

**BioTech Primer Inc.** (BTP) provides non-science professionals with a thorough understanding of the science, technology and terminology that form the foundation of the biotechnology and pharmaceutical industries. BTP products and services include courses, publications and consultancy work.

BTP clients will benefit by:

- achieving greater biotechnology and scientific literacy
- conversing more easily with industry clients, partners, colleagues and scientists
- understanding how different science disciplines and R&D entities interact
- discovering how innovative technologies work scientifically

### **BTP Courses**

Engaging, BTP-credentialed instructors teach individuals from a wide variety of professional backgrounds how new discoveries have driven innovation and application in the biotechnology industry. Clients use the *BTP Biotech Curriculum*, published by BTP, as a guide during the courses. Our limited class size and hands-on labs/activities ensure a dynamic training environment.

Individuals may choose from on-site, off-site or online classes. Companies are encouraged to work with BTP to develop customized content for groups of employees.

### **BTP Publications**

- *The Primer: A Biotechnology Guide for Non-Scientists*. Learn the basics of biotech in this easy-to-read 64-page pocket-sized booklet.
- *BTP Biotech Curriculum*, published as course reference manuals.

### **BTP Consultancy Work**

**2011:** Briefed newly elected California state legislative representatives on the basics of biotech.

**2010:** Rewrote BIO's *Guide to Biotechnology* and updated BIO's *Milestones 2010* report.

**2009:** Developed and updated material for Amgen's biotechnology outreach initiatives, including their online *Science Resource Library* and *Biotech Basics Brochure*

**2008:** Developed and delivered a day-long science program for Genentech's *Take Our Daughters and Sons to Work Day*

**2007:** Briefed the Illinois General Assembly Biotechnology House Committee on biotechnology issues

**2006:** Developed and delivered science presentations at annual company meetings including Ernst & Young, Genentech and Amgen

**2005:** Consulted for the National Museum of Dentistry on their new forensic exhibit, *Your Spitting Image*. This project included exhibit design, exhibit content, teacher/student exhibit worksheets.

**2004:** Wrote the *Basics of Biotech Booklet* for Invitrogen Corp. for distribution at the 2004 National Republican Convention

### **BTP Experience**

Over the last ten years, BTP has built relationships with many of the largest biotechnology companies. Forward-thinking, non-science professionals, whose products or services are tied to the biotechnology industries, recognize the importance of improving their skills and competencies by increasing their knowledge of scientific concepts. BTP builds on its extensive experience to facilitate this learning process.

# Learning Management

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**BioImmersion** is a three-day course for the non-scientist which delivers an understanding of both fundamental and advanced science and technology concepts. Focusing on the healthcare industry, participants learn what biologics are, as well as how they are discovered, developed and used as therapies.

**BioBasics** is a two-day course for the non-scientist which highlights science and technology concepts that are the basis of the biotechnology industry. The course is for participants that require a working knowledge of fundamental terms and applications.

**BioBriefing** is a one-day, fast paced brief overview of the biotechnology industry. Participants learn terminology as well as basic biotech concepts.

**Drug Development Briefing** is a one-day class delivering an overview of the discovery, development, and regulatory processes for bringing a new drug to market. Participants will learn about the business and scientific decisions involved in moving a product forward from basic research into preclinical and clinical trials, as well as a detailed consideration of the regulatory requirements of clinical development. Post-approval commercial considerations and risk management will also be discussed.

**Diagnostics Briefing** is a one-day class exploring the growing role of diagnostics within the biotech industry. Participants will learn about a range of different diagnostic tests and their indications as well as the basic science behind their development, culminating in a detailed overview of the US reimbursement and approval process for diagnostic devices. The course will also include an introduction to concepts specific to the diagnostic sector, including sensitivity, specificity, false positives and false negatives, as well as a discussion of current issues impacting the sector.

**BioRisk** is a two-day course which provides an overview of biotechnology concepts relevant to BioRisk and BioSafety issues encountered within research settings.

**BioFacilities** is a one-day class to further your understanding of the unique real estate and facility requirements of the dynamic and highly regulated biotech and pharmaceutical industries. Advance your knowledge of key performance and specific uses driving the cost of developing and operating these technical facilities.

**Customized Courses** allow companies to select from the above one, two, or three-day courses and/or BTP can develop and deliver a customized, in-house training program based on company content needs and time restrictions.

**BioPrinciples Online** is a highly animated, interactive 8-hour e-learning course that allows users to learn at their own pace. Through the use of a narrator, subtitles, downloadable materials, assessments and more, users learn both basic and advanced biotechnology concepts.

**Webinars** are one hour talks that explore a specific topic. These can be customized for a client.

**The Primer: A Biotechnology Guide for Non-Scientists** is an easy to read 64-page, pocket-sized booklet. Topics include: Industry Overview, Biology Basics, Stem Cells, Genomics, Proteomics, Immunomics, Drug Development.

**BioImmersion** is a three-day course for the non-scientist which delivers an understanding of both fundamental and advanced science and technology concepts. Focusing on the healthcare industry, participants learn what biologics are, as well as how they are discovered, developed and used as therapies.

## Day One

### **Industry Overview** 9:00–10:00

Biotechnology Defined  
Industry Sectors: Healthcare, Agriculture, Industrial,  
Environmental  
Evolution of a Biotech Company  
Structure of a Biotech Company

### **Biology Basics** 10:00–11:00

Biotechnology Goals  
Cell Types  
Cell Structure & Function

### **Break** 11:00–11:15

### **DNA** 11:15–12:30

DNA Structure & Function  
DNA Replication  
Chromosomes & Genes  
Inheritance  
*Lab: DNA Isolation & Extraction*

### **Lunch** 12:30–1:30

### **Genetic Variation** 1:30–2:45

Types of Mutations  
Causes of Mutations  
Genetic Basis of Disease  
Monogenic & Polygenic Pharmacogenomics  
Personalized Medicine  
*Activity: Genetic Variation Taste Test*

### **Break** 2:45–3:00

### **Gene Expression** 3:00–4:15

DNA to Proteins  
RNA  
Transcription & Translation  
Protein Structure & Function  
Measuring Gene Expression  
Microarrays  
RNA Interference

### **Q&A/Review** 4:15–4:30

## Day Two

### **Genomics** 9:00–10:30

Genomics Defined  
Restriction Enzymes  
PCR  
DNA Fingerprinting  
DNA Sequencing  
Microarrays  
*Activity: Microarray to Determine Drug Metabolism*

### **Break** 10:30–10:45

### **Genetic Engineering** 10:45–12:30

Plasmids  
Recombinant DNA  
Genetically Engineered Cells  
Recombinant Proteins (Biologics)  
Transgenic Plants & Animals  
Disease Models  
Gene Therapy

### **Lunch** 12:30–1:30

### **Proteomics** 1:30–3:00

Proteomic Endeavors  
Proteomics Defined  
Chromatography  
Immunodetection  
ELISA  
X-Ray Crystallography  
Microarrays  
*Lab: Chromatography*

### **Break** 3:00–3:15

### **Stem Cells** 3:15–4:15

Properties of Stem Cells  
Types of Stem Cells  
Stem Cells in the Lab  
Promise of Stem Cells  
Challenges

### **Q&A/Review** 4:15–4:30

## Day Three

### **Immune System** 9:00–10:00

- Non-Specific Response
- Specific Response
- Inflammation
- Monoclonal Antibodies

### **Cell Signaling** 10:00–10:30

- How Cells Communicate
- Types of Communication
- Signaling Pathways

### **Break** 10:30–10:45

### **Drug Discovery** 10:45–12:00

- Drug Discovery Timeline
- Target Identification
- Druggable Targets
- Target Validation
- Therapeutic Options
- Assay Development
- Biomarkers
- Hit to Lead

### **Lunch** 12:00–1:00

### **Drug Development** 1:00–2:15

- Regulatory Agencies
- Preclinical Trials
- Pharmacokinetics & Pharmacodynamics
- Clinical Trials
- Orphan Drugs
- Patents & Exclusivity
- Generics & BioSimilar

### **Break** 2:15–2:30

### **BioManufacturing** 2:30–3:45

- Biomanufacturing Overview
- Cell Banks
- Scale-Up
- Harvesting & Purification
- Formulation, Fill & Finish

### **Biotech Today & Tomorrow** 3:45–4:15

- Personalized Medicine
- Future Therapies
- Nanomedicine

### **Q&A/Review** 4:15–4:30

**Contact:** Stacey Franklin, CEO [franklin@biotechprimerinc.com](mailto:franklin@biotechprimerinc.com) tel. 443.798.2385

**BioBasics** is a two-day course for the non-scientist which highlights science and technology concepts that are the basis of the biotechnology industry. The course is for participants that require a working knowledge of fundamental terms and applications.

## Day One

### Industry Overview 9:00–9:30

Biotechnology Defined

Industry Sectors:

Healthcare, Agriculture, Industrial, Environmental  
Academia

### Biology: The Basis of Biotech 9:30–10:30

Biotechnology Goals

Cell Structure & Function

*Lab: DNA Isolation & Extraction*

### Break 10:30–10:45

### DNA 10:45–12:30

DNA Structure & Function

Chromosomes & Genes

*Activity: Genetics Wheel*

Mutations

Genetic Variation

*Activity: Genetic Variation Taste Test*

Genetic Basis of Disease

Personalized Medicine

### Lunch 12:30–1:30

### Gene Expression: Proteins 1:30–2:45

DNA to Proteins

Transcription & Translation

Protein Structure & Function

*Activity: Protein Synthesis Paper Lab*

Proteins in Disease

RNA Interference

### Break 2:45–3:00

### Genetic Engineering 3:00–4:15

Plasmids

Recombinant DNA

Genetically Engineered Cells

Recombinant Proteins (Biologics)

Disease Models

### Q&A/Review 4:15–4:30

## Day Two

### Genomics 9:00–10:00

Genomics Defined

Tools: PCR, DNA Sequencing, Microarrays

*Activity: Determining Drug Metabolism*

### Antibodies: The Key to Biotech 10:00–11:00

Antibodies Defined

Antibody Production

Antibodies as Research Tools

Antibodies as Diagnostics

Antibodies as Therapeutics

### Break 11:00–11:15

### Proteomics 11:15–12:30

Proteomic Defined

Tools: Chromatography, Mass Spec, Protein Microarray

*Lab: Protein Electrophoresis*

### Lunch 12:30–1:30

### Stem Cells & Regenerative Medicine 1:30–2:15

Stem Cell Properties

Promises & Challenges

Organ & Tissue Replacement

### Break 2:15–2:30

### Drug Discovery & Development 2:30–3:30

Target Identification & Validation

Therapeutic Options

Regulatory Agencies

Preclinical & Clinical Trials

### Biosimilars & Biomanufacturing 3:30–4:15

Biosimilars Defined

Generics vs. Biosimilars

Biosimilars Challenges

Biomanufacturing Overview

### Q&A/Review 4:15–4:30

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# BioBriefing™

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**BioBriefing** is a one-day, fast paced brief overview of the biotechnology industry. Participants learn terminology as well as basic biotech concepts.

## **Industry Sectors** 9:00–9:30

Biotechnology Defined

Industry Sectors:

Healthcare, Agriculture, Industrial, Environmental

## **Basic Science Drives Biotech** 9:30–10:45

Biotechnology Goals

The Cell

DNA

*Lab: DNA Isolation*

Genomes

Genetic Variation

*Activity: Genetic Variation of Taste*

Proteins

## **Break** 10:45–11:00

## **Genetic Engineering** 11:00–12:00

Plasmids

Recombinant DNA

Genetically Engineered Cells

Recombinant Proteins (Biologics)

Disease Models

## **Lunch** 12:00–1:00

## **Antibodies: The Key to Biotech** 1:00–2:00

Antibodies Defined

Antibody Production

Antibodies as Research Tools

Antibodies as Diagnostics

Antibodies as Therapeutics

## **Break** 2:00–2:15

## **Drug Discovery & Development** 2:15–3:30

Target Validation

Therapeutic Options

Clinical Trials Quick Overview

## **Biotech In The News** 3:30–4:15

Biosimilars

Personalized Medicine

Companion Diagnostics

Emerging Therapeutics

## **Q&A/Review** 4:15–4:30

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# Drug Development Briefing

**Drug Development Briefing** delivers an overview of the discovery, development, and regulatory processes for bringing a new drug (large and small molecule) to market. Participants learn about the business and scientific decisions involved in moving a product forward from basic research into preclinical and clinical trials, as well as a detailed consideration of the regulatory requirements of clinical development. Post-approval commercial considerations and risk management are also discussed.

## **Drug Development Overview** 9:00–10:00

- Success Metrics & Chances of Success
- Timelines & Costs
- Milestones
- Go/No Go Decisions
- Integrated & Global Development

## **Origin of New Drugs** 10:00–10:50

- Plants, Animals & Laboratories
- Rational Drug Design & Targets
- Combinatorial Chemistry
- Alliances
- Start-Ups

## **Break** 10:50–11:00

## **Selecting Drug Candidates** 11:00–11:45

- Macro Commercial Input
- Market Dynamics
- Chemistry
- Drugability
- Early Toxicology
- Pharmacology
- ADME

## **Target Product Profile** 11:45–12:15

- Draft Label
- Commercial Evaluation
- Exclusivity & Patents
- Waxman Hatch

## **Lunch** 12:15–1:00

## **The Regulatory Process** 1:00–1:45

- History of Regulation
- Initial New Drug Application (IND) & Clinical Trial Application (CTA)
- FDA, European Medicines Evaluation Agency (EMA) & International Conference on Harmonization (ICH)
- New Drug Application (NDA), Marketing Authorization Application (MAA) & Common Technical Document (CTD)
- Clinical Holds
- Quality Assurance
- Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) & Good Clinical Practices (GCP)

## **Drug Development Pre-IND** 1:45–2:30

- Chemistry, Manufacturing & Controls (CMC)
- Characterization, Purity & Stability
- Formulation
- Preclinical

## **Break** 2:30–2:45

## **Clinical Development** 2:45–4:15

- Clinical Trial Considerations
- Design, End Points & Statistics
- Phase 1
- Phase 2a & 2b
- Phase 3a & 3b
- Phase 4
- Safety
- Pharmacogenomics
- Life Cycle Management
- Risk Management Plan

## **Q&A/Review** 4:15–4:30

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# Diagnostics Briefing

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**Diagnostics Briefing** explores the growing role of diagnostics within the healthcare industry. Participants learn about a range of diagnostic tests and their indications, as well as the basic science behind their development. Specific terminology such as sensitivity, specificity, false positives, false negatives and ROC curves are fully explained. The day culminates in a detailed overview of the US reimbursement and approval process for diagnostic devices.

## **Diagnostics Role in Medicine Today** 9:00–10:00

Diagnosis of Disease- Do you have it?  
Following a Disease- What's your prognosis?  
Following a Treatment- Are you cured?  
Carrier- Will you pass it on to your child?

## **Statistical Features of Diagnostics** 10:00–10:50

Sensitivity and Specificity  
Positive and Negative Predictive Values  
ROC Curves  
Current Statistical Approaches to Diagnostics  
Issues with Screening Tests

## **Break** 10:50–11:00

## **Risk of Diagnostic Tests** 11:00–11:30

False Positive and False Negative  
Invasive Procedures

## **Types of Diagnostics** 11:30–12:30

Blood Tests- Biomarkers  
Physiologic Tests- Blood Pressure, EKG  
Anatomic Tests- Xray, CAT Scan, MRI, Nuclear Markers

## **Lunch** 12:30-1:30

## **How Diagnostic Tests Work** 1:30–2:30

Blood or Tissue, Microscope, Stains  
Rapid Multiplexed Analyzers  
Sandwich Immunoassay  
PCR  
SNP Chips, DNA Sequencing Machines

## **Break** 2:30–2:40

## **Diagnostic Development and Approval** 2:40–3:30

Need for "Gold Standard"  
Clinical Tests  
FDA Approval Pathway  
Device Issues  
510-K and PMA  
"Home Brew", CLIA Labs

## **How Diagnostic Tests Are Reimbursed** 3:30-4:00

CMS  
CPT Codes

## **Current Issues** 4:00–4:15

Companion Diagnostics  
IVDMIA  
Consumer Genomics

## **Q&A/Review** 4:15–4:30

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**BioRisk** is a two-day course which provides an overview of biotechnology concepts relevant to BioRisk and BioSafety issues encountered within research settings.

## Day One

### **Industry Overview** 9:00–10:30

Definition of Biotech  
Industry Sector: Healthcare  
Biotech's Driver: Research  
Definitions of Biosafety/Biohazard/Biosecurity  
Research Facilities: Biosafety Levels  
Laboratory Equipment: BSC

### **Break** 10:30–10:45

### **The Players** 10:45–12:00

Research Support Companies  
Contract Research Organizations (CRO)  
Academic Laboratories  
Private & Public Companies  
Regulatory Sectors: FDA, NIH, CDC, EPA, USDA, OSHA  
International Regulatory Agencies

### **Lunch** 12:00–1:00

### **Biology Basics** 1:00–2:00

Biotechnology Goals  
Mammalian, Virus, Prion & Bacteria  
Routes of Exposure & Particle Size  
Personal Protective Expression

### **Break** 2:00–2:15

### **DNA** 2:15–4:15

DNA Structure & Function  
DNA to Proteins  
Protein Structure & Function  
Genetic Mutations  
Genetic Variation  
Genetic Disease  
Personalized Medicine

### **Q&A/Review** 4:15–4:30

## Day Two

### **Genetic Engineering** 9:00–10:00

Plasmids  
Recombinant DNA  
Risk Assessment Requirements  
Genetically Engineered Cells  
Disease Models

### **Break** 10:00–10:15

### **Immune System** 10:15–12:00

Common Pathogens  
Exposure to Foreign Agents  
Risk Group Classifications  
Risk Factors that Influence Exposure  
Preventing Exposure  
Non-Specific Immune Response  
Specific Immune Response  
Vaccines

### **Lunch** 12:00–1:00

### **Stem Cells** 1:00–2:00

Properties of Stem Cells  
Types of Stem Cells  
Cloning & Stem Cells  
Therapeutic Potential

### **Break** 2:00–2:15

### **Drug Development** 2:15–4:00

Preclinical Trials  
Animal Use Issues  
Safety Review Boards  
Clinical Trials  
Generics & Biosimilars  
Getting a Diagnostic to Market

### **Q&A/Review** 4:00–4:30

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# BioFacilities™

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**BioFacilities** is a one-day class to further your understanding of the unique real estate and facility requirements of the dynamic and highly regulated biotech and pharmaceutical industries. Advance your knowledge of key performance and specific uses driving the cost of developing and operating these technical facilities.

## **Facility Types** 9:00–9:45

Beyond Alphabet Soup  
Tenant & Landlord Perspectives  
Purpose-Driven Facilities

## **Site Selection Fundamentals** 9:45–10:15

Process-Driven Infrastructure Requirements  
Workforce Considerations  
Quality of Life  
Cost of Living Implications  
Permitting Environment

## **Break** 10:15–10:30

## **Incentives That Matter** 10:30–11:00

Grants  
Low Cost Financing  
Permit Fee Waivers  
Property & Sales Taxes  
Industry-Specific Exemptions  
Facility Development Process

## **Fundamentals** 11:00–12:00

Performance Criteria  
Regulatory Requirements  
Design & Engineering Criteria  
Comprehensive Development Budgets  
Schedule Considerations

## **Lunch** 12:00–1:00

## **Leasing Fundamentals** 1:00–1:45

Tenant Underwriting  
Term Lengths Matched to Developmental Stage  
Security Deposits  
Tenant Improvement Allowances  
Permitted Uses  
Expansion Rights  
Restoration Clauses

## **Operating and Compliance Issues** 1:45–2:30

Typical Costs  
Strategies to Reduce Operating Costs  
Federal Compliance  
State & Regional Compliance  
Documentation & Record-Keeping

## **Break** 2:30–2:45

## **Cost Elements** 2:45–3:30

Typical Costs  
Strategies to Reduce Operating Costs

## **Case Study** 3:30–4:15

## **Q&A/Review** 4:15–4:30

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