Jumpstart Biotechnology Careers with Free Bioscience Industry Badges

Texas Health Occupations Association

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College Station, TX

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BACE™ Biotechnology Aptitude and Competency Exam

Agenda

- Brief BACE Overview & Categories
- Badging System Overview & Details
- Accessing Resources & the Badging System

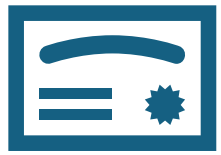
BACE™

The BACE is a national industry-recognized exam that assesses core competencies and skills identified as valuable to the bioscience industries.

Outcome of Bioscience Industry DACUM Analysis involving key stakeholders and subject matter experts

Accurately denotes the knowledge, skills, and abilities for technician-level responsibilities

Framework maintained by National Advisory Board



ISO/IEC 17024 Compliant

General requirement for bodies credentialing job-related standards

What does the Industry Value?

UF Biotility Advisory Board Member Companies & Supporters

BACE SCOPE

- Credential earners possess the ability to seamlessly enter the workplace to be quickly trained on company-specific protocols relating to:
  - Research and Development,
  - Quality Systems,
  - (Bio)manufacturing,
  - and a variety of other positions.
- Additionally, they have demonstrated an aptitude for the work, and knowledge of working in a cGMP compliant environment.

Positions

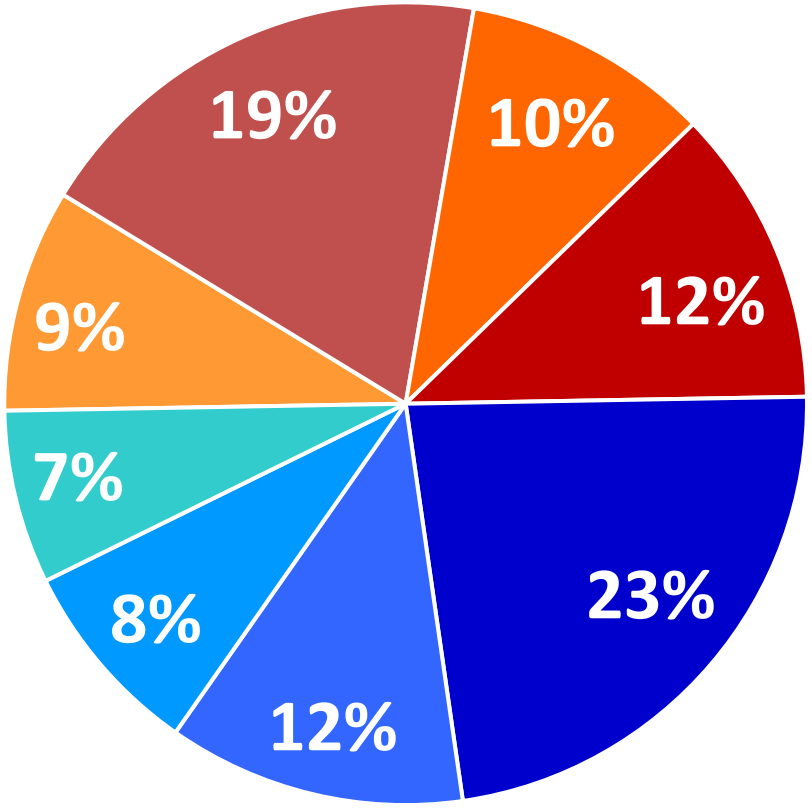
- Quality Control Technician
- Process Control Technician
- Biomanufacturing Technician
- Research Technician
- Materials Technician
- Microbiology Technician
- Specimen Collector
- Virology Technician
- Clinical Research Assistant
- Real Estate (Biotech Facilities)
- Undergraduate Research Assistant
- Paid Internship

Credential earners work in a variety of industry sectors. These include agriculture, food science, biomedical, medical device, and many more.

Sampling of BACE Credential Earner Employers

- ActiGraph
- Advent Health
- Amgen
- Andrews Research & Ed. Foundation
- ANDRITZ
- Antech Diagnostics
- AO Precsion Manufacturing
- Applied Genetic Technologies
- Avidyne
- Bayer
- BioMat USA
- Boehringer-Ingleheim
- Bureau of Public Health
- Cirsium Bioscienes
- Cutrale, Inc.
- Emerald Cloud Lab
- Emerging Pathogens Inst.
- Eurofins, TestAmerica
- FOCUS Laboratories
- Headstream Innovation
- Johns Hopkins Applied Physics Lab
- Jubilant-HollisterSteir
- Lacerta Therapeutics
- Mass. General Hospital
- Mayo Clinic
- McMaster-Carr
- Mérieux NutriSciences
- MIT Lincoln Laboratory
- MIT Teaching Systems Lab
- National Blood Testing Cooperative
- National Institute on Drug Abuse (NIDA, NIH)
- National Resilience, Inc.
- Nobel Research Institute
- Northrop Grumman
- Novabone
- NYU Langone Health
- OPharmatech, Inc
- Ritch's Pharmacy
- RTI-Surgical, Inc.
- Southern Earth Sciences
- Southwest Research Inst.
- Syngenta, Inc.
- Texas instruments
- Thermo-Fisher Scientific
- USDA
- US Sugar
- United Juice Companies of America
- Vitalent
- Walgreens Pharmacy
- Zoetis

BACE Category Distribution (Knowledge and Practical)



- Regulatory Compliance
- Technical Skills & Applications
- Biochemistry & Molecular Biology
- Workplace Safety & Culture
- Biotechnology Skills
- Applied Mathematics
- Standard Equipment
- Experimental Design & Data Analysis

Knowledge

Practical

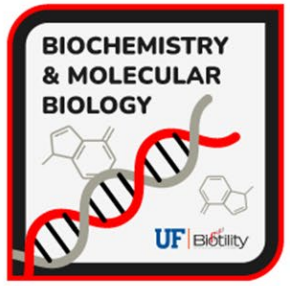
While a skill typically relates to a specific ability, competencies encompass a group of related strengths, establishing a broader set of skills, knowledge, and behaviors

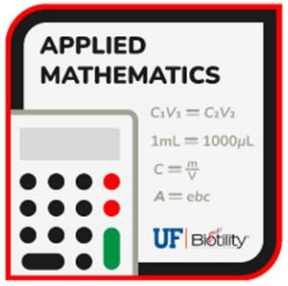
Eight Category Badges!

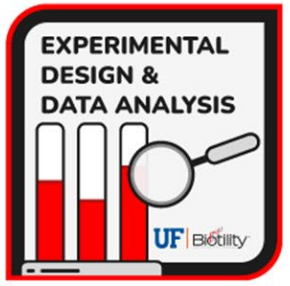
- Industry defined standards
- Bite-sized accomplishments serve as motivators
- Indicators of capabilities
- Digital credentials issued through Accredible
  - Verifiable by employer
- Tools to embed industry-defined competencies and skills into curricula
- Provide a feedback loop to instructors

BACE™ Biotechnology Aptitude and Competency Exam

Biotility BACE CREDENTIALED







Technical Skills and Applications

Foundational techniques used in biotechnology workplace settings. It includes understanding and applying methods such as;

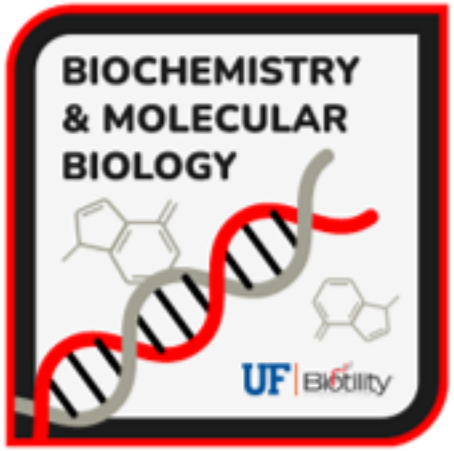
- aseptic technique,
- cell culture,
- DNA and Protein isolation,
- and various assays.

The focus is on both the theoretical principles and the practical application of these techniques.

Technical Skills & Applications

- Culturing Microorganisms
- Aseptic Technique
- DNA Isolation, Purification, Quantitation
- Restriction Enzymes/Digests/Cloning
- Transformation & Transfection
- Protein Expression
- Protein Purification and Quantitation
- Agarose & PAGE Electrophoresis
- Polymerase Chain Reaction (PCR)
- pH
- Microscopy
- Spectrometry, including infrared (FT/IR)
- Immunoassays
- Equipment Maintenance, Calibration, Validation
- Scientific Notation, Significant figures
- Assay development and validation
- Applications of lab automation and robotics
- Principles of laminar flow (cleanroom, BSC)

Biochemistry & Molecular Biology



Demonstrate understanding of;

- DNA structure and function,
- gene expression,
- protein synthesis,
- enzyme activity,
- and cell biology.

Includes processes related to molecular biology and protein expression, such as monoclonal antibody production, immunotherapy, and the role of mRNA in therapeutics.

Biochemistry and Molecular Biology

- Describe DNA structure and function
- Describe transcription, translation, and gene expression
- Explain how enzymes function and affect reaction rates
- Understand cell settling and centrifugation techniques
- Discuss proper techniques for mixing solutions and preparing reagents
- Understand the general physiology of cells
- Explain the interaction between cells, and between cells and their environment
- Understand the genetics of model organisms
- Discuss monoclonal antibody (mAb) production and applications
- Understand the role of mRNA in cellular function and therapeutics
- Discuss immunotherapy types and applications, (chimeric antigen receptor T-cell (CAR-T) and mAb)

Safety and Workplace Culture

Emphasizes the importance of;
safety, ethics, and proper behavior in the biotechnology workplace.

Includes the understanding and importance of;

- following safety protocols,
- using personal protective equipment (PPE),
- handling hazardous materials, responding to emergencies, and
- the role of OSHA.

Workplace Safety and Culture

- Ethics and bioethics in the workplace/society
- Appropriate workplace and safety behaviors
- Identify safety symbols
- Identify and explain proper use of safety equipment, including PPE
- Handling of biological and hazardous waste
- Importance of posting and complying to signage
- Safe handling/storage of chemicals
- Derive info from Safety Data Sheets (SDS)
- Properly label items, including solutions, buffers, Petri plates, samples, and products
- Recognize the role of OSHA
- Describe emergency response procedures for fires, chemical spills, or other incidents
- Discuss the process for reporting safety concerns and hazards
- Discuss the importance of proactive safety communication
- Understand the importance of comprehensive training and safety training

Regulation and Quality

Understanding the regulatory environment and quality practices associated with the development, manufacture, and testing of biotechnological-based products and processes, including;

- the roles of regulatory agencies such as the Food and Drug Administration (FDA)
- Current Good Laboratory Practices (CGLP),
- Current Good Manufacturing Practices (CGMP), and
- Good Documentation Practices (GDocP)

Regulation and Quality

- Regulatory agencies governing the manufacture and distribution of biotechnology-derived products
- Departmental Roles (R&D, QC, QA, Manuf.)
- Purpose of CGLP
- Purpose of CGMP
- Identify essential CGMP documents, such as Standard Operating Procedures (SOP), batch records, logs, and deviation reports
- Key components of GDocP
- Explain the FDA approval process for regulated products.
- Discuss strategies for maintaining security of sensitive data and Intellectual property
- Describe the significance of Health Insurance Portability and Accountability Act (HIPAA) compliance
- Describe Environmental Monitoring (EM)
- Understand the importance of audits and Corrective and Preventive Actions (CAPA) to ensure compliance and continuous improvement

Biotechnology Skills

Technical skills essential for quality work, including;

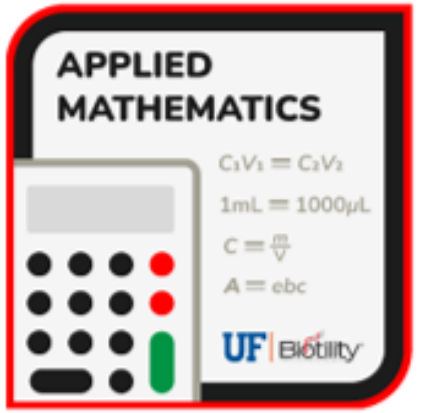
- accurately measuring liquids and solids,
- aseptic technique
- preparing solutions,
- performing serial dilutions,
- and using standard equipment.

The focus is on mastering these practical skills to ensure precise and reliable outcomes.

Biotechnology Skills

- Accurately measure liquids (micro/macro)
- Accurately measure mass
- Properly prepare solutions and buffers
- Properly measure and adjust the pH of a solution
- Properly perform a serial dilution
- Demonstrate proper aseptic technique
- Demonstrate proper culturing of microorganisms
- Discuss upstream and downstream Processing
- Proper use of a centrifuge
- Proper use of a spectrophotometer
- Describe the proper use of biosafety cabinets (BSC)
- Proper use of electrophoresis equipment
- Discuss the role and impact of automation
- Use 24-hour time correctly
- Demonstrate an understanding of how calibration and validation are critical to producing reliable, consistent results

Applied Math



Mathematical skills needed to perform common bioscience workplace calculations and data analysis, including;

- the use of scientific notation,
- significant digits,
- metric conversions,
- making dilutions,
- calculating weight and volume measurements,
- graphing data, and
- basic statistical analyses.

Applied Math

- Use scientific notation correctly
- Use significant digits correctly
- Understand and use mathematical symbols
- Understand and use fractions
- Use metric measurements
- Perform metric unit conversions
- Generate a graph using collected data
  - Properly plot data
  - Interpret data
  - Generate a standard curve
- Apply statistical techniques such as mean, median, mode, and standard deviation
- Perform calculations for serial dilutions
- Perform calculations using dilution factors
  - Solve Dilution Factor calculations
  - Solve Molarity solution calculations
  - Solve Volume/Volume (V/V) solution calculations
  - Solve Weight/Volume (W/V) solution calculations
- Describe the relationship between pH and the logarithmic scale

Standard Equipment

The proper identification, use, and maintenance of equipment, including;

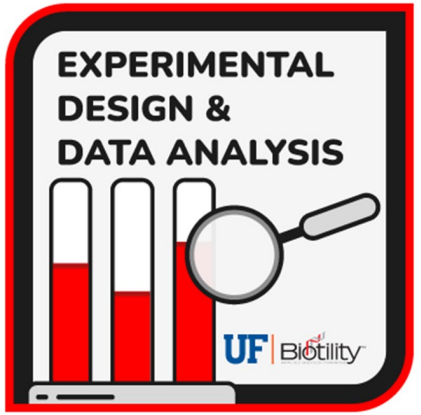
- micro and macro pipettes,
- balances,
- pH meters,
- centrifuges, and other essential tools.

Mastery ensures an aptitude for the accurate and safe handling of equipment, and parameters such as calibration, maintenance, and validation.

Standard Equipment

- Demonstrate proper and safe use of:
  - micropipettes & serological pipets
  - electronic balances
  - pH meters
  - stirrers/shakers
  - vortexers
  - water baths
  - autoclaves
  - centrifuges
  - spectrophotometers
  - microscopes
  - electrophoresis equipment
  - incubators
  - heat/cool blocks
  - biological safety cabinet
  - fume hoods
  - chromatography equipment

Experimental Design & Data Analysis



Focus is on how to design experiments, analyze data, and communicate findings effectively, including;

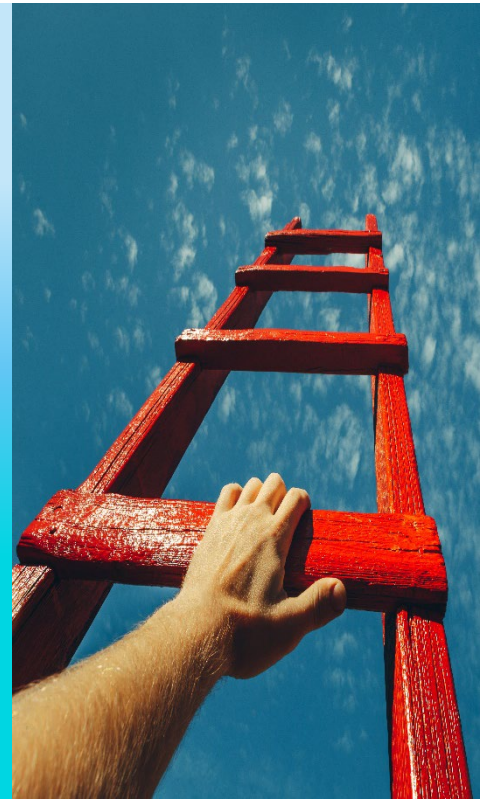
- the use of controls,
- maintaining a laboratory notebook,
- applying statistical methods,
- and adhering to the principles of Responsible Conduct of Research (RCR).

Experimental Design and Data Analysis

- Read, interpret, and draw conclusions from technical material, test records, and specification sheets
- Discuss good experimental design, including the proper use of controls
- Explain how to maintain a laboratory notebook
- Analyze and interpret data, including the use of statistical analysis
- Understand the principles of Responsible Conduct of Research (RCR)
- Demonstrate proper implementation of data integrity
- Effectively communicate scientific findings
- Identify and analyze sources of error in assay results
- Discuss the role of sample size and replication for study design

Using Resources and Badges to Drive Engagement

- 80% of exam sites that do not use the practice exam course have a 50% or lower pass rate.
- General Trend: An increase in completion of the practice exams and math practice module resulted in higher pass rates.
- Schools/Programs that register to become test sites 4 months in advance of administering the BACE have twice the pass rate of those registering 1-2 months in advance.



BACE Practice Exam Course (BPEC) Redesign

The course has undergone significant enhancements, featuring new questions and a refreshed format. Notably, it now incorporates digital badges that candidates can earn by demonstrating proficiency in BACE categories, infusing an element of engagement and achievement into the learning experience.

- *MODULE 1: **Proficiency Plotter**: Empowering Students to Navigate Their Biotech Learning Journey*
- *MODULE 2: **Regulatory Compliance and Quality Systems Review**: Bridging the Knowledge Gap for Your Students*
- *MODULE 3: **Trial Run**: Practice, Learn, and Prepare for the Challenge*
- *MODULE 4: **Number Crunch**: Strengthening Math Skills for the BACE*
- *MODULE 5: **Competency Challenge**: Empowering Students to Excel*
- *MODULE 6: **Stepping into the Biotech Workforce**: Preparing Students for Their Careers*

Instructor and Student Access

- Within two (2) weeks of Exam Site Registration, Exam Sites receive a unique **BACE Practice Exam Enrollment Link** to distribute to their users.
- Exam Site personnel and students use the same link to gain access to the BACE Practice Exam Course.
- Request Super User/TA access (if not done during test site registration)
  - Site Administrator emails BACE@research.ufl.edu and requests TA access
- Invite other educators working to prepare candidates, to enroll in the BPEC, request Super User/TA access, and make time to watch the BPEC Webinar
- Invite candidates to enroll in the BPEC – using the same link

Superuser/TA Access

For Exam Site Personnel and Educators only

Allows control of BPEC content and access to candidate results

The UF e-learning Canvas Gradebook includes global sorting options and settings you can use to organize your gradebook, student data and assignment data.

Quiz Analysis Report

- Includes statistics for overall quiz scores and student outcomes.

Item Analysis Report

- Includes statistics for items in a quiz and their correlation to the overall quiz score.

MODULE 1: Proficiency Plotter – Empowering Students to Navigate Their Biotech Learning Journey

- Designed to help students self-assess their understanding of key concepts covered in the BACE.
- Through a series of eight (8) BACE category surveys and quizzes, students evaluate their familiarity with content, creating a personalized map of their strengths and areas that may require additional focus.
- Students receive a comprehensive report that details their self-assessed proficiency across the topics.
- Report is also available to their educator, providing valuable insights that can be used to tailor instruction

MODULE 2: Regulatory Compliance and Quality Systems

- Provides crucial content relating to work in a regulated industry
  - Industry culture, structure, and departmental roles
  - Current Good Manufacturing Practices (CGMP)
  - Common Industry Documentation and Good Documentation Practices

As an educator, you have the option to incorporate the **Regulatory Compliance and Quality Systems Review** into your classroom instruction, providing your students with additional support as they engage with this important content. Encouraging them to fully utilize this module will ensure they are well-prepared not only for the BACE exam but also for the demands of the biotechnology industry.

MODULE 3: Trial Run – Practice, Learn, and Prepare for the Challenge

- Opportunity for students to engage in realistic practice before the Competency Challenge or the actual BACE exam.
- Closely mirrors content and format of the actual BACE exam, offering an accurate representation of what students will encounter.
- Students can take these practice exams multiple times, allowing them to familiarize themselves with the material and assess their understanding.
- Students receive immediate feedback, with correct answers revealed to aid learning.
- Educators have access to students' results, for identification of areas where they may need additional support, and where to offer targeted instruction and guidance.

MODULE 4: Number Crunch – Strengthening Math Skills for the BACE

- Designed to help students refine their mathematical skills, with focused practice on concepts students may find challenging.
  - scientific notation
  - significant digits
  - decimals
  - serial dilutions, solution preparation, conversions, and more.

- Embedded practice quizzes allow students to reinforce their understanding and build confidence in their math skills.
- Feedback provided after each quiz will help identify areas where they may need further review.

MODULE 5: Competency Challenge & Badges – Empowering Students to Excel

- Opportunity to earn 8 digital badges
- An exciting way to recognize student achievements and build confidence.
- Badges can be shared on resumes and professional profiles, giving students a tangible sense of accomplishment.
- Provides valuable insights into areas where students may benefit from further review. By encouraging them to carefully analyze their results, they (and educators) can fine-tune their preparation, ensuring they are fully ready to excel on the BACE.

Bioscience Industry Badges

▾ Module 5: Competency Challenge - Show What You've Learned

Knowledge Portion

- Challenge 1: Technical Skills & Applications
  36.5 pts
- Challenge 2: Safety & Workplace Culture
  13 pts
- Challenge 3: Biochemistry & Molecular Biology
  16 pts
- Challenge 4: Regulation & Quality
  26 pts

Practical Portion

- Challenge 5: Biotechnology Skills
  12 pts
- Challenge 6: Applied Mathematics
  19 pts
- Challenge 7: Standard Equipment
  17 pts
- Challenge 8: Experimental Design & Data Analysis
  8 pts

Badges

- Badge 1: Technical Skills & Applications
- Badge 2: Safety & Workplace Culture

Badges

- Badge 1: Technical Skills & Applications
- Badge 2: Safety & Workplace Culture
- Badge 3: Biochemistry & Molecular Biology
- Badge 4: Regulation & Quality
- Badge 5: Biotechnology Skills
- Badge 6: Applied Mathematics
- Badge 7: Standard Equipment
- Badge 8: Experimental Design & Data Analysis

Badge Exam Parameters

Format

- Closed Book
- Scratch Paper and basic calculator are allowed

Price

- Free

Retakes

- One Retake
- 1-day waiting period between attempts

Computer-Based

Any instructor may proctor

Unique code provided for each badge session

Scoring

- 80% or above to pass
- Candidates receive feedback on incorrect responses; however, correct answers are not disclosed.
- Badge is awarded immediately and can be accessed by clicking the badge link located within the module.

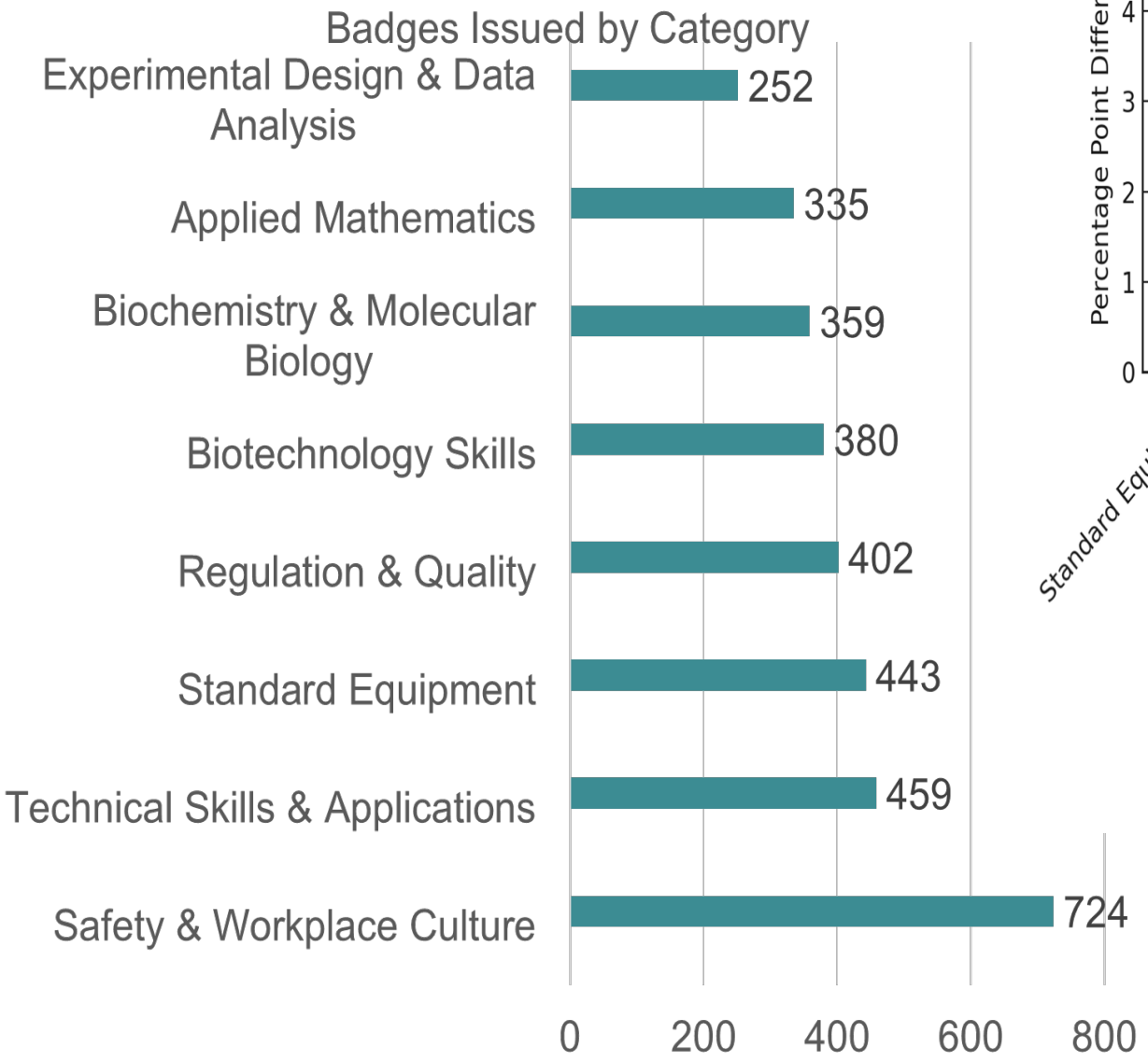
Challenge Time

Duration

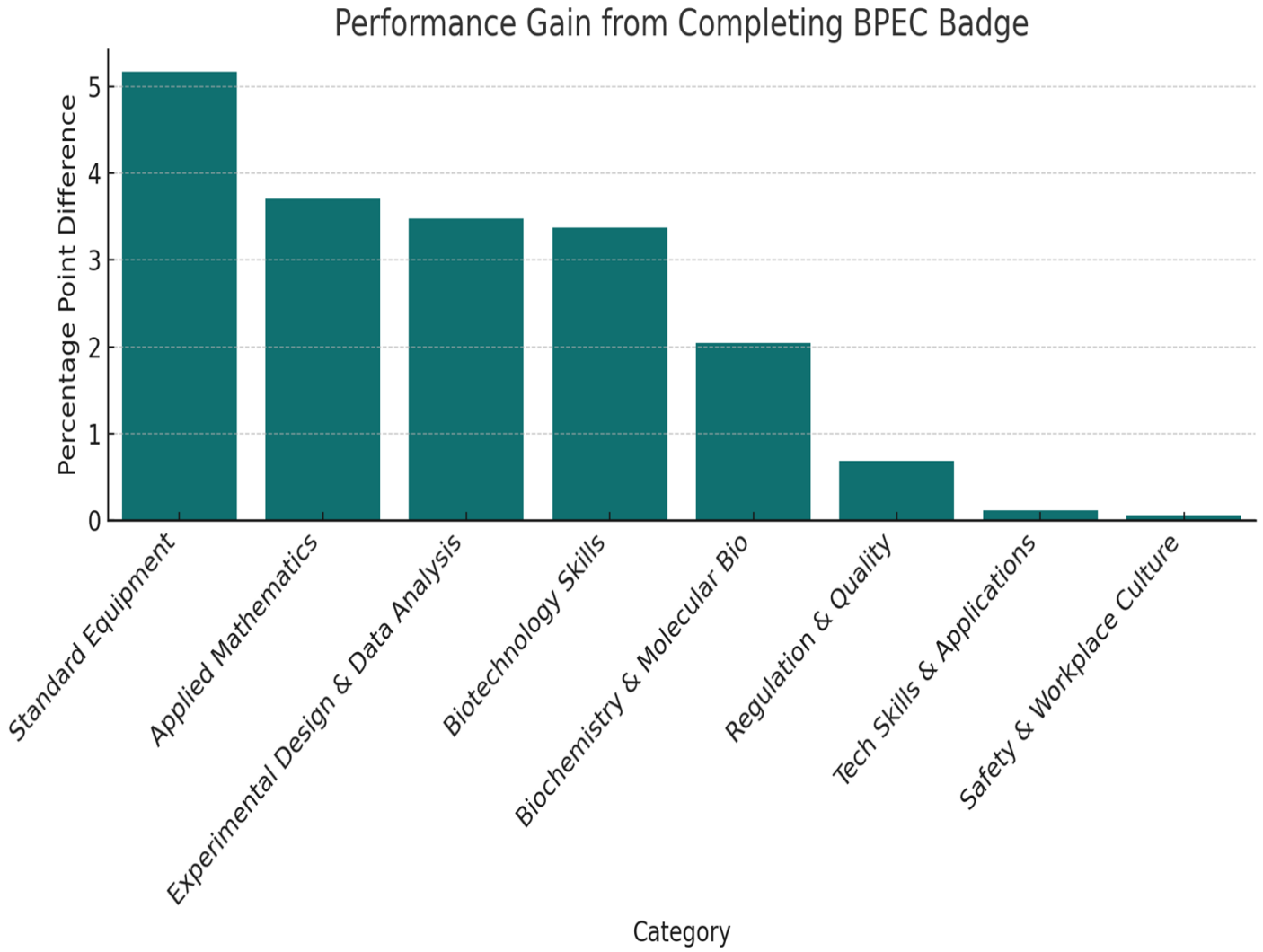
You will be sent a unique code for each challenge

Challenge Name	Access Code	Time Limit in Minutes
Competency Challenge 1: Technical Skills & Applications		45
Competency Challenge 2: Safety & Workplace Culture		40
Competency Challenge 3: Biochemistry & Molecular Biology		35
Competency Challenge 4: Regulation & Quality		30
Competency Challenge 5: Biotechnology Skills		45
Competency Challenge 6: Applied Mathematics		40
Competency Challenge 7: Standard Equipment		35
Competency Challenge 8: Experimental Design & Data Analysis		30

Badging Outcomes



3354 Badges Earned (Oct. – June, 2025)



Candidates who earned badges have a statistically significant higher pass rate (15%) than the overall exam population.

Recommended Timeline

BADGES

Exam Site Registration & Approval
4 months in advance

BACE Practice Exam Course
3 ½ months in advance

Exam Room Logistics
3 months in advance

Testing Event Logistics
2 months in advance

BACE Personnel Certification
1 month in advance

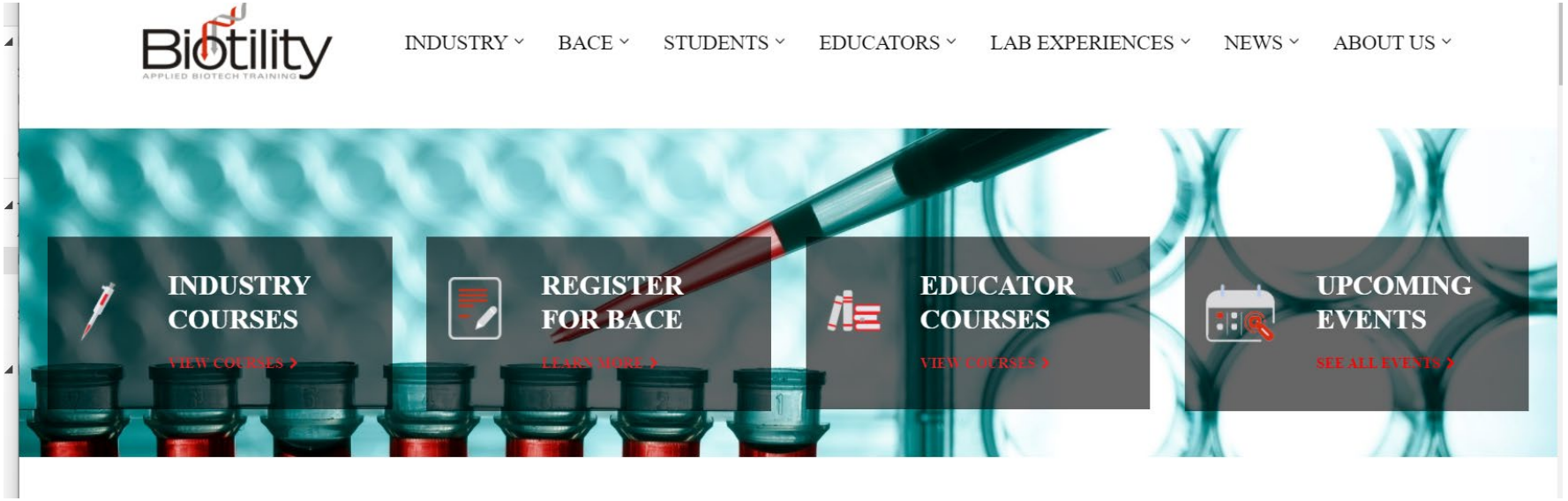
Exam Site **Registration (Step 1)**

- **Registration forms are available online**
- Registration is completed annually
- After registration Exam Sites will receive:
  - Confirmation of registration
  - Information on Exam Site Personnel Training
  - Information on Practice Exam and Practice Exam Webinar

Exam Site **Orders (Step 2)**

- **Order forms are available online**
- Test date is scheduled during the ordering process
- **Order must be placed 6 weeks before test date**
- **Order for first attempt must be placed by May**
- POs are required during the ordering process

Thank You!



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Integrating Industry Topics

PLTW Curricula

- Principles of Biomedical Sciences
- Human Body Systems
- **Medical Interventions**
- Biomedical Innovation

Analysis

- Compare course frameworks with BACE standards
- Identify agreement and gaps
- Outline to prepare PLTW BMS students for the BACE

Conclusion

- The PLTW curriculum adequately covers scientific content tested in the BACE

Gaps

- Departmental Roles
  - QC, QA, Manufacturing
- Regulatory Compliance
- Good Documentation Practices

- Project Lead The Way "Gap Analysis"

https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:1e8fbfdb-cb6a-3064-9598-a3a51980c076

BACE™ Biotechnology Aptitude and Competency Exam

PBS and BACE

Principles of Biomedical Science

Unit 1

- Lab safety, safety symbols, lab equipment, and PPE (review in all courses)
- 1.1.5 DNA Evidence
  - additional assignment- Chemistry of Life (before DNA Activity)

Unit 2

- 2.2.6 A Family Affair – Clinical Care
  - additional assignment- genetic testing- PTC lab

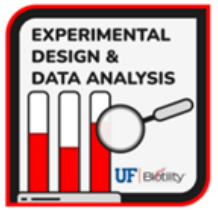
Unit 3

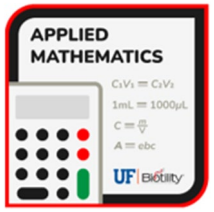
- 3.2.3 Modes of Transmission

Unit 4

- 4.1.5 Drug Design Lab
  - pH and acid/base

- *This unit is great to dive into micropipetting, gel electrophoresis, and DNA analysis*
- *I spend a lot of time on the second half – DNA profiling, PCR, Restriction Enzymes, etc.*
- *cell culture, optical microscope, biochemistry tests*
- *Math skills, conversions, Operations with SigFigs, Transformation, pGLO, concepts in genetics*
- *Science equipment and PPE is encountered through all lessons.*





HBS and BACE

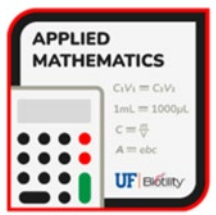
Human Body Systems

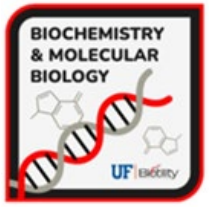
Unit 1:
Allow students to complete laboratory prep work

- 1.3.1- DNA detectives
  - additional assignment- The chemistry of life-review, DNA to 3D folding of a protein

Unit 3

- 3.2.4- Investigating Enzyme Action
  - additional lab- pH acid bath bombs and sugar scrub lab, plasmid mapping lab, restriction site prediction using NEBcutter activity, CRISPR gene editing





- *Math skills, conversions, SigFigs*
- *Good place to review metric system and chemistry review. Do in beginning with lab safety Symbols, SDS sheets.*
- *Protein/Enzyme function*
- *Describe how restriction enzymes are used, reaction rates, and mechanism of PCR. Electrophoresis*
- *By drawing the pieces of DNA, students are able to grasp the concept of replacing pieces and how they connect together.*
- *Antibody/antigen interactions*
- *SDS PAGE*

MI and BACE

Medical Interventions

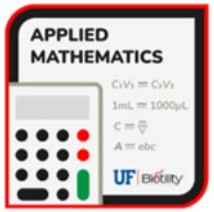
- *I think MI is actually the most closely aligned course, the others act as background*
- *Most assignments in MI help prepare for BACE.*
- *I think most of this class is strongly aligned with BACE. I spend a little extra time going over the BACE content and I reinforce it with my daily bellworks - especially the math applications*
- *MI has more opportunities for the students to enhance their lab skills*
- *Understanding each step in lab, the purpose of each step, and solutions that are being used*
- *I add in additional resources to help with Applied Mathematics in Biotechnology and General Topics in Biotechnology.*
- *I use the labs offered through PLTW as practicals and practice for the laboratory techniques to help students learn the concepts*

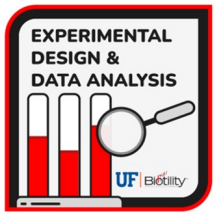
MI and the BACE, Cont.

Medical Interventions

Unit 1:

- 1.1.3- Using DNA to Identify Pathogens
  - Chemistry of life- Review; DNA, chromosomes and genes-review
- 1.2.3- Attack of the Superbugs
  - Students do all lab preps- superbug lab (sterile technique in a non-sterile environment)
  - additional lesson- aseptic technique and media preparation
  - Serial Dilutions- additional medical math assignments, Conducting a Preclinical Assay Lab





Career opportunities, professional communication, etc. This year. I am adding the additional depth of knowledge and practice during each activity.

1.1.1 biotech field, 1.1.3, 1.1.4, standard curve, 1.1.5 ELISA, serial dilutions, concentrations, standard curve; 1.2 Antibodies, antigens, pathogens, Antibiotic treatments, structures and behavior of cells, student resources such as aseptic technique, microscope usage, etc.

Cells, cell cycle, cell structures, using a microcentrifuge, using electronic balances, culturing bacteria, dilutions, transformation, DNA sequencing, PCR, ELISA
Gram Stain, Micropipetting
LOTS of Math Practice

MI and the BACE, Cont.

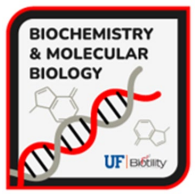
- 1.4.2 Vaccine Development
  - additional lessons - vaccine development, clinical trials webquest, department roles and utilizing controlled documents (cGMP snack mix lab and cGMP popcorn lab), writing an SOP

Unit 2

- 2.1.4 Genetic Testing (optional)- not optional

Unit 4

- 4.1.1- All about insulin
  - additional assignments- Cell factories for Insulin production



I LOVE the paper plasmid activity from this unit because I feel that it drives home how the plasmid can be used as a vector in medicine.
I first focus on students learning what happens to DNA in PCR, and all components needed in the reaction, including the role of each (I extend lesson by including what are the components in the buffer, and a little bit of the biochemistry). Before students do the lab, they have learned to identify potential reasons why a PCR may have failed. Afterwards, we do the two labs, and students are introduced to restriction enzymes. We go back to these when we start Lesson 4.1.

Electrophoresis, transformation, protein purification, PAGE, Chromatography, cell culture, aseptic technique, practice with laboratory technique
GFP with chromatography and PAGE

Lesson 4.1, Manufacturing Human Proteins

Medical Interventions

Every activity in this lesson aligns with content and skills students are expected to know for the BACE. When I teach this lesson (which spans a few weeks), I supplement it with videos on bioprocessing (with questions built in using EDPuzzle), and make sure that my students see the connection between what they're doing for the lab component of the lesson and what happens at a much larger scale in industry (I do this by grading each EDPuzzle individually and giving students feedback on their responses, in preparation for our unit test). As we move from module to module in the lab associated with this lesson, we compare and contrast our bioprocess with that of a company, focusing on aspects like the size or scale of our GFP production, how much care is put in avoiding contaminating our product, adherence to procedure, and record keeping. Students use what they learn about recombinant plasmids and bioprocessing to design their own recombinant vaccine (as an extension to the lesson, students come up with a basic design for what experiments they would run to test the effectiveness of the vaccine in mice, and in so doing review what they learned from our activity on ELISA, and from other activities we do on immunoassays).

What materials/resources do you use to prepare students for the BACE?

- I use InnovateBio website curriculum and resources. Amgen Biotech Experience.
- I use all the materials provided in the BACE site (Practice Exams, Khan Academy section on Biochem/Biotech).
- BioRad's J Kirk Brown Biotechnology: A Laboratory Skills Course.
- Ellyn Daugherty *Biotechnology Science for the New Millennium text* with PPT's, Chapter summaries, lab practices and evaluations. I use the 3 unit tests as pre-tests then again at end of course.
- YouTube videos that illustrate and explain the science behind lab techniques assessed on the BACE
- I create Kahoot! games with embedded videos and slides as an engaging way to review the theory for the knowledge portion of the BACE.

What materials/resources do you use to prepare students for the BACE? Cont.

- Saint Joseph's University Dilutions videos and worksheets are extremely helpful (https://sites.sju.edu/geprog/files/2017/07/Dilution-Video-handout.pdf)
- I recorded myself solving applied math problems so students can use them in Canvas to solve alongside me/the video. They then solve a similar problem.
- I set up stations for the techniques listed in the Biotechnology Skills.
- I collaborate with the AP bio and AP chemistry teachers for help with stats, chemistry, and math portions of the test.
- I have activities and projects to learn industry terminology
- Use of spectrophotometer to demonstrate measurement OD of bacterial culture (Beers law).
- Gram Stain, Solutions, Spectrophotometry, buffers and pH meters, Serological and Micropipette use, Safety Signs and Symbols, cGMPs, areas of industry.

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MODULE 1
INDUSTRIAL BIOTECHNOLOGY AND REGULATORY OVERVIEW

- Lesson 1: Introduction to Industrial Biotechnology
- Lesson 2: Drug Development Overview
- Lesson 3: Current Good Laboratory Practices (CGLP) and Preclinical Trials
- Lesson 4: Current Good Clinical Practices (CGCP)
- Lesson 5: Good Manufacturing Practices
- Lesson 6: Industry Documentation, Good Documentation Practices, and Data Capture
- Lesson 7: Career Opportunities in Industrial Biotechnology
- Lesson 8: Lab Safety Requirements in the Bioscience Workplace
- Lesson 9: Applied Math, Solutions, and Dilutions

MODULE 2
DNA TECHNOLOGY AND TECHNIQUES USED IN THE INDUSTRY

Recombinant DNA Technology

- Lesson 1: DNA Structure, Function and Replication
- Lesson 2: Restriction Enzymes
- Lesson 3: Bacterial Transformation and Transcriptional Regulation
- Lesson 4: Plasmid Isolation and Purification
- Lesson 5: CRISPR

DNA Analysis

- Lesson 6- PCR
- Lesson 7- Gel Electrophoresis and DNA Quantitation

MODULE 3
QUALITY MANAGEMENT SYSTEMS, QA, AND QC

- Lesson 1: Basics of Biomanufacturing, Company Departments and Career Opportunities
  - Quality Management Systems
- Lesson 2: Quality Management Systems, Quality Assurance and Change Controls
  - Quality by Design
- Lesson 3: Facility Design and Building Systems
- Lesson 4: Facility and Equipment Qualification
- Lesson 5: Preventive Maintenance and Equipment Calibration
- Lesson 6: Product Specifications
- Lesson 7: Assay and Process Validation
- Lesson 8: Quality Control, QC Sample Testing, and Environmental Monitoring

MODULE 4
UPSTREAM AND DOWNSTREAM PROCESSING TECHNIQUES

- Pre-Lesson: Protein Structure and Synthesis
- Lesson 1: Upstream Processing
- Lesson 2: Downstream Processing
- Lesson 3: Methods of Target Product Testing
- Lesson 4: Utilizing Deviations, Planned Variance & CAPA to Improve Processes

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VIRTUAL LESSON SERIES FOR BIOSCIENCE STUDENTS

Industrial Biotechnology & Regulatory Overview

This lesson series includes eight asynchronous videos designed to provide students with an in-depth look at the field of biotechnology, the drug development process, the regulatory guidelines involved in drug development, testing, and product manufacture, and the key departments that ensure these processes occur properly.

Lesson 1: Introduction to Biotechnology
Biotechnology is a broad field in which products or services are developed, manufactured, and tested utilizing biological systems. Our society has benefited in countless ways from biotechnological improvements and advancements in sectors such as Agricultural, Healthcare, and Industrial. This lesson will provide a historical overview of the word as well as important milestones in the field.

Lesson 2: Drug Development Overview
For any drug, drug product, (bio)pharmaceutical or medical device to be approved by the FDA, it must follow a stepwise development process compliant with a multitude of federal regulations. In this lesson, students will be introduced to this regulatory process, the roles of the FDA, and the historical events that led to these regulations.

Lesson 3: Current Good Laboratory Practices (CGLP) and Preclinical Trials
Current Good Laboratory Practices (CGLP) are federal regulations set in place to ensure investigational new drugs are safe before testing in humans. They are required when conducting preclinical studies to collect data for FDA review and approval, before continued studies in Phase I clinical trials. This lesson will cover fundamental CGLP concepts and its importance within a regulated laboratory environment.

Lesson 4: Current Good Clinical Practices (CGCP) and Clinical Trials
Current Good Clinical Practices (CGCP) are federal regulations enforced by the FDA during clinical trials in humans. This lesson will familiarize students with the history, purpose, phases, and basic principles of Current Good Clinical Practices.

Lesson 5: Current Good Manufacturing Practices (CGMP)
Current Good Manufacturing Practices (CGMP) are federal regulations followed by drug manufacturing companies to ensure their products are safe and effective for humans. In this lesson, students will learn the core precepts of the regulatory guidelines required for companies that manufacture drugs, drug products, and medical devices.

Lesson 6: Product Specifications
Manufacturers must demonstrate that all products meet specifications for safety, purity, potency, quality, identity, and efficacy before FDA approval. This lesson will identify and describe the product attributes, how they are connected to the final product specifications, and how these specifications are set and tested.

Lesson 7: Industry Documentation, Good Documentation Practices (GDP), and Data Capture
Good Documentation Practices (GDP) are regulatory guidelines that help drug manufacturing companies maintain a system of controlled documents. GDPs ensure proper recording, reporting, and archiving of everything involved in the manufacturing process. Students will learn the basic standards of GDP as well as the role of documentation in interdepartmental communication and the lifecycle of a drug product.

Lesson 8: Company Organization and Departmental Roles in the Bioscience Industry
The industry is divided into key departments essential to ensuring all products are of high quality, are properly tested to confirm they meet specifications, and are created in compliance with federal regulations. This lesson will outline the different departmental roles found within a (bio)pharmaceutical company, how each department communicates and depends on the others for success, and the opportunities for meaningful, high-growth careers.