

In September 2013 fourteen industry subject matter experts came together to review and update the NBC2 Biomanufacturing Skill Standards developed in 2008. A list of key activities was developed for technicians in three biomanufacturing jobs: Manufacturing Technician (Upstream and Downstream), Quality Control (Microbiology and Biochemistry) and Maintenance and Instrumentation Technician

Industry Subject Matter Experts (SMEs) in attendance

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Performance Development Site Manager
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NBC2 Biomanufacturing Key Activities (2013)

Manufacturing Technician (Upstream and Downstream)

Quality Control (Microbiology and Biochemistry)

Maintenance and Instrumentation Technician

A. Work in compliance with EH&S.	
1.	Dons appropriate personal protective equipment and/or gowning.
2.	Works in controlled/classified environments.
3.	Follows Standard Operating Procedures (SOPs).
4.	Participates in emergency drills.
5.	Participates in emergency response.
6.	Identifies unsafe conditions and takes action.
7.	Accesses production equipment.
8.	Works with hazardous/biohazard materials.
9.	Accesses and utilizes MSDS and LOTO.
10.	Performs permitting procedures.
11.	Participates in company safety training.
12.	Participates in safety audits.
13.	Performs waste treatment and/or disposal operations (e.g., sharps, chemicals, flammables).
14.	Maintains facility security.
B. Work in compliance with cGMPs.	
15.	Performs environmental monitoring activities.
16.	Records data and documents activities (e.g., paper hard copy and/or electronically).
17.	Orders raw materials, parts, components and/or equipment.
18.	Receives and stores raw materials, parts, components and/or equipment.
19.	Handles raw materials, parts, components and/or equipment.
20.	Participates in training.
21.	Documents and/or maintains individual training.
22.	Works with equipment and processes in a validated state.
23.	Follows appropriate flow of personnel, equipment, and materials.
24.	Updates, labels, and applies status to equipment and materials.
25.	Identifies and reports exception/deviation events.
26.	Reviews and/or verifies data.
27.	Participates in change control activities.
28.	Archives documentation/data.
C. Clean and maintain production areas.	
29.	Performs housekeeping.
30.	Performs pest control activities.
31.	Prepares cleaning materials and solutions.

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Maintenance and Instrumentation Technician

32.	Sanitizes and cleans facilities.
33.	Sanitizes and cleans equipment exteriors.
34.	Sanitizes and cleans equipment interior surfaces (e.g., biosafety cabinet, fume hood, incubators).
D. Maintain effective communication.	
35.	Coordinates with coworkers and/or customers about production or service requirements.
36.	Performs changeover activities.
37.	Suggests continuous improvements.
38.	Responds to auditors and inspectors.
39.	Assists in writing, reviewing, and commenting on technical documents.
40.	Reports result to appropriate departments.
41.	Interacts with vendors.
E. Prepare process materials.	
42.	Weighs, dispenses, and labels raw materials, intermediates, and consumables.
43.	Enters data into inventory control system (e.g., MRP, SAP, manual database, batch record).
44.	Prepares process solutions (e.g., media, buffers).
45.	Samples and performs in-process testing of process solutions.
46.	Prepares filters for use.
F. Prepare equipment.	
47.	Performs clean-in-place (CIP) of equipment.
48.	Performs steam-in-place (SIP) of equipment.
49.	Performs pressure test.
50.	Performs clean-out-of-place (COP) of equipment.
51.	Prepares and assembles components and equipment.
52.	Autoclaves components and equipment.
53.	Depyrogenates components and equipment.
54.	Prepares and standardizes probes and ancillary instruments.
55.	Participates in the installation, modification, and upgrade of equipment.
56.	Inspects equipment visually prior to use.
G. Perform basic manufacturing operations.	
57.	Inspects or samples materials at all stages of process to determine quality or condition.
58.	Operates, monitors, and maintains equipment, tools, and workstation (e.g., HMI, process control systems).
59.	Participates in troubleshooting, trend analysis, and root cause analysis of operations.
H. Perform upstream manufacturing operations.	

*Note: Key activities are equivalent to competencies and/or tasks.

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60.	Performs vial thaw from a cell bank.
61.	Performs cell culture expansion (scale-up).
62.	Monitors cell concentration by cell counting or measuring OD.
63.	Inoculates seed and/or production reactors.
64.	Monitors and maintains conditions for growth of cells in culture vessels.
65.	Performs aseptic additions of media, solutions, and/or gases to reactors.
66.	Performs aseptic sampling.
67.	Labels samples.
I. Perform downstream manufacturing operations.	
68.	Separates cells from media using centrifugation or filtration (e.g., TFF or depth filtration).
69.	Performs cell disruption techniques (e.g., mechanical or chemical).
70.	Performs aqueous separations (e.g., liquid extraction, precipitation).
71.	Performs chemical/enzymatic modifications to product.
72.	<i>Prepares</i> equipment for normal flow and tangential flow filtration (e.g., including microfiltration, ultrafiltration, or diafiltration).
73.	<i>Performs</i> normal flow and tangential flow filtration (e.g., including microfiltration, ultrafiltration, or diafiltration).
74.	Prepares chromatography columns (e.g., assembly, sanitization, resin packing, evaluation).
75.	Performs chromatography steps (e.g., equilibrate, load, wash, elute, clean, store).
76.	Performs viral clearance (e.g., removal/inactivation) steps.
77.	Performs bulk fill of product.
J. Perform Laboratory Work.	
78.	Prepares reagents.
79.	Performs sample receipt (stability, in-process, water, raw materials, final product, environment, validation) per batch records or plans.
80.	Qualifies sanitizing agents and disinfectants.
81.	Qualifies and maintains reference standards.
82.	Maintains reference cultures.
83.	Prepares samples for analysis.
84.	Performs upstream testing.
85.	Performs downstream testing.
86.	Evaluates data according to specifications.
K. Perform Microbiological Testing and Culturing.	
87.	Prepares working cell bank.

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88.	Tests sterilization cycles with biological indicators.
89.	Performs microbial identification.
90.	Tests for virus.
91.	Tests for mycoplasma.
92.	Tests for endotoxin/pyrogen using LAL (e.g., water, in-process, final product).
93.	Tests for bioburden (e.g., water, in-process, final product).
94.	Tests for quality of media/reagents using growth promotion tests.
95.	Conducts sterility testing on in-process materials and/or finished products.
L. Perform Chemical and Biochemical Testing	
96.	Performs chemical and/or biochemical testing for identity, potency, purity, consistency, and/or stability.
97.	Performs chemical and biochemical testing for raw material, water, and other environmental and validation samples.
M. Managing Information	
98.	Utilizes computer systems to manage data.
99.	Supports data trending activities.
100.	Generates technical reports.
N. Provide Technical and/or Validation Support	
101.	Participates in the investigation of OOS results.
102.	Assists in executing validation procedures.
103.	Standardizes equipment to ensure operation within process parameters.
O. Calibrate, monitor, maintain, and repair process or laboratory equipment.	
104.	Calibrates pressure, temperature, flow, weight, pH, DO, and other critical measurement devices and transmitters.
105.	Performs preventive maintenance (PM).
106.	Monitor, maintain and repair process vessels and fluid handling systems including pumps, pipes and valves.
107.	Monitor, maintain and repair heat transfer equipment (e.g., heat exchangers, condensers, evaporators).
108.	Monitor, maintain and repair process support equipment (e.g., autoclaves, ovens, dryers, washers).
109.	Monitor, maintain and repair refrigeration equipment (e.g., freezers, lyophilizers).
110.	Monitor, maintain and repair laboratory equipment (e.g., scales, hot plates, HPLC).
111.	Monitor, maintain and repair fill/finish equipment including automated equipment (e.g., filling machines, cap/inspect machines, packaging).
112.	Responds to equipment alarms.

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Manufacturing Technician (Upstream and Downstream)

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Maintenance and Instrumentation Technician

P. Monitor, maintain, and repair plant utility systems.	
113.	Calibrates control valves, actuators, positioners, and process switching devices.
114.	Monitors, maintains and repairs utility systems including instrument air, process gases (e.g., helium, CO ₂ , air, oxygen, nitrogen).
115.	Monitors, maintains and repairs utility systems including steam, process water types (e.g., DI, WFI, USP) and cooling/heating fluids (e.g., liquid nitrogen, glycol).
116.	Monitors, maintains and repairs utility systems including HVAC, electrical, hydraulic.
117.	Monitors, maintains and repairs waste treatment systems (e.g., waste neutralization, inactivation, scrubbers).
118.	Monitors, maintains and repairs site safety systems (e.g., fire suppression, eye wash, safety showers).
119.	Monitors, maintains and repairs security system including controlled personnel access.
120.	Monitors building management systems.
121.	Responds to building management system alarms.
122.	Performs testing of plant utilities.
Q. Maintain control systems, equipment and instrumentation.	
123.	Programs and/or replaces microprocessors, PC, PLC, and DCS controllers and devices.
124.	Maintains and repairs on-off actuators, diaphragms, electrical and pneumatic and hydraulic industrial control circuits and equipment.
R. General Engineering Technology and Maintenance Skills	
125.	Assists in installation, modification, and commissioning of equipment and facilities.
126.	Maintains spare parts inventory.
127.	Uses Computerized Maintenance Management System (CMMS) to schedule and track work orders for corrective and preventive maintenance (PMs) (e.g., Maximo, Atlas, Blue Mountain).

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