NACPT

NORTH AMERICAN COLLEGE
PHARMACEUTICAL & TECHNOLOGY

POST-SECONDARY DIPLOMA

PHARMACEUTICAL QUALITY CONTROL & QUALITY ASSURANCE

Program Code: PHA.QC.QA.DIP

Program Duration: 26 Weeks of Training with Optional Job Assistance program

Inquiry: 416-412-7374

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Program Outline

SEMESTER 1

GCCP01 – Good Manufacturing and Good Clinical Practices

- Concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP).
- GMP controls required to manufacture drug products in Canada, the United States and in many parts of the world.
- Focus on real work industrial scenarios.

ILTP02 – Introduction to Laboratory Testing & GLP

- Compliance with Good Laboratory Practice (GLP) for pharmaceuticals and biopharmaceuticals.
- Address the most important laboratory technique.
- Exposure and experience with all major pharmaceutical instruments.
- GLP guidelines widely used in pharmaceutical and related sectors.
- Understanding of instrumentations, calibration and the application of various instruments.

STW006 – Advanced Scientific-Technical Writing

- Different types of technical writing.
- SOPs, Communication Methods And Issues, Validation Report Writing, Testing Methods, CofAs, CAPA, Change Control, Gap Analysis, OOT, OOS, Deviation.

SEMESTER 2

HPL004 – High Performance Liquid Chromatography (HPLC)

- HPLC/DAD fundamentals and functionality, sample preparations and system setting-up.
- Chemstation software, IQ, OQ and PQ, testing and analyzing data.
- Troubleshooting and investigations.

HPD001 – HPLC Method Development and Method Validation

- Method development and method validation using the HPLC / DAD.
- Major industrial regulations in terms of developing and validating testing methods.

SEMESTER 3

DIS003 – Dissolution and Dissolution Hands-on Training

- Introduction to dissolution current testing practices, testing requirements, critical components, sample prep techniques, media preparation, sample testing, data analysis, report preparation, limitations, IQ / OQ / PQ, calibration, troubleshooting, maintenance.
- Out of specification investigation.
- Dissolution techniques, applications, USP apparatus, dissolution testing, report writing, calibration, troubleshooting.

GCT005 – Gas Chromatography (GC)

- Gas chromatography history, concepts, carrier gas.
- Testing requirements, critical components, sample preparation techniques.
- Sample testing, data analysis, report preparation, limitations.
- GC-FID – IQ / OQ / PQ, calibration, troubleshooting.
- Maintenance, and out-of-specification investigation.

GCUV002 – GC Method Development and Method Validation

- Method development and method validation using the GC / FID.
- Major industrial regulations, in terms of developing and validating testing methods.

For more questions
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