

1. Welcome and Instructions

Welcome to the NBC2 Task Survey!

You have been selected as a Subject Matter Expert to participate in this survey. NBC2 needs your input to better understand the following jobs:

- * **Manufacturing Technician** (Upstream and Downstream),
- * **Quality Control** (Microbiology and Biochemistry)
- * **Maintenance and Instrumentation Technician**

The survey first asks a few demographic questions, without asking for any personally identifiable information. This is done to help demonstrate compliance with Federal guidelines, but in a manner that will ensure that your responses are anonymous and confidential.

Then, the survey asks you to rate behaviors, or tasks, that are part of the jobs listed above. It will take approximately 30 minutes to complete the ratings. You only need to complete it one time, but you will need to complete it all in one sitting. Please be sure to set aside the time you need to complete the survey all at once.

The buttons at the bottom of each page of the survey allow you to go back to a previous page and to advance to the next page by selecting the appropriate button.

2. Demographics

Please complete your answers to the following questions. These are being asked without collecting your name to ensure the anonymity and confidentiality of your responses. All of the responses will be aggregated with those of the other survey participants and will be reported as a group, not individually.

Once completed, you will be moved to the job task ratings portion of the survey.

What is your gender?

- Male
- Female
- Other

What is your age? (choose the correct range for your age)

- 20 and under
- 21 to 30
- 31 to 40
- 41 to 50
- 51 to 60
- 61 to 70
- over 70

*Which job title best describes the job that you hold?

- Manufacturing Technician--Upstream
- Manufacturing Technician-- Downstream
- Quality Control--Microbiology
- Quality Control--Biochemistry
- Maintenance and Instrumentation Technician

Other (please specify)

With which race do you primarily identify?

- Asian or Pacific Islander
- Asian Indian
- Black/African American (non-Hispanic)
- Caucasian/White
- Native American
- Latino/Hispanic
- Puerto Rican
- More than one race

Other (please specify)

3. Task Rating Instructions

Following is a list of job tasks or actions performed by incumbents in your industry. These are behaviors that someone else could watch being performed on the job. They are grouped into similar duties. Please read each statement and then rate it on BOTH Importance AND Time Spent.

IMPORTANCE refers to the significance of the task to overall job performance. In evaluating Importance, consider what may happen if the task is not performed properly. (Exclude the effects of gross negligence or intentional sabotage.) Choose the Importance statement, located in the drop-down box next to the task statement, that best describes how important the task is to the job. If the task is NOT performed as part of the job, choose a zero (0). If the task IS performed as part of the job, think about how important the task is to the job, and choose the appropriate rating from 1 ("This task is NOT VERY IMPORTANT to the job I perform") to 5 ("This task is EXTREMELY IMPORTANT to the job I perform").

For the **TIME SPENT** ratings, choose the statement that best describes the amount of time spent performing the task relative to the amount of time spent on all of the other tasks of the job. If the task is NOT performed as part of the job, choose a zero (0). If the task IS performed as part of the job, think about the amount of time spent performing the task relative to the time spent on the other tasks, and choose the appropriate rating from 1 ("I spend a VERY SMALL AMOUNT OF TIME performing this task relative to that spent on the other tasks") to 5 ("I spend a VERY LARGE AMOUNT OF TIME performing this task relative to that spent on the other tasks").

*A. WORK IN COMPLIANCE WITH EH&S

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
1. Dons appropriate personal protective equipment and/or gowning.	<input type="text"/>	<input type="text"/>
2. Works in controlled/classified environments.	<input type="text"/>	<input type="text"/>
3. Participates in emergency drills.	<input type="text"/>	<input type="text"/>
4. Participates in emergency response.	<input type="text"/>	<input type="text"/>
5. Identifies unsafe conditions and takes action.	<input type="text"/>	<input type="text"/>
6. Accesses production equipment.	<input type="text"/>	<input type="text"/>
7. Works with hazardous/biohazard materials.	<input type="text"/>	<input type="text"/>
8. Accesses and utilizes MSDS and LOTO.	<input type="text"/>	<input type="text"/>
9. Performs permitting procedures.	<input type="text"/>	<input type="text"/>
10. Participates in company safety training.	<input type="text"/>	<input type="text"/>
11. Participates in safety audits.	<input type="text"/>	<input type="text"/>
12. Performs waste treatment and/or disposal operations (e.g., sharps, chemicals, flammables).	<input type="text"/>	<input type="text"/>

4. Task rating continued

*B. WORK IN COMPLIANCE WITH cGMPs

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
13. Performs environmental monitoring activities.	<input type="text"/>	<input type="text"/>
14. Records data and documents activities (e.g., paper hard copy and/or electronically).	<input type="text"/>	<input type="text"/>
15. Orders raw materials, parts, components and/or equipment.	<input type="text"/>	<input type="text"/>
16. Receives and stores raw materials, parts, components and/or equipment.	<input type="text"/>	<input type="text"/>
17. Handles raw materials, parts, components and/or equipment.	<input type="text"/>	<input type="text"/>
18. Participates in training.	<input type="text"/>	<input type="text"/>
19. Documents and/or maintains individual training.	<input type="text"/>	<input type="text"/>
20. Works with equipment and processes in a validated state.	<input type="text"/>	<input type="text"/>
21. Follows appropriate flow of personnel, equipment, and materials.	<input type="text"/>	<input type="text"/>
22. Updates, labels, and applies status to equipment and materials.	<input type="text"/>	<input type="text"/>
23. Identifies and reports exception/deviation events.	<input type="text"/>	<input type="text"/>
24. Reviews and/or verifies data.	<input type="text"/>	<input type="text"/>
25. Participates in change control activities.	<input type="text"/>	<input type="text"/>
26. Archives documentation/data.	<input type="text"/>	<input type="text"/>

5. Task rating continued

*C. CLEAN AND MAINTAIN PRODUCTION AREAS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
27. Performs housekeeping.	<input type="text"/>	<input type="text"/>
28. Performs pest control activities.	<input type="text"/>	<input type="text"/>
29. Prepares cleaning materials and solutions.	<input type="text"/>	<input type="text"/>
30. Sanitizes and cleans facilities.	<input type="text"/>	<input type="text"/>
31. Sanitizes and cleans equipment exteriors.	<input type="text"/>	<input type="text"/>
32. Sanitizes and cleans equipment interior surfaces (e.g., biosafety cabinet, fume hood, incubators).	<input type="text"/>	<input type="text"/>

*D. MAINTAIN EFFECTIVE COMMUNICATION

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
33. Coordinates with coworkers and/or customers about production or service requirements.	<input type="text"/>	<input type="text"/>
34. Performs changeover activities.	<input type="text"/>	<input type="text"/>
35. Suggests continuous improvements.	<input type="text"/>	<input type="text"/>
36. Responds to auditors and inspectors.	<input type="text"/>	<input type="text"/>
37. Assists in writing, reviewing, and commenting on technical documents.	<input type="text"/>	<input type="text"/>
38. Reports result to appropriate departments.	<input type="text"/>	<input type="text"/>
39. Interacts with vendors.	<input type="text"/>	<input type="text"/>

6. Task rating continued

*E. PREPARE PROCESS MATERIALS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
40. Weighs, dispenses, and labels raw materials, intermediates, and consumables.	<input type="text"/>	<input type="text"/>
41. Enters data into inventory control system (e.g., MRP, SAP, manual database).	<input type="text"/>	<input type="text"/>
42. Prepares process solutions (e.g., media, buffers).	<input type="text"/>	<input type="text"/>
43. Samples and performs in-process testing of process solutions.	<input type="text"/>	<input type="text"/>
44. Prepares filters for use.	<input type="text"/>	<input type="text"/>

*F. PREPARE EQUIPMENT

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
45. Performs clean-in-place (CIP) of equipment.	<input type="text"/>	<input type="text"/>
46. Performs steam-in-place (SIP) of equipment.	<input type="text"/>	<input type="text"/>
47. Performs pressure test.	<input type="text"/>	<input type="text"/>
48. Performs clean-out-of-place (COP) of equipment.	<input type="text"/>	<input type="text"/>
49. Prepares and assembles components and equipment.	<input type="text"/>	<input type="text"/>
50. Autoclaves components and equipment.	<input type="text"/>	<input type="text"/>
51. Depyrogenates components and equipment.	<input type="text"/>	<input type="text"/>
52. Prepares and standardizes probes and ancillary instruments.	<input type="text"/>	<input type="text"/>
53. Participates in the installation, modification, and upgrade of equipment.	<input type="text"/>	<input type="text"/>
54. Inspects equipment visually prior to use.	<input type="text"/>	<input type="text"/>

*G. PERFORM BASIC MANUFACTURING OPERATIONS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
55. Inspects materials at all stages of process to determine quality or condition.	<input type="text"/>	<input type="text"/>
56. Operates, monitors, and maintains equipment, tools, and workstation (e.g., HMI, process control systems).	<input type="text"/>	<input type="text"/>
57. Participates in troubleshooting and root cause analysis of operations.	<input type="text"/>	<input type="text"/>

7. Task rating continued

*H. PERFORM UPSTREAM MANUFACTURING OPERATIONS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
58. Performs vial thaw from a cell bank.	<input type="text"/>	<input type="text"/>
59. Performs cell culture expansion.	<input type="text"/>	<input type="text"/>
60. Monitors cell concentration by cell counting or measuring OD.	<input type="text"/>	<input type="text"/>
61. Inoculates seed and/or production reactors.	<input type="text"/>	<input type="text"/>
62. Monitors and maintains conditions for growth of cells in culture vessels.	<input type="text"/>	<input type="text"/>
63. Performs aseptic additions of media, solutions, and/or gases to reactors.	<input type="text"/>	<input type="text"/>
64. Performs aseptic sampling.	<input type="text"/>	<input type="text"/>
65. Labels samples.	<input type="text"/>	<input type="text"/>

*I. PERFORM DOWNSTREAM MANUFACTURING OPERATIONS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
66. Separates cells from media using centrifugation or filtration (e.g., TFF or depth filtration).	<input type="text"/>	<input type="text"/>
67. Performs cell disruption techniques (e.g., mechanical or chemical).	<input type="text"/>	<input type="text"/>
68. Performs aqueous separations (e.g., liquid extraction, precipitation).	<input type="text"/>	<input type="text"/>
69. Performs chemical/enzymatic modifications to product.	<input type="text"/>	<input type="text"/>
70. Prepares equipment for normal flow and tangential flow filtration (e.g., including microfiltration, ultrafiltration, or diafiltration).	<input type="text"/>	<input type="text"/>
71. Performs normal flow and tangential flow filtration (e.g., including microfiltration, ultrafiltration, or diafiltration).	<input type="text"/>	<input type="text"/>
72. Prepares chromatography columns (e.g., assembly, sanitization, resin packing, evaluation).	<input type="text"/>	<input type="text"/>
73. Performs chromatography steps (e.g., equilibrate, load, wash, elute, clean, store).	<input type="text"/>	<input type="text"/>
74. Performs viral clearance (e.g., removal/inactivation) steps.	<input type="text"/>	<input type="text"/>
75. Performs bulk fill of product.	<input type="text"/>	<input type="text"/>

8. Task rating continued

*J. PERFORM LABORATORY WORK

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
76. Prepares reagents.	<input type="text"/>	<input type="text"/>
77. Performs sample receipt (stability, in-process, water, raw materials, final product, environment, validation) per batch records or plans.	<input type="text"/>	<input type="text"/>
78. Qualifies sanitizing agents and disinfectants.	<input type="text"/>	<input type="text"/>
79. Qualifies and maintains reference standards.	<input type="text"/>	<input type="text"/>
80. Maintains reference cultures	<input type="text"/>	<input type="text"/>
81. Prepares samples for analysis.	<input type="text"/>	<input type="text"/>
82. Evaluates data according to specifications.	<input type="text"/>	<input type="text"/>

*K. PERFORM MICROBIOLOGICAL TESTING AND CULTURING

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
83. Tests sterilization cycles with biological indicators.	<input type="text"/>	<input type="text"/>
84. Performs microbial identification.	<input type="text"/>	<input type="text"/>
85. Tests for virus.	<input type="text"/>	<input type="text"/>
86. Tests for mycoplasma.	<input type="text"/>	<input type="text"/>
87. Tests for endotoxin/pyrogen using LAL (e.g., water, in-process, final product).	<input type="text"/>	<input type="text"/>
88. Tests for bioburden (e.g., water, in-process, final product).	<input type="text"/>	<input type="text"/>
89. Tests for quality of media/reagents using growth promotion tests.	<input type="text"/>	<input type="text"/>
90. Conducts sterility testing on in-process materials and/or finished products.	<input type="text"/>	<input type="text"/>

9. Task rating continued

*L. PERFORM CHEMICAL AND BIOCHEMICAL TESTING

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
91. Performs chemical and/or biochemical testing for identity, potency, purity, consistency, and/or stability.	<input type="text"/>	<input type="text"/>
92. Performs chemical and biochemical testing for raw material, water, and other environmental and validation samples.	<input type="text"/>	<input type="text"/>

*M. MANAGING INFORMATION

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
93. Utilizes computer systems to manage data.	<input type="text"/>	<input type="text"/>
94. Supports data trending activities.	<input type="text"/>	<input type="text"/>
95. Generates technical reports.	<input type="text"/>	<input type="text"/>

*N. PROVIDE TECHNICAL AND/OR VALIDATION SUPPORT

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
96. Participates in the investigation of OOS results.	<input type="text"/>	<input type="text"/>
97. Assists in executing validation procedures.	<input type="text"/>	<input type="text"/>
98. Standardizes equipment to ensure operation within process parameters.	<input type="text"/>	<input type="text"/>

10. Task rating continued

*O. CALIBRATE, MONITOR, MAINTAIN, AND REPAIR PROCESS OR LABORATORY EQUIPMENT

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
99. Calibrates pressure, temperature, flow, weight, pH, DO, and other critical measurement devices and transmitters.	<input type="text"/>	<input type="text"/>
100. Performs preventive maintenance (PM).	<input type="text"/>	<input type="text"/>
101. Monitor, maintain and repair process vessels and fluid handling systems including pumps, pipes and valves.	<input type="text"/>	<input type="text"/>
102. Monitor, maintain and repair heat transfer equipment (e.g., heat exchangers, condensers, evaporators).	<input type="text"/>	<input type="text"/>
103. Monitor, maintain and repair process support equipment (e.g., autoclaves, ovens, dryers, washers).	<input type="text"/>	<input type="text"/>
104. Monitor, maintain and repair refrigeration equipment (e.g., freezers, lyophilizers).	<input type="text"/>	<input type="text"/>
105. Monitor, maintain and repair laboratory equipment (e.g., scales, hot plates, HPLC).	<input type="text"/>	<input type="text"/>
106. Monitor, maintain and repair fill/finish equipment including automated equipment (e.g., filling machines, cap/inspect machines, packaging).	<input type="text"/>	<input type="text"/>
107. Responds to equipment alarms.	<input type="text"/>	<input type="text"/>

11. Task rating continued

*P. MONITOR, MAINTAIN, AND REPAIR PLANT UTILITY SYSTEMS

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
108. Calibrates control valves, actuators, positioners, and process switching devices.	<input type="text"/>	<input type="text"/>
109. Monitors, maintains and repairs utility systems including instrument air, process gases (e.g., helium, CO2, air, oxygen, nitrogen).	<input type="text"/>	<input type="text"/>
110. 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).	<input type="text"/>	<input type="text"/>
111. Monitors, maintains and repairs utility systems including HVAC, electrical, hydraulic.	<input type="text"/>	<input type="text"/>
112. Monitors, maintains and repairs waste treatment systems (e.g., waste neutralization, inactivation, scrubbers).	<input type="text"/>	<input type="text"/>
113. Monitors, maintains and repairs site safety systems (e.g., fire suppression, eye wash, safety showers)	<input type="text"/>	<input type="text"/>
114. Monitors, maintains and repairs security system including controlled personnel access.	<input type="text"/>	<input type="text"/>
115. Monitors building management systems.	<input type="text"/>	<input type="text"/>
116. Responds to building management system alarms.	<input type="text"/>	<input type="text"/>
117. Performs testing of plant utilities.	<input type="text"/>	<input type="text"/>

***Q. MAINTAIN CONTROL SYSTEMS,EQUIPMENT AND INSTRUMENTATION**

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
118. Programs and/or replaces microprocessors, PC, PLC, and DCS controllers and devices.	<input type="text"/>	<input type="text"/>
119. Maintains and repairs on-off actuators, diaphragms, electrical and pneumatic and hydraulic industrial control circuits and equipment.	<input type="text"/>	<input type="text"/>

***R. GENERAL ENGINEERING TECHNOLOGY AND MAINTENANCE**

Rate each task below for both Importance and Time Spent.

	Importance	Time Spent
120. Assists in installation, modification, and commissioning of equipment and facilities.	<input type="text"/>	<input type="text"/>
121. Maintains spare parts inventory.	<input type="text"/>	<input type="text"/>
122. Uses Computerized Maintenance Management System (CMMS) to schedule and track work orders for corrective and preventive maintenance (PMs) (e.g., Maximo, Atlas, Blue Mountain).	<input type="text"/>	<input type="text"/>

13. Thank you.

You have finished the survey. We thank you for your participation. Your responses will be analyzed with the others we receive.

Submit your survey by selecting "Done" below.