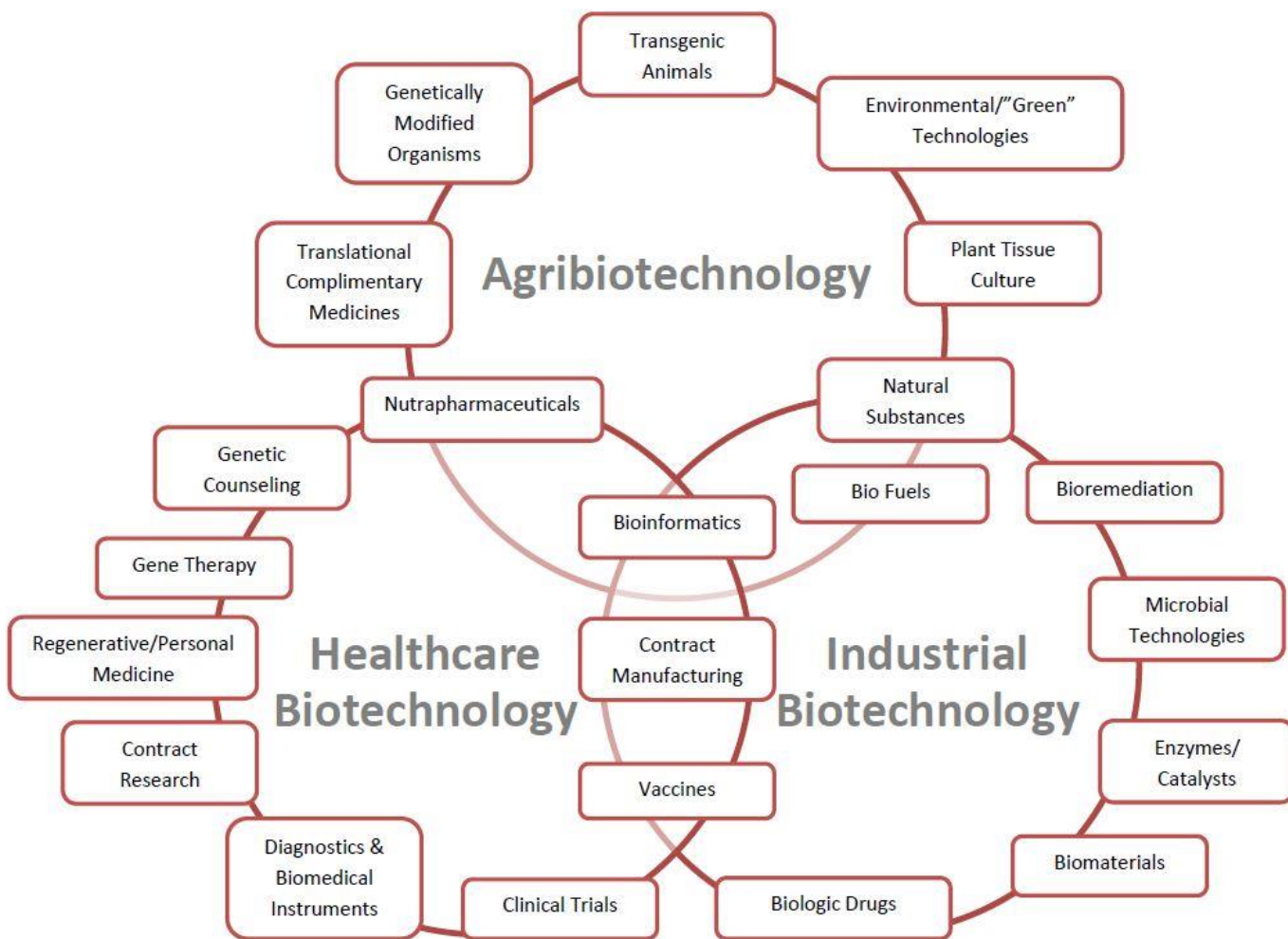


## Biotechnician Assistant Credentialing Exam

The Biotechnician Assistant Credentialing Exam includes both written and practical components developed to reflect competencies and skills outlined by the performance and academic standards of Florida’s secondary Industrial Biotechnology Program (#8736000). The standards are based on Florida’s industry-described requirements for entry-level positions (<http://www.fldoe.org/academics/career-adult-edu/career-tech-edu/curriculum->



[frameworks/index.shtml](#)). PLTW's BMS courses cover the majority of these standards. It is important to remember that, while the Industrial Biotechnology and PLTW BMS curricula may seem very different at first, both utilize the same foundational skill and knowledge sets. Whether performing basic science research or manufacturing a new vaccine, scientists use the same knowledge of how cells work and use the same techniques in manipulating those cells.

Biotechnology is defined as “the study and manipulation of living things or their component molecules, cells, tissues, or organs.”<sup>1</sup> Biotechnology is applied to the study and manufacture a wide array of products in a variety of fields, including healthcare biotechnology, industrial biotechnology, and agribiotechnology (see Figure 1), including vaccines, drugs, diagnostics, biofuels, and crops.

Suggested supplementary materials include *Biotechnology: A Laboratory Skills Course* (Bio-Rad 1661025EDU; ISBN 978-0-9832396-0-4), which offers detailed information on techniques and protocols to reinforce laboratory skills. It also explains the process of manufacturing a biologic drug and how the Food and Drug Administration (FDA) regulates the process, as well as the pathway biotech companies must follow to bring a biologic drug to market. Another excellent resource is *Biotechnology Science for the New Millennium* (Ellyn Daugherty, Paradigm Publishing, Inc., <http://biotech.com/>).

Students should have a basic understanding of the FDA regulatory process. Some of the FDA's responsibilities include:

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective, and
- Advancing the public health by helping to speed product innovations.

FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.<sup>2</sup>

The FDA is made up of several centers that each focus on a group of particular products. The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER is a consumer watchdog in America's healthcare

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<sup>1</sup> <http://biotech.com/biotechtext.htm>

<sup>2</sup> <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm>

system. CDER's best-known job is to evaluate new drugs before they can be sold. The Center's review of new drug applications not only prevents quackery, but it provides doctors and patients with the information they need to use medicines wisely. The Center makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.<sup>3</sup>

The Center for Biologics Evaluation and Research (CBER) is the Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. Biologics, in contrast to chemically-synthesized drugs, are derived from living sources (such as humans, animals, and microorganisms), are not easily identified or characterized, and many are manufactured using biotechnology. These products often represent cutting-edge biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have few or no other treatment options. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. Biologic drugs must be made under the same regulations as chemical drugs, but also have additional regulations placed on their manufacture by CBER. CBER also provides the public with information to promote the safe and appropriate use of biological products<sup>4</sup>

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<sup>3</sup><http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/default.htm#1>

<sup>4</sup> <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm>

## Gap Analysis

Below are side by side comparisons of each program with corresponding year of course. These are unabridged Knowledge and Skills (KSA) addressed for the Florida program and an abridged alignment of PLTW PBS, HBS, MI, and BI course KSA's. The course link column, provided in the middle, is the most direct alignment to cover the gap between the programs for the PLTW classes. These lessons, activities, and projects should be covered in order to successfully prepare PLTW students for the industry certification exam.

### Industrial Biotechnology Year 1 Course Links to PLTW: PBS

UF: Industrial Biotechnology 1 (KSA's)	Course Link	PLTW: PBS Course (KSA's)
Matter , energy, chemical processes of cells organisms	Act. 2.2.3/ ppt Chemistry of Life	Structure of macromolecules, nutrients, minerals in food, calorimetry, Hydrolysis, dehydration synthesis
Cell molecular structure & function, DNA Plasmids reproduction, membranes	Lesson 3.2, Lesson 3.3	
Protein synthesis, germ theory	Lesson 3.2, Unit 5 Infectious Disease; more covered in Medical intervention 3 year course	Sequence of nucleotides in DNA, protein synthesis, base pair mutations, analyze protein structural change, interactions between amino acids, b-globin sickle cell disease
Molecular genetics, biotech, restriction digestion, DNA analysis, PCR	Lesson 1.2; Act 1.2.3; more covered in Medical intervention 3 year course	Describe the relationship between DNA, genes, chromosomes, restriction enzymes, gel electrophoresis, RFLPs
Bioethics	Act. 3.3.3 The Immortal Cells, Problem 2.3.4 present a good point to introduce bioethics by the instructor	

UF: Industrial Biotechnology 1 (KSA's)	Course Link	PLTW: PBS Course (KSA's)
Interdependence of organisms, humans, environment	5.1.2 infectious agents, Project 6.1.1 parts make a whole	Reproduction of various infectious agents, prevention treatment, basic structure of bacterial cell, immune system response, isolate bacterial colonies
Genetic diversity, selection, adaptations	Lesson 3.4 Inheritance	Pedigrees, determine more of inheritance of genetic disease, Punnet Square, calculate probability of inheriting a trait or disease
Careers, connection between biotech, agricultural, food, medicine	Problem 2.3.4, All units with career journal entries Units 1-6. Act 3.3.3 The immortal cells	

All material in Florida's first year Industrial Biotechnology course (#3027010 Biotechnology 1) was included in the areas that students will have learned after completion of PBS. There are many areas within the PLTW PBS course that fit with the Industrial Biotechnology program for year one; there is material covered in the PLTW PBS course that has no immediate bearing on course alignment for the first year. The lessons and problem activities mentioned above along with the prep work done in the lab for the lessons will prepare a student for the UF BACE. It is important to have the students involved in as much prep work and lab time as possible from the first year on, in order to help acquaint students how to work in a lab. This lab preparation will also help the students in identifying the proper use of lab equipment that will be on the industry certification test.

## Industrial Biotechnology Year 2 Course Links to PLTW: HBS

UF: Biotechnology 2 KSA's	Course Link	PLTW: HBS Course KSA's
Nature of Science, scientific habits, laboratory technologies	Act 1.3.1 DNA Detectives. Important to allow students to complete as much if not all prep work in activity to help them understand Laboratory techniques, and technology. Units 1-6.	This area is address throughout the curriculum
Chemical Processes in biotech, pH, solutions, molarity	Project 3.2.4 Amylase Experiment Unit 3 Lesson 2. Have students help in lab prep and explain pH, solutions and molarity, when making required lab materials. Unit 2 lesson 3 Chemical Communication, Unit 3 Lesson 4	Experimental design, ATP energy stored, enzymes, catalyst, solutions, pH, temperature, concentration level, molarity. Hormones help maintain homeostasis, communication through chemical signals, maintain the pH balance of blood, ADH
Cell propagation, growth, and cultures for Biotech	(PBS) Unit 5 Act. 5.1.3 Isolating Bacteria, Act. 5.1.4 Gram Staining, Act. 5.1.5 Bacterial Identification	
Biochemistry, proteins, enzymes, plasmids, recombinants, blood borne pathogens	Act 3.2.1 Action Molecules, Act. 3.1.1 Blood Detectives, additional material will be needed to cover blood borne pathogens	Restriction Enzymes cut DNA, Gel electrophoresis separates fragments, RFLP's, Physical characteristics used to confirm identity. Hormones help maintain Homeostasis
Genetics, gene selection, transformation, analysis	Act. 1.3.1 DNA Detectives, covered more in MI	Describe the genetics of blood type, simulate blood samples produce/analysis family pedigree

UF: Biotechnology 2 KSA's	Course Link	PLTW: HBS Course KSA's
		for blood type, determine potential donors for a transfusion
Structure and function of various organisms, used as genetic models	Will be covered in M.I	
Interdependence of organisms, humans, and the environment	Project 3.2.2 Digestive system design, importance of bacterial organisms in the process needs to be addressed as well, Unit 6 lesson 1, Problem 6.1.1	Health and Wellness, external environment affecting the body's internal environment, Human body systems work together to defend against disease and injury
Genetic Diversity and selection	(PBS) Lesson 3.4 Inheritance (PBS) Act. 3.2.2 Genetic Code	
Connections between biotech, agricultural, food, medicine and careers	Unit 6 Homeostasis Problem 6.1.3 Building a case. These are topics that can be covered or made part of building a case project.	Trace disease in human systems by generating a fictional case study and compiling a patient case file
Bioethics	Project 1.3.3 Biometrics, part of this project asks about ethical issues that might arise from using biometric tech in different areas of daily life	Physical characteristics can be used to confirm or authenticate identity, outline current biometrics technology

Florida's Industrial Biotechnology 2 (2<sup>nd</sup> year, course #3027020) covers a wide array of areas addressed in PLTW (2<sup>nd</sup> year course), Principles of Biomedical Sciences, and those that will be covered in depth in PLTW (3<sup>rd</sup> year course), Medical Interventions. Listed above are the appropriate projects, activities, and problems that correspond to the KSA's that Florida's Industrial Biotechnology year 2 program covers. While much of the PLTW curriculum from HBS is not mentioned above, this analysis is meant to address the areas required to be covered to prepare students for success on the BACE. As each year progresses in the PLTW program, it is important to have the students do as much (if not all of) the prep work for the labs as possible under the guidance of the teacher. This work will enhance the students' ability to work in a lab setting and gain a greater understanding of the lab equipment.

### Industrial Biotechnology Year 3 Course Links to PLTW: MI

UF: Biotechnology 3 KSA's	Course Link	PLTW: MI KSA's
History, Career fields benefits of biotechnology	Act. 1.1.1 Intervention inventory; Act 4.1.5 Careers in Protein Production	Recognize that medical interventions are measures to improve health or alter the course of an illness, can be used to prevent, diagnose, and treat disease, describe the evolution of the methods used to diagnose and treat diabetes from the 1800's through today
Safety Procedures, monitor, use and store chemicals, MSDS, manage inventory procedures	Laboratory safety and procedures should be covered every year as part of PLTW and OSHA policy. When using chemical teacher should introduce MSDS's to students and what they mean	No specific KSA for this area in any of the PLTW frameworks, but is an underlining theme and protocol for all labs
Communicate and use interpersonal skills effectively	PBS, HBS, MI and BI all required students to work within different group settings and dynamics in all 4 years	Part of the core frame work of all PLTW courses and labs
Basic skills in scientific inquires, calculations and analysis	Act 1.1.3 Using DNA to identify pathogens,	Recognize that diagnostic test for infectious diseases can provide qualitative and quantitative results, bioinformatics collection classification storage using computers
Organism structure and function, nucleic acids, how cells are engineered	Act. 1.2.1 Antibiotic Therapy; Act 3.1.3 When cells lose control	Label structures of bacterial cell, describe pathways through which bacterial cells transfer genes, recognize that there are many



UF: Biotechnology 3 KSA's	Course Link	PLTW: MI KSA's
		different types of cancer cells, Perform a simulated DNA microarray
Biotechnical materials analysis skills, cell culture, sterile techniques, column chromatography, monitor protein production (PAGE)	Act 4.1.2 Protein Factories; Act. 4.1.3 Protein Purification	Calculate transformation efficiency to determine the success of a laboratory experiment, isolate a protein based on its chemical properties using column chromatography
Basic Chemistry as applied to biotechnology procedures, pH, balancing equations, dilutions, molarity, stoichiometry, mixtures	Act. 2.1.2 Copying our genes; Act. 2.1.3 Test your own genes. Problem 1.1.4 what is the Concentration;	Touched on in PBS but no KSA specific for this area in PLTW courses. Best method of approach: pick certain activities within the programs and teach this in the lab prep side. Serial dilutions is covered in MI.
Microbiology, blood borne diseases, microbial taxonomy, sterilization techniques, artificial culture media, inoculation transfer of cultures, disinfection techniques, conditions that promote cell growth antigen antibody testing	Project 1.2.3 Attack of the superbugs; Act 1.2.2 Which antibiotic is the best choice; Act 4.1.2 Protein Factories; Act 1.1.5 ELISA	Explain and perform ELISA testing; show how antibodies can be used to test for disease, use ELISA to test for concentration of infectious bacteria in simulated body fluids, insert plasmid DNA into bacterial cells in the lab and observe how this genetic information relates to new traits of the bacteria
Legal and ethical responsibilities	Unit 2 Lesson 2.1; Act. 1.3.3 Cochlear implant debate, Act 1.4.1 Disease prevention through vaccinations; Act 4.1.5 Replacement Parts	Investigate the available types of genetic testing, describe how vaccines interact with the human immune system
Literacy and computer skills applicable to the biotech industry, use internet to gather share scientific regulatory information, use word processing, spreadsheet,	Act 2.2.1 Gene Therapy; Project 3.3.4 Tiny Treatment; Act 4.1.5 Replacement parts; Act 4.4.2 Bionic Human	Explore the variety of research study designs available and investigate how to set up and conduct valid reliable studies; Identify a variety of tissues and organs that can be

UF: Biotechnology 3 KSA's	Course Link	PLTW: MI KSA's
presentation programs to analyze data		transplanted from one person to another
Employability Skills, conduct job searches, create a resume, evaluate the overall condition of personal work habits	Students have done career searches in Journals throughout the course of PBS, HBS, MI. Also they have done peer reviews of their work ethics/habits	

It is also extremely important for the students to take part in as much of the laboratory preparations as possible, including making solutions and media, dilutions, agarose gels, in addition to use of lab equipment when possible. This lab preparation will also help the students in identifying and the proper use of lab equipment that will be included in the industry certification test. Additionally, the practice exam is available online and in the Teacher's Guide.

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## Summary

While Medical Interventions (MI) is not the capstone class of the PLTW Biomedical program, it can serve as the point where students are adequately prepared to be successful at the University of Florida's Biotechnician Assistant Credentialing Exam (BACE). PLTW Medical Interventions course covers a wide variety of lab and course work. By the time students have reached Medical Interventions course they will likely have already taken Biology and Chemistry. During the student's chemistry course, it is important that the PLTW Teacher address the understanding of basic chemistry that the students will have by this time and include this knowledge into daily instruction.

Allow the students to do "ALL" prep work under the supervision of the instructor to help solidify and improve laboratory techniques and skills of the students. Students will prepare their own dilutions, mixtures, agarose gels, acid and base solutions as well. This preparation will help simulate the students working in a real lab environment or in a career, which also meets the goals of Florida's program.

Within this report the "GAP" is not within the curriculum. The gap is in the instructional technique used by the PLTW teachers/ staff in the classroom. "After careful review and from personal classroom student success at the University of Florida's BACE in the school year of 2012-2013, I see no reason that the students cannot be successful." - David Woods, PLTW BMS Teacher Taylor County High School. The PLTW curriculum more than adequately covers the required areas that are tested in BACE. Careful planning and integration of the PLTW program within the science departments in school districts can address the few areas that need assistance, most notably Chemistry.