF | Key Functions & Tasks (Downstream Manufacturing Technician) |
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| 1 | Work in compliance with EH&S. |
| 1.a | Wear appropriate personal protective equipment. |
| 1.b | Work in controlled environments. |
| 1.c | Participate in emergency drills and emergency response teams. |
| 1.d | Identify unsafe conditions and take corrective action. |
| 1.e | Appropriately and safely access production equipment. |
| 1.f | Handle, label, and dispose of hazardous / biohazard materials. |
| 1.g | Access and utilize MSDS. |
| 1.h | Perform permitting procedures. |
| 1.i | Carries out operations with attention to OSHA and EPA regulations, and other applicable state and federal regulations. |
| 1.j | Keeps work areas clean and safety equipment in order. |
| 1.k | Participate in all company safety training and audits as required. |
| 1.l | Assists with waste treatment operations. |
| 2 | Work in compliance with cGMPs. |
| 2.a | Assists in environmental monitoring activities. |
| 2.b | Follow SOPs for all operations. |
| 2.c | Records process data and completes batch records as required. |
| 2.d | Maintain equipment logbooks. |
| 2.e | Control and receipt of raw materials. |
| 2.f | Maintain training documentation. |
| 2.g | Maintain equipment and processes in a validated state. |
| 2.h | Working in controlled/classified areas (gowning, aseptic technique). |
| 2.i | Ensure appropriate flow of personnel, equipment, and materials. |
| 2.j | Change control for process, equipment, and documentation. |
| 2.k | Label and apply status to equipment and materials. |
| 2.l | Identify and report exception events and CAPA. |
| 3 | Clean and maintain production areas. |
| 3.a | Housekeeping / pest control. |
| 3.b | Sanitize and clean of controlled spaces. |
| 3.c | Preparation of cleaning materials and solutions. |
| 3.d | Assist in environmental monitoring for routine and changeover operations. |
| 3.e | Document cleaning. |
| 4 | Maintain effective communication. |
| 4.a | Deliver shift change update. |
| 4.b | Communicate with coworkers and/or customers to ensure production or service meets requirements. |
| 4.c | Suggest continuous improvements. |
| 4.d | Coordinate with work teams / internal customers. |
| 4.e | Maintain security and confidentiality. |
| 4.f | Respond appropriately to internal auditors and external inspectors. |
| 4.g | Assist in writing, reviewing, and commenting on technical documents. |

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| 5 | Prepare process materials. |
| 5.a | Weigh, dispense, and label raw materials for use in production. |
| 5.b | Dispense consumables and intermediates. |
| 5.c | Control and reconcile inventory with enterprise control system (MRP, SAP, manual database). |
| 5.d | Prepare and sterilize buffers and solutions. |
| 5.e | Sample and test buffers and solutions. |
| 5.f | Transfer buffers and solutions to use point. |
| 5.g | Prepare filters for use. |
| 5.h | Prepare, pasteurize / sterilize, and titrate media and feed solutions. |
| 5.i | Manage chromatography resins. |
| 6 | Prepare equipment. |
| 6.a | Clean CIP vessels, transfer lines, and filter trains . |
| 6.b | Clean COP equipment (or sonicator). |
| 6.c | Depyrogenate components and equipment. |
| 6.d | Sterilize SIP vessels, transfer lines, and sampling ports. |
| 6.e | Perform pressure test. |
| 6.f | Prepare and assemble components and equipment. |
| 6.g | Autoclave components and equipment. |
| 6.h | Perform WFI flush of transfer lines. |
| 6.i | Perform scheduled sanitizations of hoods. |
| 6.j | Prepare and standardize probes and ancillary instruments. |
| 6.k | Prepare, assembly, and integrity test filters. |
| 6.l | Visually inspect equipment. |
| 6.m | Maintain equipment logs and status tags. |
| 6.n | Complete, review and approve equipment process records. |
| 7 | Perform basic manufacturing operations. |
| 7.a | Perform processes following batch records, validation protocols, and/or SOPs. |
| 7.b | Maintains and controls processes in an automated control environment. |
| 7.c | Record process data. |
| 7.d | Inspect materials at all stages of process to determine quality or condition. |
| 7.e | Participate in the installation, modification, and upgrade of equipment. |
| 7.f | Operate, monitor, and maintain equipment, tools, and workstation. |
| 7.g | Recognize and respond appropriately to atypical events. |
| 7.h | Participate in troubleshooting and root cause analysis of operations. |
| 8 | Perform downstream manufacturing operations. |
| 8.a | Receive material from upstream processing. |
| 8.b | Separate cells from media using centrifugation or filtration (TFF or depth filtration). |
| 8.c | Perform cell disruption techniques (mechanical or chemical). |
| 8.d | Perform aqueous separations (liquid liquid extraction, precipitation). |
| 8.e | Perform chemical/enzymatic modifications to product. |
| 8.f | Perform normal flow and tangential flow filtration (including microfiltration, ultrafiltration, or diafiltration). |
| 8.g | Prepare chromatography columns (assembly, sanitization, resin packing, evaluation). |
| 8.h | Perform chromatography steps (equilibrate, load, wash, elute, clean, store). |
| 8.i | Perform viral clearance (removal/inactivation) steps. |
| 8.j | Bulk fill purified product. |
| 9 | Perform Sampling. |
| 9.a | Prepare sample port for aseptic sampling. |
| 9.b | Obtain in-process samples according to batch records or sampling plans. |
| 9.c | Label samples appropriately. |
| 9.d | Record sample collection and distribution (storage and chain of custody) |
| 9.e | Perform in-process chemical and/or microbiological tests. |