ACADEMIC AFFAIRS

Course Number:	BMT-228	Department:	Mechanical Engineering Tech.		
Course Title:	Quality Concepts for the Medical Industry	Semester:	Spring	Year:	2019

Objectives/Competencies

Course Objective	Competencies
1. Implement laboratory and manufacturing practices	1. Demonstrate an understanding of Good Laboratory Practices (GLP). 2. Demonstrate and understanding of the FDA's Current Good Manufacturing Practices (cGMP) 3. Discuss Medical Device Classifications: Class I, II and III 4. Perform continuous improvement. 5. Perform validation testing 6. Create Standard operating Procedures.

Course Objective	Competencies
2. Understand Regulatory Compliance	1. Demonstrate a working knowledge of federal regulatory agencies: • US Food and Drug Administration • US Department of Agriculture • National Institute of Health • National Research Council • Department of transportation • Center for disease control and prevention • Nuclear regulatory commission • Clinical laboratory improvement amendments

Course Objective	Competencies
3. Apply Microsoft Excel to the field of quality control.	2. Program a quality control application using Excel 97 spreadsheet and programming (with Visual Basic for Application) tools. 3. Write and record macros to automate tasks on an Excel spreadsheet. 4. Write VBA code to link several macros to perform multiple functions within the quality application. 5. Develop Active X controls on a worksheet within Excel. 6. Generate custom forms to allow easy data entry. 7. Link the custom forms and Active X controls to macros to create a Quality Information System. 8. Demonstrate the ability to use Excel to perform what-if analysis, summarize data with Pivot tables, and analyzing List Data.

Course Objective	Competencies
4. Complete sections from the CQE body of knowledge.	1. The student will demonstrate proficiency in establishing sampling plans from MIL-STD-414 and MIL-STD-105E tables. 2. The student will construct an Operating Characteristic Curve manually and using Excel. 3. The student will calculate system reliability for components in series and in parallel. 4. The student will calculate Failure Rates and MTBF estimates.