Biotility™ APPLIED BIOTECH TRAINING

UF Center of Excellence for Regenerative Health Biotechnology UNIVERSITY of FLORIDA

BACE Biotechnology Aptitude and Competency Exam

AY 25-26

CBT

CANDIDATE INFORMATION BULLETIN FOR COMPUTER-BASED TESTING

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Introduction to the BACE

Earning your Biotechnology Aptitude and Competency Credential demonstrates a solid foundation in the knowledge and skills required in today's biotech workforce. Whether you aim to excel in academia or thrive in private industry, this credential proves to your future employers that you have dedicated time and effort to become the best in your field.

The Biotechnology Aptitude and Competency Credential is a respected, industry-recognized credential designed to verify that you have mastered the foundational concepts and skills identified by the bioscience industry as valuable in a workplace setting. To earn the credential, you must demonstrate proficiency in biotechnology theory and techniques by passing the Biotechnology Aptitude and Competency Exam (BACE).

Administered by Biotility at the University of Florida's Center of Excellence for Regenerative Health Biotechnology (UF CERHB), the BACE assesses your capabilities through two integrated portions: Knowledge and Practical. Both sections are delivered online through UF e-Learning and are proctored to ensure exam integrity. You will take the exam in a computer lab or a standard classroom using your personal computer.

BACE Details

Exam Specifications

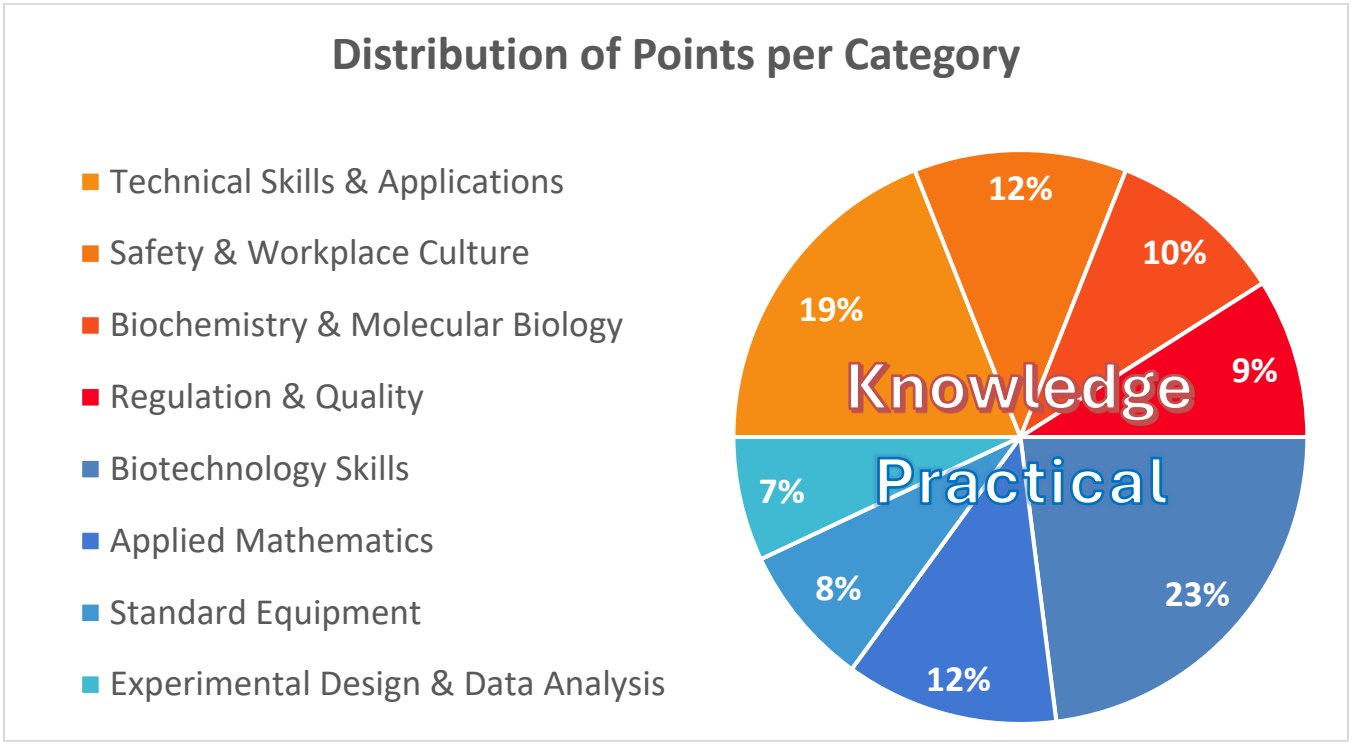
The **Biotechnology Aptitude and Competency Exam (BACE)** consists of two portions: a knowledge portion and a practical portion. Candidates take both portions, which cover eight categories, in a single session. To pass the BACE, candidates must score 80% or higher.

The Computer-Based Testing option must be administered at an Exam Site with live proctors and is conducted in a computer lab or standard classroom. **The exam is closed book with a duration of 4 hours.** The following descriptions for each portion include the total questions, categories covered, questions per category, points per category, and total points.

Category	Questions	Points
BACE Knowledge Portion		
Technical Skills & Applications	22	33.25
Safety and Workplace Culture	15	21
Biochemistry & Molecular Biology	15	17.5
Regulation & Quality	12	15.75
BACE Practical Portion		
Biotechnology Skills	19	40.25
Applied Mathematics	13	21
Standard Equipment	10	14
Experimental Design & Data Analysis	10	12.25
Total	**116**	**175**

Category Distribution

For a detailed breakdown of the exam categories, please refer to the chart below. The BACE is divided into two portions: the Knowledge Portion and the Practical Portion. The Knowledge Portion includes four categories, **Technical Skills & Applications**, **Safety & Workplace Culture**, **Biochemistry & Molecular Biology**, and **Regulation & Quality**, which are represented by the warm colors on the pie chart. The Practical Portion also consists of four categories, **Biotechnology Skills**, **Applied Mathematics**, **Standard Equipment**, and **Experimental Design & Data Analysis,** shown in cool colors.



It is important to recognize that significant portions of the exam's points are concentrated in the Technical Skills & Applications categories within the Knowledge Portion and the Biotechnology Skills category within the Practical Portion. Together, these two categories account for 42% of the total exam, underscoring their pivotal role in the assessment.

While all categories contain rigorous content, candidates often find the Technical Skills & Applications and Applied Mathematics categories to be particularly challenging. To help candidates strengthen their proficiency across all areas, preparation and practice resources are available in the BACE Practice Exam Course.

Eligibility Requirement

While there are no strict prerequisites for taking the BACE, it is strongly recommended that examinees have completed at least two years of hands-on experience in a biotechnology program.

Exam Retakes and Wait Time

You are permitted to take the BACE up to three times within an academic year. All attempts must be completed by July 31. Your second attempt is offered free of charge, while a fee of $50 applies for the third attempt. Please note that if a third-party proctor is required, additional fees may be incurred.

If you do not pass within the academic year, you may continue testing in the following year, with your attempt count resetting. Graduating candidates who are no longer affiliated with a program may also continue testing through the Computer-Based Testing via Remote Testing Option (RTO), which allows you to schedule attempts independently with a remote proctor.

To ensure thorough preparation and maintain the integrity of the exam, there is a mandatory 20-day waiting period between each attempt. However, Biotility recommends that candidates space their retakes at least six weeks apart. This allows you ample time to utilize the Practice Exam Course and other review resources to strengthen your knowledge and skills before retaking the exam.

Renewing Your Credential

To renew your BACE credential, you will need to challenge the exam again. The BACE credential is valid for a period of five years from the date of certification. Approximately six months before your credential is set to expire, you will receive an automated notification via email reminding you of the upcoming expiration. This email will outline your renewal options and provide guidance on the next steps.

If you have any questions or need assistance with the renewal process, you are encouraged to contact Biotility directly. Our team will be happy to help you explore your options and ensure you have all the information you need to successfully renew your credential and continue demonstrating your expertise in biotechnology.

Scoring and Score Results

To pass the BACE and earn your BACE Credential, you must achieve an overall score of 80%. Within two (2) weeks of passing the BACE, electronic credentials are issued. Electronic credentials are issued as a digital certification and a badge from Accredible. These credentials may be displayed on Facebook or LinkedIn and digitally verified online by anyone. For more information, review the Digital Credentials section of this document.

Viewing Results

Candidates who take the exam on a computer may preview their unofficial results immediately through UF e-Learning (UFEL). To view category results online, candidates can sign into UF e-Learning, navigate to the course, and switch to the "Learning Mastery" Gradebook. The official score report, including overall and category results, is sent to the Exam Site Administrator within two weeks.

Exam Policies

Exam Rules

Read the following rules and policies carefully. Violations of the following standards will result in the invalidation of your exam scores. The following rules must be observed at all times during the exam session.

- You are not permitted to start your exam until instructed by a proctor.
- You are not permitted to communicate with other candidates during the exam. If you have a question during the exam, raise your hand and a proctor will assist you.
- This is a CLOSED book exam. You are not permitted to search external references for answers during the exam. External references include, but are not limited to, books, notebooks, or the internet.
- Personal items are NOT permitted at your desk. Examples of personal items include, but are not limited to, electronic devices (such as cell phones, smart watches, or tablets), food and/or drink, and calculators.
- You are not permitted to leave the Exam Room unless all Exam Materials given to you are collected by a proctor.

Required, Permitted, and Prohibited Items

The BACE is a closed book exam. You are NOT permitted to bring any items other than your ID into the Exam Room. All permitted Exam Materials will be provided by the proctor. On the day of the exam, all candidates must present a valid form of identification during the check in process. Acceptable IDs include a school ID or a government-issued ID (state or federal). Teachers or Exam Site Personnel are not allowed to confirm a candidate's identity without the appropriate identification.

Items Provided by Proctor	Prohibited Items
• Pencil • Scratch Paper ***Note: An online calculator will be available within the exam interface.***	• No cell phones or other electronic devices • No food or drinks • No reference materials • No personal notebooks or scratch paper

Accommodating persons with disabilities/IEP

Candidates with disabilities or an Individualized Education Program (IEP) are eligible for exam accommodations; however, all accommodations must be coordinated prior to the testing date. If you need exam accommodations, please inform your Exam Site immediately.

Exam and Candidate Integrity

Academic Honesty

BACE Candidates are expected to behave ethically and honorably. Academic dishonesty includes any action (received or given) that creates an unfair advantage on the exam. Examples of academic dishonesty include but are not limited to:

- Accepting or giving assistance to another candidate during the exam
- Discussing specific exam questions with another candidate or individual
- Copying, photographing, recording, posting, or reproducing exam content in any medium
- Using stolen exam content to prepare for the exam

Academic dishonesty may be reported to Exam Site Personnel or anonymously to Biotility. To report academic dishonesty to Biotility, contact us at 386-462-3181 Option #1 or BACE@research.ufl.edu.

Ensuring Credential Validity

Biotility maintains the validity of its credentials by protecting the content of its exams. The Biotechnology Aptitude and Competency Exam (BACE) is the intellectual property of Biotility and the University of Florida and copyrighted under the laws of the United States.

Biotility reserves the right to withhold exam results or invalidate credentials when evidence of a testing abnormality is detected or reported. Biotility may also elect to pursue all available civil and criminal remedies if its intellectual property rights are violated.

Review and Appeals Process

Any candidate whose scores have been withheld, who has been denied certification, or whose certification has been revoked or suspended has the right to appeal the decision. Biotility has a formal review and appeals process in place, providing candidates the opportunity to present their concerns in a fair and impartial forum. Please note that candidates are not entitled to receive a copy of the certification examination or the answers to any exam questions.

To initiate an appeal, candidates must submit a written request to BACE@research.ufl.edu within ninety days of the testing date. Upon receipt of the appeal, it will be reviewed by an independent committee. Candidates can expect to receive a response within 30 days. The outcome of the appeal will be communicated in writing, and the decision of the committee is final.

Name Corrections or Changes

Ensuring your name is accurately reflected in all Biotility systems is crucial for maintaining the integrity of your performance. If you notice an inaccuracy, please request a correction as soon as possible by choosing one of the following options:

1. **Candidate Request**: Email BACE@research.ufl.edu from the address on file, or attend a Zoom meeting to verify your identity and request the correction.

2. **Exam Site Administrator Request**: The Exam Site Administrator may email BACE@research.ufl.edu on behalf of their candidates from their address on file to request the correction.

For legal name changes, such as those due to marriage or court orders, please include official documentation with your request. Promptly reporting corrections and changes ensures that all records remain accurate and up-to-date.

Confidentiality and Data Privacy Policy

Biotility is committed to upholding the highest standards of confidentiality and data privacy while facilitating an effective and transparent certification process. Biotility adheres to all applicable federal, state, and local regulations regarding student data privacy, including, but not limited to, Family Educational Rights and Privacy Act (FERPA), Children's Online Privacy Protection Act (COPPA), and Protection of Pupil Rights Amendment (PPRA). Additionally, with most participating sites, Biotility enters into a Data Privacy Agreement and completes a risk assessment and/or a HECVAT.

Biotility maintains strict confidentiality and security measures to protect candidate data. All records containing candidate information are secured physically and electronically, with access restricted to authorized personnel only. Data shared with exam site personnel is limited to what is necessary for the certification process and is handled in accordance with confidentiality agreements, ensuring the privacy of all candidates.

Biotility does not share any other confidential information without the candidate's explicit consent. This policy ensures that all data is handled with the utmost care and security, respecting the candidate's privacy at all times.

Preparing for the BACE

Exam References

The following references provide the primary sources for exam content. Candidates should be familiar with at least one of the listed biotechnology laboratory texts, in addition to the Biotility resource on regulatory compliance and quality systems.

- Brown, A. (2018). ***Biotechnology: A Laboratory Skills Course* (2nd ed.)**. Bio-Rad Laboratories, Inc.

  Alternate References to Biotechnology: A Laboratory Skills Course
  - Daugherty, E. L. (2017). *Biotechnology: Science for the New Millennium* (2nd ed.). Paradigm Publishing.
  - Seidman, L. A. (2021). *Basic Laboratory Methods for Biotechnology* (3rd ed.). CRC Press.

- Pruitt, H. (2024). **Regulatory Compliance and Quality Systems Overview**. Biotility, University of Florida.

Recommended Pathways for Preparation

The Biotechnology Aptitude and Competency Credential is a highly valued addition across multi-level educational pathways in biotechnology. Whether you are enrolled in a high school, community college, university, or vocational training program, the BACE Credential serves as a recognized standard of work-force readiness in the biotechnology industry. It validates your knowledge and skills to employers, making it a beneficial asset to your portfolio regardless of how you prepared to sit for the exam.

Before sitting for the BACE, candidates are encouraged to complete a rigorous biotechnology program that emphasizes industry standards and hands-on experience. Regardless of the specific curriculum used, most institutions are focused on preparing candidates for the Biotechnology workforce, which ensures a natural alignment with the BACE.

Common Pathways

- **Traditional Biotech Programs:** The most common sources of biotechnology curricula are typically industry-aligned, state-adopted programs that integrate well-established educational resources. These programs often utilize materials like ***Bio-Rad's Biotechnology: A Laboratory Skills Course*** (Brown, 2018), Ellyn Daugherty's ***Biotechnology: Science for the New Millennium and Laboratory Manual*** (Daugherty, 2017), or Lisa Seidman's ***Basic Laboratory Methods for Biotechnology*** (Seidman, 2021). These texts are widely recognized for their alignment with industry standards and their comprehensive approach to both theoretical knowledge and practical biotech skills, which are essential for students preparing for the BACE.
- **Project Lead the Way (PLTW):** Many institutions follow the Project Lead the Way (PLTW) Biomedical Science Pathway, which offers a project-based learning experience that integrates biology, chemistry, and biotechnology. These pathways emphasize critical thinking, problem-solving, and hands-on skills that are directly applicable to the biotechnology field.
- **Customized Curricula:** Some institutions also develop their own customized curricula tailored to their specific educational goals and the needs of their local industry. These custom curricula may draw from a combination of established resources and original content designed by educators to provide a unique learning experience.

It is important to note that anybody may sit for the exam, whether as an individual who has prepared through experience, practice, and study, or as a student who has participated in a bioscience-based program. It is highly recommended that all registered candidates make use of the free resources available on our Candidate Preparation website.

Additional Study Resources

In addition to the primary resources mentioned above, you may also benefit from the following supplementary materials:

AP Biology Textbooks and Lab Manuals: For students with a strong foundation in AP Biology, the associated textbooks and lab manuals can serve as valuable review tools, particularly for reinforcing concepts related to genetics, molecular biology, and laboratory techniques.

Online Resources and Study Guides: A variety of online platforms offer interactive learning opportunities to enhance your BACE preparation. These resources provide additional practice and reinforce your understanding of key topics. Biotility has curated a recommended list of these resources, available on our Candidate Preparation website.

BACE Practice Exam Course

The **BACE Practice Exam Course** is your comprehensive guide to mastering the Biotechnology Aptitude and Competency Exam (BACE). Designed to enhance your preparation, this free course offers a variety of tools and resources to help you navigate the exam content with confidence. Whether you're just starting to assess your strengths or fine-tuning your skills, this course provides valuable practice proven to improve performance on the BACE.

Your Exam Site will provide the link to enroll, giving you full access to modules that assess your knowledge, practice key concepts, and prepare you for a future in biotechnology. Candidates who use the **BACE Practice Exam Course** consistently perform better on the actual exam. Check out the module descriptions below and take full advantage of these resources.

Module 1: Proficiency Plotter – Graph Your Biotech Strengths and Gaps

In this module, you'll chart your strengths and areas for growth across key BACE topics. Through eight unique surveys, you'll self-assess your familiarity with various subcategories. After completing the module, you'll have access to a detailed report highlighting your biotech strengths and areas needing more focus. This activity can be completed multiple times as you prepare for the exam, giving you an opportunity to chart your growth. Your teacher can also access this report to personalize your training, ensuring you're fully prepared to tackle the BACE.

Module 2: Regulatory Compliance and Quality Systems Review – The Secret Sauce for Biotech Success

This module provides an in-depth exploration of Regulatory Compliance and Quality Systems, a critical area often missing from traditional biotech curricula but essential for the BACE. This module explores regulations, Current Good Manufacturing Practices, Current Good Documentation Practices, and biotech company operations, equipping you with knowledge crucial for both the exam and your future career. This comprehensive review fills the knowledge gap and is also available publicly on our Candidate Preparation website.

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

This module offers realistic practice before tackling the Competency Challenge or the actual BACE. Here, you can freely test your biotech knowledge, hone your skills, and build the confidence you

need to succeed. The Practice Exams included are an excellent representation of the real exam content. You can retake them as often as needed to familiarize yourself with the format and refine your understanding. Your teacher can also review your results to offer personalized guidance, ensuring you're fully supported as you prepare for the challenges ahead.

Module 4: Number Crunch – Strengthen Your Biotech Math Skills

This module provides additional math practice to help you tackle the specific mathematical concepts essential for success on the BACE. Whether you need a quick refresher or more in-depth practice, dedicating time to this module will ensure your math skills are strong and ready for the exam, giving you an extra edge in your preparation.

In addition to the practice activities, this module now includes a video resource**, Applied Math in Biotechnology – What You Need to Know**. This video provides a clear and accessible review of the mathematical concepts covered in the BACE Applied Mathematics category, including scientific notation, significant digits, metric conversions, dilutions, solution preparation, and basic statistics. By walking through real-world biotechnology examples, the video helps you connect abstract math skills to practical applications in the lab.

Module 5: Competency Challenge & Badges – Show What You've Learned

Badge up and share your success! In this module, you'll tackle another set of 8 BACE category quizzes, each designed to reflect the content and complexity of the BACE. As you complete each quiz, you'll earn digital badges that recognize your proficiency in key biotech areas. Candidates have two opportunities to complete each quiz and earn the associated badge. While earning badges is a great way to showcase your strengths, be sure to review your results carefully to identify any areas needing further study. The Competency Challenge helps you confirm your readiness for the BACE by highlighting both strengths and areas for improvement.

Module 6: Stepping into the Biotech Workforce – Launch Your Career

This module focuses on preparing you for the professional world, offering practical tools and resources that are crucial for your career but **not included on the BACE**. You'll learn how to create a professional LinkedIn profile, discover effective networking strategies, and access resources to prepare for interviews and enhance communication skills. The module also provides guidance on crafting strong resumes, cover letters, and other essential job application documents. By engaging with this module, you'll be well-prepared to enter the biotech industry with confidence, equipped with the knowledge and tools you need to succeed.

Guide to UF e-Learning

This section explains how new and existing users complete the candidate enrollment process. To access an existing enrollment, see Log in to UF e-Learning Courses at the end of this document. For step-by-step enrollment instructions with screen shots, review either of these documents.

- Enrollment Guide for Sponsored Candidates – for candidates whose fees are fully covered by an institution, program, or exam site.

- Enrollment Guide for Self-Pay Candidates – for candidates who pay all or part of their fees.

Enroll in UF e-Learning Courses

Candidate enrollment for Biotility courses and exams within UF e-Learning is managed through UF Professional and Workforce Development (UF PWD). At least one week before the course or testing event window, Biotility sends Enrollment Links directly to the Exam Site Administrator. The Site Administrator is responsible for distributing the Enrollment Links and Coupon Code to candidates.

Candidate Enrollment

1. Select the Enrollment Link.
2. On the **Biotility Course Enrollment** page:
    a. Review the Course Description.
    b. Select the **orange plus (+)** next to the course offering.
    c. Select **Add to Cart**.
3. In the **Cart View**:
    a. If the total is not zero, candidates registered through an Exam Site should select **Apply Discount** and enter their Exam Site provided **Coupon Code**.
    b. Select **Checkout**.

Account Creation or Confirmation

4. Select the desired social account type and sign in (Google, LinkedIn, or Microsoft).
    - **New Users:** Follow the prompts to search for an existing account. Enter the required information (name, date of birth, email, and phone number), and then select **Submit**.
    - **Existing Users:** After signing in, you are advanced directly to the Payment page (Step 6).

Checkout Process

5. On the My Profile page -
    a. Confirm or enter the required information.
    b. Accept UF's Privacy Policy by typing your initials.

Tips for Candidate Enrollment and Account Creation

- **Create or Use an Accessible Account**: If you don't have a school or social account (e.g., Google, LinkedIn, Microsoft), create one that you can access from your exam site.
- **Choose the Right Account**: Use an account registered under your legal name with correct spelling and capitalization. This should be the account connected to your true identity.
- **Consistency is Key**: Use the same account for enrollment, account creation, and signing in to ensure seamless access to your course and exam materials.
- **One Enrollment per Course:** Avoid attempting to enroll in the same course multiple times, but ensure you enroll in both the *BACE Practice Exam Course* and the *BACE Exam Course*.
- **Plan for Long-Term Access:** Choose an account you can access long-term. If using a school account, update your contact information with Biotility before you graduate to maintain access.

   c. Select **Continue Checkout.**
6. On the Payment page –
   a. Confirm or enter the required information.
   b. Answer the Questionnaire.
   c. Read and accept the Payment Policy Confirmation.
   d. Select **Continue Checkout**.
7. You are redirected to the Receipt page. A copy of your receipt and registration confirmation is sent to the email address on file. This page confirms that your enrollment in the course is complete. To enroll in additional courses or course sections, obtain a separate enrollment link for each and repeat the process.

Troubleshooting

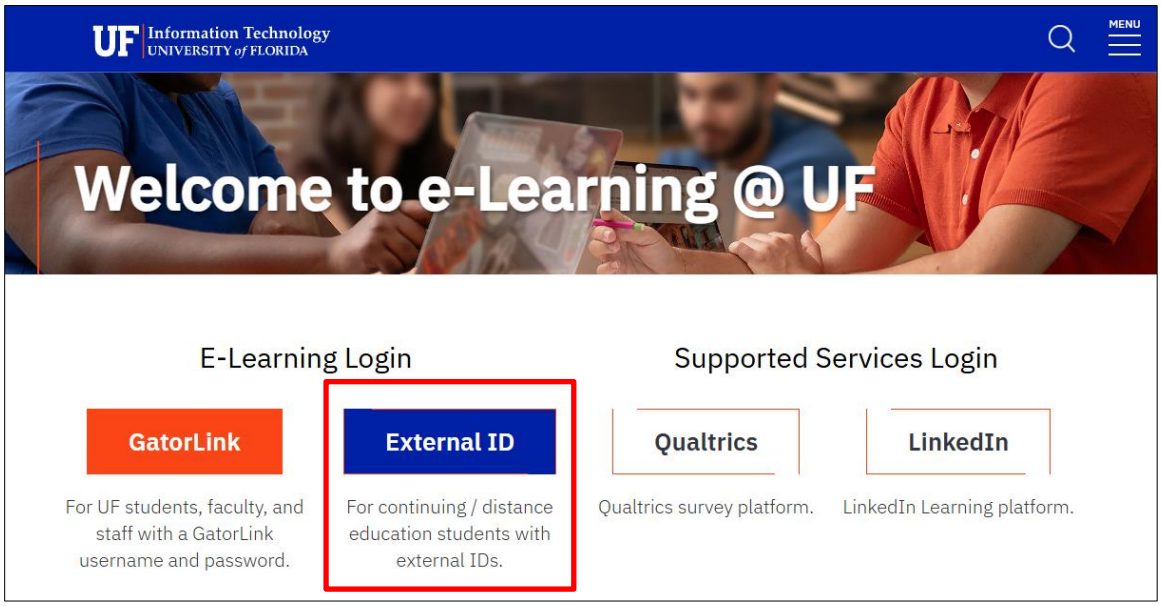
Not receiving our verification emails? Check your spam folder or update your email settings to allow emails from the following domains:

- @ufl.edu
- @cerhb.ufl.edu
- @research.ufl.edu

Log in to UF e-Learning Courses

To access courses you are enrolled in, follow the steps below:

1. Navigate to the UF e-Learning sign-in page.
2. Select **External ID**.



3. Sign in with the social account you enrolled through.
4. Once in UF e-Learning, select the appropriate course tile from your dashboard.

Note: Access to the Practice Exam Course and the BACE within UF e-Learning is managed through Enrollment Links. Your Site Administrator will distribute the Enrollment Link to you.

Navigate Within UF e-Learning Courses

Once you've accessed your course in UF e-Learning, you'll find several key areas to help you stay organized and on track:

- **Home**: The "Home" page is your starting point. Here, you'll see an overview of your course, including important announcements, upcoming assignments, and recent activity.
- **Modules**: The course content is organized into modules. Click on the "Modules" tab to access lessons, readings, quizzes, and assignments in a structured sequence.
- **Quizzes**: Use the "Quizzes" tab to access and complete quizzes related to your course material. Your scores will be available here after submission.
- **Grades**: Keep an eye on your performance by selecting the "Grades" tab, where you can view scores and feedback on your assignments and quizzes.

For more detailed instructions on navigating UF e-Learning, please refer to the Canvas Student Guide.

Your Credential at Work

Within two weeks of passing the Biotechnology Aptitude and Competency Exam (BACE), Biotility will send a digital credential to the candidate's registered email address. These credentials are issued through Accredible, providing candidates with a branded, secure, and verifiable digital certificate. The BACE credential is valid for five years, during which it can be shared and displayed in a variety of ways, including:

- **Social Media Profiles**: Enhance your online presence by adding the credential to platforms like LinkedIn. Accredible makes this easy with a feature that allows you to add the credential directly to your LinkedIn profile from your credential dashboard.
- **Websites and Blogs**: Showcase your achievements on personal or professional websites by embedding the unique credential URL.
- **Digital Resumes**: Include the unique URL in your resume to allow employers to easily verify your qualifications.
- **Email Signatures**: Add the credential to your email signature to highlight your professional achievements.

By placing the credential's unique URL in these locations, stakeholders such as admissions officers and potential employers can easily view and verify your credential. The link also provides detailed information about the BACE, helping stakeholders better understand the rigor and significance of the credential you've earned.

Credential Verification

Employers and other stakeholders can verify a BACE credential online using Accredible's Credential Verification Tool. This tool offers several methods for verification:

- **Credential Link**: Input the URL of the credential to verify its authenticity.
- **Credential ID**: Enter the Credential ID number to confirm the credential.
- **Open Badge Image Upload**: Upload an open badge image to verify its legitimacy. The tool reads the embedded metadata in the badge image to confirm its authenticity.

To maintain the validity of the credential, candidates must retake and pass the BACE before the end of the five-year period. Keeping the credential up to date ensures that your skills and knowledge remain current in the rapidly evolving biotechnology field.

Sharing Digital Credentials through LinkedIn

Candidates have multiple options for sharing their digital credentials. Detailed instructions on all available sharing options can be found in Accredible's Recipient Knowledge Base. Here's a quick guide to adding your credential to LinkedIn:

1. Select the ellipsis (...) menu at the bottom of the credential window, then choose **Add to LinkedIn Profile**.
2. A dialog will appear with the necessary information to copy and paste to your LinkedIn profile.
3. Select **Open LinkedIn** at the bottom of the dialog.
4. Copy and paste the relevant information into the appropriate fields on your LinkedIn profile.
5. Once all the information is copied over, save and close the LinkedIn form.

For more tips and tricks on how to amplify the power of your credential through LinkedIn and get workforce ready, check out Module 6 of the BACE Practice Exam Course: Stepping into the Biotech Workforce

Spotlight – Biotility's National Registry of Credentials

Biotility offers a public registry where credentialed candidates can opt to showcase their BACE Credential. Spotlight is an invaluable tool for credentialed candidates looking to boost their professional profile. By opting into this public registry, your verified achievements become easily accessible to potential employers, providing a robust platform for professional recognition. Employers often use such registries to verify credentials, and being listed in Spotlight adds a layer of credibility to your accomplishments.

The benefits of joining Spotlight are numerous. It significantly enhances your visibility within the industry, opening up new networking opportunities with like-minded professionals. Being part of this registry can also serve as a powerful reference point for career advancement, helping you stand out to employers who prioritize candidates with recognized credentials.

Detail of Exam Categories

Each of the eight BACE categories represent a major area of focus and the category descriptions summarize the key ideas and goals within that area. Subcategories go a step further by breaking down these larger categories into specific topics or skills you need to know.

Knowledge Categories

Technical Skills & Applications

Technical Skills & Applications covers the foundational techniques used in biotechnology workplace settings. It includes understanding and applying methods such as aseptic technique, cell culture, DNA isolation, and various assays. The focus is on both the theoretical principles and the practical application of these techniques, including the use of advanced equipment and procedures such as polymerase chain reaction (PCR), gel electrophoresis, and chromatography.

- Discuss current techniques used in biotechnology and their applications
- Describe the proper use of microscopes
- Discuss cell staining, and distinguish between gram-positive/negative cells
- Describe the process of culturing microorganisms and tissues using aseptic technique
- Discuss the differences between sterilization, decontamination, and disinfection
- Understand the principle by which a pH meter works
- Explain the principles of spectrophotometry, including Fourier-transform infrared (FT/IR) spectrophotometry
- Understand the basic principle of the Beer-Lambert law
- Discuss methods of chromosomal and plasmid DNA isolation, purification, and quantification
- Discuss gel electrophoresis techniques, including agarose and polyacrylamide gel electrophoresis (PAGE)
- Understand how restriction enzymes are used
- Describe recombinant DNA and cloning techniques
- Describe the mechanism of PCR, including the theory and practical use of conventional and real-time PCR (qPCR) thermal cyclers
- Discuss protein expression in model organisms
- Discuss methods of molecule/protein isolation, purification, and quantification
- Understand the principles of enzyme-linked immunosorbent assay (ELISA) and other immunoassays
- Understand molecular diagnostics techniques and their applications
- Discuss assay development and validation
- Understand the principles and applications of flow cytometry and cell sorting
- Discuss the principles of centrifugation and its applications
- Understand the basics of chromatography techniques
- Discuss transformation and transfection of model organisms
- Understand applications of lab automation and robotics in biotechnology

- Demonstrate an understanding of how calibration and validation are critical to producing reliable, consistent results
- Discuss the principles and applications of laminar flow in a cleanroom or manufacturing environment

Safety & Workplace Culture

Safety and Workplace Culture emphasizes the importance of safety, ethics, and proper behavior in the biotechnology workplace. It includes understanding and following safety protocols, using personal protective equipment (PPE), handling hazardous materials, and responding to emergencies. It also covers the ethical considerations in biotechnology, workplace behaviors, and compliance with regulations enforced by agencies such as the Occupational Safety and Health Administration (OSHA).

- Discuss ethics and bioethics in the workplace and society
- Describe appropriate workplace behaviors
- Identify proper workplace safety behaviors
- Identify safety symbols
- Identify and explain proper use of safety equipment
- Identify and properly use PPE
- Exercise proper safety protocols
- Describe proper handling of biological and hazardous waste
- Explain the importance of posting and complying with signage
- Describe procedures for safe handling and storage of chemicals
- Derive information from safety data sheets (SDS)
- Discuss key OSHA regulations applicable to biotechnology workplaces
- Describe proper lockout/tagout procedures for machinery and equipment
- Describe emergency response procedures for fires, chemical spills, or other incidents
- Discuss the process for reporting safety concerns and hazards, including near misses
- Discuss the importance of proactive safety communication
- Understand the importance of comprehensive training and safety training in biotechnology workplaces
- Properly label items, including solutions, buffers, Petri plates, samples, and products

Biochemistry & Molecular Biology

Biochemistry & Molecular Biology focuses on the molecular and biochemical principles that underpin biotechnology. It includes understanding DNA structure and function, gene expression, protein synthesis, enzyme activity, and cell biology. It also covers processes and techniques related to molecular biology and protein expression, such as monoclonal antibody production, immunotherapy, and the role of mRNA in therapeutics.

- Understand the chemistry of molecules and macromolecules
- Describe DNA structure and function
- Describe transcription

- Describe translation and gene expression
- Describe protein structure and function
- 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, such as chimeric antigen receptor T-cell (CAR-T) and mAb

Regulation & Quality

Regulation & Quality involves understanding the regulatory environment and quality practices associated with the development, manufacture, and testing of biotechnology-based products and processes. It covers the roles of Current Good Laboratory Practices (CGLP), Current Good Manufacturing Practices (CGMP), Good Documentation Practices (GDocP), and regulatory agencies such as the Food and Drug Administration (FDA). It also includes knowledge of the processes involved in product development, regulatory approval, departmental roles, and maintaining data integrity and security.

- Discuss regulatory agencies governing the manufacture and distribution of biotechnology-derived products
- Outline the roles of various departments in a company, including Research and Development (R&D), Quality Assurance (QA), Quality Control (QC), and Manufacturing
- Understand the purpose of CGLP in non-clinical studies
- Understand the purpose of CGMP
- Follow practices associated with regulatory compliance
- Discuss key components of GDocP, including contemporaneous documentation, controlled documents, and approvals
- Identify the proper use and essential elements of CGMP documents, such as Standard Operating Procedures (SOP), batch records, logs, and deviation reports
- Explain the objectives of research and development with the goal of launching an FDA regulated product.
- Explain the FDA approval process for regulated products
- Outline the manufacturing process in bioprocessing and production facilities
- Discuss Upstream (USP) and Downstream Processing (DSP), including the key steps and equipment involved in each process
- Describe Environmental Monitoring (EM) in a controlled space
- Understand the importance of audits and Corrective and Preventive Actions (CAPA) to ensure compliance and continuous improvement
- Discuss Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA) principles and FDA guidelines on data integrity and compliance

- Discuss strategies for maintaining security of sensitive data and intellectual property
- Describe the significance of Health Insurance Portability and Accountability Act (HIPAA) compliance and the protection of personal health information

Practical Categories

Biotechnology Skills

Biotechnology Skills centers on technical skills essential for quality work. It includes accurately measuring liquids and solids, preparing solutions, performing serial dilutions, and using standard equipment such as centrifuges, spectrophotometers, and biosafety cabinets. The focus is on mastering these practical skills to ensure precise and reliable outcomes.

- Accurately measure liquids with micro and macro scale equipment
- Accurately measure mass using electronic balances
- Properly prepare solutions and buffers
- Properly measure and adjust the pH of a solution
- Properly perform a serial dilution
- Identify and properly handle reagents
- Demonstrate proper aseptic/sterile technique
- Demonstrate proper culturing of microorganisms
- Describe the proper use of a centrifuge
- Describe the proper use of a spectrophotometer
- Describe the proper use and maintenance of biological safety cabinets (BSC)
- Demonstrate proper use of electrophoresis equipment
- Discuss the role and impact of automation in the biotechnology industry
- Use 24-hour time correctly

Applied Mathematics

Applied Mathematics covers the mathematical skills needed to perform common bioscience workplace calculations and data analysis. It includes using scientific notation, significant digits, metric conversions, making dilutions, calculating weight and volume measurements for buffer and media prep, graphing data, and performing statistical analyses. These skills are crucial for designing experiments, preparing reagents and solutions, and interpreting results.

- Use scientific notation correctly
- Use significant digits correctly
- Understand and use mathematical symbols
- Understand and use fractions
- Use metric measurements and perform metric unit conversions
- Generate a graph using collected data
    - Properly plot data
    - Interpret data
    - Generate a standard curve

- 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 measurements and the logarithmic scale
- Apply basic statistical techniques such as mean, median, mode, and standard deviation to analyze data

Standard Equipment

Standard Equipment focuses on the proper identification, use, and maintenance of standard equipment. It includes understanding the safe operation of 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 critical parameters such as calibration, maintenance, and validation.

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

Experimental Design & Data Analysis

Experimental Design & Data Analysis involves understanding how to design experiments, analyze data, and communicate findings effectively. It covers the use of controls, maintaining a laboratory notebook, applying statistical methods, and adhering to the principles of Responsible Conduct of Research (RCR). The focus is on ensuring that experiments are well-designed, data is accurately interpreted, and results are clearly communicated.

- 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 and apply the principles of RCR
- Demonstrate proper implementation of data integrity principles
- Effectively communicate scientific findings
- Understand applications of Principal Component Analysis (PCA)
- Identify and analyze sources of error in assay results

- Discuss the role of sample size and replication for study design

Definitions

In this section, you'll find clear definitions for terminology used in the category descriptions and subcategories that are important for your understanding of content covered on the BACE. Understanding these definitions will help you navigate the content more easily and ensure you're fully prepared in each area.

Agarose Gel Electrophoresis: A method used to separate DNA or RNA molecules based on their size by applying an electric field to an agarose gel matrix. The agarose gel acts as a sieve, allowing smaller molecules to move faster through the gel while larger molecules move more slowly, enabling the separation and analysis of nucleic acids.

Aseptic Technique: A set of practices used to prevent contamination by pathogens or unwanted microorganisms during procedures, crucial for maintaining sterile conditions in cell culture and other sensitive processes.

Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA): Principles that ensure data integrity in regulated environments, ensuring that data is reliable, accurate, and trustworthy.

Autoclave: A device used to sterilize equipment and materials using high-pressure steam, commonly used in laboratory, industrial, and medical settings to ensure that tools and materials are free of microbial contamination.

Automation: The use of technology to automate biotechnology processes, increasing efficiency and reducing human error, commonly employed in high-throughput screening and sample processing.

Batch Record: A controlled document that contains instructions for manufacturing a regulated product. It also captures contemporaneous data relevant to the manufacture of that product.

Beer-Lambert law (also written Beer's Law)**:** A principle that describes the linear relationship between the concentration of a solute in a solution and the absorbance of light at a particular wavelength, used in quantitative spectrophotometry.

Buffer: A solution that resists changes in pH when small amounts of acid or base are added, commonly used in biological experiments to maintain a stable pH environment.

Biosafety Cabinet (BSC): Enclosed, ventilated workspace designed to protect the user, the product, and the environment from exposure to biohazards and contamination.

Calibration: The process of adjusting and standardizing the measurements of an instrument or device to ensure accuracy and reliability, which is essential for maintaining data integrity.

Cell Culture: The process of growing cells in a controlled, artificial environment, typically using a nutrient-rich culture medium, for research, production of biologics, or other biotechnological applications.

Cell Sorting: A method of separating cells based on specific characteristics, often using flow cytometry to isolate particular cell types for further study or therapeutic use.

Cell Staining: The process of applying dyes to cells or tissues to enhance contrast under a microscope, enabling the visualization of cellular components, often used in identifying cell structures or distinguishing between cell types.

Centrifuge: A machine that spins samples at high speeds to separate components based on their density, commonly used to isolate cells, organelles, or macromolecules in biological research.

Chromatography: A technique for separating and analyzing the components of a mixture based on their different interactions with a stationary phase and a mobile phase, commonly used in protein purification, drug testing, and biochemical analysis.

Cloning Techniques: Methods used to create copies of DNA fragments, cells, or organisms, often used in research, therapeutic applications, and genetic engineering.

Corrective and Preventive Actions (CAPA): A systematic approach used in manufacturing and quality management to identify, investigate, and correct the root causes of problems to prevent their recurrence. Corrective actions address immediate issues, while preventive actions focus on eliminating potential future problems.

Current Good Manufacturing Practices (CGMP): Regulations enforced by the FDA to ensure that products are produced in a consistent and controlled manner according to quality standards, covering all aspects of manufacturing.

DNA Isolation: The process of extracting DNA from cells or tissues, allowing it to be used for various downstream applications such as PCR, sequencing, or cloning.

Downstream Processing (DSP): The phase that follows upstream processing in bioprocessing, involving the purification and recovery of the product from the complex mixture produced during upstream processing. It includes techniques such as filtration, chromatography, and crystallization to isolate and purify the final product.

Electrophoresis Equipment: Instruments used to perform gel electrophoresis, a technique for separating DNA, RNA, or proteins based on their size and charge.

Enzyme-linked Immunosorbent Assay (ELISA): A plate-based assay technique used to detect and quantify specific proteins, antibodies, or hormones, widely used in diagnostics and research.

Environmental Monitoring (EM): Involves the systematic collection of data to detect contaminants in a controlled environment, such as a cleanroom or manufacturing facility. It ensures that the environment meets specified cleanliness and safety standards, crucial for maintaining product quality in industries like biotechnology and pharmaceuticals.

Flow Cytometry: A technology used to analyze the physical and chemical characteristics of cells or particles as they pass through a laser, allowing for the measurement of various cellular properties, including size, complexity, and fluorescence.

Food and Drug Administration (FDA): A regulatory agency of the United States Department of Health and Human Services responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, biological products, medical devices, food, and cosmetics. In the biotech industry, the FDA regulates the development, testing, manufacturing, and approval of biotechnological products, including pharmaceuticals, vaccines, and diagnostic tools.

Fourier-transform Infrared (FT/IR) Spectrophotometry: A type of infrared spectroscopy that collects spectral data over a wide range of wavelengths simultaneously, used to identify chemical bonds and molecular structures.

Gel Electrophoresis: A method used to separate mixtures of DNA, RNA, or proteins based on their size and charge by applying an electric field to a gel matrix, causing molecules to migrate through the gel.

Good Documentation Practices (GDocP): Guidelines for accurately recording and maintaining documents, ensuring they are complete, consistent, and easily retrievable, which is critical in regulated environments.

Good Laboratory Practices (GLP): A set of principles intended to ensure the quality and integrity of non-clinical laboratory studies, regulated by agencies like the FDA.

Gram Staining: A differential staining technique that distinguishes between Gram-positive and Gram-negative bacteria based on the properties of their cell walls, used for bacterial classification and diagnosis.

Health Insurance Portability and Accountability Act (HIPAA): U.S. legislation that provides data privacy and security provisions to safeguard medical information, ensuring that personal health information is protected.

Immunoassay: A biochemical test that measures the presence or concentration of a substance in a solution using the reaction of an antibody or antibodies to its antigen.

Immunotherapy: A type of treatment that uses the immune system to fight diseases such as cancer, often involving the use of monoclonal antibodies, CAR-T cells, or other immune-modulating therapies.

Incubator: A device used to maintain a controlled environment, typically with regulated temperature and humidity, for the growth and development of microorganisms or cell cultures.

Laminar Flow: A smooth, uniform flow of air in one direction, typically used in cleanrooms or biosafety cabinets to prevent contamination during sensitive procedures.

Manufacturing: The department within a drug manufacturing company responsible for producing the product. This department is also sometimes referred to as "Production."

Micropipette: Precision instrument used to measure and transfer small volumes of liquid, essential for accurate experimental work.

Microscopy: The use of microscopes to view and analyze structures that are too small to be seen with the naked eye, such as cells, tissues, or microorganisms.

Monoclonal Antibody (mAb): Antibodies that are identical and produced by a single clone of cells, used in various therapeutic and diagnostic applications due to their specificity for a particular antigen.

Occupational Safety and Health Administration (OSHA): A regulatory agency of the United States Department of Labor that is responsible for ensuring safe and healthy working conditions for employees by setting and enforcing workplace safety standards. OSHA provides training, outreach, education, and assistance to employers and workers, and it enforces compliance through inspections and penalties.

Personal Protective Equipment (PPE): Equipment worn to minimize exposure to hazards that can cause serious workplace injuries or illnesses, including items such as gloves, masks, goggles, and lab coats.

Polyacrylamide Gel Electrophoresis (PAGE): A technique used to separate proteins or smaller DNA/RNA fragments based on their size and charge by applying an electric field to a polyacrylamide gel. The polyacrylamide gel provides a high-resolution medium for the separation of molecules, making it particularly useful for protein analysis and the study of small nucleic acid fragments.

Polymerase Chain Reaction (PCR): A technique used to amplify small segments of DNA by generating thousands to millions of copies of a particular DNA sequence, often used in molecular biology for various applications such as cloning, gene expression analysis, and genotyping.

Principal Component Analysis (PCA): A statistical method used to reduce the dimensionality of data while preserving as much variance as possible, often used in data analysis to simplify complex datasets.

Quality Assurance (QA): The department within a drug manufacturing company responsible for ensuring compliance with CGMP. QA reviews and approves documentation, oversees personnel training, and has the ultimate authority to release or reject a product.

Quality Control (QC): The department within a drug manufacturing company responsible for performing all required testing to ensure that the final product meets its specifications.

Reagent: A substance or compound that is added to a system to cause a chemical reaction or test for the presence of another substance, widely used in experiments.

Real-Time PCR (also known as quantitative PCR, **qPCR)**: A laboratory technique used to simultaneously amplify and quantify a targeted DNA molecule. It allows the detection of the amount of a specific DNA sequence in real-time as the amplification process proceeds, typically using fluorescent markers that emit signals in proportion to the amount of DNA.

Recombinant DNA: DNA molecules that are artificially created by combining DNA from different organisms, used in genetic engineering to express new genes in host cells.

Research and Development (R&D): Refers to the process or department through which companies and organizations develop new products, technologies, or processes, and improve existing ones. In the biotech industry, R&D involves scientific research to discover new biological insights, develop innovative therapies, improve manufacturing processes, and create new biotechnological products such as drugs, vaccines, and diagnostic tools.

Responsible Conduct of Research (RCR): The ethical and professional standards that guide researchers in the planning, conduct, and reporting of research. It encompasses principles such as honesty, accuracy, efficiency, and objectivity in scientific work. In the biotech industry, RCR is critical for ensuring the integrity of research processes, including the proper handling of data, ethical treatment of human and animal subjects, and the transparent reporting of research findings.

Restriction Enzyme: A protein that cuts DNA at a specific sequence, used in molecular cloning, genetic engineering, and various molecular biology applications to manipulate DNA.

Safety Data Sheet (SDS): A document that provides information on the properties of a chemical substance, including handling, storage, and emergency measures, required by OSHA for hazardous chemicals.

Serial Dilution: A stepwise dilution of a substance in solution, used to reduce the concentration of cells, bacteria, or viruses, making it easier to measure or quantify them.

Spectrophotometer: An instrument used to measure the intensity of light absorbed by a sample, used in quantifying nucleic acids, proteins, and other molecules.

Standard Curve: A graph used in quantitative analysis that plots known concentrations of a substance against their corresponding measurement signals, allowing for the determination of unknown concentrations in samples.

Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity in performing specific functions, essential for ensuring consistency and compliance in laboratory and manufacturing processes.

Sterilization: The process of eliminating all forms of life, including microorganisms, from an object or environment, usually achieved through heat, chemicals, or radiation.

Test Record: A controlled document that provides instructions for testing a regulated product after its production. It also captures contemporaneous data relevant to the identity, safety, efficacy, potency, purity, and quality of the product.

Transfection: The process of introducing nucleic acids (DNA or RNA) into eukaryotic cells, often used in research to study gene function and protein expression.

Transformation: The genetic alteration of a cell resulting from the direct uptake and incorporation of exogenous genetic material, typically used in bacteria to introduce new genes.

Upstream Processing (USP): Refers to the initial phase of bioprocessing where biological materials (such as cells or microbes) are prepared, grown, and optimized to produce a desired product, such as proteins or other biomolecules. This phase often includes cell culture, fermentation, and optimization of growth conditions.

Validation: The process of proving that a method, process, or piece of equipment consistently produces results that meet predetermined criteria, essential for ensuring quality and reliability in biotechnology.

Vortexer: A device used to mix small vials of liquid quickly and thoroughly by creating a vortex, commonly used in sample preparation.

Water Bath: Equipment that uses heated water to incubate samples at a constant temperature over a period of time, often used in biological and chemical experiments.

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