Approved Innovative Course

- *Districts must have local board approval to implement innovative courses*
- *Innovative courses may meet state elective credit only*
- *CTE Innovative courses may not be the final course in a coherent sequence for an endorsement*
- *Course requirements must be met without modification*

Course: Quality Assurance for Biosciences
PEIMS Code: N1303771
Abbreviation: QABIOS
Grade Level(s): 11-12
Number of Credits: 1.0

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 the biomedical device industries. This course focuses on exploring online regulatory websites, such as FDA.gov, and discovering how new regulations arise and how to find and interpret them. A large component of this course requires students to participate in discussions related to bioethics and the controversial issues surrounding bioethics and regulations governing the biotechnology industry and quality assurance. This course is a broad overview that covers regulations of drugs, biologics, medical devices, food and other products; however, students are encouraged to investigate further in areas of interest.

Essential knowledge and skills:

(a) General requirements. This course is recommended for students in grades 11-12. Prerequisite: Biotechnology 1.

(b) Introduction.

(1) Career and Technical Education (CTE) 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 (e.g., physical science, social science, engineering) including laboratory and testing services, and research and development services.

(3) 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 the biomedical device industries. This course focuses on exploring online regulatory websites, such as FDA.gov, and discovering how new regulations arise and how to find and interpret them. A large component of this course requires students to participate in discussions related to bioethics and the controversial issues surrounding bioethics and regulations governing the biotechnology industry and quality assurance. This course is a broad overview that covers regulations of drugs, biologics, medical devices, food and other products; however, students are encouraged to investigate further in areas of interest. Students are encouraged to participate in extended learning experiences such as career and technical student organizations and other leadership or extracurricular organizations.

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

(c) Knowledge and Skills

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

(A) demonstrate how to dress appropriately, speak politely, and conduct oneself in a manner appropriate for the profession;

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

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

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

(E) demonstrate punctuality, dependability, reliability, and responsibility in performing assigned tasks as directed.

(2) The student understands the role of quality in biotechnology company. The student is expected to:

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

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

(C) research potential biotechnology jobs in our community;

(D) discuss "quality" as it ensures that customers are satisfied with the service or product;

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

(F) explain why "quality" needs to be part of the mission statement.

(3) The student demonstrates knowledge of Quality and Quality Management Systems (QMS). The student is expected to:

(A) discuss major contributions made by Edwards Deming, Joseph Juran, Philip B. Crosby, Armand Feigenbaum, and Genichi Taguchi to the field of quality

(B) discuss Total Quality Management (TQM) and how it differs from other management styles;

(C) apply the Plan-Do-Check-Act Cycle;

(D) distinguish between inspection, audit, surveillance, and prevention;

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

(F) explain how to apply non-conformance reporting.

(G) compare and contrast Statistical Quality Control (SQC) and Statistical Process Control (SPC);

(H) define a Quality Management System and outline its importance in producing a quality product;

(I) differentiate various quality systems – both voluntary and mandatory;

(J) explain International Standard Operations (ISO) standards and how they help a company with quality;

(K) define the basic components of quality management including TQM, continuous improvement, Six Sigma, and ISO;

(L) identify and explain the requirements of and ISO and Good Manufacturing Practices certification;

(M) explain who audits and enforces ISO and cGMP certifications; and

(N) explain the motivations of a company that decides to follow a Quality Management System (QMS)

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

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

(B) discuss the functions and responsibilities of the Food and Drug

Administration;

(C) discuss the organizational structure of the Food and Drug Administration;

(D) identify products the FDA regulates;

(E) identify the various FDA offices and centers responsible for product approval;

(F) define and distinguish between Council on Foreign Relations (CFR), Guidelines, and Points to Ponder; and

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

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

(A) research Good Guidance Practices 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) explain Current Good Manufacturing Practices (cGMP);

(G) research regulations relating to cGMPs;

(H) research the basic principles the FDA uses when adopting cGMPs;

(I) explain Good Documentation Practices (GDP);

(J) explain what corrective and preventive action (CAPA) is and its importance to the FDA and cGMPs;

(K) identify and research various Quality Documents used in biomanufacturing; and

(L) explain why documentation is important to a QMS and cGMPs.

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

(A) differentiate between the terms pharmaceutical, biopharmaceutical,

biologic, generic, biosimilar and drug;

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

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

(D) research exceptions to the drug review and patent process;

(E) use FDA databases to look up drugs including the orange book, clinical trials, and drug database; and

(F) demonstrate knowledge of prescription drug labeling and explain limitations to drug advertising.

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

(A) define and discuss biological therapeutic products;

(B) research the approval process for biologics;

(C) demonstrate understanding of the different product categories the Center for Biologics Evaluation and Research (CBER) has regulatory authority over, particularly pertaining to therapeutic biologics; and

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

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

(A) explain how the FDA classifies a medical device;

(B) research medical device products and their approval using the FDA website;

(C) describe how FDA regulates approvals including pre-market notification (PMN), pre-market approval (PMA), Investigational Device Exemption (IDE), and Institutional Review Board (IRB);

(D) research and apply specific regulations that govern medical devices

(E) explain how the FDA determines which regulatory pathway (center overseeing product), and why;

(F) apply medical device application process to class I, II, and III products;

(G) distinguish between In Vitro Diagnostics (IVD), Investigational Use Only (IUO), Research Use Only (RUO), LTD, General Purpose Reagent (GPR), and Analyte Specific Reagents (ASR); and

(H) explain ISO 13485 and its importance in device regulation.

(9) The student explains the regulations and regulators for foods and other products in the United States. 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 overlapping responsibilities of the FDA, Environmental Protection Agency (EPA), and United States Department of Agriculture (USDA) to regulate genetically modified organisms (GMOs);

(D) research the Food Safety Modernization Act (FSMA) and the five main elemental changes brought about in food safety including recall authority in food;

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

(F) identify various veterinary products and explain how and why the FDA regulates them; and

(G) research how the FDA regulates cosmetics and why they regulate them.

(10) The student understands FDA Monitoring and Enforcement Practice. The student is expected to:

(A) identify FDA monitoring and enforcement practices and from where or who the FDA obtains regulatory authority to do so;

(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;

(D) explain the limitations of the FDA to monitor and enforce regulations including recall authority and criminal prosecution;

(E) research warning letters, 483s, press releases, and recall notices at the FDA;

(F) discuss the authority of the FDA to recall products;

(G) distinguish between class I, II, and II recall product; and

(H) identify products that are outside of the authority of the FDA recall process.

Description of specific student needs this course is designed to meet:

This course prepares high school students to enter the workforce. Students will be prepared to complete the entry level Biotechnology Certificate as well as prepared for a third-party certification exam, the Biotechnician Assistant Credentialing Exam (BACE).

Major resources and materials:

O'Grady, J. (2017). *Quality Assurance & Regulatory Affairs for the Biosciences*. Retrieved from https://drive.google.com/file/d/0B7NLuI9NmMhUTTE2aXg4ZDN5Q2c/view?usp=sharing

Quality Assurance Curriculum Resources. (n.d.). Retrieved October 27, 2017, from http://biomanufacturing.org/curriculum-resources/program-units/quality-assurance

bio.org. (2014, 1 1). *Bio.org*. Retrieved from bio.org: http://www.bio.org/

Daugherty, E. (2012). *Biotechnology: Science for the New Millennium.* St. Paul: Paradign Publishing, Inc.

EPA. (2016, 1 1). *EPA.gov*. Retrieved from EPA.gov: www.epa.gov

FDA. (2016, 02 10). Retrieved from fda.gov: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm

FDA. (2016, 02 10). *FDA Global engagement report*. Retrieved from FDA.gov: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf

FDA. (2016, 01 01). *FDA.gov*. Retrieved from FDA - Food and Drug Administration: http://www.fda.gov/
Federal Food, Drug, and Cosmetic Act, FD&C Act (75th United States Congress 1938).

Food, F. (2016, 04 04). *FDA Food Recall*. Retrieved from FDA: http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm482807.htm

Foundation, F. (2016, 1 1). *Feigenbaum Foundation*. Retrieved from Feigenbaum Foundation: http://www.feigenbaumfoundation.org/

Innovations, P. (2016, November 29). *Paragon Innovations*. Retrieved from Paragon Innovations: http://www.paragoninnovations.com/ng4/guide.shtml

Institute, J. (2016, 01 01). *The Juran Institute*. Retrieved from The Juran Institute: Juran Institute Website: http://www.juran.com/

ISO. (2015, 09 12). *ISO*. Retrieved from ISO: http://www.iso.org/iso/home.html, http://www.iso.org/iso/documented_information.pdf

Public Health Services Act, Section 351(i) (78th United States Congress July 1, 1944).

Standards, I. O. (2016, 01 01). *ISO.org*. Retrieved from ISO: http://www.iso.org/iso/about.htm

Summers, D. (2010). *Quality.* New Jersey: Prentice Hall.

Recommended course activities:

Students demonstrate learning by:

- discussing and analyzing case study scenarios
- creating a biotechnology product using regulations and guidelines learned throughout the course
- Identifying violations in the workplace
- Creating a product to pipeline drug

Suggested methods for evaluating student outcomes:

- Test and Quiz questions available with teacher validation
- Rubics associated with case study evaluation

- Student presentations on product development and guidelines
- Team discussion on development of products.

Teacher qualifications:

Science Composite-high school or the following CTE certifications

- Health Science: Grades 6-12.
- Health Science Technology Education: Grades 8-12.
- Vocational Health Occupations.
- Vocational Health Science Technology.

Additional information: