

# STRANDS AND STANDARDS

## BIOMANUFACTURING 1



### Course Description

The first in a sequence of courses that prepares students by focusing on developing skills required for entry-level employment in the medical devices industry. Students will develop a foundation in essential abilities and attitudes that will in turn expand their occupational opportunities in the biomedical world.

<b>Core Code</b>	38.01.00.00.171
Concurrent Enrollment Core Code	None
Units of Credit	0.5
Intended Grade Level	10-12
Prerequisite	None
Skill Certification Test Number	None
Test Weight	None
<b>License Type</b>	Secondary Education 6-12
<b>Required Endorsement(s)</b>	Technology & Engineering, or Engineering

## STRAND 1

**Students will follow safety practices.**

### Standard 1

Identify potential safety hazards and follow general laboratory safety practices.

- Assess workplace conditions regarding safety and health.
- Identify potential safety issues and align with relevant safety standards to ensure a safe workplace/jobsite.
- Locate and understand the use of shop safety equipment.
- Select appropriate personal protective equipment.
- Learn about and obtain useful information from Safety Data Sheets.

### Standard 2

Use safe work practices.

- Use personal protective equipment according to manufacturer rules and regulations.
- Follow correct procedures when using any hand or power tools.
  - Ref: <https://schools.utah.gov/cte/engineering/resources> under the Safety Program and Management tab.

### Standard 3

Complete a basic safety test without errors (100%) before using any tools or shop equipment.

## STRAND 2

**Students will be introduced to and develop a general understanding of the medical device industry.**

### Standard 1

Identify at least four biomedical companies in Utah and the medical devices they produce and their application.

### Standard 2

List the basic job families in the medical device industry and examples of positions in each family.

- engineering (R&D, manufacturing)
- quality and regulatory (quality assurance, regulatory affairs)
- manufacturing (assemblers, supervisors, technicians, supply chain analyst, materials management, machine operators)
- sales and marketing (sales representative, clinical specialist, product management)
- administrative (finance, HR, IT)

## STRAND 3

**Students will develop the basic manufacturing skills required in the medical device industry.**

## Standard 1

Demonstrate how to maintain a clean, contamination- and clutter-free environment, as appropriate.

## Standard 2

Learn and practice accepted clean room procedures.

## Standard 3

Demonstrate Good Documentation Practice (GDP).

## Standard 4

Apply Lean Manufacturing principles.

## Standard 5

Recognize unsafe or undesirable conditions and take corrective and/or preventative action(s).

## Standard 6

Follow relevant safety policies, guidelines, and regulations.

- Company
- Occupational Safety & Health Administration (OSHA)
- U.S Environmental Protection Agency (EPA)
- Centers for Disease Control & Prevention (CDC)
- U.S. Food & Drug Administration (FDA)
- International Standards Organization (ISO)

## Standard 7

Access and use Safety Data Sheets (SDS) and other safety information and resources.

## Standard 8

Analyze Bills of Materials (BOMs), inventories, and a Kanban system.

## Standard 9

Prepare materials/supplies/equipment for routine use.

## Standard 10

Collect and prepare samples appropriately for testing purposes.

## Standard 11

Follow appropriate manufacturing Standard Operating Procedures (SOPs), Work Instruction Documents (WIDs) and drawings, or test procedures. Operate within validated parameters.

## Standard 12

Document data & results according to established procedures.

## Standard 13

Interpret and/or analyze data & results as appropriate.

## Standard 14

Perform statistical data analysis.

## STRAND 4

**Students will be introduced to and develop an understanding of the U.S. Food & Drug Administration (FDA) regulations as they apply to the medical device industry.**

### Standard 1

Explain how and why the medical device industry is regulated.

### Standard 2

Describe the mission and organization of the U.S. Food & Drug Administration (FDA).

### Standard 3

Locate current laws and regulations that regulate the medical device industry.

### Standard 4

Describe Good Manufacturing Practices (GMP) that comprise FDA required quality systems and why GMP is important.

### Standard 5

Describe Good Documentation Practices (GDP) and the consequences of non-compliance.

### Standard 6

Describe the three classes of medical devices as defined by the FDA and general regulatory strategy of each.

### Standard 7

Describe the main pathways for FDA approval or clearance of new medical devices and how they apply to each device classification.

- Premarket Approval (PMA)
- Premarket Notification (PMN) or 510(k)
- Exempt

### Standard 8

Explain how a medical device product moves through a product life-cycle and identify issues that must be addressed at each step.

- Development
- Design
- Production
- Regulatory Approval
- Post-market surveillance

### Standard 9

Describe how a change request moves from initiation to implementation.

- Evaluation of type of change (specification, labeling, SOP, etc.)
- Determine the requirements for justifying change
- Make (process) the change
- Training / certification if required
- Full implementation

## Standard 10

Apply customer and user inputs towards product modifications and improvements by using revised engineering specifications and design outputs to produce a device that better meets users' needs.

## Standard 11

Explain the value of post-market requirements for approved devices as required by the FDA.

## Standard 12

Access online information effectively.

## Standard 13

Give an example, relevant to the medical device industry, of why training is important for regulatory compliance.

## STRAND 5

**Students will be introduced to and describe the consequences of failing to comply with an established quality system.**

### Standard 1

Describe potential consequences that stem from non-compliance to the quality system at a medical device manufacturer.

### Standard 2

Explain the benefits of internal audits at a medical device manufacturer.

### Standard 3

Give three examples of do's and don'ts during an audit.

### Standard 4

Describe that different product regulatory standards exist in each country including ISO 13485.

### Standard 5

Explain the function of GMP controls including design controls, purchasing controls, and production & processes controls.

### Standard 6

Explain the importance of product identification and traceability.

- Segregation - Conforming materials are not intermingled with nonconforming materials.

- An accurate record of configuration must be maintained at the device level to provide objective evidence of conformance to requirements.
- Traceability is critical with respect to being able to distinguish at what point material and component changes are made, which in turn is critical for failure investigations and potential product recalls.

## Standard 7

Explain the importance of acceptance activities.

- Verify and document that requirements necessary to ensure conformity, safety, performance and effectiveness have been performed.
  - Incoming Inspection
  - In-Process Inspection
  - Final Inspection
  - Final Test
  - Final Equipment Installation

## Standard 8

Explain the controls needed for medical device nonconforming product.

## Standard 9

Describe elements of a Quality Assurance System used to identify products or processes that do not meet specifications.

- Non-Conformance Reports (NCR)
- Root Cause Analysis
- Corrective Action/Preventive Action (CAPA)
- Correction

## Standard 10

Explain the purpose of labeling and packaging control.

## Standard 11

Explain the purpose of handling storage, distribution, and installation controls.

## Standard 12

Explain the significance of record retention and controls.

## Skill Certificate Test Points by Strand

None

## Performance Skills

1. Create and utilize an engineering notebook per established conventions.  
<https://schools.utah.gov/cte/engineering/resources>
2. Demonstrate practice of the *Technology & Engineering Professional Workplace Skills*.  
<https://schools.utah.gov/cte/engineering/resources>