Who Should Attend
This overview course is intended for those having specific responsibilities in the areas of sterile drug product science and technology. It will be of particular value to those in:
- Research and Development
- Production
- Quality Assurance and Quality Control

Those who wish to broaden their appreciation of these technologies and review the latest developments, as well as managers who have responsibility for a broader base of activities will find the course of interest.

Learning Objectives
Upon completion of this course, you will have an appreciation of current parenteral systems and some insight into parenteral systems of the future. You will also be able to:
- Define the unique characteristics of sterile dosage forms, how these characteristics are achieved and maintained
- Recognize the significant developments and special procedures important in the use of these products
- Identify the current and advanced formulation approaches, parenteral packaging systems, special stability requirements and manufacturing processes and controls used to obtain a quality sterile product
- Describe the aseptic manufacturing processes and all unit operations involved in sterile product manufacturing and control, including sterilization, filtration and lyophilization
- Outline the facility, personnel, and microbial control requirements, fostering an appreciation of the distinctive requirements of sterile products and acquaintance with quality control procedures and international regulations
- List the trends in cGMP compliance as applied to sterile product manufacturing and control

Course Description
This comprehensive course provides an appreciation and general understanding of the overall contemporary state of science and technology of the design, development and manufacturing of sterile drug dosage forms. Emphasis will be oriented toward formulation development and product manufacture of quality sterile dosage forms that meet or exceed expected good manufacturing practice requirements.

Course Director
Dr. Gregory A. Sacha, is a Senior Research Scientist for Baxter BioPharma Solutions in Bloomington, IN. He received a BS in Pharmacy from Butler University in 1993 and earned a PhD in Industrial and Physical Pharmacy from Purdue University in 1999. Dr. Sacha specializes in the formulation of sterile solutions and lyophilized solids for large and small molecules. His research includes thermal characterization of pharmaceutical solutions, development and optimization of lyophilization cycles, and identification of particles through microscopic and spectroscopic methods. Dr. Sacha is experienced in technology transfer, scale-up and process improvement for solid oral and parenteral manufacturing processes and has presented lectures for this course since 2005 in Europe and the United States.

Recommended Reading
FIRST DAY
8:30-9:00
Registration
9:00-17:30

Learning Objectives/Overview of Sterile Dosage Form: Definitions, types and classification of sterile products, historical review, advantages and disadvantages, basic characteristics and requirements, routes of administration, needles, hazards of parenteral administration.

Formulation of Solutions: Principles of designing stable sterile solutions, formulation approaches to overcome problems with drug solubility and stability. Solvent systems and additives (solubilizers, stabilizers, preservatives, competitive binders, and tonicity adjusters) used in small molecule and biopharmaceutical sterile dosage forms.

Preparation for Sterile Manufacturing: Application of GMP regulations to sterile manufacturing, facility and personnel requirements, air systems, room classification, equipment and packaging preparation, overview of complete process.

Formulation of Dispersed Systems: Design, development and manufacture of micro-and nanosuspensions. Also basic formulation of emulsions and liposomes.

Formulation of Lyophilized Products: Steps in the development of freeze-dried formulations, packaging and processes with focus on proteins. Freezing effects on stability, critical temperature determination, molecular mobility, product collapse. Thorough coverage of additives with focus on stabilizers and their mechanisms. Introduction of the interplay between formulation and cycle development. New delivery systems for lyophilized products.

TUITION AND PAYMENT

Early registration:
(received before February 27th, 2015) - Euro 1500+VAT/1350+VAT (group discount*)

Regular registration:
(received after February 27th, 2015) - Euro 1700+VAT/1530+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)

*Group discount is for two or more enrolments from the same company.

Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

SECOND DAY
8:30-17:30

Sterile Manufacturing Unit Operations: Water for injection, compounding and mixing, filtration, filling, stoppering, sealing, and finishing, isolator technology. What can go wrong during manufacturing and how to overcome.

Processing of Lyophilized Products: Description of equipment, cooling and drying phases, process optimization. Temperature, pressure, formulation and packaging effects on process and final product quality. Discussion of scale-up, technology transfer, and process validation.

Sterility Assurance: Basics of microbiology, components of contamination control, cleaning and sanitization, depyrogenation, stabilization, aseptic processing, environmental monitoring. Aseptic process validation with emphasis of FDA guidelines for aseptic processing and coverage of EU GMP guidelines for manufacture of sterile medicinal agents.

QC Testing-Sterility, Endotoxin, and Stability: Basic principles and methods in sterility testing, pyrogen testing, endotoxin testing and GMP stability testing. Review of major degradation mechanisms for injectable drugs, and FDA/EU stability requirements for NDA and ANDA submissions.

Visual Inspection and Particulate Matter: Methods involved in human and mechanical inspections for visible particles (and other product defects), requirements and systems for subvisible particulate matter evaluation. Current issues with visual inspection practices and acceptance criteria especially for biological products.

Parenteral Product Packaging: Discussion of packaging options for different formulations. Explore the effects of formulation and packaging materials on the stability of the product.

Assessment Opportunity

General information
Cancellations received after April 7, 2015 will be invoiced completely. All cancellations will be subject to euro 250 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:
Office: +34 93 4487156
Cell: +34 691676055
Fax: +34 93 4037109
e-mail: info@sitec-pharmabio.com