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The Department of Process Engineering and Far Sight Skills Development present

present a Short Course on—

Aseptic Processing in the Manufacture of Biotech & Pharmaceutical Products

2 CPD points ECSA accredited

Course language: English

The new on-line format for this short course will be open for viewing between 2 – 6 August 2021

ENGINEERING
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COURSE OFFERING:

The six sessions listed in the COURSE DESCRIPTION below are presented using approximately 12 hours of video lectures combined with summary slides. Participants will have access to web-based video lectures between ***2 – 6 August 2021,*** which can be viewed independently in your own space and time. However it is essential that at least **2 full days are booked out** for working through the course material. Electronic copies of the course notes will be provided on the ***2nd of August*** and a hard copy will be couriered together with your attendance certificate. The course includes three one-hour on-line discussions with the presenter using a virtual meeting room. Exact times for the discussions will be set in consultation with the course participants.
A Certificate of Attendance, with 2 ECSA accredited CPD Points, will be issued by the Stellenbosch University to participants, after completion of the course.

REGISTRATION COSTS:

Participant	*Early bird registration prior to 16 JULY 2021*	*Registration after 16 JULY 2021*
Industry	R6 100 per person	R6 600 per person
Academia ***(full-time students only)***	R2 100 per person	R2 400 per person

METHOD OF PAYMENT:

An invoice will be issued upon receipt of the online Registration Form. Payment to be made upon invoice only. PLEASE E-MAIL PROOF OF PAYMENT to Anita Kleinschmidt **(anitak@sun.ac.za).** For invoice purposes, please be sure to include the company's VAT No. and Registration No.

COURSE 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 links.
https://shortcourses.sun.ac.za/application-form.html?scourseid=1868

FOR MORE INFORMATION CONTACT:

Johann Görgens	Dale C. Gyure
Department of Process Engineering Stellenbosch University Email: jgorgens@sun.ac.za Phone: 021 808 3503 / 082 448 4648	Far Sight Skills Development Email: dalegyure@gmail.com Phone: 072 986 7719

CANCELLATION POLICY:

- If you want to cancel your short course attendance, you must do so in writing at least seven days before the start of the course. Your course fees will be repaid to you minus a 5% administration fee.
- If you cancel your attendance less than seven days before the start of the course, a cancellation fee of 15% will be deducted from your course fees to pay for the costs that the University has incurred in preparation for your attendance.
- If you cancel your attendance less than 24 hours before the start of the course, you will remain liable for 90% of your course fees.
- The abovementioned deductions will also apply if your employer or another company or institution paid for your fees.
- There may be instances where the University decides that your circumstances made it impossible for you to attend and will waive the deductions. This will be entirely the University's decision and you may be required to provide supporting documentation.

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 continu
· 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

Virtual Meeting Room Discussion #1 – to be scheduled at the start of the course.

Virtual Meeting Room Discussion #2 – to be scheduled approximately mid-way through the course.

Virtual Meeting Room Discussion #3 – to be scheduled after the close of the video lecture viewing period.

SHORT COURSE INSTRUCTOR:

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 and lectures at Cape Pennisula University of Technology.

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.