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The Department of Process Engineering and Far Sight Skills Development

present a Short Course on—

Aseptic Processing in the Manufacture of Biotech & Pharmaceutical Products

2 CPD points ECSA accredited
Course language: English

Date: **9 – 10 September 2019**
Time: **08h00 — 17h00**

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REGISTRATION COSTS:

Participant	*Early bird registration prior to : 19 August 2019*	*Registration after: 19 August 2019*
Industry	R5 600 per person	R6 100 per person
Academia ***(full - time students only)***	R1 800 per person	R2 100 per person

METHOD OF PAYMENT:

An invoice will be issued upon receipt of the Registration Form. Payment to be made upon invoice only. PLEASE FAX / E-MAIL PROOF OF PAYMENT to Anita Kleinschmidt. For invoice purposes, please be sure to include the company's VAT No. and Registration No.

REGISTRATION:

To register for this course, please use the following link on the University's Short Course Website. Click APPLY in the middle of the page and follow the link: **https://shortcourses.sun.ac.za/application-form.html?offeringid=b1102130-6280-e911-9b88-0050568000ff**

VENUE:

Room 229 / 230 - Annex
Dept of Process Engineering
Faculty of Engineering
University of Stellenbosch
Banghoek Street
Stellenbosch

COURSE FEES INCLUDE:

- Tea / Coffee / Refreshments
- Light Lunches
- Full set of course notes & solutions to in-class problems
- **Bring your own notebook, pen & hand calculator**

FOR MORE INFORMATION REGARDING THE COURSE CONTACT:

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Dept Process Engineering
University of Stellenbosch
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or

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Cancellation Policy: Registrants will be responsible for the full course fee prior to the course commences. Should cancellation be made during the last 7 days before the course, registrants will be responsible for the full course fee. Cancellations 7-14 days before the course will be subject to a 50% cancellation fee. Substitutes are accepted. Organisers withhold the right to cancel the course should the minimum number of delegates not be reached by **19 August 2019**. In this event, registrants will either be refunded in full or can elect to attend a course during the next round of presentation.

I/we hereby acknowledge to have read and understood the terms and conditions of registration.

Signed …… Date ……

LEARNING OBJECTIVES:

During and upon completion of this course, you will—

- Understand the importance of sanitary design principles in aseptic processing
- Approach cleaning validation as a quantitative science
- Know how to properly sterilize equipment in preparation for processing
- Learn the difference between aseptic processing and terminal sterilization
- Appreciate what is expected in the operation of an aseptic filling operation
- Understand the technical fundamentals behind filter sterilization
- Begin to apply risk management strategies to aseptic operations
- Be in a better position to manage the use of clean rooms and isolators
- Know more about chemical and ra1diation sterilization
- Learn the concept of validation as defined and interpreted by compliance bodies
- Understand the broader requirements of Good Manufacturing Practice
- Solve a variety of practical problems related to aseptic processing operations
- Receive practical tips on how to troubleshoot your aseptic operations
- Learn how to use the case study approach to solve contamination problems

COURSE DESCRIPTION: This course presents the technical fundamentals that govern aseptic processing operations and provides sufficient practical advice for attendees to effectively troubleshoot and manage their own operations. Following an introduction to sanitary principles of engineering and quantitative microbiology, this short course reviews steam, heat, chemical and radiation sterilization of objects, devices and products, filter sterilization of liquids and gases, aseptic fill and finish operations and validation as they are applied in the fermentation, biotech and pharmaceutical industries. These diverse processing methods and strategies are presented with technical explanations of how and why these methods work. Case studies are used to illustrate practical applications. The course is not about regulatory compliance but does address sterile practice in the context of Good Manufacturing Practice guidelines where appropriate. The course includes in-class problems and solutions to help participants apply what they have learned.

SHORT COURSE AGENDA: DAY ONE

Introduction and Course Overview

· Spectrum of products that require aseptic processing
· Quantitative industrial microbiology
· Sterility Assurance Limit—defined and quantified

Sanitary Design Principles

· The importance of sanitary design in aseptic processing
· Principles of sanitary design and special components
· Process goals and objectives for CIP (clean-in-place) systems

Preparing and Operating Aseptic Process Equipment

· The mechanics of steam sterilization (batch and continuous)
· Defining the sterilization protocol
· Monitoring operations to ensure sterility

Terminal Sterilization of Solids, Liquids and Gases

· Sterile filtration for liquids and filter integrity testing
· Sterile filtration for gases
· Batch autoclaving and cycle development strategies

SHORT COURSE AGENDA: DAY TWO

Other Sterilization and Aseptic Processing Techniques

· Sterilization using dry heat and radiation; cycle development methods
· Chemical sterilization (e.g., ethylene oxide, hydrogen peroxide, ozone); developing cycles
· Virus particles and viral clearance methods

Packaging Aseptically Processed Materials

· General facility requirements and environmental monitoring
· Clean rooms – theory, construction and operation
· Defining and managing the critical zone
· Technical specifications, compliance and risk
· People as a part of aseptic packaging operations

Validation of Aseptic Processing Operations

· Validation and Good Manufacturing Practice -- definitions
· Validation examples - cleaning, viral clearance, stability and sterility testing, container/closure integrity
· Design and conduct of sterile media fills

Managing and Troubleshooting Aseptic Processing Operations

· The importance of preventative audits and maintenance
· The troubleshooting mindset and approach to risk management
· Using the case study approach to maximum advantage

WHO SHOULD ATTEND: This is a two-day course for people who need to understand the technical fundamentals of aseptic processing or who are responsible for aseptic operations in a lab, pilot or commercial setting. The course is ideally suited to students and professionals in industrial microbiology, biotechnology and engineering with either technical or managerial responsibilities in the biotechnology and pharmaceutical industries. Senior management and regulatory affairs specialists will particularly benefit from the sessions devoted to validation, risk management and troubleshooting.

SHORT COURSE DIRECTOR: Dale Gyure, PhD, Chemical Engineering, has over thirty years of experience in the chemical and bioprocess industries with heavy emphasis on the development of chemical, biochemical and bioprocess technology and the commercialization and manufacture of related products. He has been teaching and presenting public courses in chemical engineering technology, aseptic processing and regulatory compliance for the last fifteen years. Dale is currently Business Transformation Specialist for Far Sight Skills Development following on from eight years at National Bioproducts Institute (NBI) in Durban, South Africa where he was responsible for producing parenteral blood plasma-derived therapeutic biologics. Prior to NBI Dale served as Bioprocessing Portfolio Manager for LIFElab (now the Technology Innovation Agency). Dale is appointed as an Extraordinary Professor at the University of Stellenbosch.