UNIVERSITEIT iYUNIVESITHI STELLENBOSCH UNIVERSITY

100
1918 · 2018

The Department of Process Engineering and Far Sight Skills Development present

Good Manufacturing Practice for Food Biotech & Pharmaceutical Products

2 CPD points ECSA accredited
NQF level: 7
Course language: English

The new on-line format for this short course will be open for viewing between 01 –11 September 2020

ENGINEERING
EZOBUNJINELI
INGENIEURSWESE

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 ***01 and 11 September 2020,*** which they can view independently in their own space and time. Electronic copies of the course notes will be provided on *01 September 2020.* The course includes two 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.

PREVIEW THE COURSE:

A 12-minute preview trailer of the course is available for viewing at: **www.farsightcoaching.co.za**. From the main menu select the "Development" tab and then select "Professional Development". Scroll down to the course "GMP for Food, Biotech and Pharmaceutical Products" and click on the button to watch the preview. Be sure to watch the preview for the two-day course and not "Introduction to GMP". This brochure is also downloadable from that same page.

REGISTRATION COSTS:

Participant	*Early bird registration PRIOR to 18 AUGUST 2020*	*Registration after 18 AUGUST 2020*
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/applicationform.html?offeringid=49534533-f190-ea11-9d0d-0050568000ff

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:

Upon completion of this course, you will/can:

- Implement Good Manufacturing Practice in a manufacturing environment.
- Develop a practical compliance strategy for your Department.
- Institute changes in your organization that will improve GMP compliance.
- Audit your own manufacturing organization.
- Know how to validate a manufacturing process or unit operation.
- Challenge the proper installation and commissioning of new equipment.
- See Good Manufacturing Practice as part of a total quality control system.
- Appreciate the challenges faced by regulatory agencies themselves.
- Have sufficient knowledge to train others in GMP compliance.
- Cite examples of compliance in a manufacturing environment.

COURSE DESCRIPTION:

Manufacturers of foods, pharmaceuticals. vaccines and biologics follow Good Manufacturing Practice (GMP) guidelines so that products can be sold into regulated markets. The goal of this course is to train technical professionals and manufacturing managers in the practical implementation of Good Manufacturing Practice so they know how to comply with standards set by PICs and other regulatory bodies. The course teaches ten overarching principles of Good Manufacturing Practice using lectures, specific examples and recent case studies that illustrate how GMP works in practice. The course is unique because it avoids tedious recitation of the written regulations as a means of presenting and illustrating the GMP guidelines.

A formal competency exam for use by companies sponsoring delegates is available from Far Sight Skills Development on request and for an extra cost after delegates have completed the course.

SHORT COURSE AGENDA: DAY ONE

1.0 Contextual Background

Introductory Remarks
Origins of Good Manufacturing Practice
Important GMP Fundamentals
Regulatory Agencies – General Comments
The Role of the Pharmacist in GMP
Recap and Summary

2.0 Principles of Good Manufacturing Practice

Written Procedures with examples
Following Written Procedures with examples
Documenting for Traceability with examples

3.0 Principles of Good Manufacturing Practice

Designing facilities and equipment with examples
Maintaining facilities and equipment with examples
Job Competence with examples

SHORT COURSE AGENDA: DAY TWO

4.0 Principles of Good Manufacturing Practice

- Cleanliness (with examples)
- Validating Work (with examples)
- Recap and Summary

5.0 Principles of Good Manufacturing Practice

- Process Control
  - Process Control (Incoming Materials)
  - Process Control (In-Process Steps)
  - Process Control (Finished Material)
- Auditing for Compliance

6.0 Special Topics and More Examples / Case Studies

- Food vs. Pharma GMPs
- Adulteration and Compliance
- Preparing for Agency Inspections
- HACCP vs. GMP
- Botanical products and GAP
- Cold Chain Management (case study)
- More on biological products
- Aseptic Processing Topics

Virtual Meeting Room Discussion #1 – to be scheduled approximately mid-way through the course.

Virtual Meeting Room Discussion #2 – 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 technical professionals and manufacturing managers with prior exposure to Good Manufacturing Practice but who need help with implementing GMP in an actual manufacturing environment. Ideally, delegates will be involved in product development and manufacturing in the pharmaceutical and allied industries. Although Good Manufacturing Practice is not a technically intensive topic, a background in process science, engineering or the life sciences will help delegates appreciate the examples and case studies included in the course. People in the following industries have been helped by this course – food and food ingredient processing and packaging, dietary supplement production, manufacture of active pharmaceutical ingredients (APIs), solid dosage forms, small and large volume parenterals, vaccines, biologics and the design and specification of equipment used to make these products.