# IIT Mandi Proposal for a New Course

**Course number** : **BE308**
**Course Name** : **Introduction to Biomanufacturing**
**Credit Distribution** : ***3-0-2-4***
**Intended for** : B.Tech.-M.Tech. Integrated Dual Degree in Bio-Engineering
**Prerequisite** : IC 136 Understanding Biotechnology and its Applications or Consent of Faculty Member
**Mutual Exclusion** : NA

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## 1. Preamble:

The course is designed to introduce **Principles of Biomanufacturing** including the biological, material and engineering aspects. The course will provide a thorough understanding of biomanufacturing concepts, design, good manufacturing practices and translation for both biologicals and tissue engineered/ 3D printed/ 3D Bio-printed products. The course will also focus on the regulatory and process development aspects of the biomanufacturing process.

**Course Modules with quantitative lecture hours (42 total hours):**

***Module 1: Manufacturing of Biomolecules*** (12 Hours)

Introduction to Biologicals, Biomolecules for industrial application, Stages of biomanufacturing, Case studies, Expression systems, Nutritional strategies/cell culture media, Cell growth, Bioreactor design, operation, and control,

***Module 2: Production, Isolation & Purification*** (12 Hours)

Cell separation: centrifugation and depth filtration, Chromatography, Viral clearance, Ultrafiltration and diafiltration, Bulk filling

***Module 3: Industrial Scaleup*** (12 Hours)

Applicable Regulations and Guidelines, GMP and GDP. Clinical evaluation, Registration or licensing, Quality assessment, Stages of Process Development- early, mid, late, Process characterization, Process validation, Scale-up considerations

***Module 4: Policies & Future Directions in Biomanufacturing*** (6 Hours)

Bench to bedside concept, Development of new stem-cell- based therapies, tissue engineered,

3D-Bioprinted tissues/ organs, Preclinical studies for first-in-human studies, Discovery process in cell and gene therapy/ tissue engineering, First-in-humans studies, Phase 1 first-in-human studies, target product profile (TPP), Human subject ethical issues.

**Laboratory Experiments (28 Hours):**

1. Alginate bead encapsulation
2. Chromatography
3. Ultrafiltration and diafiltration
4. Cell separation

## 2. Text books:

1. **Gilleskie, Gary, Charles Rutter, and Becky McCuen. Biopharmaceutical Manufacturing: Principles, Processes, and Practices. Walter de Gruyter GmbH & Co KG, 2021.**
2. **Atala, Anthony, and Julie Allickson, eds. Translational regenerative medicine. Academic Press, 2014.**
3. **Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; Wiley,2013**

## 3. References:

1. **Online Textbook: https://biomanufacturing.org/curriculum-resources/textbooks-manuals/introduction-to-biomanufacturing**
2. **Related journal article**

## 4. Similarity with the existing courses:
**(Similarity content is declared as per the number of lecture hours on similar topics)**

| S. No. | | Course Code | Similarity Content | Approx. % of Content |
|---|---|---|---|---|
| 1. | Tissue Engineering | BE507 | Development of tissue engineered products | 2% |
| 2. | Enzymology and Bioprocessing | BE 203 | Bioreactor operation | 3% |

**6. Justification of new course proposal if cumulative similarity content is >30%: NA**
**Approvals:**