

**Course Description****ET12404 | Advanced Manufacturing Technology | 3.00 credits**

This is a course for students intending to work in manufacturing environments. Students will learn the basic concepts about advanced manufacturing operations and processes, including sourcing materials, production planning and process monitoring, and control to distribution activities. Students also review the facility and regulatory requirements needed to support manufacturing operations. Activities may include facility tours and site visits.

**Course Competencies**

**Competency 1:** The student will demonstrate knowledge of key manufacturing principles by:

1. Describing the fundamental differences between manufacturing and service organizations
2. Identifying different types of manufacturing industries including life sciences
3. Comparing organizational structures required to support various manufacturing industries
4. Defining productivity and giving examples of how operations managers contribute to productivity
5. Identifying key roles in manufacturing organizations
6. Detailing common manufacturing processes and operations
7. Discussing the value chain and its relationship to competitive advantage
8. Discussing fundamental design and process methods for different industrial sectors
9. Differentiating unit operations and design requirements for various industrial sectors

**Competency 2:** The student will demonstrate an understanding of facility requirements to support manufacturing operations by:

1. Comparing utility system requirements for various manufacturing industries
2. Defining facility and equipment documentation requirements to support commercial production
3. Discussing expectations of equipment maintenance activities
4. Reviewing process equipment needs to support specific manufacturing applications, e.g., pharmaceutical, device, biologics, and others
5. Evaluating environmental control requirements for various manufacturing operations
6. Summarizing the material control systems required for a manufacturing product
7. Discussing the various types of interface terminals (portable and stationary) used to monitor and make necessary process modifications
8. Discussing how the input/output signals from various interface terminals perform required process actions

**Competency 3:** The student will demonstrate an understanding of technology transfer activities required to move from development/engineering to commercial production by:

1. Defining technology transfer and creating a checklist of activities required to move from development operations into commercial scale operations
2. Comparing quality requirements of development records against commercial recording requirements
3. Discussing expectations of equipment maintenance activities and defining preventative maintenance systems

**Competency 4:** The student will demonstrate an understanding of the functions of typical manufacturing operations by:

4. Outlining the steps involved in typical manufacturing operations, e.g., sourcing to packaging for device, pharmaceutical, and biologic
5. Describing the major types of robotic and electromechanical components and/or systems applied in the biotechnology and pharmaceutical industries as well as in other manufacturing sectors
6. Describing how to operate and how to troubleshoot industrial robotic and electromechanical components and/or systems used in the manufacturing environment
7. Comparing the material management requirements in various manufacturing environments, e.g.,

electronics, pharmaceutical, biologics, etc.

8. Reviewing the criticality of controlled documents and distinguishing the difference between standard operating procedures and batch records
9. Describing the training procedures for manufacturing personnel operators
10. Defining the roles and functions of line personnel and management in the manufacturing environment

**Competency 5:** The student will demonstrate an understanding of the functions of typical manufacturing processes by:

1. Creating, reading and interpreting a process flow diagram (PFD)
2. Explaining the phases of packaging and labeling operations
3. Describing the interaction that exists between instruments and active operation in a process
4. Performing process monitoring and process activities utilizing manual and automation systems
5. Discussing the use of instrumentation to monitor process metrics
6. Writing a specification to obtain the proper instrument for a given processing need
7. Performing simulated automated process activities employing both discrete and analog movements

**Competency 6:** The student will demonstrate knowledge of automation technologies used in manufacturing by:

1. Defining programmable logic controllers (PLC) and identifying PLC input and output modules
2. Outlining the key requirements of 21 CFR Part 11 regarding the control of electronic records and signatures
3. Describing ladder logic and how it is used in programming controllers
4. Interpreting ladder logic diagrams/schematics
5. Explaining the benefits of using enterprise resource management systems
6. Describing the functionality of building management systems
7. Discussing the validation requirements for implementing automated systems
8. Identifying key advantages and challenges of implementing electronic production records

**Competency 7:** The student will demonstrate knowledge of Quality Management system activities associated with manufacturing by:

1. Outlining the components of Total Quality Management (TQM)
2. Defining quality tools and processes used to monitor and control production processes including statistical process control (SPC) and statistical quality control (SQC) trend analysis
3. Highlighting the principles of Six Sigma
4. Summarizing the philosophy of Continuous Process Improvement
5. Discussing the process of obtaining certification from the International Organization for Standardization (ISO)

**Competency 8:** The student will demonstrate an understanding of alternative production strategies used in manufacturing by:

1. Evaluating and recommending when to use outsourced manufacturing operations versus in- house manufacturing
2. Discussing the technical and regulatory challenges of outsourced manufacturing
3. Comparing the advantages and disadvantages of using disposable technologies for manufacturing

**Learning Outcomes:**

- Use quantitative analytical skills to evaluate and process numerical data
- Solve problems using critical and creative thinking and scientific reasoning
- Describe how natural systems function and recognize the impact of humans on the environment