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PHAR-IN
Lifelong Learning Programme
Competences for industrial pharmacy practice in biotechnology

- **HOME**
- **ONLINE TRAINING**

Our online training courses consist of;

- **eLearning courses**- which provide an audio/visual lecture, pdf of eLecture notes and reading material , multiple choice assessment questions, and certificate of completion stating the number of CPE/CPD accredited hours achieved. The delegate can contact the author at any time during the presentation to discuss any aspect of the course
- **Our Training Management System** will track all training achievements , of employees in Business management schemes and Individual delegates, so that a log of CPE/CPD credits are kept for submission to Regulatory and Professional Authorities to prove the individuals fitness to practice

Access to Phar-in Courses

Any person clicking on this link can register and have access to any of the free 15 Biopharmaceutical courses:

http://www.pharin.vydiatech.com/advanced_catalogue.html

If you wish to only review the courses then please send your email address to;
john.jolley@pharmaconsultglobal.com

Catalogue of Phar-in Biopharmaceutical Courses

Note; Glossary of terms for all 15 Biopharmaceutical courses is included in the reading for Biopharmaceutical Development ID : PHAR-IN 1

Biopharmaceutical Development ID : PHAR-IN 1

This eLearning lecture will review the evolution of Medicines to the present Types of Biopharmaceuticals and outline the process knowledge and understanding of downstream and upstream processing.

Learning Objectives:

The course will provide the student with an understanding of Biopharmaceutics and how they have been evolved and provide an outline of the manufacturing process

Product and Process Development of Biopharmaceuticals ID : PHAR-IN 2

This eLearning lecture will review the product and process development of a Biopharmaceutical product and consider the Quality by Design criteria necessary to ensure the consistent quality of the product

Learning Objectives

This course will provide the student with a good understanding of the development process for Biopharmaceutical manufacturing Processes

The History and Concepts for Vaccine Formulation ID : PHAR-IN 3

This lecture deals with the History, mode of action and development of the Formulation of the vaccine.

Learning Objectives

This eLearning lectures will provide the student with a good understanding of the history of the use of vaccines, Terminologies and Concepts , vaccine formulation and routes of administration.

Vaccine Manufacture and Testing ID : PHAR-IN 4

Vaccine production techniques are evolving. Cultured mammalian cells are expected to become increasingly important, compared to conventional options such as chicken eggs, due to greater productivity and low incidence of problems with contamination. Recombination technology that produces genetically detoxified vaccine is expected to grow in popularity for the production of bacterial vaccines that use toxoids.

Learning Objectives

This eLecture will review the stages in Vaccine production; First, the antigen itself is generated. Viruses are grown either on primary cells such as chicken eggs (e.g., for influenza) or on continuous cell lines such as cultured human cells (e.g., for hepatitis A).[1] Bacteria are grown in bioreactors (e.g., *Haemophilus influenzae* type b). Likewise, a recombinant protein derived from the viruses or bacteria can be generated in yeast, bacteria, or cell cultures.

Which Can depend on

– "source" of Ag/Ab (traditional or biosynthetic)

– mode of dosing injection or non-sterile

– presence and nature of adjuvants

Drug Delivery of Biopharmaceuticals ID : PHAR-IN 5

This eLearning lecture provides an Introductory course to drug delivery of Biopharmaceuticals and an introduction to the global market opportunities for the latest developments in Biologics .

Learning Objectives

On completion of this course, the student will have understanding of;

- The Industrial perspectives on the commercial importance of Biopharmaceuticals.
- Application of drug delivery systems for parenteral delivery of biologics.
- Beyond parenteral delivery.

Cell Culture – the Basis for Biopharmaceuticals / Biosimilars ID : PHAR-IN 6

Cell culture is the process by which cells are grown under controlled conditions, generally outside of their natural environment. In practice, the term "cell culture" now refers to the culturing of cells derived from multi-cellular eukaryotes, and unicellular prokaryotes.

Learning objectives;

In this course we will review ; .

- The process of Cell Culture
- The risks of Transfection during growth process

- The different Reactor types used and
- The nutritional requirements during cell Banking

Characterisation of Biopharmaceuticals ID : Phar-IN 7

In this presentation we will rewiew the principals of Characterisization and qualification of cell substrates, viral seeds, and other biological materials used for the production of Biopharmaceuticals for human use.

Learning Objectives

On completion of the course the student will have an understanding of;

- The process of Creating the Master and Working Cell banks
- Cell bank characterization

Biotech Manufacturing ID : PHAR-IN 8

This lecture will provide you with the facilities required and the critical nature the manufacturing process necessary for manufacture of Biopharmaceuticals.

Learning Objectives

This lecture will demonstrate that manufacturing processes for Biopharmaceuticals are highly product specific and almost always designed to fit the Bio pharmaceutical molecule, and will provide the delegate with the following skills;

- A specific scientific knowledge of Biopharmaceuticals manufacture
- The techniques used in Biopharmaceutical Manufacture
- The Equipment necessary

Biotech Good Manufacturing Practices ID : PHAR-IN 9

The course provides an introduction to GMP standards required to support manufacturing and inspection activities of biotech manufacturing facilities and drug products.

Learning Objectives:

To introduce the principles of GMPs as they relate to biopharmaceuticals

This lecture will demonstrate that manufacturing processes for Biopharmaceuticals are highly product specific and almost always designed to fit the Bio pharmaceutical molecule, and will provide the delegate with the following skills;

- Regulatory Standards for GMP compliance
- A specific scientific knowledge of Biopharmaceuticals manufacture

- The techniques used in Biopharmaceutical Manufacture
- The Equipment necessary

Aseptic Processing and the Unique Requirements ID : PHAR-IN10

This eLearning lecture provides an overview of the Regulations and Guidelines governing the production of sterile products by aseptic processing and defines the process controls, personal behaviour ,cleaning and validation that need to be in place to assure the sterility of the product

Learning Objectives:

The course will provide an understanding of the Aseptic production process, and the monitoring systems require to mitigate the risks and controls necessary to assure the sterility of the completed product. Delegates completing this eLearning course will have a clear understanding of;

- Regulations and Guidelines
- Aseptic Processing
- Personal Behaviour
- Aseptic process controls
- Cleaning and Process Validation
- Special Consideration for Aseptic Processing

The Unique Requirements for a Biopharmaceutical/Biosimilar Manufacturing Facility ID : PHAR-IN11

This lecture will provide an insight in to the specialized facilities required for the production of Biopharmaceuticals products.

Learning Objectives:

This lecture will detail the Manufacturing facilitates required for the production of Biopharmaceuticals, and will provide;

- An Update on Regulations and Guidelines
- Review of Facility design and control
- Requirement for Cleaning Facility
- Facility Environmental and Utilities Monitoring
- Water Specification Requirements

Stability Testing of Biopharmaceuticals ID : PHAR-IN 12

This eLearning course will outline the requirements for Stability Testing of Biotechnological biological Products biotechnological/biological products and the distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm the stability of Biopharmaceutical products during the intended storage period. Biopharmaceutical products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary.

Learning Objectives:

This course will provide the methods for the evaluation of stability which may necessitate

- Complex analytical methodologies.
- Assays for biological activity, where applicable, should be part of the pivotal stability studies.
- Appropriate physico-chemical, biochemical and immunochemical methods for the analysis of the molecular entity and the quantitative detection of degradation products which should also be part of the stability program whenever purity and molecular characteristics of the product permit use of these methodologies

Specifications for Biopharmaceuticals ID : PHAR-IN 13

Specifications are chosen to confirm the quality all aspects of the process and the product and are not required to represent routine characterization.

Learning Objectives:

This course will provide the competencies necessary for specification setting for Biopharmaceuticals and will detail;

- General Concepts of setting specifications.
- Critical to Establishing Specifications.
- Characterization.
- Common Specification Considerations (Acceptance Criteria)

Analytical Skills and Methods required ID : PHAR-IN 14

This elecure provides information on bioanalytical method validation for analytical procedures such as gas chromatography (GC), high-pressure liquid chromatography (LC), combined GC and LC mass spectrometric (MS) procedures such as LC-MS, LC-MS-MS, GC-MS, and GC-MS-MS performed for the quantitative determination of drugs and/or metabolites in biological matrices such as blood, serum, plasma, or urine.

Learning Objectives:

On completing the course the delegate will have an understanding of

- The Regulatory Overview for Bioanalytical procedures and methods for Biopharmaceuticals;
- Analytical Method Development for; Chemical assay;
    - Selectivity, Specificity
    - Accuracy , precision and Repeatability
    - Linearity, Range , Detection Limits Robustness
    - Principals of Bioanalytical method validation and establishment
- Analytical Method Development for ;Microbiological & Ligand Binding assays; for Selectivity and Quantification Issues
- Application of validated method Acceptance for Acceptance criteria for the batch

Biosafety of Biopharmaceutical Drug Products ID : PHAR-IN 15

This course will Introduce concept of Biosafety in Biopharmaceutical products and will explain the measures taken to provide the assurances that adventitious agents and known microbiological organisms, including viruses, are controlled if accidentally or unintentionally introduced in the manufacturing process, are not likely to be present in Biopharmaceuticals where there is a potential to injury patients.

Learning Objectives:

The delegate will have an understanding of Biosafety assurance measures taken during the Product Manufacture process to illuminate Adventitious agents, accidentally or unintentionally introduced in to the manufacturing process. This course provides a working knowledge of

- Regulatory Guidance.
- Assurance of Biosafety from Manufacturing and filtration processes,
- facility design elements to assure biosafety.