NACPT

NORTH AMERICAN COLLEGE
PHARMACEUTICAL & TECHNOLOGY

POST-SECONDARY DIPLOMA

PHARMACEUTICAL FORMULATION & VALIDATION TECHNOLOGY

Program Code: PHA.FOR.VALTECH.DIP

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

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Program Outline

SEMESTER 1

GCCP01 – Good Manufacturing and Good Clinical Practices

- The program covers 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.

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

- Manufacturing technology, all types of process validation.
- Drug formulation.
- Manufacturing technologies.

STW005 – Scientific-Technical Writing

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

SEMESTER 2

ETUF05 – Collective Validation

- Collective validation & technology regulations
- Equipment validation, Thermal validation, Utility validation, Computer & Facility Validation.

PMF001 – Manufacturing Formulation 1

- Objectives of formulation, pre-formulation techniques, manufacturing formulation techniques, and related regulations.
- Pre-formulation techniques.
- Manufacturing formulation techniques.

PKV04 – Packaging Validation & Packaging Components

- Packaging validation concept and packaging components.
- Writing protocols.
- Reports and master validation plans.
- Regulatory requirements of packaging validation.

PRV03 – Process Validation

- Process Performance Qualification And Continuous Process Improvements
- Process validation concept, rationale, writing protocols, reports, and master validation plans.
- Regulatory requirements of process validation.
- Focus on real work industrial scenarios.

SEMESTER 3

PMF002 – Manufacturing Formulation 2

- Formulation mechanism for liquid, suspension, power, fermentation, filtration, media preparation.
- Process analytical techniques and dosage evaluation.
- Effective usage liquid, suspension, powder, fermentation, filtration, media preparation, and related mechanisms in pharma, biopharmaceutical, and medical device industries.

CLVM02 – Advance Cleaning Validation

- Assessment of complex cleaning validation processes.
- The development process of new equipment/product, worst case selection process.
- Risk-based analysis for a technical overview.

PPRV05 – Advance Process & Packaging Validation

- Complex processes and packaging validation techniques.
- Risk-based analysis, technology transfer, feasibility studies.

For more questions
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