LIFESCIENCES
INDUSTRIAL TECHNICAL TRAINING PROGRAM

NAAN MUDHALVAN PROJECT

COURSE CURRICULUM

Sector: LifeSciences

MAY 8, 2023

PHARMAGENIE COMPLIANCE

CHENNAI

COURSE DETAILS:

Program Code	**NMP-003**
Course Title	**International Regulatory Requirements for Good Manufacturing Practices**
Hours	**40**
Mode	**Hybrid**
Online Training Platform	**Google Meet / MS Teams**
Minimum Batch size	**600**
Eligibility criteria	**Bachelors/Masters in Lifesciences** **Bachelors/Masters in Pharmacy** **Bachelors/Masters in Computer science/IT/Mech/Electrical**

COURSE OBJECTIVE:

- Understanding the concept of good manufacturing practices and its importance in the manufacturing of drug substances, Drug Products, Biologics, Medical devices.
- Gaining advanced knowledge on key activities in the manufacturing process such as sterilization, terminal sterilization, filtration, Gamma radiation for sterile drug products.
- Applying the concepts of industrial good manufacturing practices and Good automated manufacturing practices for producing quality life-saving drugs.
- Understanding the importance of product quality, patient safety, efficacy of the drugs being manufactured in sites.
- Understanding the concepts of Data integrity assurance.

COURSE CONTENT:

Training Modules	Titles	Hours
Module 1	Overview on Product Life cycle Management	2
Module 2	Good Manufacturing Practices and its Regulations	2
Module 3	Functions of pharmaceutical and healthcare industries (Quality, Production, RA, R&D)	2
Module 4	Good Documentation Practices	2
Module 4	Data Integrity Assurance	2
Module 5	Conducting and Facing Self-Inspection and Quality Audits	2

Module 6	Qualification and Validation	2
Module 7	Change Control	2
Module 7	Deviation Management	2
Module 7	Out of specifications	1
Module 7	Root causes and investigations	2
Module 7	CAPA & QRM	2
Module 8	Complaint Handling & Product Recall	1
Module 9	GMP requirements in Medical Devices	1
Module 9	GMP Requirements in Pharmaceutical Drug substances and products	3
Module 10	GMP for Biologics products	3
Module 10	GMP Guidance for Injectables products	3
Module 11	21 CFR Part 210, 211 and EU GMP Comparison and importance	3
Module 11	GMP for Combination drugs	3
	TOTAL HOURS	**40**

COURSE OUTCOMES:

Students will be able to:

- Understand the concepts of good manufacturing practices from USFDA, EU, WHO on drug quality requirements in the pharmaceutical, biologics and medical devices industries.
- Importance of product quality and risk associated in the drug manufacturing.
- Importance of patient safety and risk to non-compliance.
- Ability to thinking critically on the importance quality.
- Building next generation professionals with good recent and advanced technology with Quality mindset and Quality culture.
- Immediate job opportunities in pharmaceutical, Biopharmaceutical and medical devices industries.

ONLINE REFERENCES:

https://www.who.int/news-room/questions-and-answers/item/medicines-good-manufacturing-processes

https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice

SOFTWARE REQUIREMENT:

NA

HARDWARE REQUIREMENT:

NA

INDUSTRY SCOPE:

On Completion of this course, participants get an opportunity to work in the pharmaceutical, biologics, medical devices related industries in the Quality, Production, Warehouse departments as a Trainee or Junior Executive or Quality Analyst, Warehouse In charge, Production Chemist etc.,

INDUSTRY USE CASES

- Assist in document preparation
- Assist in SOP, Specification preparation
- Support for Seniors in preparation of protocol and execution
- Review of all GxP documents
- Provide support for site related training related activities
- Assist in production and warehouse activities
- Support and execute batch manufacturing activities
- Good documentation practices for all critical operations etc.,
- Incoming material management
- Manufacturing accessories issuance and controls