STERILE MANUFACTURING SYSTEMS COURSE

YOUR PARTNER IN GROWTH

Who Should Attend?

THIS INTENSIVE COURSE IS INTENDED FOR THOSE NEW TO THE TOPICS OF PARENTERAL PRODUCT DEVELOPMENT AND ASEPTIC MANUFACTURING AND THOSE NEEDING A REFRESHER ON THE TOPICS AS WELL AS THOSE SEEKING CONFIRMATION OF ACCEPTABILITY OF EXISTING PRACTICES. IT WILL BE OF PARTICULAR VALUE TO THOSE IN:

- Manufacturing/Production
- Research & Development
- Quality Assurance and Control

LEARNING OBJECTIVES

UPON COMPLETION OF THIS COURSE, YOU WILL BE ABLE TO:

LIST THE REGULATORY CHALLENGES THAT MUST BE CONSIDERED AT S.D.F. FACILITY

IDENTIFY THE BASIC CONCEPTS APPLYING TO PROCESSING OF SOLID DOSAGE FORMS

DESIGN, MODIFY AND CONTROL A PROCESS TO PRODUCE PRODUCTS THAT HAVE THE DESIRED PROPERTIES

SELECT TESTS TO ENSURE T HE PERFORMANCE OF THE PROCESS

COURSE TOPICS

IINFRASTRUCTURE:

A. FACILITIES, UTILITIES &EQUIPMENT
B. ENVIRONMENTAL MONITORING

NONSTERILE MANUFACTURING SYSTEMS

A. STERILE FORMULATION
B. PROCESSES & EQUIPMENT
C. STERILIZATION PRINCIPLES
D. IN-PROCESS CONTROL

FILLING, PACKAGING, LABELING

A. FILLING OPERATIONS AND CONTROL
B. PARENTERAL INSPECTIONPA
C. MEDIA FILL

Course Objectives

UBON COMPLETION OF THIS COURSE YOU WILL BEABLE TO :

DEFINE THE UNIQUE CHARACTERISTICS OF STERILE DOSAGE FORMS, HOW THESE CHARACTERISTICS ARE ACHIEVED AND MAINTAINED

EXAMINE APPROACHES TO FORMULATION AND PROCESS DEVELOPMENT FOR PARENTERAL PRODUCTS

DESCRIBE THE ASEPTIC MANUFACTURING PROCESSES AND ALL UNIT OPERATIONS INVOLVED IN STERILE PRODUCT MANUFACTURING AND CONTROL, INCLUDING STERILIZATION, FILTRATION

OUTLINE THE FACILITY, PERSONNEL, AND MICROBIAL CONTROL REQUIREMENTS,

DEFINE THE FACTORS AFFECTING ASEPTIC TECHNIQUE

COURSE DURATION : 12 HRS (4 WEEK DAYS)