



BIOPHARMACEUTICAL **careers**

teacher guide

**FOR USE WITH THE FOLLOWING VIDEOS,
FOUND AT *ABOUTBIOSCIENCE.ORG*:**

quality assurance associate
quality control associate
validation specialist

DEVELOPED BY



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FUNDED BY



[biogenidec.com/site/
company-foundation.html](http://biogenidec.com/site/company-foundation.html)

BIOPHARMACEUTICAL careers

teacher guide overview

Exciting career opportunities exist for students who are interested in working in the biopharmaceutical industry and making a positive contribution to the lives of millions of people who will benefit from the medical advances this industry creates.

This teacher guide is designed to be used in conjunction with the three biopharmaceutical career videos developed by the North Carolina Association for Biomedical Research (NCABR) for *North Carolina's Bioscience Clearinghouse* (aboutbioscience.org). Options are offered for middle and high school students.

The videos, and the written career profiles that accompany them, can be found at the following URLs:

Quality assurance associate

aboutbioscience.org/quality_assurance_associate.html

Quality control associate

aboutbioscience.org/quality_control_associate.html

Validation specialist

aboutbioscience.org/validation_specialist.html

BIOPHARMACEUTICAL careers

activity #1: survey

TYPE: Knowledge and opinion survey

GRADE LEVEL: Middle school and high school

TIME NEEDED: 10 minutes in class

This survey is designed to be administered *before* the students see any videos.

1. Provide one survey per student and ask each student to quickly answer the 10 survey questions.
2. Collect the surveys and store them in a secure file.

At the conclusion of instruction about biopharmaceutical careers, you will hand out a clean set of surveys and have students “retake” the survey.

Then, return to each student his/her original survey and ask each student to compare his/her responses from the first survey to the second.

Discussion questions at the conclusion of this activity may include:

- What have you learned about biopharmaceutical careers?
- Would you consider pursuing a biopharmaceutical career? Why or why not?

Question 9 does not have a “correct” answer. Correct answers to the other questions are as follows:

- Question 1: Agree (3)
- Question 2: Agree (3)
- Question 3: Disagree (1)
- Question 4: Disagree (1)
- Question 5: Disagree (1)
- Question 6: Disagree (1)
- Question 7: Agree (3)
- Question 8: Disagree (1)

BIPHARMACEUTICAL careers

activity #1: student response sheet

NAME: _____

DATE: _____

Please answer each question as honestly as possible. Your answers will be kept confidential. Use the following scale when selecting your answer:

3 = Agree

2 = Unsure

1 = Disagree

- _____ 1. Working in the biopharmaceutical industry gives one person the chance to have an impact on many peoples' lives.
- _____ 2. In a biopharmaceutical laboratory, it is important to wear special clothing to protect yourself from the potentially harmful products with which you are working — and also to protect the products from you.
- _____ 3. Every day in a biopharmaceutical career is pretty much just like every other day.
- _____ 4. Standard Operating Procedures, or “SOPs,” must be followed 75 percent of the time.
- _____ 5. You must have a bachelor’s degree to work in a biopharmaceutical career.
- _____ 6. It is important that someone who works in a biopharmaceutical laboratory be able to work better alone than with others.
- _____ 7. Skills learned in English class are important for working in a biopharmaceutical career.
- _____ 8. Computer skills are not very important for working in a biopharmaceutical career.
- _____ 9. I would consider a biopharmaceutical career.

BIOPHARMACEUTICAL careers

activity #2: career poster

TYPE: Poster

GRADE LEVEL: Middle school and high school

TIME NEEDED: 30 minutes in class *or* homework assignment

This activity is designed to help students focus on the various aspects of a biopharmaceutical career.

1. Determine if this will be a classroom activity or a homework assignment.
2. Make sure you have the proper materials for the activity, which might include one poster board per student, as well as ample markers and art materials. If this is to be a homework assignment, make sure students know the expectations for the poster board needed to complete the assignment and allow plenty of time for students to obtain the needed supplies.
3. Explain to students they will be creating a poster to illustrate a biopharmaceutical career.
4. Have students watch each of the three videos (quality assurance associate, quality control associate, validation specialist) and *take notes* during the videos about the important aspects of each career.
5. After viewing the videos, review important concepts about each career in class. It is best to ask students to share observations and allow them to write down additional ideas about each career.
6. Assign students to select one of the three careers and develop a poster that illustrates the specific career. The poster must include the name of the career (quality assurance associate, quality control associate, validation specialist) and should include words and pictures that show the tasks, setting and value of the career. Suggest to students they explore the accompanying career profiles at aboutbioscience.org/bc_title.html to find information that will help them get even more information. They also can explore the “Day in the Life” section of the *Mapping Your Future: Careers in Biomanufacturing* curriculum manual, which starts on page 55 (ncabr.org/bioman/exploring_careers_in_biomanufacturing.pdf).

Use the *Activity #2: Evaluation Rubric*, on page 5, to evaluate each poster, and display the posters around the school or the classroom.

BIOPHARMACEUTICAL careers

activity #2: evaluation rubric

STUDENT NAME: _____

DATE: _____

| ITEM EVALUATED | POINTS ALLOCATED | | | | |
|---|---|-----------|------|------|------|
| | SUPERIOR | EXCELLENT | GOOD | FAIR | POOR |
| Educational value | | | | | |
| a. Learning value of the poster | 15 | 12 | 9 | 6 | 3 |
| b. Interpretation of the career (creativity) | 15 | 12 | 9 | 6 | 3 |
| c. Poster contains accurate information | 15 | 12 | 9 | 6 | 3 |
| d. Information is clear, understandable and spelled correctly | 15 | 12 | 9 | 6 | 3 |
| Quality of work | | | | | |
| e. Imaginative and innovative design | 15 | 12 | 9 | 6 | 3 |
| f. Arrangement is visually appealing | 10 | 8 | 6 | 4 | 2 |
| g. Color and accent are used effectively | 5 | 4 | 3 | 2 | 1 |
| h. Overall appearance is neat and attractive | 10 | 8 | 6 | 4 | 2 |
| Total points (100 possible) |  | | | | |

BIOPHARMACEUTICAL careers

activity #3: career chart

TYPE: Web-based research and videos

GRADE LEVEL: High school

TIME NEEDED: 30 minutes in class *or* homework assignment

This activity is designed to help students use the Internet to find information about instructional programs that lead to careers in the biopharmaceutical industry.

1. Give each student a copy of the chart.
2. Have the students watch all three videos (quality assurance associate, quality control associate, validation specialist).
3. Ask students to fill in the “Tasks” column with information that was shared in the videos.
4. Have students complete the chart using the Internet. You might suggest to students they explore the accompanying career profiles at aboutbioscience.org/bc_title.html to find information. They also can explore the “Day in the Life” section of the *Mapping Your Future: Careers in Biomanufacturing* curriculum manual, which starts on page 55 (ncabr.org/bioman/exploring_careers_in_biomanufacturing.pdf).

The purpose of the activity is to reinforce the skills necessary to find information, as well as to identify local and state schools that have biopharmaceutical/biomanufacturing programs. One such school of particular note is North Carolina State University, in Raleigh, whose Biomanufacturing Training and Education Center (www.btec.ncsu.edu) is a leading training facility for a wide range of related careers.

BIOPHARMACEUTICAL careers

activity #3: student response sheet

NAME: _____

DATE: _____

| CAREER | DESCRIPTION | TASKS | DETAILS | |
|-----------------------------|--|-------|--------------------------|--|
| Quality assurance associate | Works to ensure products meet all the quality attributes required by customers and regulatory agencies. | | Annual earnings | |
| | | | Educational requirements | |
| | | | Nearest college | |
| Quality control associate | Does testing and analysis to ensure research studies and products meet specifications and regulatory guidelines. | | Annual earnings | |
| | | | Educational requirements | |
| | | | Nearest college | |
| Validation specialist | Act as equipment auditors by inspecting, confirming and documenting that equipment is in working order. | | Annual earnings | |
| | | | Educational requirements | |
| | | | Nearest college | |

BIPHARMACEUTICAL careers

activity #4: video review

TYPE: Video review

GRADE LEVEL: Middle school and high school

TIME NEEDED: 20 minutes in class *or* homework assignment

This activity is designed to help students learn about biopharmaceutical careers by watching the three videos (quality assurance associate, quality control associate, validation specialist) and answering comprehension and application questions based on what they saw.

Teacher explanation: “After watching all three videos, you should be able to come to some conclusions about biopharmaceutical careers. Read and answer the questions in the worksheet.” (*Note: page 9 in this guide*)

BIOPHARMACEUTICAL careers

activity #4: student response sheet

NAME: _____

DATE: _____

1. What do the three careers have in common?

| CAREER | HOW ARE THEY ALIKE: |
|--|---------------------|
| Quality assurance associate (woman in orange blazer) | |
| Quality control associate (woman in purple shirt) | |
| Validation specialist (man in white polo shirt) | |

2. How is each career different from the other two?

| CAREER | HOW IS EACH DIFFERENT: |
|--|------------------------|
| Quality assurance associate (woman in orange blazer) | |
| Quality control associate (woman in purple shirt) | |
| Validation specialist (man in white polo shirt) | |

3. Place a check mark (✓) beside each statement that describes a biopharmaceutical career.

- | | |
|--|---|
| _____ Interaction with others required | _____ Must pay attention to details and follow rules |
| _____ Lots of variety in the job | _____ Most of day spent sitting at a desk |
| _____ Lots of travel required | _____ Must have English, math and computer skills |
| _____ Must have at least a 4-year degree | _____ Opportunities to advance with additional training |

BIOPHARMACEUTICAL careers

national health care skill standards

The following standards and accountability criteria are addressed in the videos and in this guide:

- 3.11 Understand the health care delivery system (public, private, government and nonprofit)
- 4.11 Classify personal traits or attitudes desirable in a member of the health care team.
- 4.12 Summarize basic professional standards of health care workers as they apply to hygiene, dress, language, confidentiality and behavior.
- 4.31 Compare careers within the health science career pathways (diagnostic services, therapeutic services, health informatics, support services or biotechnology research and development).
- 4.32 Recognize levels of education, credentialing requirements, employment opportunities, workplace environments and career growth potential.
- 6.21 Apply ethical behaviors in health care.
- 7.11 Explain principles of infection control.
- 7.21 Apply personal safety procedures based on OSHA and CDC regulations (including standard precautions).
- 7.31 Evaluate environment to recognize safe and unsafe working conditions.
- 8.12 Recognize characteristics of effective teams.

BIOPHARMACEUTICAL careers

career profile: quality assurance associate

quick facts

Entry-level salary range:
\$40,000 to \$50,000 per year

Minimum education:
High school degree

Quality assurance (QA) associates work to ensure that biotechnology products meet all the quality attributes — safety, efficacy, potency and purity — required by customers and regulatory agencies. Whether a particular product is going to be consumed by people and animals or distributed into the environment, QA associates validate that these products comply with all product label claims and regulatory filings. Also called quality assurance auditors and quality assurance specialists, QA associates maintain the quality systems, such as laboratory control, investigation management, materials management, document control and training to ensure control of the manufacturing process.

Nearly all biotech firms employ QA associates to review good manufacturing practices (GMP) documents. GMPs are manufacturing guidelines and legal regulations put forth by the FDA to ensure the safety and effectiveness of drug products and medical devices. GMPs only define the required outcome, not how work is to be performed, so each organization is free to choose how to achieve the end product. QA associates work to review company procedures for compliance with GMP documents, spending a significant percentage of their time assessing discrepancies from procedures and reviewing GMP raw data for compliance. QA associates also are involved in the review and approval of GMP procedures as well as the preparation of measurement standards for quality compliance.

career opportunities

Most companies employ several QA associates who collaborate across projects and who work regularly with other internal organizational units, under the supervision of a QA manager to ensure compliance with applicable regulatory requirements. Individuals with strong interpersonal, analytical and organizational skills will be well-suited for the position's activities. Associates should be able to understand and interpret written material as well



as explain those materials and new regulations to team members and employees. Associates conduct audits; training programs; data and documentation reviews; and analysis. Some associates write and revise standard operating procedures and related manufacturing documents. Documentation is a large part of the QA associate's job and vital for his or her organization.

Many biotech firms have four levels of QA associates that require increasing skill levels. With experience and demonstrated success, associates may advance into these positions and work towards becoming the organization's QA manager.

education/training

QA positions are open to individuals with a variety of education and training backgrounds. Detail-oriented individuals with excellent communication skills and experience in the biotech industry may secure a job with only a high school diploma. However, obtaining a position as a QA is more common for graduates of a four-year college with a degree in the life sciences or engineering and minimal industry experience. Most companies offer on-the-job training. The number of programs offering master's degrees in QA and Regulatory Science is increasing as well.

salary

The average starting salary in the United States for an entry level quality assurance position is \$37,403, according to June 2008 data from salary.com. The median salary is \$47, 141. These salaries vary based on education, training, level of experience and geography.

► **[go to aboutbioscience.org/quality_assurance_associate.html](http://aboutbioscience.org/quality_assurance_associate.html) to watch the quality assurance associate video**

BIOPHARMACEUTICAL careers

career profile: quality control associate

quick facts

Entry-level salary range:
\$40,000 to \$50,000 per year

Minimum education:
Associate degree

A quality control (QC) associate carries out testing and analysis to ensure that biomedical research studies and biomedical products meet specifications and regulatory guidelines. QC associates work in quality control laboratories and in biomanufacturing environments, using complex instrumentation and laboratory equipment to conduct tests and analyses that are used in product quality regulations or scientific research studies. Because the products being developed or manufactured directly impact people's lives, strict Food and Drug Administration regulations must be followed and documented at every step. In the manufacturing of pharmaceutical products, companies are required to follow SOPs (standard operating procedures) and every step of every process must have a traceable, written record. QC associates are responsible for this documentation. The QC associate performs analytical tests, gathers and assesses data from those tests and writes documentation and reports.

career opportunities

QC associates often are employed by biomanufacturing or biopharmaceutical companies when products are created in sterile, or "clean-room," environments. The product might be a vaccine, a medicine or an enzyme used in food production. Opportunities for employment also are available at agricultural organizations that develop genetically modified foods, such as drought-resistant crops, and at energy companies that are developing and manufacturing cleaner fuels, such as bioethanol and methane. Finally, opportunities are available in the chemical industry and in industrial settings such as paper-and-pulp and textile manufacturers where biotechnology is being used to reduce the environmental impact of manufacturing.

education/training

First and foremost, emphasis on science disciplines during high school is important. After high school, a two-year Associate Degree in Applied Science (A.A.S.) from a community college is one path to a career as a QC associate. The areas of specialization might include agricultural,



biotechnology, industrial pharmaceutical or bioprocess technology. If you choose to attend a four-year college or university, a Bachelor of Science (B.S.) degree in chemistry or biology will provide a solid foundation. You also could choose a more targeted degree at a four-year college or university, such as biochemistry, microbiology or biopharmaceutical science.

salary

The salary for a QC associate generally will fall between \$30,000 and \$60,000 per year. Salaries vary based on a number of factors, such as educational degree, years of experience, type of industry and geographic location. Salary information is current as of June 2008.

► [go to aboutbioscience.org/quality_control_associate.html](http://aboutbioscience.org/quality_control_associate.html) to watch the quality control associate video

BIOPHARMACEUTICAL careers

career profile: validation specialist

quick facts

Entry-level salary range:
\$40,000 to \$50,000 per year

Minimum education:
High school degree

Pharmaceutical manufacturing facilities and laboratories are equipped with a variety of testing equipment vital everyday operations. Validation specialists, also called validation or testing technicians, act as equipment auditors by inspecting, confirming and documenting that their organization's equipment is in working order.

The tests that validation specialists perform ensure that a pharmaceutical product is manufactured according to various regulations, organization guidelines and industry standards. Validation specialists meticulously record all testing data before analyzing it. This information then is used to prepare regular reports to management. In some organizations, specialists prepare and present weekly reports to management on their findings.

In addition to excellent written and oral communication skills, knowledge of spreadsheet and word processing software is required.

While much of the specialist's work is routine in nature, specialists also work as investigators by offering reasons for validation failures in their weekly reports.

career opportunities

Validation specialists work alongside other specialists in most organizations, under direct supervision. With experience, specialists may become intimately familiar with the standard concepts, practices and procedures in their field and develop strong troubleshooting capabilities. Individuals in these cases may advance to supervisory positions or to a related position such as a validation engineer. In some cases, validation engineers may serve as the department manager. Validation specialists with a high school diploma may need to complete a bachelor's degree in a science-related major to advance into this position.



education/training

Most entry level positions require a bachelor's degree. However, individuals with an associate's degree and two to three years of work experience, or a high school diploma and four to five years of work experience, also may be qualified for these positions. While it is useful to know industry guidelines and organizational practices, most organizations offer on-the-job training in specific procedures.

salary

On average, beginning validation technicians earn \$36,451, with more senior technicians earning \$43,787 annually, according to salary.com. Salary information is current as of June 2008.

▶ **[go to aboutbioscience.org/validation_specialist.html](http://aboutbioscience.org/validation_specialist.html) to watch the validation specialist video**