NACPT
PHARMA COLLEGE
O/A NORTH AMERICAN COLLEGE OF PHARMACEUTICAL TECHNOLOGY
www.nacptpharmacollege.com

POSTGRADUATE DIPLOMA

PHARMACEUTICAL & BIO-PHARMACEUTICAL CLINICAL RESEARCH

ADMISSION REQUIREMENTS

Students above or at the age of 18 years.
Graduates with a University degree or equivalent qualification.

Program Code: PHA.BIO.CLINR.PGDIP
Program Duration: 1 Year of Training with Optional Job Assistance program

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Program Outline

SEMESTER 1

ICS01 – Clinical Science

- Anatomy
- Physiology
- Pathology
- Molecular Biology
- Immunology
- Molecular Genetics

ICS002 – Introduction to Clinical Studies (GCP)

- The key elements of the ICH Good Clinical Practices.
- Ethical and scientific quality standards for designing, conducting, recording the graduates will be able to demonstrate a good understanding.
- Ethical principles related to clinical trial.
- Roles and responsibilities of an investigator, a sponsor, a Clinical Research Organization, the Research Ethics Board, and the subjects in a clinical trial.

RGS01 – Regulations and Standards in Clinical Research

- Regulations, guidelines and standards governing the clinical research.

- Review of the historical context that led to the creation of the Health Canada and Food and Drug Administration (U.S.) regulations.
- Current issues and topics in the Canadian regulatory body will also be evaluated and discussed.
- Good understanding of Health Canada, US Food and Drug Administration, and EMEA requirements for conducting clinical trials.
- Completion of a Clinical Trial Application to Health Canada and Investigational New Drug Application to the US FDA.

CRMD01 – Clinical Research in Medical Device

- Clinical trials in the medical device industry.
- Clinical research in the medical device industry.
- Protection of public health and safety with the development of useful devices.
- Understand the roles and responsibilities of an investigator, a sponsor, a Clinical Research Organization, and the Research Ethics Board.
- Subjects in a clinical trial within the medical device industry

EHPC01 – Ethics and Human Protection

- Ethics and human protection in clinical research
- Role of the Research Ethics Board (REB) in safeguarding the rights, safety and wellbeing of all research subjects.
- Compromising of protocol/amendments, Informed Consent Form, Subject Recruitment Procedures, Investigator's Brochure.

- Current issues in ethics and human protection in clinical research.

CQA01 – Quality Assurance

- Introduction of quality assurance.
- Quality management in clinical research and the value of audits.
- Role/responsibility of clinical quality assurance professional in ensuring data integrity of a clinical trial.
- Quality Management System
- Prepare for an audit, conduct an audit, generate audit reports and follow up on corrective actions.

SEMESTER 2

DCTM01 – Development of Clinical Trial Protocols

- Introduction to protocol
- The development of the clinical trial protocol
- Importance of a protocol

PHSA01 – Preparing and Hosting Audits and Inspections

- Preparing and conducting sponsor audits and regulatory inspections.
- Process of preparation for the audit/inspections.
- Introduction to documentation.

DCS01 – Development of SOP

- Development and use of Standard Operating Procedures (SOPs)

- Development of clinical Standard Operating Procedure.
- Thorough knowledge of the SOP life cycle.

EG01 – Clinical Regulatory Affairs I

- Understanding of the trends in the pharmaceutical industry.
- Regulatory strategies in developing a product.
- Post-approval management of the product.
- Completion of the required regulatory documents.

PMCS01 – Project Management I

- Introduce successful planning, scheduling and executing clinical study projects.
- Introduce a high level of leadership skills, and produce productive and quality results for targeted projects.

PVC01 – Privacy

- Introduction to Canadian Regulation PIPEDA “Privacy” in clinical studies.
- Privacy principles, interpretation of the principals, and applications in real work scenarios.
- Canadian Act PIPEDA (personal information protection and electronic documents act) and the 10 principles of PIPEDA.
- 10 principles of Privacy to clinical trials, Interpretation of principles of PIPEDA in clinical trials, Application of PIPEDA principles to everyday clinical trials.

SEMESTER 3

GDPC01 – Good Documentation Practices

- GDP in completing essential documents of clinical trials.
- Importance of GDP in recording, reviewing, verifying and approving documents in clinical trials.

CMT01 – Clinical Trial Monitoring

- Clinical trial monitoring.
- Overseeing the progress of a clinical trial.
- Site identification to performing study closeout visit in a clinical trial site.
- Understanding the basic roles and responsibilities of a sponsor, a monitor, an investigator, and a regulatory agency.

CDMB01 – Clinical Data Management and Biostatistics

- The clinical data management process.
- Biostatistics techniques.

PPP01 – Principles and Practices in Pharmacovigilance

- Principles of Pharmacovigilance
- The guidelines and regulations governing Pharmacovigilance.

REG02 – Clinical Regulatory Affairs II

- Builds upon the clinical regulatory foundation built in REG01.

- Understanding the trends in the pharmaceutical industry with regards to policy making and product development.
- Regulatory strategies in developing a product and post-approval management of the product.

ERCV01 – Electronic Records and Computer Validation

- Computer system requirements for clinical sites.
- Electronic Recording and Computer Validation.
- Importance of data quality.

PMCS02 – Project Management II

- Negotiation method.
- Unplanned negotiation.
- Post negotiation self-assessment.
- Plan and conduct technical and non-technical negotiations.

For more questions
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