

# Medical Device Skill Standards

Working in partnership with industry, the Medical Device Hub of The Community College Consortium for Bioscience Credentials (c3bc) has developed the first Medical Device Skills Standards. Thanks to the national engagement of c3bc, the Medical Device Skill Standards harmonize with the Bioscience Core Skill Standards that have been developed through the multi-industry collaboration of c3bc and its partner colleges.

The Medical Device Skill Standards' value to employers is better, more effective instruction for people seeking entry-level positions at medical device manufacturers and other FDA-regulated workplaces. Students who complete programs based on the Medical Device Skill Standards will be workforce-ready, potentially saving companies time and money on in-house training.

*"We continue to support the development of the multi-disciplinary skill set standard and believe that it will be a significant opportunity for those that aspire to enter the medical device industry and for those within the industry that are looking to augment their current skills and knowledge base."*

**Chris Kilander**

Global Product Manager  
Team Leader – Peripheral Intervention  
Cook Incorporated



**MDM West Panel:  
Development of the First Medical Device Industry  
Entry-Level Job Skill Set Standard and Its Implications**

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The Medical Device Skill Standards are the product of a three-year collaboration between medical device manufacturers and community colleges. The standards clarify the key activities and underlying knowledge that individuals need in order to perform proficiently in the workplace within the following identified critical work functions:

- Performing measurements, tests, and assays**
- Maintaining a safe and productive work environment**
- Providing routine facility support**
- Complying with applicable regulations and standards**
- Managing and communicating information**
- Performing mathematical manipulations**

*Excerpt from Medical Device Skill Standards*

### **CFW - Comply with Applicable Regulations and Standards**

| <b>Key Activity</b>                        | <b>Performance Indicators</b>   | <b>Underlying Knowledge</b>   | <b>Assessments</b>  |
|--|---|---|---|
| Follow established policies and procedures | GXP's (Good Manufacturing, Laboratory, and Documentation Practices) are executed correctly and completely | Knowledge of applicable sections of 21 CFR 820 and ISO 13485; Familiarity with applicable current federal, state, local and industry regulations and standards, Quality Management Systems (QMS), key elements of QS, roles of management and workers in a quality system, role of procedures | Exam questions around what is the basic structure of the quality system and what are the responsibilities of the individuals in the company |
|  |   | Applicable websites containing current industry regulations and standards   | Navigate applicable medical device related databases to find 510 K's, adverse event reports, etc. in response to a case study               |
|  |   | Consequences of noncompliance (impacts on operations, company customers, FDA - 483s, warning letters, field actions, and other enforcement actions)   | Research 483s, warning letters, etc. in response to a case study  |

Full version of Medical Device Skill Standards at <http://www.bio-link.org/home2/resource/bioscience-skill-standards>

The c3bc Medical Device Skill Standards and other deliverables from c3bc's TAACCCT grant will be archived at <https://www.nterlearning.org/> and <https://www.skillscommons.org/>



Assessments are built into the six matrices of the Medical Device Skill Standards to ensure students meet employers' expectations.

All the content within the matrices has the potential for customized modification of content and assessments to suit the specific needs of employers.



## The Medical Device Skill Standards Are Already Incorporated in Programs Offered at

- Anoka Ramsey Community College in Minnesota
- Austin Community College in Texas \*
- College of the Canyons in California
- Ivy Tech Community College in Indiana \*
- Moorpark College in California
- Mount Wachusett Community College in Massachusetts
- Saint Petersburg College in Florida \*
- Salt Lake Community College in Utah \*
- Southern California Biomedical Council in California
- Ventura College in California
- William Moor College of Technology in Tennessee

\*c3bc-funded colleges

*The process of defining and developing the entry-level skill and knowledge elements that are needed across key functional areas—like engineering, quality assurance, manufacturing, regulatory compliance and facilities—is going to be enormously helpful to medical device companies. The regions that embrace this and do it best will inherently create an element of infrastructure that will motivate companies to stay or locate in those regions.*

### **Steve Sawin**

President & CEO  
Operon Resource Management





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**The Medical Device Hub of c3bc recommends employers use the Medical Device Skill Standards to:**

- **Partner with local community colleges**
- **Explore building new Medical Device Manufacturing programs**

To learn more about utilizing the Medical Device Skill Standards or for information about hiring graduates of established Medical Device Manufacturing programs contact:

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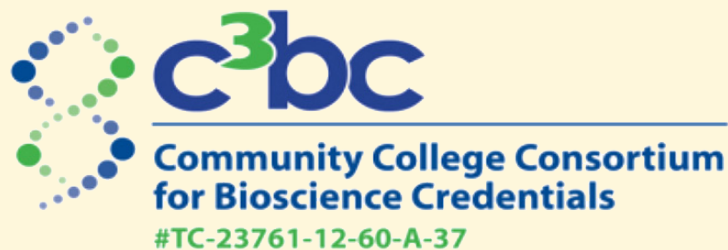
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This product was funded by a grant awarded by the U.S. Department of Labor's Employment and Training administration. The product was created by the grantee and does not necessarily reflect the official position of the U. S. Department of Labor. The Department of Labor makes no guarantees, warranties, or assurances of any kind, express or implied, with respect to such information, including any information on linked sites and including, but not limited to, accuracy of the information or its completeness, timeliness, usefulness, adequacy, continued availability, or ownership.