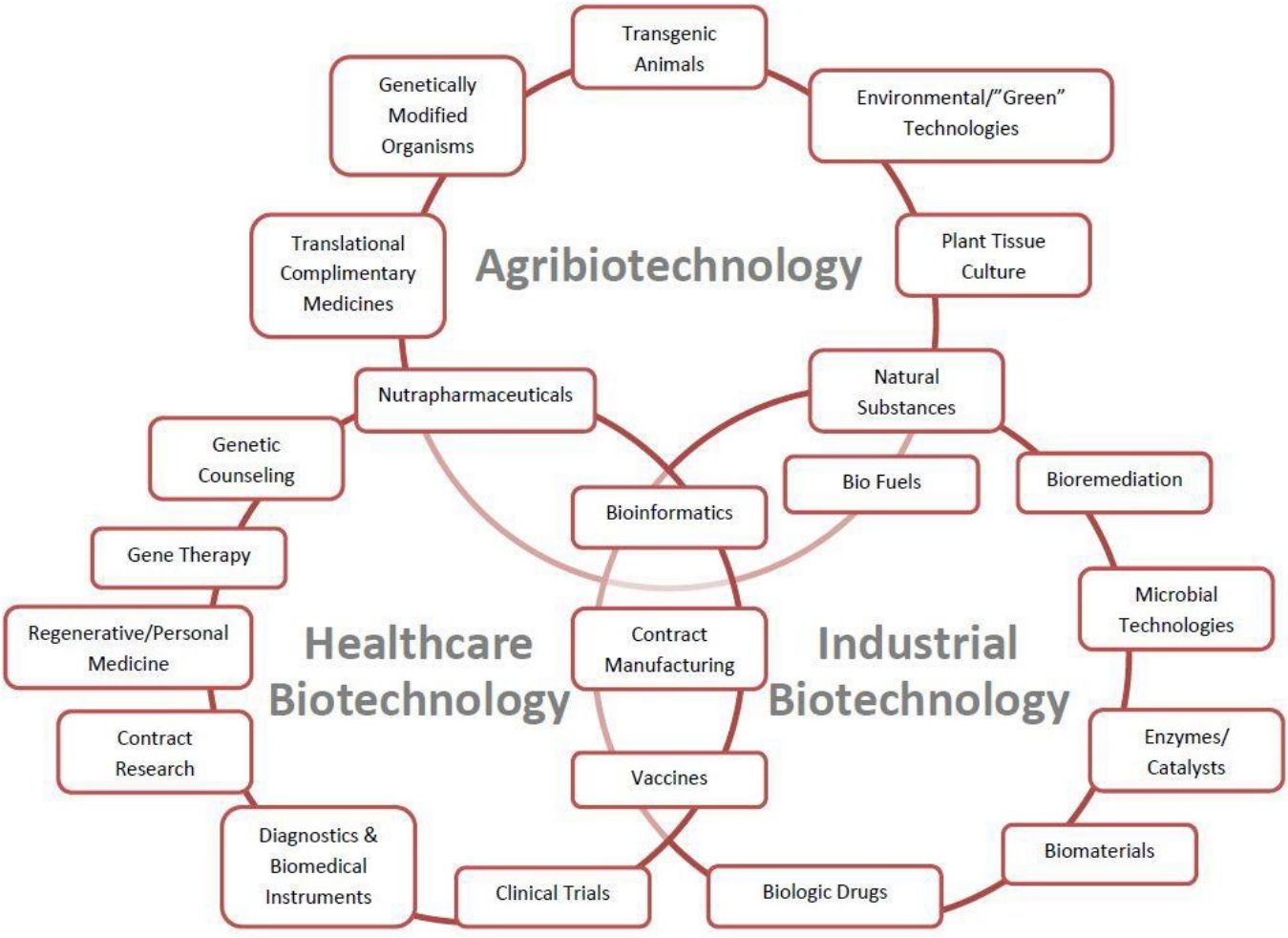
BACE Biotechnician™ Assistant Credentialing Exam

PROJECT LEAD THE WAY PLTW

Biotechnician Assistant Credentialing Exam

The Biotechnician Assistant Credentialing Exam (BACE) is an industry-recognized credentialing exam designed to assess knowledge and skill sets valued by the bioscience industry when hiring for technician-level positions. Developed from a framework of industry defined standards for knowledge and skill sets, the BACE is updated and reviewed each year by a National Advisory Board, ensuring the most current industry topics are tested and relevant skills are demonstrated.



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.

Supplemental Resources:

Biotechnology is defined as "the study and manipulation of living things or their component molecules, cells, tissues, or organs."[1] Biotechnology is applied to the study and manufacture of 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, how the Food and Drug Administration (FDA) regulates the process, and 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://bioteched.com/).

Additional Critical Topics are described below:

The Food and Drug Administration (FDA), the role of its Centers, and the Purpose of Regulations

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.[2]

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 small molecule drugs (chemically synthesized, such as aspirin) are safe and effective, and that the health benefits outweigh known risks before being approved for use by the public. Pharmaceuticals include prescription and over-the-counter drugs, both brand name and

generic. As part of the FDA, CDER is a consumer watchdog in America's healthcare system. The Center's review of new drug applications not only prevents quackery, but provides doctors and patients with the information they need to use medicines wisely. [3]

The Center for Biologics Evaluation and Research (CBER) is the Center within FDA that regulates biological products for human use. 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[4]

The Center for Devices and Radiological Health (CDRH) is the FDA center responsible for overseeing the safety and efficacy of medical devices, which also includes diagnostic assays.

Regulatory Compliance

Students should also know the purpose of FDA regulations, which are practices followed to ensure products are safe and perform as intended. These practices include current Good Laboratory Practices (cGLP), which are followed when collecting data from preclinical or animal studies to be evaluated by the FDA when assessing product safety prior to testing in humans. Current Good Clinical Practices (cGCP) are followed during clinical trials to test an investigational new drug's safety and efficacy. Current Good Manufacturing Practices (cGMP) are followed after a product has been approved by the FDA and is being manufactured and tested for sale to the public.

Departmental Roles and Responsibilities

Companies are typically divided into major departments, each responsible for critical functions in ensuring products meet specific quality parameters prior to being released to the public.

- Quality Assurance
- Manufacturing
- Quality Control
- Facilities

Common Documents

- Batch Records
- Test Records
- Equipment Logs
- Standard Operating Procedures (SOPs)

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[1] http://bioteched.com/biotechtext.htm
[2] http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm

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[3] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/default.htm#1

[4] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm

Gap Analysis

Below are side by side comparisons of the BACE framework with the corresponding PLTW course. These are unabridged Knowledge and Skills (KSA) addressed in the framework, 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.

BACE KSA's with Course Links to PLTW: PBS

BACE KSA's	Course Link	PLTW: PBS Course (KSA's)
Matter, energy, chemical processes of cells and organisms	Activity 2.1.5; Activity 3.2.2; Activity 4.1.5	Macromolecule structure; digestion of macromolecules; cell membrane transport and water balance
Cell molecular structure & function, DNA plasmids, membranes	Activity 1.1.5; Activity 2.1.5; Activity 3.2.2	DNA structure and function; cell structure and function; membrane structure and transport
Protein synthesis, germ theory	Lesson 2.2; Lesson 3.1; *more content covered in PLTW Medical interventions	Sequence of nucleotides in DNA; protein synthesis; base pair mutations; microbiology and infection
Molecular genetics, biotech, restriction digestion, DNA analysis, PCR	Activity 1.1.6; Project 2.2.6; *more content covered in PLTW Medical interventions	Restriction enzymes and digestion; gel electrophoresis; RFLPs
Bioethics	Activity 1.1.2; Activity 1.1.6; Activity 2.1.2, Activity 2.2.3; Activity 3.1.1; Activity 3.2.4; Activity 4.2.2	Patient privacy and medical records; DNA technology; genetic testing and screening; crisis communication; patents on biological resources

BACE KSA's	Course Link	PLTW: PBS Course (KSA's)
Interdependence of organisms, humans and the environment	Activity 3.1.2, Activity 3.1.3; Project 4.1.6; Activity 4.2.1; Activity 4.2.2	Reproduction of infectious agents; prevention and treatment of disease; cell structure; immune system response; biomimicry; high throughput screening
Genetic diversity, selection, adaptations	Lesson 2.2; Project 4.1.6	Pedigrees; inheritance of genetic disease; probability of inheritance; adaptations
Careers, connection between biotech, agricultural, food, medicine	Infused throughout the entire course - 35 career spotlights or profiles across all disciplines	

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 BACE. It is important to have the students involved in as much prep work and lab time as possible from PBS on, in order to help acquaint students how to work in a lab. It is critical too, to consistently review and practice the applied math for making solutions (molar, percent volume, and dilutions). This lab preparation will also help the students in identifying the proper use of lab equipment that will be on the industry certification exam.

BACE KSA's with Course Links to PLTW: HBS

BACE KSA's	Course Link	PLTW: HBS Course KSA's
Nature of science, scientific habits, laboratory technologies	*Important: allow students to complete laboratory prep work. Units 1-5 cover lab techniques core to the exam.	This area is addressed throughout the curriculum
Chemical processes in biotech, pH, solutions, molarity	Project 3.2.4; Lesson 2.3; Lesson 3.4	Experimental design, solutions and molarity; enzymes and factors impacting enzyme action; hormones and homeostasis; communication through chemical signals
Cell propagation, growth, and cultures for biotechnology	Not covered in HBS *(PBS) Lesson 3.1 and (MI) Lesson 4.1	
Biochemistry, proteins, enzymes, plasmids, recombinants, bloodborne pathogens	Activity 1.3.1; Activity 3.2.1, Project 3.2.4 *additional material required to cover bloodborne pathogens (discussed in PBS Activity 3.2.3)	Restriction enzymes; gel electrophoresis; RFLPs; hormone action and feedback; enzyme action
Genetics, gene selection, transformation, analysis	Activity 5.3.2 *covered more in PLTW MI	Genetics of blood type; pedigree analysis; transfusion compatibility

BACE KSA's	Course Link	PLTW: HBS Course KSA's
Structure and function of various organisms - used as genetic models	Covered in PBS and MI	

Interdependence of organisms, humans, and the environment	Project 3.2.2; Problem 6.1.1; Problem 6.1.3	Health and wellness; external environment affecting the body's internal environment; homeostasis and disease
Genetic diversity and selection	(PBS) Lesson 2.2	
Connections between biotech, agricultural, food, medicine and careers	Problem 6.1.3 *Career connections are highlighted throughout the course.	Trace disease in human systems by generation of a fictional case study
Bioethics	Project 1.3.3	Biometrics

Listed above are the appropriate projects, activities, and problems within HBS that correspond to BACE KSA's. 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 continue 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, and review/practice the applied math skills. This work will enhance the students' ability to work in a lab setting and gain a greater understanding of the lab equipment.

BACE KSA's with Links to PLTW: MI

BACE KSA's	Course Link	PLTW: MI KSA's
History, career fields, benefits of biotechnology	Activity 1.1.1; Activity 4.1.1; Activity 4.1.5 (careers)	Medical interventions for disease; history of diabetes management and treatment
Safety procedures, use and storage of chemicals, SDS's, inventory procedures	Laboratory safety and procedures should be covered every year as part of PLTW and OSHA policy. When using chemicals introduce specific safety information and protocols	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 framework of all PLTW courses and labs is professional communication
Basic skills in scientific inquiry, calculations and analysis	Problem 1.1.4; Activity 1.1.3, Activity 3.1.5; Activity 4.1.4 *many opportunities for data analysis throughout curriculum	Standard curves, bioinformatics; statistical analysis; data analysis
Organism structure and function, nucleic acids, how cells are engineered	Activity 1.2.1; Project 1.2.3; Activity 3.1.3; Activity 4.1.2	Bacterial cell structure; bacterial gene transfer; cell cycle regulation; transformation
Biotechnical materials analysis skills, cell culture, sterile technique, column chromatography, protein production (PAGE)	Project 1.2.3; Activity 2.1.4; Activity 4.1.2; Activity 4.1.3, Activity 4.1.4	Electrophoresis; transformation; protein purification; aseptic technique

Basic chemistry as applied to biotechnology procedures, pH, balancing equations, dilutions, molarity, stoichiometry, mixtures	Problem 1.1.4; Activity 1.1.5;	Standard curves; serial dilutions
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	Activity 1.2.2; Activity 1.1.5; Project 1.2.3; Activity 4.1.2	Antibody testing for infectious disease; aseptic technique, antibiotic selection
Legal and ethical responsibilities	Lesson 2.1; Activity 1.3.3, Activity 1.4.1; Activity 4.3.1, Activity 4.3.2; Activity 4.4.1	Cochlear implants and other medical devices; vaccination; genetic testing; organ transplants; tissue engineering
Literacy and computer skills applicable to the biotech industry, use internet to gather share scientific regulatory information, use word processing, spreadsheet, presentation programs to analyze data	Activity 1.1.3; Activity 3.1.5; Activity 3.2.3; Activity 3.4.1	Bioinformatics; precision medicine; statistical analysis; scientific research
Employability skills, conducting job searches, creating a resume, evaluationof personal work habits	Career exploration throughout all BMS courses; PBS, HBS and MI/BI (Preparing for the Future) cover resumes; Practice in transportable skills such as communication, collaboration, and problem solving	Cover letters, resumes, professionalcommunication; professional networking

It is 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 help identify and use lab equipment included in the BACE.

*****Students participating in MI who are preparing for the BACE should begin taking advantage of the BACE Practice Exams as soon as possible, which are available for no cost to registered testing sites (also no cost). The sooner students start the better, as both they and their instructors can utilize their scores to identify areas for improvement and added practice. Additional resources related to exam preparation and practice are available at https://biotility.research.ufl.edu/bace/.**

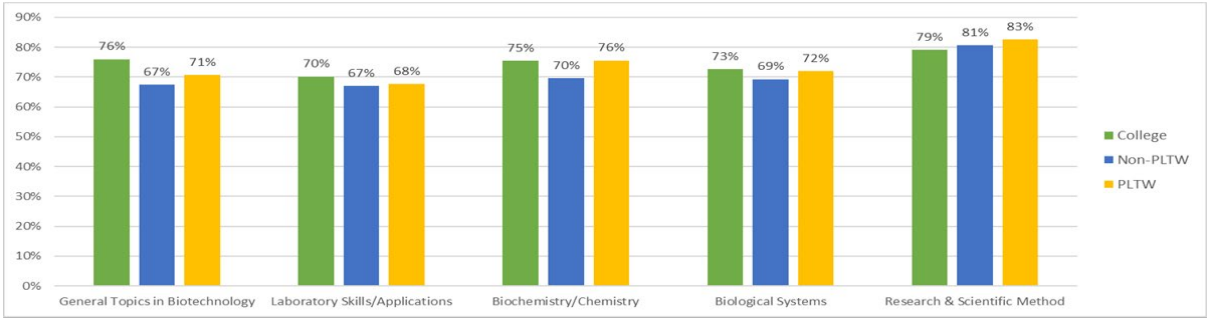
Summary

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 with the Biotechnician Assistant Credentialing Exam (BACE). By the time students have reached Medical Interventions course they will likely have completed Biology and Chemistry. Incorporating basic chemistry and biological concepts into MI will serve to reinforce their application.

Allow the students to do prep work under the supervision of the instructor to help solidify and improve laboratory techniques and skills of the students. Students should prepare their own dilutions, mixtures, agarose gels, acid and base solutions when possible. This preparation will simulate work in a research or industry career, and will provide critical practice with applied math and the techniques.

Based on the findings of this gap analysis, there is not a significant difference between the KSA's of the BACE and PLTW BMS curricula. Slight discrepancy is in the integration of industry practices, including departmental roles, basics of regulatory compliance, and industry documentation. Careful review of recommended resources will address this gap. Outcomes from the 2019/2020 BACE season support this conclusion, with candidates from PLTW programs performing equally as candidates from industrial biotechnology programs (non-PLTW). For both groups, the biggest challenge is the applied math.

Knowledge Exam Topics Comparison by Program



Practical Exam Topics by Program