Course Description:

**Biotech for Beginners** is a comprehensive, two-day course meant to provide you with an overview of the development of biopharmaceuticals. The course will start with foundational basics and give a detailed overview of the entire process from discovery to commercialization. As an attendee, you will learn a bit of the science behind biotech products, the clinical research process, regulatory filings, and scale-up for manufacturing. Different types of products such as biologic drugs, biosimilars, personalized medicine, stem cell, and regenerative medicine will be outlined.

This training will progress under the umbrella of the development timeline, from start to finish.

**Learning Objectives:**

Over two days, this interactive course will…

- **Explain** the biotech processes, what they are and how they work
- **Explain** the biotech lab, what it looks like and how it operates
- **Explain** the biotech product development process
- **Examine** how manufacturing facilities are built and operate
- **Examine** the evolution of biotech manufacturing
- **Relate** each step to the previous steps, and provide you with a seamless, consistent overview
- **Provide** you with an overview of basic science, terminology, and common areas of failure in product development
- **Prepare** you to improve in your current role, or be ready to enter the biotech field with some foundational knowledge

**Who Should Attend?**

This course will benefit anyone who is new to the biotech/biopharma industries, needs to know the process at a high-level, or those who need a refresher. There is no level of prerequisite knowledge or understanding necessary to attend. Additionally, this course will be of value to those who support any step within the development process, including outside vendors.

## Course Agenda – Day One:

**Introductions**

**Part 1: Overview of the Biotechnology Industry**

1. Basic Biology
    a. Cellular Biology
    b. Microorganisms (bacteria, virus)
    c. DNA/RNA/Proteins
    d. PCR and Genetic engineering

2. Product Categories
    a. Traditional pharmaceuticals (antibiotics, attenuated vaccines, pharmaceuticals, generics)
    b. Biologics (recombinant proteins, antibodies, and biosimilars)
    c. Antibody-Drug Conjugates
    d. Regenerative medicine advanced therapy (RMAT)
    e. Live virus

3. Pre-Clinical and Clinical Trials
    a. FDA Phases of Product Testing for Commercial Approval
    b. Role of Clinical Research Organizations (CRO)
    c. Description of each phase up to NDA or BLA

4. Biotechnology economics
    a. Market Size
    b. Drug development costs
    c. US and global economy

**Part 2: Biologics**

1. Production and purification of a biologic
    a. Mammalian production process
        i. Expression System (cells, vector)
        ii. Master and Working Cell Banks
        iii. Seed Train
        iv. Production Process (Cell Culture - Batch, Fed-batch, Perfusion)
        v. Purification
        vi. Fill and Finish
    b. Bacterial production process
        i. Expression system

   ii. Production (Fermentation)
c. Drug Conjugates

2. Biotech operations and product development
   a. Discovery Research
   b. Pre-clinical
   c. Development
   d. Manufacturing
   e. Quality
   f. Clinical

3. Regulations
   a. Regulatory Agencies (FDA, EMA, JP)
      i. Risk Based Approach
      ii. ICH
   b. Regulatory document types and activities
      i. IND
      ii. BLA
      iii. Process Validation
      iv. PAI
      v. 483s

4. Manufacturing Facilities
   a. Layout and Design
   b. Equipment and Utilities
   c. cGMP Requirements
   d. Quality Systems

5. Manufacturing Strategy and Challenges
   a. Outsourcing (manufacturing, testing)
   b. Supply Chain
   c. Scale-up or Scale-out?
   d. Process changes / site changes
   e. Capacity planning

**Course Agenda – Day Two:**

**Part 3: Regenerative Medicine Advanced Therapy (RMAT)**

1. Overview of Stem Cells and Immunology
   a. Blood, Hematopoiesis, and Hematopoietic Stem Cells (HSC)
   b. PBMCs, T-cells and B-cells
   c. Non-HSC Stem Cells: Mesenchymal, Embryonic, and Induced Pluripotent stem cells

2. Stem Cell Transplants – HSCs: the original cell therapy
    a. Donor matching
    b. Starting tissue: bone marrow, mobilized stem cells, cord blood

3. Organ Transplants – the practice and the promise
    a. History of solid organ transplants and issues with field
    b. Promise and growing need driving cell and tissue manufacturing

4. Cell Therapy Manufacturing Processes
    a. Overview of general manufacturing operations
    b. Autologous vs allogenic starting tissue
    c. Scale-up vs scale-out
    d. Cryopreservation
    e. Drive towards automation and closed processing

5. RMAT Product Types
    a. CAR T-cells
    b. Tumor Infiltrating Lymphocytes
    c. Other Immune Cells
    d. Mesenchymal Stem Cells
    e. Pluripotent Stem cells
    f. Gene Therapy

**Part 4: The Business of Biotech**

1. Product Development Cycle
    a. Discovery to commercialization (timeline, costs)
    b. Challenges: where and when to manufacture and how much to make

2. Company Strategies
    a. Intellectual Property, Patents, and Trade Secrets
    b. Small Biotech
        i. Spin-outs, Academic starts, and Licensing
        ii. Funding, partnerships, venture capital
        iii. Going to market
        iv. Exit strategies
    c. Big Pharma
        i. Internal Innovation vs external collaboration/acquisition

General Q&A/Wrap-up