

Biocon-KGI Certificate Program in Biosciences

Course Details

Course Code ALS 300

Molecular Biotechnology

In this module, students will be exposed to the conceptual foundations of biotechnology and the role played by discoveries and applications of molecular biology principles in advancing biotechnology horizons. This is a case-based course in which students learn about landmark original papers and patents that shaped biotechnology.

Upon completion of this course, students will gain an understanding of the concepts and techniques that are currently being used in the biotechnology and pharmaceutical industry.

Course Code ALS 333

Pharmaceutical Development

The course is designed to provide an understanding of how Pharmaceutical companies discover, develop, and bring drugs and biopharmaceuticals to market. This course will focus on development of traditional and biological drugs. It will cover the process of drug development, taking the drug substance through the process of becoming a drug product, and then into clinical development and commercialization.

Case studies from industry will be presented detailing companies and products that utilize state-of-the-art discovery techniques and advanced drug delivery systems. This is a science course that freely intersperses business and regulatory issues into the lectures and assignments.

Course Code ALS 418

Biopharmaceutical Quality Assurance and Control

Production of biotechnology products requires comprehensive quality standards and systems that meet global cGMP expectations and are based upon thorough scientific knowledge of the product and process. Professionals knowledgeable in the principles and practice of biopharmaceutical quality management are in high demand and hold positions of significant responsibility within the private and public sectors of the healthcare industry.

The primary goal of this course is to provide students with an advanced background in the principles and requirements of biopharmaceutical quality assurance and control. Through a series of lectures and case studies, this course will develop the critical thinking and judgment skills that are needed for the development of quality systems and the resolution of product quality issues.

Course Code ALS 419

CMC Regulations of Pharmaceuticals

Regulatory Chemistry, Manufacturing and Control (CMC) requirements determine the strategy parameters for new pharmaceutical process development and changes post approval. Knowledge of CMC requirements and relevant agencies is a key success factor in pharmaceutical approval and compliance. In particular, globalization has caused a significantly more complex regulatory environment for the manufacture and distribution of pharmaceuticals (and medical devices). Most product supply chains are now multinationals with an increasing trend towards investment in rapidly developing but poorly regulated nations.

The development of regulatory strategies for product development and post approval changes require the understanding of many national regulatory agencies and international harmonization efforts. Often the introduction of product production and distribution improvements is limited by the effectiveness of the Chemistry, Manufacturing and Control (CMC) regulatory strategy employed by the firm.

Effective CMC organizations coordinate with global regulatory agencies to develop risk-based approaches to inspection frequency and focus. Similar risk-based approaches are developed with global regulatory agencies to detect and prevent counterfeiting and product diversion.

Professionals knowledgeable in the principles and practice of regulatory CMC requirements are in high demand and hold positions of significant responsibility within the private and public sectors of the healthcare industry. The primary goal of this course is to provide students with an advanced background in the principles and requirements of regulatory CMC including Post-Approval reporting requirements, Deviation reporting, Inspection coordination and resolution, and Good Distribution Practices (GDP) practices. Through a series of lectures and case studies, this course will teach the critical thinking and judgment skills that are required for the development of CMC regulatory strategies and influence.

Course Code ALS 462

Introduction to US FDA and European Laws and Regulations

This course will provide students with broad general competencies in regulatory affairs for all US FDA regulated product classes (drugs, biologics and devices) throughout the product lifecycle (pre-clinical development, clinical development and post marketing). Emphasis will be placed on regulatory interactions, submissions, other communications and inspections, for each product class and for each phase of the product lifecycle. European regulations will also be reviewed.

Course Code ALS 427A

Fermentation Principles - Module I

Fermentation as a part of the bioprocess industry makes use of the microbial, animal and plant cells, and components of cells such as enzymes to manufacture enormous range of commercial products from relatively cheaper material such as industrial alcohol and organic solvents to expensive specialty chemicals such as antibiotics, therapeutic proteins and vaccines. The advancement and development of

the fermentation process have led to the manufacturing of recombinant DNA derived products such as insulin, human growth hormone and interferon.

The knowledge and skills required to turn these products into commercial reality requires working with various interdisciplinary scientists and engineers to develop the necessary platforms from genetic manipulation and cell line development to scaling up the process to a pilot scale bioreactor and eventually industrial scale operations.

This course will focus on both the fermentation processes and the principles of bioprocessing engineering through a series of lectures, presentations and case studies.

Course Code ALS 427B

Mammalian Cell Biotechnology - Module II

Mammalian cell biotechnology has undergone explosive growth over the last 30 years. Bioscientists skilled in mammalian cell biotechnology are in high demand. The primary goal of this course is to provide students with an advanced background in mammalian cell biotechnology. The scientific, engineering, and practical industrial aspects will be presented through a series of lectures and student presentations.

This course will focus on both the fermentation processes and the principles of bioprocessing engineering through a series of lectures, presentations and case studies. Students should have a background in chemistry, biological science or a related discipline.

Course Code ALS 429

Bioseparation Engineering and Science

Bioprocess engineering, including bioseparations, was and often still is a major skill set of professionals like brewers, winemakers, or in ancient times, wizards or sorcerers. Success in large-scale recombinant protein manufacturing is a recent manifestation of a long and glorious history of the field.

The primary goal of this course is to provide students with an advanced background in bioseparations science and engineering. Graduates in molecular biology, bioengineering, and many other fields can potentially take advantage of opportunities in pharmaceutical biotechnology, biotechnology development, manufacturing, commercial operations, quality assurance, regulatory affairs, business development, licensing, and investment fund management. To access such opportunities quickly and successfully, it is valuable to understand the basic principles of bioprocess engineering and to have an advanced background in a subspecialty or application area, such as fermentation, cell culture, and/or bioseparations. This type of knowledge and experience can be applied to a career in pharmaceutical biotechnology, and to other areas of biotechnology, such as biofuels.

Professional Skills Development

To complement the technical functional skills, the Professional Skills Development course has been integrated in the program curriculum to help students develop their professional skills. This course module includes:

- Campus to Corporate - Introduction
- Report Writing
- Office Etiquette
- Email Etiquette
- Networking
- Presentation Skills
- Communication Skills
- Giving a successful interview

Industry – Academy Interaction

The course will encompass face-to-face interaction with the subject matter experts from Biocon, others in the industry and academia.