

# Introductory Programs

Ivy Tech Community College - Bloomington currently offers two certificate programs for college credit. These introductory programs are open to individuals with little to no experience in biotechnology. Individuals already working in the biotechnology industry may also find these certificates useful to further develop their careers.

There are few prerequisites for these certificates, so in one semester you could earn one or both of these certificates. Both certificates were developed with significant industry input, so you will learn the concepts that local companies feel are the most important.

## Survey of Biotechnology Manufacturing (BIOT 102)

Survey of Biotechnology Manufacturing covers basic biotechnology manufacturing principles and introduces students to the local biotechnology industry. After learning the basics, students can choose their certificate focus in either biomanufacturing or medical device manufacturing. In addition to a certificate, successful completion of the program (final grade with C or above) earns students three college credits that can be applied toward the biotechnology Associate Degree program. The 16-class meetings (3 hours each) are mostly hands-on.

## Survey of Regulatory Affairs (BIOT 105)

Survey of Regulatory Affairs covers basic topics in regulatory affairs that are extremely important to the biotechnology industry. Students will meet for 16 class meetings that are 3 hours each, for a total of 48 hours of class time. Classes cover global regulatory guidelines to the biotechnology industry, product life cycle, clinical trials, risk management, and audits (both internal and external). Successful participants in the program will earn a certificate as well as three college credits that can be applied toward the Biotechnology Associate Degree with a concentration in Regulatory Affairs.

BIOT 102 and BIOT 105 are taught primarily by subject-matter experts working at Baxter, Cook Pharmica, Cook Inc, BioConvergence, Boston Scientific and Cook Urological.

### BIOT 102 Topics Covered:

#### First half of program

- Basics of life science
- Overview of biomanufacturing and medical devices industry
- QA, QC, cGXP
- Metrology
- Aseptic/Control processing
- Assessment

#### Second half of program

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| <ul style="list-style-type: none"> <li>• Biomanufacturing</li> <li>• Overview of the industry</li> <li>• Biopharmaceutical quality</li> <li>• Biopharmaceutical quality</li> <li>• Upstream process</li> <li>• Downstream process</li> <li>• Process control</li> <li>• Pharmaceutical manufacturing</li> <li>• Assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Medical Device Manufacturing</li> <li>• Device manufacturing overview</li> <li>• Human anatomy &amp; physiology</li> <li>• Quality</li> <li>• Basic print reading</li> <li>• Metrology</li> <li>• Work process</li> <li>• Assessment</li> </ul> |
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### BIOT 105 Topics Covered:

- Overview of the pharmaceutical industry
- Overview of the medical device industry
- Overview of regulatory affairs
- US Food and Drug regulations and standards: drugs and medical devices
- Global regulations and standards: drugs and medical devices

#### Midterm exam

- Product life cycles – drugs, medical devices and other products
- Quality systems
- Risk management
- Regulatory body interactions

#### Final exam

