Guidelines to develop education & training programs for medical device industry careers

# c³bc Medical Device Skill Standards

Community College Consortium for Bioscience Credentials

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## The Community College Consortium for Bioscience Credentials

## A Message from c³bc's Project Director

The Community College Consortium for Bioscience Credentials (c³bc) has many accomplishments. Among the most important is the Medical Device Hub's creation of the c³bc Medical Device Skill Standards, which are printed in their entirety in this publication beginning on page 14. They are, to our knowledge, the first set of industry skill standards in the medical device arena where industry representation was at the table throughout the whole development process. The industry partners of the c³bc Medical Device Hub provided great input and advice.

We are proud of Dr. Sengyong Lee and the entire c³bc Medical Device Skill Standards team for their leadership and contributions to the efforts of our national consortium.

Russ H. Read

c³bc Project Director

Executive Director, National Center for the Biotechnology Workforce

Forsyth Technical Community College

# PREFACE

My office window at Ivy Tech Community College Bloomington, Indiana, faces the spectacular setting of the global headquarters of Cook Medical, one of the world's largest surgical device manufacturers. The advancement of medical technology and growing health care needs for elderly populations around the globe have accelerated the growth of many companies like Cook Medical in recent decades. Like many other industries, the medical device industry is in need of a continuous pipeline of skilled workers to meet their growth demands.

During my 15 years as a faculty member teaching biotechnology at Ivy Tech, I have worked very closely with our local bioscience employers, primarily medical device manufacturers and contract manufacturing organizations for major pharmaceutical companies. My top priorities have included understanding their exact education and training needs and building educational programs based on those needs.

> "The continuous growth of the medical device industry is vital to regional and national economic health."

In 2012 the Community College Consortium for Bioscience Credentials (c³bc) received a $15 million Trade Adjustment Assistance Community College and Career Training (TAACCCT) grant from the U.S. Department of Labor. With a partnership among 12 community colleges, c³bc set an ambitious goal of developing education programs to fill the geographical, industry-sector, and skill-based gaps existing within the bioscience industry.

Among the major accomplishments of the c³bc project was the development of the first skill standards for entry-level jobs within the medical device industry. Skill standards are used as the blueprints in building technical education programs as they identify specific jobs and the required knowledge and skills for such jobs. Numerous skill standards have been developed to support programs for major bioscience industry sectors like biomanufacturing, biotechnology, and manufacturing. With DOL grant support, c³bc made significant strides toward addressing the workforce needs of the medical device industry.

The process of developing new skill standards for an industry is a daunting task, especially when the industry offers so many jobs requiring multiple layers of skills and knowledge. The c³bc Medical Device Skill Standards are the result of numerous regional and national discussions, reviews, and validation processes among industry experts. Our partners invested much personal or company time in our project without the expectation of immediate financial return. They and the educators involved in c³bc are hopeful of a long-term return on investment in the form of graduates and trainees from community colleges who will need less internal training, make fewer manufacturing errors, and adhere to good manufacturing practices at their companies.

As the c³bc medical device hub leader, I had the great privilege of working with many industry and education partners from all over the U.S. Getting acquainted with them through the project was a rewarding experience. Our partners fully appreciated the significance and the quality of the outcome from the project. As a true collaboration it is gratifying for all of us to know that the c³bc Medical Device Skill Standards will provide educators and industry trainers with a blueprint for the medical device topics they should teach. As part of their grant work, the c³bc medical device education partners have already used the skill standards to create new and revise existing educational modules, courses, certificates, degrees and pathways to those credentials. Many of the materials based on the c³bc Medical Device Skill Standards are freely available through three open resource outlets: NTER, SkillsCommons, and Bio-Link.

The continuous growth of the medical device industry is vital to regional and national economic health. Such growth requires nurturing environments that support courageous entrepreneurship, continuous innovation and invention based on technology, and a well-connected workforce development pipeline between education systems and employers.

To the educators and manufacturers who will use them, and the students and employees whose learning will be shaped by them, I proudly deliver the first skill set standards for entry-level jobs in the U.S. medical device industry.

Sengyong Lee, PhD

c³bc Medical Device Hub Leader

Professor & Chair of Biotechnology

Ivy Tech Community College Bloomington

## c³bc Hub Accomplishes Complex Task of Developing Medical Device Skill Standards

Upon receiving a $15 million TAACCCT grant from the Department of Labor in fall 2012, the Community College Consortium of Bioscience Credentials (c³bc) engaged in a national effort to develop training to expand workforce skills for the bioscience industry.

One of the four-year project's goals was the harmonization of core bioscience competencies for three major sectors within the bioscience industry that employ technicians: laboratories, biomanufacturers, and medical device manufacturers. Several of the consortium's education partners had previously developed laboratory and biomanufacturing skill standards as part of their work on other initiatives. However, no skill standards existed for entry-level jobs with medical device manufacturers.

Working with industry to develop medical device manufacturing skill standards became the paramount goal of the c³bc Medical Device Hub. This national effort resulted in a complete draft of the c³bc Medical Device Skill Standards, which are on pages 14 to 22 in this publication. Since 2014 the partner colleges have used the skill standards to revise curricula and create new courses to incorporate the skills and knowledge identified in the industry-vetted standards. Key skills, knowledge, tasks, and assessments were also included in c³bc's parallel effort to harmonize bioscience skill standards across the consortium's Biomanufacturing, Lab Skills, and Medical Device hubs.

The Medical Device Hub was able to accomplish its goals and keep medical device industry representatives engaged in the three-year development of the skill standards by following the advice of Russ H. Read, c³bc director: "Listen to what employers say, write it down, and act on it."

### Groundwork for Medical Device Skill Standards

Work toward c³bc's Medical Device Skill Standards began in advance of the Department of Labor's TAACCCT program.

At the 2011 Community College Program at BIO, the annual international biotechnology industry conference, there was consensus among the biotech employers and educators about the pressing need for industry-recognized credentials. Those at the meeting also agreed that a core set of skills would "correct" the problem of each state having a different approach to credentials.

In addition to employers' confusion about the qualifications of applicants, without skill standards community colleges, particularly in the medical device realm, were stymied. They had no national guidelines for writing curricula for courses that would lead to credentials that mattered to employers. A lack of national core skill standards for medical device manufacturing limited effective recruitment and training opportunities for displaced workers who could be suited for employment in this growing industry. Without skill standards, there were barriers to colleges using prior learning assessments, credit-transfer, and other articulation agreements that could help prospective technicians return to work or "up-skill" to advance in their careers.

In March 2012, 35 biotechnology educators met in North Carolina at Forsyth Technical Community College to consider more fully the possibility of developing a bioscience credential. A week later the Department of Labor announced its TAACCCT grant program.

The c³bc Medical Device Hub was led by Sengyong Lee, biotechnology professor and chair at Ivy Tech Community College in Bloomington, Indiana. "There is a strong need for well-educated, well-skilled workers in this area," Lee said.

In addition to Ivy Tech, the Medical Device Hub has two other funded community college partners: Salt Lake Community College in Utah and St. Petersburg College in Florida.

The questions facing the Medical Device Hub were so compelling that other colleges joined the work without receiving financial support from the c³bc DOL TAACCCT grant. Those colleges are Anoka-Ramsey Community College in Minnesota; College of the Canyons in California; Irvine Valley College in California: Moorpark College in California; Mount Wachusett Community College in Massachusetts; Ventura College in California; and William R. Moore College of Technology in Tennessee. Austin Community College, which received c³bc DOL TAACCCT grant funds as a part of the Lab Skills Hub, joined the Medical Device Hub too. The Southern California Biomedical Council is also a partner.




The planning to submit a grant proposal, as a consortium, brought together community college biotechnology educators across the United States who knew each other from previous individual and collaborative work on Advanced Technological Education grants funded by the National Science Foundation and other Department of Labor initiatives.

For the TAACCCT grant proposal they all agreed on an ambitious, complex goal: to develop stacked and latticed credentials in the biosciences. For the educators who formed the Medical Device Hub of the consortium, their focus became the education of entry-level employees at medical device manufacturers.

> The FDA's broad definition of medical devices encompasses everything from toothbrushes to implantable devices like pacemakers.

### Preliminary Collection of Information from Local Industry Partners

The education partners began by examining the job openings at their local medical device companies to glean the initial job titles and skills. The five main functional groups within the medical device industry emerged from this compilation.

Then the educators met in person with the medical device manufacturers in the regions served by their colleges. Ivy Tech educators consulted with employers near Bloomington, Indiana. Salt Lake Community College and St. Petersburg College educators talked with the employers in the metropolitan areas they serve in Utah and Florida, respectively.

In addition to confirming the skills that the large and small companies look for when hiring for entry-level jobs, the educators asked why medical device manufacturers want certain skills. These rich conversations expanded the educators' understanding of the connection between campus labs and classrooms and the manufacturers' advanced technology workplaces.

The partner colleges then sent the information they gathered to Ivy Tech for initial sorting.

Thanks to his 15 years teaching biosciences, Sengyong Lee, the leader of the c³bc Medical Device Hub, served as the chief discerner for resolving conflicts and deciphering technical nuances. Lee worked with Coy and Sarah Cote, associate professor of biotechnology at Ivy Tech. Together they condensed the key skills and knowledge compiled by five colleges—St. Petersburg College, Salt Lake Community College, William R. Moore College of Technology, Mount Wachusett Community College, and Ivy Tech Community College—into one cohesive document.

"It was a difficult process because each college focused on its own local industry feedback, which differed across regions," Amy Coy explained of the variations in companies' priority skills. As the project coordinator, Coy's tasks included finding the commonalities upon which the skill standards could be built.

"The task of melding all of the feedback was daunting, but in the end everyone was heard," Coy said of the filtering and sorting process.

The Medical Device Hub then invited subject-matter experts from medical device manufacturers and industry associations to more in-depth, small

group deliberations about the skills. Some of these experts were individuals who had provided input during the colleges' conversations with their local medical device manufacturers.

The five main functional areas in the medical device industry are

- ✔ regulatory affairs
- ✔ engineering
- ✔ manufacturing
- ✔ quality
- ✔ instrumentation

### Hub Partners Convene for First Time

The first national meeting of all the Medical Device Hub partners was convened on March 26 and 27, 2013, at Ivy Tech's campus in Bloomington. Twenty-one industry people from major medical device manufacturing companies and trade organizations and 21 educators worked together in small groups. In the discussions about the skills and knowledge that employers want now and that they will likely need in the future, the opinions and insights of the industry people carried the most weight. When the discussion questions moved to what to teach students and how to assess students' acquisition of knowledge and skills, the instructors and curriculum developers took the lead. All these discussions helped to refine the lists of workplace tasks and the attributes needed to accomplish them.

At this meeting the process of editing and validating the already-collected tasks and skills for each functional area began.

The c³bc Medical Device Skill Standards cover the critical work functions that are common across these functional areas. The standards reflect the workplace tasks that the medical device industry expects entry-level technical employees to carry out in compliance with U.S. Food and Drug Administration regulations.

### Chairman of c³bc's National Advisory Council Offers Historical Perspective on Skill Standards

The national dialogue in the early 1990s about educational quality and the nation's need for a more highly skilled workforce was led by the Commission on the Skills of the American Workforce. Its recommendations included making skill standards the focus of technological education reform. In 1994 the Goals 2000: Educate America Act passed by Congress established the National Skill Standards Board to promote the development of a national system of voluntary industry-based skill standards.

Five of the 22 projects overseen by the National Skill Standards Board related to the highly regulated bioscience, pharmaceutical, biotechnology, clinical chemistry, and biomedical industries. The savvy work of the Education Development Center, project manager for the Bioscience Industry Skill Standards Project, led to consensus among the five bioscience industries. Hundreds of company managers, technicians, manufacturing experts, as well as community college and university faculty, provided input for *Gateway to the Future: Skill Standards for the Bioscience Industry for Technical Workers in Pharmaceutical Companies, Biotechnology Companies, and Clinical Laboratories* published in April 1995.

Since then the 251-page publication has had an extraordinary impact on higher education institutions, training organizations, companies, and government agencies. It served as the framework for the biomanufacturing education activities of the Northeast Biomanufacturing Center and Collaborative (NBC2), created with National Science Foundation support in 2002. NBC2's development of biomanufacturing technician skill standards, Shoreline Community College's publication in 2007 of Biotechnology & Biomedical Skill Standards, and Bio-Link's work on laboratory technician skill standards provided the foundation for the medical device skill standards initiative led by c³bc's Medical Device Hub. The c³bc Medical Device Skill Standards contained in this publication are the first ever developed for entry-level technical jobs in the medical device industry anywhere in the world.

The intellectual contributions of industry and education on these new skill standards are an important addition to work begun 25 years ago.

A. Stephen Dahms, PhD

Chairman, c³bc National Advisory Council

Vice President of Academic, Industry, and Government Relations

Southern California Biomedical Council



### Second Hub Meeting Focuses on Competency Levels

The second national meeting of the Medical Device Hub was held September 17 and 18, 2013, at St. Petersburg College. The first task of the industry representatives and educators at this gathering was to examine the matrices of the tasks that entry-level technicians perform in the five functional areas. The matrices were devised by Ivy Tech personnel prior to the hub meetings to organize the massive amount of information expected to come out of the discussions.

For the meeting in St. Petersburg, the industry representatives were divided into groups by the functional areas in which they work. Educators were assigned to these groups as well. However, the discussions were led by the subject-matter experts from industry. Their primary task at the meeting was to identify the level of competency needed (using Bloom's Taxonomy) for each skill and knowledge item listed. They also went through the matrices, offering comments and suggestions for changes.

The concept of establishing core medical device skill standards across the functional areas was first introduced at this meeting. A draft was started and a plan was established to devote more attention to the common skills at the next hub meeting.

The meeting attendees then reviewed existing education and training programs. Representatives of each of the partner colleges described their programs and explained how their curricula related to items in the matrices. Participants were asked to share their opinions about the skills taught in the programs and whether they were meeting employers' needs.

Following the second hub meeting, Ivy Tech personnel revised the content of the matrices based on the input collected during the meeting. They began tracking the recommendations for modifications to existing courses and the suggestions for better alignment of certificates and degrees to industry's needs.

The hub educators also worked together to identify a core set of medical device standards based on commonalities across the five functional areas.

### Skill Standards Validated at Third Hub Meeting

The third meeting of medical device hub partners on October 28 and 29, 2014, at Salt Lake Community College began with small group discussions among the 19 industry representatives and 16 educators about the draft of the core medical device standards that had been written by the educators since the meeting.

This major shift grew out of the discussions at the previous meetings, the sorting of the information, and follow-up informal conversations between participants via phone and e-mail. Rather than creating specific skill sets for each functional area, there was widespread agreement among the participants that their efforts going forward should focus on commonalities across the medical device industry.

With this new focus participants were asked to consider: Is each item listed on the matrices necessary? Does it fit with the expectations for entry-level medical device manufacturing positions?

The draft that resulted from this dialogue was more precise than previous versions. Industry representatives agreed that these skill standards correlated to the tasks entry-level technicians are expected to do across all aspects of the medical device industry. At this time the document was given the working title Core Medical Device Skill Standards.

The balance of the meeting was devoted to the question of how to assess students' skills and knowledge vis-à-vis the key activities listed by critical work function (CWF) in the skill standards. The educators and the industry people brainstormed ways to assess the skills. In several exchanges, employers shared examples from their operations so that the educators could add real-world content to their lessons and tests.

Afterward, the educators conferred to revise the working documents from the meeting. With the practical examples provided by employers and their own knowledge of instructional design and how students learn, the educators rewrote the assessments. These assessments were then shared by the hub educators with their regional industry partners, who provided additional information for another round of revisions to the assessments.

# SKILL STANDARDS DEVELOPMENT PROCESS

### Assessments Shared at Fourth Hub Meeting

During the fourth Medical Device Hub meeting on April 14 and 15, 2015, at the College of the Canyons in California, the educators shared the assessments they had developed since the previous hub meeting. The 18 industry representatives and 23 educators reviewed this iteration of the assessments and offered suggestions to improve them. Following these discussions, the assessments became part of the c³bc Medical Device Skill Standards.

Four students participated in a panel discussion at this meeting. They explained how the c³bc programs they had attended at partner colleges had reset their careers and improved their lives.

### Fifth Meeting Focuses on Colleges' Use of Skill Standards

At the fifth and final meeting of the Medical Device Hub on February 10, 2016, at Irvine Valley College in California, the educators reported on the status of their efforts to incorporate the skill standards into their colleges' programs. They also discussed their plans to maximize dissemination of the c³bc Medical Device Skill Standards and courses developed during the U.S. Department of Labor TAACCCT grant by archiving deliverables in three places:

- ✔ www.nterlearning.org;
- ✔ www.skillscommons.org;
- ✔ www.bio-link.org/home2/resource/bioscience-skill-standards.

### c³bc Medical Device Skill Standards Presented at Industry Conference

c³bc education and industry leaders explained the c³bc Medical Device Skill Standards at the Medical Design & Manufacturing West Conference in Anaheim, California, on February 9, 2016.

The presentations by the seven panelists summarized the process used to develop the skill standards. Several of the panelists also provided a clear overview of how colleges have implemented the skill standards to improve the alignment of their programs with workforce needs.

### Manufacturer Considers Good Communication Key to Success of Skill Standards Development

William Pratt, vice president of Operations and Creative Design at Kinamed Incorporated, served as an informal translator between the medical device industry representatives and the educators when they began work on the c³bc Medical Device Skill Standards.

Although everyone at the Medical Device Hub meeting in March 2013 conversed in English, their professional backgrounds and the priorities of their jobs differed enough that some preliminary work was necessary to find common ground.

"We don't understand each other. Industry has got different time lines, different budgets, different approval processes that we've got to go through. Education has its own. They have a completely different world. We don't know about curriculum committees. We don't know that you have to go to the state chancellor's office to get your certificate program approved," he said.

Pratt was well suited to serve in the role of translator. Prior to joining the c³bc National Advisory Council, Pratt served on the Ventura County Workforce Development Board committee that combined manufacturing courses from Ventura College with biotech courses from Moorpark College for a biomedical device manufacturing certificate program.

Pratt explained that c³bc's skill standards development process, like the Ventura County effort, had to start with academicians and employers "building trust and respect, learning each others' problems and challenges." Once all the hub participants shared their perspectives and experiences, they were able to tackle the tasks that led to their creation of the first medical device skill standards for entry-level technicians.

During c³bc's presentation at the Medical Design & Manufacturing West Conference on February 9, 2016, Pratt said: "Our challenge was to generate talent-capable and hands-on, technically-skilled manufacturing [employees] prepared to function and contribute in the controlled environment of medical device manufacturing. Then secondarily, how do we create a pathway to the technician level? Those are the people that really make our factories go: the people that are multi-disciplinary, interdisciplinary, [and] that can talk across different issues."

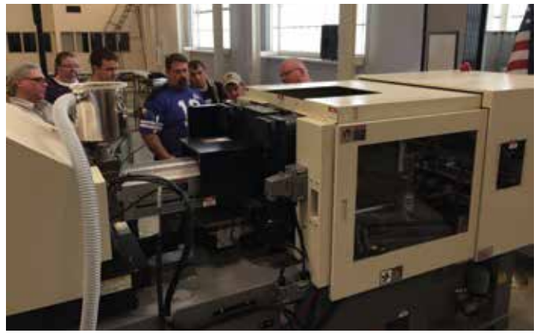


# PARTNER COLLEGES' IMPLEMENTATION

### c³bc Outcomes: New Plastics Program & Regulatory Affairs Certificate

At Ivy Tech Community College Bloomington, c³bc spurred development of a new plastics technology program for medical device manufacturing and influenced revisions in the college's regulatory affairs courses.

To help dislocated workers and others find employment with South Central Indiana's medical device manufacturers, Ivy Tech Bloomington faculty developed three courses: Introduction to Plastics, Injection Molding I, and Plastics Extrusion.



With the U.S. Department of Labor grant funds, the college purchased a training suite that includes equipment for thermoforming, injection molding, and plastic extrusion. The state-of-the-art equipment, which is similar to what is used by industry, was installed for student instruction at the Indiana Center for the Life Sciences, the building that also houses Ivy Tech Bloomington's biotechnology program.

Because the plastics courses are part of the design technology program within Ivy Tech's School of Technology, c³bc was also the impetus for new collaborations between the School of Technology and the School of Applied Science and Engineering, which includes the biotechnology program.

"Many programs operate in silos, but the collaboration between the biotechnology program and the School of Technology has been a wonderful partnership to provide students with vital work skills the medical device industry needs," said Kirk Barnes, professor and dean of Technology, Applied Science and Engineering Technology at Ivy Tech Bloomington.

Regardless of whether medical devices are made of plastic, metal, composites, or biologics, they must be manufactured in compliance with Food and Drug Administration regulations.

Responding to the regulations as well as the valuable information the faculty gained in the process of working with industry and academic partners on the c³bc Medical Device Skill Standards, the biotechnology faculty revised four regulatory affairs courses to align with the skill standards and created a certificate program.

The new Regulatory Affairs certificate program combines the revised versions of Food & Drug Law, Clinical Trials, Risk Management, and Product Life Cycle Capstone, with a technical writing course.

Ivy Tech Bloomington began offering regulatory affairs courses in 2009 at the request of Cook Medical.

In 2016 Cook employees worked with Dean Miller, Ivy Tech regulatory affairs instructor, on building three capstone project modules for the Product Life Cycle Capstone course that is one of three courses configured for c³bc's Course in a Box project.

### An Educator Reflects on What He Learned during Skill Standards Development

John Milburn, director of the Employee Training Institute at the College of the Canyons, California, used his participation in the development of the c³bc Medical Device Skill Standards to strengthen his college's programs.

Vetting the various drafts of the skill standards with medical device manufacturers in the Santa Clarita Valley boosted his relationship with employers and industry experts. Milburn also shared the drafts of the skill standards with four part-time instructors who are subject-matter experts with medical device industry experience.

When he shared their feedback at the Medical Device Hub meetings, it carried a lot of weight with people around the table. "Industry input is really valuable," he said.

He described the discussions at the c³bc Medical Device Hub meetings as "very robust. People working together and collaborating in ways that stretches our ability pushes us to try harder."

He added, "I think people have really tried to go the extra distance in this because we know it is a first-ever effort."

Milburn, whose background is in traditional manufacturing not medical devices, said interacting at the hub meetings with medical device manufacturers and educators from other states broadened his understanding of the industry. He then used what he learned to explain to colleagues at the College of the Canyons how medical device manufacturing crosses disciplines and requires knowledge of bioscience, human biology, anatomy, and manufacturing.

## Partnership Increases Access for Students in 2 States

A conversation at a c³bc Medical Device Hub meeting led to a collaboration between Anoka-Ramsey Community College in Minnesota and Ivy Tech Community College in Indiana that is helping students complete their clinical trials course requirements in more timely fashion.

Prior to the shared course arrangement that allows Anoka-Ramsey students to pay Indiana in-state tuition of $130 per credit hour plus fees for Ivy Tech's online Clinical Trials for Medical Products course, the hurdle for students at both colleges stemmed from institutional financial considerations. Anoka-Ramsey offered the course on campus only if 12 students enrolled. At Ivy Tech, unless eight students signed up for the online course it was not offered.

The conversation between Sengyong Lee, chair of Ivy Tech's Biotechnology Department, and Matthew Salo, program advisor and manager of Anoka-Ramsey's Biomedical Market Development, at a c³bc Medical Device Hub meeting turned into a productive brainstorming session of options for resolving the problem of delayed graduations and students leaving their programs without the regulatory course.

When Ivy Tech offered the 16-week, online Clinical Trials for Medical Products course in 2015, it had been revised to align with c³bc Medical Device Skill Standards. Nine Anoka-Ramsey students and five Ivy Tech students took the course. For spring semester 2016, four Anoka-Ramsey students and nine Ivy Tech students enrolled.

“It was a great thing to help our students,” Salo said, adding, “I’m excited to see where it goes.”

Lee explained that with Ivy Tech's capacity of 30 students per course per semester other colleges or individuals could join Ivy Tech's online course, and other course-sharing arrangements among the c³bc colleges could provide more specialized courses to more students.

“The shared arrangement,” Lee said, “is a win-win for both colleges.”

## Shared Course Key to Internship & Job

When only two people enrolled in the clinical trials course at Minnesota’s Anoka-Ramsey Community College in spring 2014, the cancellation due to low enrollment was "a real let down" for Frances Beech. She had planned to take it and two other required courses to finish her Clinical Research Professional certificate that semester. "It was the clinical trials course that held me back," she said.

The next two semesters she took elective courses in anatomy, technical writing, and accounting. "I was afraid if I just stopped taking classes, I wouldn't finish," she said. Beech had earned an aquatic biology degree in 1987 but was out of the workforce for several years to raise her three children.

She was happy in January 2015 to be among the first group of Anoka-Ramsey students to take Ivy Tech Community College's Clinical Trials for Medical Products course online in a shared course arrangement that grew out of c³bc. She was even happier a few weeks later when her enrollment in the course led to her selection for a paid internship at Galil Medical in Arden Hills, Minnesota.

"That was the perfect combination because it was like having a lab with the course," Beech said. Galil hired her in June 2015 as a clinical research coordinator. The part-time position assisting with the company's clinical trials of cryoablation across medical specialties is her dream job. "What I was really looking for was a job that was challenging and interesting, and that's what this is," she said.

As for the skills and knowledge she learned in the clinical trials course, Beech describes them as "essential" to her work.



## Biomedical Technology Program Opens Array of Jobs to Students

St. Petersburg College developed a Biomedical Equipment Technician I certificate program to help students enter the workforce while its proposed Biomedical Engineering Technology associate degree made its way through the approval process.

"The majority of our students want to be in an environment where they are responsible for managing the equipment, which is installation, maintenance, and repair," explained Giovanna Taylor, director of Biomedical Technologies and Medical Devices at St. Petersburg College in Florida.

In Central Florida, the highest, most consistent demand for people with medical device technical skills comes from the regional hospital system and other healthcare providers. Because there are also several hundred medical device manufacturers in the state, the program was designed to address their workforce needs too.

Taylor said industry's input on the curriculum and the core skills identified in the c³bc Medical Device Skill Standards helped her and others at the college prepare students for work in this field. Taylor and her colleagues created eight new courses that prepare students to enter the workforce anywhere along the continuum, from entry-level biomedical equipment technician to instrumentation specialist.

"My thinking was, if students know how to take it [equipment] apart and put it back together, they can move up and down this continuum anywhere. They can go on the design side. They can do the manufacturing side. They can move into the regulatory side. They can go into sales. They can go into training. They can go into maintenance and repair. Pretty much, there's nothing they can't easily do once they know the intricacies of the devices themselves," Taylor said.

After two years of testing on the non-credit side of the college's operations, articulation agreements allowed for the courses to become credit options within the existing Engineering Technology degree program. The Biomedical Engineering Technology degree won all necessary college approvals; in the winter of 2016 final approval was pending with the Southern Association of Colleges and Schools accrediting organization. The new associate degree program has been aligned to prepare students to qualify for three industry certifications.

## Biomedical Technology Program Brings Mid-Career Changer Choice of Jobs

In 2013, with encouragement from his wife, Andrew Wright began looking for a new career and enrolled at St. Petersburg College in Florida, where she had earned a registered nursing degree.

Early in 2016 he had three job offers even before graduating.

"The program works," Wright said of the biomedical technology certificate and degree program developed at St. Petersburg College as part of c³bc. He talked about his mid-career academic experience during a panel discussion at the Medical Design & Manufacturing West Conference in Anaheim, California, on February 9, 2016.

The three healthcare employers who offered him jobs are all "excited" that the biomedical technology certificate and degree program that St. Petersburg College developed as part of c³bc would provide them with a source for new biomedical technicians.

Wright initially enrolled in the college's Quality Medical Systems program with a plan to find work at a medical device manufacturer. After hearing a presentation about the non-credit Biomedical Technology certificate program and its free tuition, he decided that—based on his previous work experience—maintaining and repairing medical equipment was a better choice. For several years he worked as an independent contractor installing original equipment upgrades such as rear camera systems in new cars and providing on-site training to new car owners.

When he completed the Biomedical Technology certificate in December 2015 and had just a few courses left to finish his associate degree, Wright began filling out job applications. He expected it would take a few months to obtain a full-time job. Within weeks he was hired for an entry-level job at a small company. Then two large companies offered him interviews and then jobs. He gave two-weeks' notice to the first employer and in February started work as Biomedical Technologist I with BayCare Health System, a 14-hospital system in Central Florida. He plans to wrap up the last few courses he needs for an associate degree by the end of 2016.

## Employees from 10 Medical Device Companies Take c³bc Courses

Salt Lake Community College

The emphasis of the U.S. Department of Labor's TAACCCT grant on short-term workforce training led biotechnology faculty members at Salt Lake Community College (SLCC) to think "we can do something new here," said Jie Gu, manager of the college's Medical Device Program.

Rather than create a two-year degree for c³bc, the biotechnology educators worked with the college's Continuing Education Division to create a non-credit medical device certificate. Together they developed four courses: Introduction to Medical Device Industry, Basic Manufacturing Skills, Introduction to FDA Regulations, and Introduction to Quality Systems.

Of the 73 participants enrolled through February 2016, 49 were already employed with a medical device company when they began the continuing education courses. Their goals were to improve their knowledge along with the 24 people who were interested in starting new careers in the medical device industry.

Altogether, 10 different medical device companies' employees have taken one or more of the courses since 2014. Most of the companies have paid all or part of the tuition, which ranges from $299 to $320.50 per course. Some companies have offered incentives to employees who complete either a course or the entire four-course certificate.

"Not only are participants in our program learning valuable industry knowledge, they also feel appreciated by their employers because their company is investing in them," said Kay Carter, manager of the Encore Institute in SLCC's Continuing Education Division. For c³bc she and Gu met face-to-face with managers at large and small medical device companies to explain that the courses are based on national skill standards created with industry input. "The company support has been huge," Carter said.

Students who complete the four courses receive a Medical Device Manufacturing Processes and Practices Core Skills and Knowledge certificate. The certificate qualifies the student for five college credits toward a Biotechnology Associate in Science degree. In 2016, the program added two more courses—Introduction to Quality Control, and QA [Quality Assurance] Auditing Concepts—to provide experienced medical device technicians with deeper knowledge and preparation for American Society for Quality certifications.

The medical device manufacturing industry is growing rapidly in Utah where demand is high for qualified employees. Multiple companies have asked Carter for résumés of students who have completed the program.

Salt Lake Community College is able to provide training for those starting a new career, or incumbent workers looking to upscale their knowledge. The workforce training being provided not only helps the employers and job seekers but also helps boost the local economy.

### CEO Endorses SLCC Programs

ATL Technology CEO Brad Brown wants as many of his employees as possible to take the medical device courses that Salt Lake Community College developed as part of c³bc. As an incentive he is paying 1% raises for each course employees complete.

Brown says the company's costs, even with the raises and tuition, are less than other training programs. The courses have the added benefit of more employees being "engaged in the actual quality of the products we make because they understand the workings better. So, it's been a positive for us so far," Brown said.

As of February 2016, 18 of the 60 employees at the company in Springvale, Utah, who were offered the incentive had taken at least one of the eight-week courses. One employee had completed the entire four-course sequence.

"The emphasis here is to get everybody in the company up to speed on the basics," Brown said. Notably, the incentive is available to the entire company, including administrative assistants, purchasing and sales personnel, and manufacturing technicians.

To encourage more people to enroll for the upcoming spring semester, Brown was planning to post on company bulletin boards the list of every employee, including himself, with Xs in the appropriate columns to show who had completed courses. He planned to headline it: "How would you like a raise?"

Before offering the incentive, Brown took SLCC's non-credit Introduction to Medical Device course in 2015 with two other employees. "The instruction has just been outstanding," Brown said, adding, "We couldn't ask for better."

When he compared the quality and cost of the SLCC courses "the dollar value seemed to be five to six times more cost effective than the training that I have been doing." ATL Technology routinely sends managers and quality systems personnel for multi-day intense training programs.

Adding to the value for CEO Brown is that the information taught in the SLCC courses is "cemented" in employees because they attend classes for eight weeks.





## Medical Device Hub Creates 3 Courses & 2 Modules in a "Box"

To help educators incorporate the c³bc Medical Device Skill Standards into their classrooms and labs, the Medical Device Hub created Courses in a Box materials with industry subject-matter experts.

The courses are Quality Practices, Metrology, and Product Life Cycle Capstone from Ivy Tech Community College Bloomington in Indiana, and its industry partners; and two modules on Root Cause Analysis from Mount Wachusett Community College in Massachusetts. They can be downloaded from NTER at www.nterlearning.org and SkillsCommons www.skillscommons.org.

The virtual "box" contains everything an instructor needs to teach the course or module online or in person, according to Sarah Cote, associate professor of biotechnology and project manager of c³bc's Medical Device Hub.

These downloadable, digital materials include syllabi, lesson plans, a cross-walk showing the relationships between items in the skill sets and the course content, lectures, lab notes, slides, assignments, assessments, recommended credentialing for instructors, pre-requisites for students, lists of equipment and supplies, and formatting instructions for online delivery.

The Quality Practices course is based on the knowledge needed to obtain American Society for Quality certifications for Certified Quality Improvement Associate and Certified Quality Process Analyst positions. It covers everything from quality tools to data collection and team dynamics.

The Metrology course uses medical device manufacturing activities and scenarios. The course emphasizes calibration, but also covers how to carry out inspections and perform quality audits among other important tasks.

In the Product Life Cycle Capstone course students have their choice of three projects. Each project requires students to take on a role in a scenario, execute tasks through the life cycle of a medical device, and then write precisely about each process and outcome.

"A big part of regulatory responsibility is synthesizing a good story about your product using scientific data," says Christopher Kilander, global product manager/team leader for peripheral intervention at COOK Incorporated. He worked with Dean Miller, an Ivy Tech regulatory affairs instructor, on the course modules.

The Online Root Cause Analysis Modules from Mount Wachusett Community College teach key problem-solving tools that are useful when conducting investigations into the root cause of process or equipment failures. They are "problem understanding" and "problem-cause brainstorming." The course uses interactive animations for case studies from medical device manufacturers. Students are assessed according to their decision-making and approach to problems.

### College Aligns Courses to c³bc Medical Device Skill Standards

Mount Wachusett Community College aligned four on-campus courses to the c³bc Medical Device Skill Standards.

Quality and Compliance was part of the biotech program. The three other courses were developed in 2013 for the Analytical Laboratory and Quality Systems certificate and degree program. A National Science Foundation Advanced Technological Education grant supported creation of the curriculum, which meets American Society for Quality certification expectations.

"Early in the development phase of the curriculum I became aware of the skill standards mapping project, which dovetailed nicely into the project. I kept the map in mind as the courses were created," explained Gretchen Ingvason, senior learning specialist for Analytical Laboratory & Quality Systems.

Below are the four courses and the critical work functions (CWFs) to which they are aligned.

**Instrumental Analysis**

- ✔ Perform Measurements/Tests/Assays
- ✔ Perform Mathematical Manipulations

**Introduction to Metrology**

- ✔ Perform Measurements/Tests/Assays
- ✔ Perform Mathematical Manipulations
- ✔ Manage and Communicate Information

**Introduction to Quality and Auditing**

- ✔ Comply with Applicable Regulations and Standards
- ✔ Manage and Communicate Information

**Quality and Compliance**

- ✔ Comply with Applicable Regulations and Standards
- ✔ Manage and Communicate Information

## Partner College Plan to Build on c³bc Success

In the future the c³bc partner colleges plan to continue building on the accomplishments facilitated by the Department of Labor Trade Adjustment Assistance Community College Career Training (DOL TAACCCT) grant. All of them expect to incorporate the c³bc Medical Device Skill Standards as they apply to the medical device manufacturing curricula they develop.

**Anoka-Ramsey Community College** (Minnesota) may offer risk management and other biomedical specialty courses via shared course arrangements like the one it established in 2015 with Ivy Tech Community College for an online Clinical Trials for Medical Products course. The hands-on technical training programs the college has offered in its Medical Device Manufacturing Skills Lab since it opened in 2015 are influenced by the c³bc Medical Device Skill Standards. The college offers an accelerated, non-credit certificate and Biomedical Equipment Technician associate degree.

**College of the Canyons** (California) is preparing to relaunch its biotechnology program. New courses and revisions to existing courses will utilize the c³bc Medical Device Skill Standards to support career pathways that cross both biotechnology and advanced manufacturing.

**Irvine Valley College** (California) used the c³bc Medical Device Skill Standards as the basis for a new medical device program starting in 2016. Mapping the new credit courses to the skill standards shortened the curriculum approval process to eight months from the 24 months it typically takes. The new program will focus on quality assurance and regulation. This specialization complements the core biotechnology courses that the college offers as part of the Orange County Biotech Education Partnership with four other community colleges.

**Ivy Tech Community College Bloomington** (Indiana) faculty would like to add advanced courses in injection molding and extrusion to the three plastics courses they developed as part of their c³bc work. The five courses plus a design course would then form a Design Technology-Plastics certificate. Eventually, faculty hope to add a Medical Device Quality certificate program that would have dual credit introductory courses in biotechnology and biomanufacturing for high school students. This certificate would include existing quality, safety and regulatory, and design courses, as well as the metrology course created as a c³bc Course in a Box.

**Mount Wachusett Community College** (Massachusetts) plans to combine the revisions to its program based on the c³bc Medical Device Skill Standards with courses it developed with two other federal grants. The resulting quality courses will be packaged for individuals employed by medical device manufacturers and other manufacturers to move into quality control positions. The college is a funded partner on a mechatronics-focused DOL TAACCCT grant and an Advanced Technological Education grant from the National Science Foundation for stackable credentials for analytical lab technicians.

**St. Petersburg College** (Florida) will work with its industry partners to develop training that prepares students for the national industry credential known as CBET (Certified Biomedical Equipment Technician). It is also exploring articulation of its biomedical technician program with a university program. The process that the college's biomedical technology personnel devised during c³bc to convert non-credit courses to credit courses is being formalized for college-wide use.

**Salt Lake Community College** (Utah) is creating two online medical device courses based on the c³bc Medical Device Skill Standards. The courses will use a competency-based model that allows for open-entry, open-exit from the courses based on students' attainment of skills. The courses are Introduction to Quality Systems, from the non-credit certificate program the college created for c³bc, and Introduction to Quality Control, a new course. In the future the college may add on-campus labs where faculty would be available to coach students enrolled in the online courses.

**William R. Moore College of Technology** (Tennessee) plans to continue recruiting students to meet the needs of orthopedic device manufacturers in Memphis for skilled employees. Since it became a c³bc partner in 2013, the college's machining technology program has added a precision medical machining course based on the c³bc Medical Device Skill Standards.



## c³bc Skill Standards Serve as "Backbone" for New Austin Community College Program

Using the c³bc Medical Device Skill Standards, Austin Community College faculty saved about a year of work when planning the curriculum for a new medical device manufacturing program in Texas.

The c³bc's skill standards "will basically be our backbone for setting up the curriculum," explained Sulatha Dwarakanath, biotechnology professor at Austin Community College. She served as the college's lead for the DOL TAACCCT grant and is principal investigator of the Wagner-Peyser grant that provided the funding to start the college's medical device program.

She based her estimate on the time it took her and Linnea Fletcher, ACC Biotech Department chair, to prepare biomanufacturing skill standards for the college's launch of that new program in 2014. Creating the biomanufacturing skill standards involved several lengthy meetings with industry representatives over a 12-month period. After the skill standards were identified, they had to be approved by the Texas Skill Standards Board.

Thanks to the development of the c³bc Medical Device Skill Standards, the conversations between local medical device manufacturers and instructors from the college's biotech, and physics and engineering departments began at a much higher level.

Industry representatives reviewed the c³bc Medical Device Skill Standards, liked what they saw, and offered just a few suggestions for fine tuning course content to address their specific needs. "They were quite happy," Dwarakanath said.

Thanks to the c³bc work on the skill standards, less than four months after receiving notification of the $483,200 grant to start the medical device program, the multi-disciplinary faculty team presented its plans to the college's Curriculum Review Committee.

Once the committee gives its approval, Dwarakanath said the next step will be to submit the curriculum to the Texas Skill Standards Board. Given c³bc's vetting of the standards with industry and educators nationally, she was optimistic in February 2016 that state approval would arrive in time for the college to begin the program in fall 2016.

The new associate degree and one-year advanced technical certificate, which is for people who already have a bachelor's degree, will be offered through ACC's physics department because it has several of the manufacturing technology courses already in place.

Students in the program will take the existing introductory biotech courses as well as the new medical device course that the biotechnology department will create based on the curriculum from Ivy Tech Community College in Indiana and St. Petersburg College in Florida. Both of these c³bc partner colleges' courses have been revised to align with the c³bc Medical Device Skill Standards.

### Entry-Level Jobs in the Medical Device Industry

The c³bc Medical Device Skill Standards were developed by medical device industry representatives and community college bioscience educators to prepare people for the following entry-level jobs in the medical device industry.

- ✔ Assembler
- ✔ Calibration Technician
- ✔ Design Control Technician
- ✔ Documentation Technician
- ✔ Engineering Technician
- ✔ Inspector
- ✔ Lab Technician
- ✔ Mechanical Technician
- ✔ Operator
- ✔ Production Technician
- ✔ Prototype Technician Quality Coordinator
- ✔ Quality Investigator
- ✔ Regulatory Affairs Clerk
- ✔ Regulatory Affairs Coordinator
- ✔ Regulatory Affairs Scientist
- ✔ Regulatory Affairs Specialist
- ✔ Regulatory Affairs Technician

# c³bc MEDICAL DEVICE SKILL STANDARDS



## Definitions of Terms Used in c³bc Medical Device Skill Standards

The c³bc Medical Device Skill Standards were developed by industry representatives and community college bioscience educators who worked together as the Medical Device Hub of the Community College Consortium for Bioscience Credentials from 2013 to 2016. These skill standards were adapted from c³bc Core Skills Standards, which were developed through a parallel collaborative process with the goal of finding commonalities in skills across the work environments typical of the biomanufacturing, bioscience laboratory, and medical device industry sub-sectors. (See https://sites.google.com/site/c3bcbiosciencesskillstandards/.) The work for both sets of skill standards was supported by a Trade Adjustment Assistance Community College and Career Training grant from the U.S. Department of Labor.

**Critical Work Functions** are the broadest areas of responsibility for an entry-level medical device technician.

A **Key Activity** is an essential task performed by an entry-level medical device technician.

A **Performance Indicator** is a guide that can be used to determine if a key activity has been performed well.

**Underlying Technical Knowledge** includes areas of expertise that an entry-level medical device technician must have in order to excel in performing a key activity.

An **Assessment** is an exercise that can be undertaken to determine an individual's proficiency in performing a key activity.

### CRITICAL WORK FUNCTION - MAINTAIN A SAFE AND PRODUCTIVE WORK ENVIRONMENT

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Recognize unsafe conditions and take corrective and/or preventive action(s). | Different types of hazards (e.g. biological, chemical, physical, electrical, radiological) are identified. | Meaning of safety symbols & signs; OSHA and EPA principles | Match the safety symbol to its meaning. |
| | | Basic understanding of electricity and electrical hazards | Scenario: Show a picture of a storage room that has two heavy boxes on the top shelf, not properly secured, and an overloaded circuit with daisy-chained power strips and numerous cords plugged into each strip. Describe what unsafe conditions exist, if any, and what could be done to correct them. |
| | | Types of physical hazards | Scenario: A bottle fell off a shelf and is broken on the floor, spilling most of its chemical contents. Demonstrate what to do and explain aloud what needs to be done to deal with this situation, and why. |
| | | Proper identification, handling, and storage of hazardous materials (acids, bases, corrosives, oxidizers, explosive, flammable, etc.) | |
| | Emergency procedures are demonstrated. | Location, purpose, and proper use of safety equipment | On a map of the facility, indicate the type and location of all safety equipment (teaching lab). |
| | | | Explain the conditions under which specified safety equipment is used. |
| | | | Don and remove PPE equipment properly. |
| | | Sources of safety information (MSDS/SDS) | Demonstrate proper procedures in response to a simulated emergency. |
| | | General procedure one would follow in various emergency situations | Give examples of various emergency situations (e.g. earthquake, fire, tornado, active shooter) and ask for description of proper responses. |

### CRITICAL WORK FUNCTION - MAINTAIN A SAFE AND PRODUCTIVE WORK ENVIRONMENT

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Follow relevant safety policies, guidelines, protocols, and regulations (e.g. company, OSHA, EPA, CDC). | Workplace behavior/actions compliant with industrial and regulatory safety standards are demonstrated (e.g. LOTO, confined space, PPE, egress). | OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200; OSHA HCS guidance document [www.osha.gov/Publications/OSHA3695.pdf]; | Execute the steps needed, in the correct order, to properly lock-out-tag-out (LOTO) the piece of equipment in preparation for maintenance. |
| | | OSHA HC Program fact sheet [www.osha.gov/Publications/OSHA3696.pdf] | Demonstrate appropriate response to a given scenario where a standard should be applied. |
| | Appropriate resources are used to identify proper disposal/waste treatment procedures. | Awareness of safety training requirements from all federal and state regulatory bodies as well as company specific policies | Choose a chemical/material and ask student to: (1) retrieve SDS, (2) identify PPE, (3) describe special handling procedures, (4) describe special hazardous waste and disposal procedures. |
| | | How to locate and use MSDS/SDS | |
| Access and use MSDS (SDS) and other safety information sources. | Safe material handling and storage are demonstrated. | Proper use of fume hood and biosafety cabinet | |
| | | How to locate and use MSDS/SDS | |
| | | Function and proper use of various types of PPE | Demonstrate appropriate use of PPE for a given situation. |
| | | How to locate and use MSDS/SDS | |
| | Safe use of lasers, high voltage, radiological equipment, etc. is demonstrated. | How to locate and use equipment instructions and other safety information sources | Demonstrate appropriate safe use of such equipment for a given situation. |
| Maintain a safe, clean, contamination-free, and clutter-free environment, as appropriate. | Workspace is cleaned before and after use. | Nature of contamination, and the principles of containment, sterilization (e.g. CIP/SIP), and disinfection | Demonstrate appropriate workspace cleaning procedure. |
| | Good housekeeping practices using tools such as 5S (sort, straighten, shine, standardize, sustain) and visual workplace philosophy are correctly applied. | Tools used for good housekeeping such as 5S and visual workplace | Maintain an organized work space to minimize clutter and remove unessential objects during each lab period. |
| | Line clearance prior to activity is demonstrated. | Principles and purpose of line clearance | Pre-clean as appropriate and remove/ put back all materials, supplies, equipment, etc. not needed for the production run. |
| | Environmental monitoring activities are performed. | Use of particle counter, air sampler, basic microbiology monitoring/test methods, etc. | Demonstrate basic environmental monitoring techniques: (1) Perform air sampling and particulate counting in the clean area/room; (2) Perform surface swab of cleaned spaces (e.g. work bench), and identify microbial contaminant(s) [simulated scenario]; (3) Describe appropriate response(s) if contaminations (particles and/or microbes) are discovered. |
| | | Actions to take when nonconformances are identified | |
| | | ISO, U.S., and European standards for clean room settings | Use appropriate aseptic techniques matching clean room specifications. |
| | | Appropriate gowning procedure and clean room behavior | Demonstrate proper gowning procedure in simulated ante and clean rooms layout. |
| | | | Identify appropriate and undesirable behaviors in a video of people working in a clean room/area, and explain why. |
| Select appropriate PPE to use to protect self from biological, chemical, and/or physical hazards. | Different types of PPE are identified and their functions are described. | Function and proper use of various types of PPE | Select appropriate PPE for given scenarios. |
| Participate in appropriate business philosophies as defined and established. | Business philosophy principles and concepts (Lean, Six Sigma, Kaizen, etc.) are applied correctly. | Lean, Six Sigma, and Kaizen concepts | Based on a scenario, use business philosophies to identify where they can be applied. |
| Conduct job functions appropriately, consistently and accurately. | Applicable job function procedures are followed. | Importance of procedures and underlying regulatory ramifications | Follow a given procedure (ex. SOP). |
| | | Consequences of non-compliances | Follow a given procedure (ex. SOP). |
| Recognize inappropriate work environment and take corrective and/or preventive actions. | Different types of inappropriate work environments (temperature, humidity, lighting, noise level, particulates, etc.) are identified. | ISO, U.S., and European standards for work environments | Recognize inappropriate work environments based on given scenarios (e.g. data, picture of leak, etc.). |

# c³bc MEDICAL DEVICE SKILL STANDARDS



## CRITICAL WORK FUNCTION - PROVIDE ROUTINE FACILITY SUPPORT

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Monitor, maintain, troubleshoot/repair equipment. | Preventive maintenance is performed as specified. | Maintenance requirements of different pieces of equipment | Assign equipment to students to monitor, maintain, and troubleshoot. Document each of these tasks properly in the equipment logbook. |
| | Monitoring activities are performed and documented according to established procedures. | Proper data collection and documentation procedures (equipment log book, SOPs, process specifications, and other technical documents) | Scenario: Describe a specific piece of equipment that is not working. Have students access users' manual and list reasons why equipment is not working. |
| | Basic equipment troubleshooting is performed. | How to use equipment user manuals and/or how to contact manufacturer for help | |
| Use equipment correctly according to manufacturer's guidelines. | Equipment performance is verified prior to use. | Calibration, qualification, verification, and validation and the differences among them | Describe/show what must be considered or done prior to use of a particular piece of equipment. |
| | Recommended operating conditions of the equipment are used. | General principles of metrology | Select appropriate measurement or calibration device for required process. |
| | Initialization and shutdown of equipment are performed correctly. | Use of national and international calibration standards and traceability | Properly perform calibration on a piece of equipment. |
| Maintain inventory of raw materials, parts, components, and/or equipment. | Periodic inventory of stock/supplies is taken in compliance with established procedures. | Inventory control principles and rules for ordering, e.g. first in first out (FIFO) | Answer real-world questions about reordering based on a materials database and inventory procedure set up for a mock company. |
| | Materials, parts, and equipment are stored appropriately. | Storage considerations of materials, interpretation of the MSDS/ SDS | Demonstrate materials storage per MSDS/SDS. |
| | Expired materials, parts, and equipment are discarded according to established procedures. | | Perform an inventory of materials, parts, and equipment, and explain what the next steps should be (e.g. (re)ordering, obsoleting, discarding expired, etc.) based on the inventory results. |
| | Materials are identified to ensure traceability. | Lot traceability, bar coding, QR, and labeling systems | Apply traceability techniques using the system available in the lab. |
| Prepare materials/supplies/equipment for use. | Correct selection and quantity of necessary materials/supplies/equipment for the activity are gathered and prepared for use. | Proper preparation procedures for materials/supplies/equipment | Demonstrate the necessary set-up to run a particular test/assay or use of a piece of equipment. |
| Conduct root cause analysis. | Minor equipment failures are identified and corrected. | Troubleshooting techniques | Scenario: Given a particular product or process that has failed, investigate to determine possible causes (or the root cause, if possible). |
| | | Conditions that cause equipment to go out of calibration | Given a scenario, identify conditions that caused equipment to go out of calibration. |
| | | Root cause analysis tools (fishbone, 5 Whys) | Given a scenario, conduct root cause analysis using appropriate tool. |
| Use proper cleaning procedure for work areas. | Work area maintenance is performed appropriately and documented, including clean rooms if appropriate. | Proper gowning procedures | Demonstrate clean room gowning. |
| | | Disinfectants, cleaning methods, environmental monitoring methods | Demonstrate cleaning procedures appropriate for the work area. |
| | | Documentation of cleaning inspection | Use check-off list to demonstrate proper cleaning. |
| Follow waste management procedures. | Materials are discarded according to established procedures. | Classification of materials and proper disposal including toxic/ hazardous waste | Demonstrate safe disposal procedures for given scenarios and materials. |

## CRITICAL WORK FUNCTION - PERFORM MEASUREMENTS/ TESTS/ ASSAYS

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Collect samples according to established procedures and applicable sampling plans. | Samples are collected according to established procedures for testing purpose. | Sampling procedures for material/product | Scenario: An in-process (or raw material or final product) testing is being done for a production run. The run has been simulated for the responsible person, who then demonstrates collection, preparation, labeling, and storage of samples for testing according to the in-process (or raw material or final product) testing procedure (provided). |
| | | Statistical sampling plans to be followed for testing | |
| | | Chain of custody requirements for samples | |
| Prepare samples according to established procedures. | Samples are prepared (if required) according to established procedures for testing purpose. | Sample preparation procedures | |
| Label samples properly for identification and traceability, including raw materials, in-process samples, and finished goods . | Samples are labeled according to established procedures for testing purpose. | Labeling procedures | |
| Store samples properly, including raw materials, in-process samples, and finished goods. | Samples are stored according to established procedures for testing purpose. | Storage procedures and conditions appropriate for the sample | |
| Follow appropriate test procedures/instructions. | Test(s) are performed according to established procedures. | Relevant measurement range and sensitivity of different tools | Given specification and tolerance, select correct tool. |
| | | Recognize and distinguish between types and causes of measurement error | Demonstrate use of selected tool to make measurement. |
| | | | Identify abnormal results; identify source of the abnormal results. |
| | | Distinction between accuracy and precision | Use class data to determine accuracy and precision. |
| | | | Reflect on accuracy and precision of each tool choice available. |
| | Appropriate measurement/test tool(s) is(are) chosen for the application. | Relevant measurement range and resolution of different tools | |
| | | Uncertainty in measurement | |
| | Measurement/test tool(s) is(are) used correctly. | | |
| Document data & results according to established procedures. | Documentation is maintained properly. | Format and function of different document types (e.g. lab notebooks, batch records, SOPs, protocols, forms, etc.) | Create portfolio of documentation examples including lab notebooks, batch records, SOPs, protocols, forms, etc. |
| | Batch records and forms are completed properly. | Good documentation practices including electronic records | Create portfolio of documentation examples including lab notebooks, batch records, SOPs, protocols, forms, etc. |
| | Information is entered and verified correctly in final format (lab notebook, electronic database, etc.) | Data entry methods acceptable for document type | Demonstrate entering and verification of collected data set. |
| Interpret and/or analyze data & results as appropriate. | Test-specific mathematical calculations are performed. | Principles of descriptive statistics (mean, median, mode, standard deviation, range, linear regression) | Demonstrate data processing and presentation through a laboratory activity. |
| | Data & results are presented in an appropriate manner. | Creation and interpretation of graphs, tables, etc.; familiarity with graphing software | Develop a report from a given set of data. |

# c³bc MEDICAL DEVICE SKILL STANDARDS



## CRITICAL WORK FUNCTION - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Follow established policies and procedures. | GXPs (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 | Answer exam questions: What is the basic structure of the quality system? 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 Ks, 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. |
| | Deviations are handled appropriately. | Policy/procedures for deviations | Scenario: A technician executing an established procedure encounters a need for a deviation from the procedure. Describe what must be done in order for the deviation to be allowed and executed. |
| | Necessity for and fundamentals of regulations are understood. | FDA - history including enacted laws/ promulgated regulations, organizational structure, premarket approvals | Identify landmark events that brought about regulatory laws. |
| | | FDA organizational structure | Draw an organizational chart showing FDA divisions and describe how they are related. |
| | | Regulatory submissions [premarket approvals (PMA), and premarket notifications (510k)] | Given a scenario, identify which submission is appropriate. |
| | | Classifications of Medical Devices (Class I, Class II, and Class III) | Given a variety of devices, research and determine the classification of each. |
| | Knowledge of appropriate regulatory expectations is demonstrated. | Quality manual, including the quality policy, standard operating procedures, work instructions | Given a regulation (ISO 13485 and 21 CFR 820), (1) highlight the key pieces that need to be in our quality manual; (2) identify what procedures would then be needed. |
| | | Industry Standard Operations (ISO): ISO 14971 (Environmental Management and ISO 13485 (Medical Device Quality Management), ISO 15189 (GLPs) 21 CFR 820, MDD (ISO 9001: 2015 TBD) | Create outline of applicable regulations (see underlying knowledge) and identify when to apply and scope. |
| Record information according to established procedures. | Good documentation practices are demonstrated. | Types of records [lab notebooks, batch records, logs, Design History Files (DHF), Device History Record (DHR), Device Master Record (DMR), production records, etc.], their purposes, and how to properly complete each type | Correctly and completely fill out various types of records, including making corrections correctly (e.g. crossing out error with a single line through, writing the correct entry adjacent to the error, and adding initials and date). |
| Exercise proper document control. | Documents are managed according to proper document control, including using proper change control systems to make changes in documents. | Knowledge of applicable sections of 21 CFR 820 and ISO 13485 | Demonstrate, using a revised controlled document and change control procedures [provided as props], how the document becomes effective, and once it does, describe what must be done to ensure the previous version does not get used inadvertently. |
| | | Concepts related to document changes, approvals, and distribution of documents | |
| Participate in required training. | Required training is completed by the specified deadline and competencies are demonstrated. | Formal training process (training matrix; training policies in effect; re-training frequencies; consequences of missed (re)training deadlines) and mandatory requirements in regulations/standards | Student is assigned to "attend" an on-line training. Then, the student is tested over that training topic; and should describe why training is important. |
| Respond to audit-related activities | Knowledge of position-specific role in the audit process is demonstrated. | Types of audits | Test question: Describe different types of audits. |
| | | The audit process | Participate in mock audit. (Demonstrate appropriate behaviors during a mock audit with role playing.) |
| | | Role of various positions during audits | |
| | | What to include and not include in a response during an audit interview, appropriate responses | |
| Adhere to control principles in accordance with the established quality system. | Knowledge of change control is demonstrated. | General change control philosophy; potential consequences that may arise when change is not controlled | Explain what is meant by change control. In your explanation, describe the key benefits as well as the consequences of not following change control. |
| | Knowledge of design control is demonstrated. | Design control philosophy; relationships among customer requirements, company specifications, design inputs and outputs, design reviews, design verification, and design validation | Scenario: A company is approached by its best customer about designing an improved version of the product that your company currently manufactures. Describe what design control steps an engineer would take from the customer's requirements and design a new and improved product that meets the requirements and fulfills its intended use. |
| | | Applicable sections of 21CFR 820 and ISO 13485 covering design control including Design History File (DHF) | |

## CRITICAL WORK FUNCTION - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| | Knowledge of purchasing control is demonstrated. | Supplier relationships; supplier agreements; supplier qualifications; supplier management; supply chain management; purchasing documentation, traceability, and approvals | Scenario: Personnel in the purchasing department report that supplier for raw material X will discontinue production in the near future. An alternate source for X has been identified. What steps need to be taken with regard to purchasing in order to comply with the company's quality system? |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering supplier approval, raw material specifications, purchase orders | |
| | Knowledge of production & process control is demonstrated. | General philosophy with consideration of materials, methods, machine, man, and environment; monitoring program; material control and traceability; established procedures and compliance with them; equipment monitoring, inspection, maintenance, and repair; personnel with appropriate and current training; facility and environmental control for product/process quality/consistency | Design a cGMP facility that enables appropriate work flow. |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering control of production and production-related processes | |
| | Knowledge of labeling & packaging control is demonstrated. | Label integrity, appropriate label information content, inspection of labeling, storage, and controlled issuance for use, packaging selection considerations | Scenario: An employee is assigned to execute a production run for a batch of 5,000. Materials has issued the employee 5,050 labels (per labeling policy). At the conclusion of the production run, the employee has made 5,003 units and has 39 labels remaining. What are the employee's obligations to close out this production run? |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering key elements of labeling and packaging control. | |
| | Knowledge of environmental control is demonstrated. | Work environment requirements for product consistency, how to enter and work in special work environments, safety concerns | Students participate in gowning training and verification via plating, if possible. While gowned, students perform cleaning and verification of cleaning activity as well as environmental monitoring activities. |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering controlled environments, PPE, Hazmat, clean room gowning, clean room behavior, gowning verification | |
| | Knowledge of management controls is demonstrated. | Management responsibility for operations, including production, quality, continuous improvement, resources, and customer satisfaction | Students are given a scenario in which a manager is facing an issue within the company. Students write a paragraph indicating how the manager should respond and act to resolve the issue in accordance with applicable regulations. |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering management review, authority, delegation, quality management representative, provision of resources | |
| | Knowledge of materials management / control is demonstrated. | Incoming raw materials handling (quarantine, acceptance or rejection after inspection/QC testing, storage for use or disposition of rejected material), FIFO (first in first out), inventory, purchasing | According to 21 CFR 820 and ISO 13485, what should be done to properly manage materials (raw materials, in-process materials, and finished goods)? |
| | | Applicable sections of 21 CFR 820 and ISO 13485 covering control of materials | |
| Adhere to traceability principles. | Items (e.g. raw materials, in-process product, final product, samples, etc.) are labeled appropriately and lot numbers are recorded. | Concept and importance of traceability within the medical device workplace; traceability of materials, documentation, and training | Compliance review a completed batch record for lot numbers and equipment ID numbers (record can be a prop, or one filled out by another student). Describe the information that must be tracked in order to trace a material from receiving all the way through to delivery to the customer. |
| | | Device History Record (DHR), Device Master Record (DMR), Manufacturing Process--BOM (Bill of Materials); product status, label elements, key items on the label, minimum label requirements, lot # part #, status, equipment identification | |
| Participate in validation activities. | Draft procedure is tested according to validation protocol and feedback to author is provided. | Types of validation: equipment (Installation Qualification, Operational Qualification, Process Qualification), methods, validation protocol, protocol deviations, documentation | Students test simple devices while following validation protocols (PQ), or students set up a small device (microwave) and see that it works (IQ), or set equipment across range to see where to obtain best results (OQ), or describe the IQ, OQ, and PQ of a new piece of equipment purchased for manufacturing. |

# c³bc MEDICAL DEVICE SKILL STANDARDS



## CRITICAL WORK FUNCTION - COMPLY WITH APPLICABLE REGULATIONS AND STANDARDS

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Recognize and address nonconformances. | Appropriate corrective and/or preventive action(s) is(are) taken and documented. | Investigating a nonconformance, risk review, material review board, containment, correction, CAPA, root cause | Scenario: Manufacture of device [use given procedure]<br><br>Part 1: Does this device pass or fail QC check? [provide props; fail cue to not meeting spec = nonconformance]<br><br>Part 2: An individual has been assigned to investigate. Describe an appropriate process for the investigation, including all possible causes. [Intent is root cause analysis].<br><br>Part 3: What would be an appropriate approach for eliminating each of the possible causes?<br><br>Part 4: The root cause was determined to be a raw material. [Specifically, the raw material was released without proper review/testing. This event triggered an internal audit.] |
| Understand risk management principles. | Patient risk factors associated with the employee's work are understood.<br><br>Unforeseen risks are identified and communicated appropriately.<br><br>Risk mitigation activities are supported as requested. | ISO 14971 (Medical Device Risk Management), different risk assessment tools, FMEA (Failure Mode Effects Analysis), and 3x3 matrix (acceptability criteria) | Consider an insulin pump. Identify and describe/assess risks related to the materials used to manufacture it; the production processes used; the equipment used in manufacturing; the end user. For each identified risk, provide ways that the risk can be mitigated. |
| Understand the principles of post market surveillance. | Recalls, complaints, and MDR's are supported as requested. | Purpose and requirements of the post market surveillance system<br><br>Applicable standards and regulations 21 CFR 7, 803, 806 and 820 and ISO 13485 | Describe the benefits of participating in post-market surveillance. Provide specific examples of surveillance-related benefits. |

## CRITICAL WORK FUNCTION - MANAGE AND COMMUNICATE INFORMATION

| Key Activity | Performance Indicators | Underlying Knowledge | Assessments |
|---|---|---|---|
| Comply with company communication policies. | Consequences of noncompliance with communication policies are explained. | Purpose of nondisclosure agreements, Sunshine Act, interactions with health care professionals<br><br>Typical company specific communication policies (e.g. nondisclosure agreements, quality policies, mission/vision statements, HR policies, EH&S policies, etc.)<br><br>Social, legal, and ethical issues relating to information and its use and labeling | Given a scenario (e.g. production run that spans two shifts and several days; or a set of lab tests that span two shifts and multiple days, and a necessary change in work flow), students take the role of a shift leader and draft an e-mail communicating the appropriate details about the work flow change and a proposal to the other shift and leader regarding how the two shifts can work together to accomplish the newly assigned task. |
| Communicate information in an appropriate manner. | Proper communication method is chosen and used (e.g. formal reports, memos, e-mail, etc.). | Types of communication methods (e-mail, word processing, etc.) and their best uses<br><br>Safety and security of communication; permanent nature of documented communication; need for accurate and complete records in permanent communication<br><br>Appropriate and inappropriate styles and content for all correspondence | Give students information they need to communicate and tell with whom they need to share the information. Students must then identify the best way to communicate that information and develop a mock communication (e-mail, word processing, etc.).<br><br>Early in the semester, teach students a procedure and have them write down how to complete that procedure. At the end of the semester, have them perform the same procedure using only their notes.<br><br>Given an example of internal communication, students must respond appropriately and/or critique it. |
| Assist in reviewing/commenting, revising, and writing technical documents. | Errors in technical documents are recognized and appropriate changes are suggested. | Required components and format of technical documents | Have students write a technical document (SOP, report, WID, or other document) and exchange documents within the class for peer review and revision. |
| Suggest continuous improvements. | Inefficiencies are recognized and appropriate action is taken. | 5S, mistake proofing<br><br>Appropriate applications of technical documents | Peer review technical documents, or when given an inefficient document, identify how to improve it. |
| Use computer tools effectively. | Basic word processing tasks are performed. | Basic features of word processing applications | Choose any type of assignment and students must match the required specifications (e.g. margins, page layout, headers/footers, font type, font size, acceptable use of bold/italic, etc.) |
| | Spreadsheet software is used. | Basic features of spreadsheet applications<br><br>Different types of graphs and the scope of use of each type<br><br>Different functions available for formulas | Given data from a test/production run, use spreadsheet software to create a table to (1) display the data in a clear and understandable manner; (2) plot the data using an appropriate graphing method; (3) calculate average, standard deviation, and CV for the data set as directed. |
| | Presentations are created. | Basic features of presentation applications<br><br>Characteristics of effective presentations | |
| | Online information is accessed. | Use of search engines with effective search criteria | Given a described request for information, determine/select key words for searching and execute a search that successfully retrieves a particular document or web page. |
| | Other workplace-relevant software applications are navigated proficiently. | Usage and purpose of medical device industry or position-specific applications | |

# c³bc MEDICAL DEVICE SKILL STANDARDS

| CRITICAL WORK FUNCTION - PERFORM MATHEMATICAL MANIPULATIONS | | | |
|---|---|---|---|
| **Key Activity** | **Performance Indicators** | **Underlying Knowledge** | **Assessments** |
| Perform calculations relating to work function. | Basic manipulations involving exponents are performed correctly.<br>Significant figures, when taking and rounding measurements, are used correctly. | Basic mathematical concepts involving exponents<br>Proficiency in the concept of significant figures | Perform calculations involving exponents.<br>Identify significant figures with measurements and record correctly according to measurement requirements. |
| | Conversions between standard and scientific notation are performed correctly. | Expression of values in different formats and why | Convert data between standard form and scientific notation correctly. |
| | Calculations of logs and antilogs for powers of ten are performed correctly. | Difference between logs and antilogs for power of ten | Perform sample problems. |
| | Conversions between proportions, decimals, percentages, fractions, and ratios (including dilutions) (e.g. $C_1V_1 = C_2V_2$ equation) are applied correctly. | Basic mathematical concepts involving proportions, decimals, percentages, fractions, and ratios<br>Relationship between variables in an equation | Perform calculations involving conversions.<br>Predict the change correctly based on the relationship between variables in an equation. |
| | Conversions between units of measure (e.g. within the metric system and between metric and U.S. systems) are performed correctly. | Metric system and common prefixes, U.S. system, and conversion factors between related units of measure | Convert measurements between metric and U.S. systems correctly. |
| Perform data analysis. | Data is correctly analyzed using descriptive statistical functions. | Purpose of various statistical functions, such as mean, mode, standard deviation, coefficient of variation, chi squared tests and $r^2$ values | For measurements of samples taken from a variety of production lots, calculate the mean and standard deviation for the samples from each lot. |
| | Data is graphed using the appropriate graphing method. | Appropriate application of graphs and charts<br>Standard curve principles | Graph data using appropriate chart. |



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To download the full version of the c³bc Medical Device Skill Standards go to

www.bio-link.org/home2/resource/bioscience-skill-standards

The c³bc Medical Device Skill Standards and other deliverables from c³bc 's TAACCCT grant are archived at www.nterlearning.org and www.skillscommons.org.

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