Quality Assurance for Biosciences

PEIMS Code: N1303771

Abbreviation: QABIOS

Grade Level(s): 11-12

Award of Credit: 1.0

Approved Innovative Course

- Districts must have local board approval to implement innovative courses.
- In accordance with Texas Administrative Code (TAC) §74.27, school districts must provide instruction in all essential knowledge and skills identified in this innovative course.
- Innovative courses may only satisfy elective credit toward graduation requirements.
- Please refer to TAC §74.13 for guidance on endorsements.

Course Description:

Quality Assurance for the Biosciences is designed to introduce the student to quality principles and regulatory affairs as they apply to the biotechnology, biopharmaceutical, and biomedical device industries. This course focuses on exploring online regulatory websites, such as FDA.gov, discovering how new regulations arise, and learning how to find and understand them. This course is a broad overview spanning regulations of drugs, biologics, medical devices, food, and other products; however, students are encouraged to investigate further in areas that interest them through a capstone creative project.

Essential Knowledge and Skills:

(a) General Requirements. This course is recommended for students in grades 11-12. Prerequisite or corequisite: Biotechnology I.

(b) Introduction.

(1) [Career and technical education instruction provides content aligned with challenging academic standards and relevant technical knowledge and skills for students to further their education and succeed in current or emerging professions.

(2) The Science, Technology, Engineering, and Mathematics (STEM) Career Cluster focuses on planning, managing, and providing scientific research and professional and technical services including laboratory and testing services, and research and development services.

(3) In Quality Assurance for the Biosciences, students will be introduced to quality principles and regulatory affairs as they apply to the biotechnology, biopharmaceutical, and biomedical device industries. Students will investigate and identify online regulatory websites such as FDA.gov, explain how new regulations arise, locate new regulations, and interpret new regulations.

(4) This course is a broad overview spanning regulations of drugs, biologics, medical devices, food, and other products; however, students are encouraged to investigate further in areas that interest them through a capstone creative project.

(5) Students are encouraged to participate in extended learning experiences such as career and technical student organizations and other leadership or extracurricular organizations.

(6) Statements that contain the word "including" reference content that must be mastered, while those containing the phrase "such as" reference content that is intended as possible illustrative examples.

(c) Knowledge and Skills.

(1) The student demonstrates professional standards and employability skills as required by business and industry. The student is expected to:

(A) explain the importance of appropriately, speak politely, and conduct oneself in a manner appropriate for the profession;

(B) cooperate, contribute, and collaborate as a member of a group in an effort to achieve a positive collective outcome;

(C) present written and oral communication in a clear, concise, and effective manner;

(D) demonstrate time-management skills by prioritizing tasks, following schedules, and performing goal-relevant activities in ways that produces efficient results; and

(E) explain the importance of punctuality, dependability, reliability, and responsibility in performing assigned tasks as directed.

(2) The student analyzes the importance of quality in biotechnology as both an industry-level and a company-level standard. The student is expected to:

(A) define biotechnology;

(B) describe the responsibilities of departments in a biotechnology company;

(C) distinguish between quality assurance and quality control job functions;

(D) identify biotechnology jobs in our community and state;

(E) discuss quality as it relates to the customer, such as suppliers, hospitals, patients;

(F) explain the importance of a company vision and mission statement; and

(G) explain the basis for the importance of quality in a company.

(3) The student discusses quantity and quality management systems (QMS). The student is expected to:

(A) identify and describe major contributions to the field of quality including Edwards Deming, Joseph M. Juran, Philip Crosby, Armad V. Feigenbaum, and Genichi Taguchi;

(B) discuss total quality management (TQM) and how it differs from other management styles, such as Servant, Adaptive and Rational;

(C) define and apply the plan-do-check-act cycle;

(D) define and explain Juran's "fitness for use" definition of quality;

(E) distinguish between inspection, audit, surveillance, prevention;

(F) explain variation as it applies to biomanufacturing and how specification and tolerance limits relate to variation;

(G) define and apply nonconformance;

(H) explain the difference between statistical quality control (SQC) and statistical process control (SPC);

(I) define a quality management system (QMS);

(J) identify and compare various quality systems, including voluntary and mandatory;

(K) define international standard operations (ISO);

(L) identify different ISO standards;

(M) define the basics of quality management, including TQM, continuous improvement, Six Sigma, 5S, Lean, and ISO;

(N) explain how a company earns ISO certification and Good Manufacturing Practices (GMP) certification;

(O) explain who audits or enforces both quantitative and qualitative of QMS; and

(P) explain why a company would follow a QMS if they are not required to have one by law.

(4) The student examines the role of the Federal Drug Administration (FDA) in the bioscience industry. The student is expected to:

(A) identify the origin of regulations in the United States;

(B) explain the role of the FDA and identify and explain the FDA's three classes of medical devices based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness;

(C) identify products that the FDA has regulatory authority over;

(D) define and discuss the various FDA offices and centers responsible for product approval;

(E) define and apply Title 21 Code of Federal Relations (CFR); and

(F) demonstrate the use of the electronic CFR database to locate regulations.

(5) The student investigates Good Guidance Practices. The student is expected to:

(A) identify Good Guidance Practices (GXPs) that companies must follow when manufacturing biotechnology products;

(B) differentiate between Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), Good Documentation Practices (GDP), and Good Lab Practices (GLP);

(C) explain GLPs as they apply to animal testing labs;

(D) describe the process for clinical studies and how GCPs contribute to safe, effective, and ethical studies;

(E) demonstrate the use of clinical studies websites to research current and past clinical studies;

(F) define Current Good Manufacturing Practices (CGMP), explain how to research regulations relating to CGMPs, and describe the basic principles the FDA uses when adopting CGMPs;

(G) identify Good Documentation Practices (GDP);

(H) explain what corrective and preventive action (CAPA) is and why CAPA is essential to the FDA and CGMPs;

(I) research different quality documents used in biomanufacturing and explain the importance of the statement “if it isn’t written down, it wasn’t done”; and

(J) identify types of documentation such as manuals, procedures, and records and explain their importance to a QMS and CGMPs.

(6) The student examines the drug approval process. The student is expected to:

(A) differentiate between the terms pharmaceutical, biopharmaceutical, biologic, generic, biosimilar, and drug;

(B) Describe the important milestones in manufacturing a drug, including research and development (R&D), pre-clinical studies, clinical studies, the application process for new products, and post-market surveillance;

(C) differentiate between the different drug application review processes, including the New Drug Application (NDA), Biologics License Application (BLA), fast track, Over-the Counter (OTC), priority, and orphan;

(D) justify two exceptions to the FDA’s drug approval process;

(E) use FDA databases such as the Orange Book to look up drugs; and

(F) describe prescription drug labeling structures and explain limitations to drug advertising.

(7) The student examines the regulation of biologics. The student is expected to:

(A) explain what constitutes a biological therapeutic product;

(B) describe the complex approval process for biologics;

(C) describe the different product categories that the Center for Biologics Evaluation and Research (CBER) has regulatory authority over, including therapeutic biologics; and

(D) distinguish between a drug, biologic, generic drug, reference product, and biosimilar.

(8) The student examines medical devices and combination products. The student is expected to:

(A) explain how the FDA classifies a medical device using the FDA website search tool for medical device products and diagram the approval process;

(B) describe how the FDA regulates approvals, including pre-market notification (PMN), pre-market approval (PMA), investigational device exemption (IDE), and Institutional Review Board (IRB);

(C) identify specific regulations that govern medical devices and how to locate these regulations on the FDA website;

(D) research and apply CFR 820 as it relates to GGMP;

(E) evaluate how the FDA determines which regulatory pathway oversees products;

(F) differentiate between a class I, II, and III medical device;

(G) explain how the medical device application process is different depending on the class of product;

(H) distinguish between in vitro diagnostics (IVD), investigational use only (IUO), research use only (RUO), laboratory developed test (LTD), general purpose reagent (GPR), and analyte specific reagent (ASR); and

(I) explain ISO 13485, the requirements for a quality management system, and why it is important in device regulation even though it is regulated by the FDA through CFR 820.

(9) The student demonstrates an understanding of regulatory practices governing food and consumer safety foods and other products. The student is expected to:

(A) explain the FDA's regulatory authority over food;

(B) describe the regulatory functions of the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and Center for Veterinary Biologics (CVB);

(C) explain the main focus of the FDA, Environmental Protection Agency (EPA), and United States Department of Agriculture (USDA) and explain how they together regulate genetically modified organisms (GMOs);

(D) explain the Food Safety Modernization Act (FSMA) and the five main elemental changes brought about in food safety as a result of the FSMA, including recall authority in food;

(E) define what medical foods are and explain how medical foods are regulated;

(F) identify several veterinary products and explain how and why the FDA regulates veterinarian products; and

(G) explain how the FDA regulates cosmetics and why the FDA regulates these products.

(10) The student examines FDA monitoring and enforcement practices. The student is expected to:

(A) identify the statutes granting the FDA authority, which includes monitoring and enforcement practices;

(B) explain enforcement terminology such as misbranding, adulteration, recall, inspection, injunction, and debarment;

(C) explain the civil and criminal enforcement tools at the FDA's disposal, including seizure, injunction, warning letters, 483, recall, debarments, civil money penalty, and criminal enforcement and explain the level of severity of these tools;

(D) identify the limitations to FDA monitoring and enforcement, including recall authority and criminal prosecution;

(E) find and discuss warning letters, 483s, press releases, and recall notices issued by the FDA;

(F) distinguish between the products that the FDA has recall authority over and the ones that the FDA does not have recall authority over; and

(G) classify past recalls into different categories, including class I, class II, and class III recalls.

Recommended Resources and Materials:

Fletcher, Linnea and O'Grady, Jack. Quality Assurance & Regulatory Affairs for the Biosciences. 2023th-2024th edition .BITC1340 COURSE TEXTBOOK. Austin, Texas: Austin Community College, Biotechnology Program, 2024.

Commissioner, O. (n.d.). U.S. Food and Drug Administration. Retrieved April 20, 2023, from http://www.fda.gov/

Center for Drug Evaluation and Research. “Drug Development & Approval Process.” Accessed April 20, 2023.

https://www.fda.gov/drugs/development-approval-process-drugs

Center for Devices and Radiological Health. “Cdrh Learn.” U.S. Food and Drug Administration. FDA. Accessed April 20, 2023. https://www.fda.gov/training-and-continuing-education/cdrh-learn.

Sumers, Donna. Quality. 5th ed. Pearson Education, 2010.

Recommended Course Activities:

- “Popcorn GMP Laboratory pdf” found online at Biomanufacturing.org
- “Making the Call: Quality in Biomanufacturing video” found online at franklinbiologics.org or at the InnovATEBIO website.
- “Exercises for Quality and CGMP” found at the North Carolina Biotechnology Center website

Suggested methods for evaluating student outcomes:

- Certificate earned for GMP online course
- Case Studies in Quality Assurance
- Quality Assurance Capstone Project
- Summative Chapter Test
- Scenario Discussion Board post

Teacher qualifications:

- Agriculture, Food, and Natural Resources: Grades 6-12.
- Agricultural Science and Technology: Grades 6-12.
- Any vocational agriculture certificate.
- Health Science: Grades 6-12. This assignment requires a bachelor's degree.
- Health Science Technology Education: Grades 8-12. This assignment requires a bachelor's degree.
- Life Science: Grades 7-12.
- Life Science: Grades 8-12.
- Legacy Master Science Teacher (Grades 8-12).
- Science: Grades 7-12.
- Science: Grades 8-12.
- Secondary Biology (Grades 6-12).
- Secondary Science (Grades 6-12).
- Secondary Science, Composite (Grades 6-12).
- Trade and Industrial Education: Grades 6-12. This assignment requires appropriate work approval.
- Trade and Industrial Education: Grades 8-12. This assignment requires appropriate work approval.

- Trade and Industrial Workforce Training: Grades 6-12. This assignment requires appropriate work approval.
- Vocational Health Occupations. This assignment requires a bachelor's degree.
- Vocational Health Science Technology. This assignment requires a bachelor's degree.

Additional information: