**COLLIN COLLEGE**

**COURSE SYLLABUS**

Course Information

**Course Number:** BITC 1340

**Course Title:** Quality Assurance for the Biosciences

**Course Description:** Quality assurance principles and applications. Includes quality control and Federal Drug Administration (FDA) regulations to the biotechnology, biopharmaceutical, and biomedical device industries. Additionally, BITC 1340 Quality Assurance for the Biosciences is a course designed to introduce the student to quality principles as they apply to the biotechnology, biopharmaceutical, and the biomedical device industries. Theories and application of quality assurance and quality control will be presented and several different quality systems will be discussed such as cGMP, ISO9000, Six Sigma and Lean. This class will be focused on quality in the bioscience workplace and therefore will include many applied assignments, which include internet research in current regulations and discussion board participation.

**Course Credit Hours:** 3

Lecture Hours**:** 3

**Prerequisite / Concurrent Enrollment:** BIOL 1415 or consent of Instructor

**Student Learning Outcomes:**

* **State-mandated Outcomes:** Upon successful completion of this course, students will:

1. Describe the benefits and applications of quality assurance.
2. Demonstrate proficiency in the use of the tools of quality assurance and quality control.
3. Apply sampling techniques.
4. Evaluate quality assurance standards.
5. Perform system audits and implement a corrective and preventative action plan.
6. Explain and implement GMP, GLP, and the appropriate FDA guidelines and regulations as they pertain to the bioscience industry.

* **Additional Collin Outcomes:**

1. Understand what biotechnology is and the organization of a typical biotechnology company.
2. Review the history of quality philosophies and regulations.
3. Understand basic quality systems such as ISO9000, lean, Six Sigma and GXP and how they relate to developing quality products.
4. Investigate comprehensive quality systems in regulated (GXP) and non-regulated (ISO9000) environments and understand when regulations apply. Explore medical device regulations.
5. Learn important documentation requirements of both regulated and non-regulated bioscience work environments.
6. Understand how a biopharmaceutical product is made, what regulations apply to this industry and important documentation that is required.
7. Learn how to apply quality principles when designing assays and providing quality control results and documentation.

**Withdrawal Policy:** See the current *Collin Registration Guide* for last day to withdraw.

**Collin College Academic Policies:** See the current *Collin Student Handbook.*

**Americans with Disabilities Act Statement:** Collin College will adhere to all applicable federal, state and local laws, regulations and guidelines with respect to providing reasonable accommodations as required to afford equal educational opportunity. It is the student’s responsibility to contact the ACCESS office, SCC-D140 or 972.881.5898 (V/TTD: 972.881.5950) to arrange for appropriate accommodations. See the current *Collin Student Handbook* for additional information.

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