NACPT

NORTH AMERICAN COLLEGE
PHARMACEUTICAL & TECHNOLOGY

POSTGRADUATE DIPLOMA

PHARMACEUTICAL & BIOTECHNOLOGY ADVANCED DIPLOMA

Inquiry: 416-412-7374

Call / Text: 647-998-7374

info@nacptpharmacollege.com

Program Code: PHA.BIO.ADIP

Full-time: 48 weeks

Part-time: 116 weeks

Program Outline

SEMESTER 1

GCCP01 – Good Manufacturing and Good Clinical Practices

- Introduction of Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP)
- GMP Controls

ILTP02 – Introduction to Laboratory Testing & GLP

- Important laboratory techniques
- Exposure to major pharmaceutical instruments
- GLP Guidelines

PMVT01 – Pharmaceutical / Bio-Pharmaceutical Manufacturing Formulation & Validation Technology

- Pharmaceutical and Biotechnology Formulation and Manufacturing Technology
- Drug Formulation
- Manufacturing Technologies

ICS002 – Introduction to Clinical Studies

- Introduction to the concept of Good Clinical Practice in clinical research
- The key elements of the ICH Good Clinical Practices
- Ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects

STW005 – Scientific-Technical Writing

- Different types of technical writing in many areas (QA, QC, R&D, Manufacturing, Pharmaceutical And Biotechnology Formulation And Validation)
- SOPs, Communication Methods And Issues, Validation Reports Writing, Testing Methods, CofAs, CAPA, Change Control, Gap Analysis, OOT, OOS, Deviation
- Dealing with batch records, auditing reports, investigations and real work industrial scenarios.

SEMESTER 2

HPL004 – High-performance Liquid Chromatography (HPLC)

- HPLC fundamentals and functionality
- Sample preparations
- Setting-up system
- Chemstation software
- Testing and analyzing data
- Troubleshooting and investigations

HPD001 – HPLC Method Development & Method Validation

- HPLC/DAD method development and validation for various drug products
- Writing validation protocols
- Testing and writing validation reports
- Troubleshooting and investigations

ETUF05 – Collective Validation

- Equipment Validation &Thermal Validation
- Utility Validation, Computer Validation & Facility Validation

CLVM01 – Cleaning & Sterile Validation

- Current cleaning validation practices
- Writing Protocols, Reports And Master Validation Plans
- Regulatory requirements of Cleaning Validation
- Real Work Industrial Scenarios

IRA001 – Introduction to Regulatory Affairs

- Introduction on Health Canada
- Role of regulatory affairs, regulatory terminologies

PRV03 – Process Validation

- Process Validation Concept
- Rationale, Writing Protocols, Reports and Master Validation Plans
- Real Work Industrial Scenarios

SEMESTER 3

DIS003 – Dissolution & Dissolution Hands-on Training

- Dissolution Techniques & Applications, USP apparatus, Dissolution Testing

- Report Writing, Calibration, Troubleshooting and Maintenance
- Out of Specification Investigation

GCT005 – Gas Chromatography (GC)

- Introduction to Gas Chromatography
- Sample Preparation Techniques, Sample Testing
- Data processing, Analysis, Report Preparation
- GC/FID – IQ / OQ / PQ

GCUV002 – GC Method Development & Method Validation

- Method Development and Method Validation Using the GC / FID
- Major industrial regulations, in terms of developing and validating testing methods
- Performing method development/validation using GC
- Writing validation report

PKV04 – Packaging Validation & Packaging Components

- Packaging validation concept and packaging components
- Writing protocols, reports and master validation plans

PRA004 – Professional Regulatory Affairs

- An understanding of trends in the pharmaceutical industry
- Policymaking and product development
- Regulatory strategies in developing a product
- Post-approval management of the product

For more questions Visit Us at

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