



Baldiri Reixac 10; 08028 Barcelona Spain

# Sterile Products Development and Manufacturing

14 - 15 OCTOBER 2019

## Course topics include:

- Principles of designing stable sterile formulation
- Formulations of Proteins, Antibodies, Antibody-Drug Conjugates
- Dispersed systems
- Lyophilized Products
- Sterile manufacturing and quality control
- Packaging
- cGMP trends
- Auditing and inspection

With optional half-day short course on  
**cGMP Updates in Sterile Products:  
Auditing, Inspection and Trends**

16 OCTOBER 2019

## Course description

The **2 days course** introduces to sterile products development, manufacturing, and quality assurance. The first day focuses on formulation and process development of solutions, dispersed systems, and freeze-dried products, with emphasis on development of biomolecules, supported by specific case studies. Parenteral manufacturing operations, quality control testing, and packaging are thoroughly discussed in the second day. The **optional, half-day short course** discusses the most recent trends on cGMP regulations, quality auditing, and considerations for responses to Agencies observations.

## Who should attend

The course is intended for people specifically interested or involved in parenteral products development, manufacturing, QA and QC. Details are provided to aid attendees in applying the information, and becoming aware of the key aspects to address during sterile products development and manufacturing. Attendees may include project managers, technical services and operations, quality assurance, product development.

## Learning objectives

- Understand types of sterile products and their different requirements.
- Become aware of current and future topics affecting sterile product development and manufacturing.
- Understand how excipients are used to stabilize small and large molecules formulations.
- Learn differences in formulation components and processing for solutions, dispersed systems and lyophilized formulations.
- Learn the fundamentals for aseptic manufacturing in a cGMP environment and become familiar with unit operations required for different products.
- Consider analytical tests needed for quality control of sterile products.
- Understand the importance of packaging materials for the stability of formulated products and for ease of manufacturing.
- Evaluate current trends in cGMP inspections and discuss how they are related to regulations.
- Consider approaches to auditing in a cGMP environment and how to respond to questions.

## Course directors

**Dr. Gregory A. Sacha**, Senior Research Scientist for Baxter BioPharma Solutions. B.S. in Pharmacy from Butler University, and a PhD in Industrial and Physical Pharmacy from Purdue University, Dr. Sacha specializes in 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 in these subjects since 2005 in Europe and USA.

**Margo J. Sacha**, Senior Manager Quality Assurance for Catalent Biologics. She has a B.S. in Chemistry from Indiana University, and holds a Certificate in Quality and Regulatory Sciences from Purdue University. Margo has over 20 years of experience in the Quality sectors of pharma industry. She focuses on auditing drug product manufacturers, specializing in the areas of data integrity, quality management systems, laboratories, and computer systems lifecycle management. She facilitated and responded to many regulatory and inspectorate bodies worldwide.

8:30-09:00

**Registration**

09:00 -17:30

**Introduction**

- Historical review of injectable products and events that influenced manufacturing types of sterile products with hands-on examples.
- Considerations for routes of administration.
- Hot topics.

**Formulation Development for Small and Large Molecules**

- Principles of designing stable sterile solutions. Formulation approaches used to overcome problems with drug solubility and stability
- Coverage of solvent systems and additives (solubilizers, stabilizers, preservatives, competitive binders, and tonicity adjusters) used in small molecule and in biopharmaceutical sterile dosage forms
- Special focus on biopharmaceutical formulation development of Proteins, Monoclonal Antibodies, Antibody-Drug Conjugates.

**Formulation of Dispersed Systems**

- Design, development and manufacturing of macro-suspensions (including Antibodies, ADC's and Vaccines) , micro-and nanosuspensions. Also formulation of emulsions and liposomes.

**Formulation of Lyophilized Products**

- In depth evaluation of data needed to support formulation development for a lyophilized product.
- Excipients used in the formulations and their purpose.
- Thermal characterization and identification of the failure point.
- Considerations for evaluation of the finished product.
- Data needed to support a successful Technical Transfer.

**Process Development for Lyophilized Products**

- Fundamentals of freeze drying , design and operation of equipment.
- Evaluation of in-process data in the laboratory and at full-scale: methods of data collection, data needed to support Technology Transfer and routine manufacturing.

8:30-17:30

**Preparation for Sterile Manufacturing**

Application of cGMP regulations to sterile manufacturing, facility and personnel requirements, air systems, room classification, equipment and packaging preparation, overview of complete process.

**Sterile Manufacturing Unit Operations**

- Basics of microbiology, components of contamination control, cleaning and sanitization, depyrogenation, sterilization, 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.

**Quality Control Testings**

Basic principles and methods in sterility testing, pyrogen testing, specific testing methods for lyophilized products, visual inspection and particulate matter, and methods of automated inspection.

**Parenteral Products Packaging**

- Discussion of packaging options for different sterile formulations.
- Explore the effects of formulation and packaging materials on product stability.

**cGMP updates: Auditing, Inspection and Trends**

The half-day course consists of two sections: one lecture evaluates trends in observations and the regulations that support them. The second lecture provides an overview of conducting cGMP audits, how to relate observations directly to regulations, and considerations for responses.

8:30-12:45

**GMP Updates and Recent Trends**

- What is new in the EMA, FDA, ISO 13485, Mexico, and other regulatory environments.
- Recent findings and how they apply to the industry

**Auditing in a GMP Environment**

- Practical approach to auditing based on following regulations.
- Auditing of manufacturers and third party suppliers.

**Group Discussion and wrap-up**

**2-days Course (14 - 15 October)**

**Regular registration** - Euro 1850+VAT/1650+VAT (group discount\*\*)

**Optional half-day Short Course (16 October):** Euro 400+VAT

\*\*Group discount is for two or more enrollments from the same company registered at the same time.

**Fees include course materials, lunches and coffee breaks.**

**Participants are responsible for their own hotel reservations.**

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

Name ..... Surname .....

Position..... Organization .....

VAT .....

Adress .....

Postal code ..... City .....

Country .....

Phone .....

Participant e-mail .....

Billing e-mail .....

PLEASE RETURN BY E-MAIL

**Course Location**



**General information**

Cancellations received after September 23 , 2019 will be invoiced completely. All cancellations will be subject to euro 300 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates of attendance will be issued to participants upon completion of the course.

**For Information please contact us at:**

**Office: +34 93 4487156**

**Cell: +34 691676055**

**e-mail: info@sitec-pharmabio.com**