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The Department of Process Engineering and Far Sight Skills Development

present a Short Course on—

Good Manufacturing Practice for Food & Pharmaceutical Products

2 CPD points ECSA accredited
Course language: English

Date: **12 — 13 September 2019**
Time: **08h00—17h00**

INGENIEURSWESE
ENGINEERING
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REGISTRATION COSTS:

Participant	*Early bird registration PRIOR to 22 AUGUST 2019*	*Registration after 22 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 links.
https://shortcourses.sun.ac.za/application-form.html?offeringid=5d659f88-7da1-e911-80e7-0050568033a6

VENUE:

Annex 229—230
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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University of Stellenbosch
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or

Dale C. Gyure
Far Sight Skills Development
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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 **22 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:

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.
The course includes a series of study guides and exam questions that encourage in-class discussion and help reinforce what has been taught. A formal competency exam for use by companies sponsoring delegates is available on request after delegates have completed the course.

SHORT COURSE AGENDA: DAY ONE

Introduction and Course Overview

- The importance of GMP in manufacturing
- Understanding the "c" in cGMP
- Understanding the role of the pharmacist in a production environment
- Reviewing the challenges faced by regulatory agencies
- Current status for South African manufacturers

GMP Principles 1 – 3 (with examples and case studies)

- Written procedures (Master Batch Records; SOPs; tips on writing robust procedures)
- Following procedures (role of the employee; deviations; notifications; Applicant Review Boards)
- Documenting for traceability (historical basis; consequences of non-compliance)
- Legal definitions of adulteration and GMP compliance

GMP Principles 4 – 6 (with examples and case studies)

- Proper design of facilities and equipment (movement of people and materials; aseptic areas; dos and don'ts)
- Engineering fundamentals put into practice (sanitary design; utilities; design philosophies)
- Maintaining facilities and equipment (equipment logs and SOPs; the ideal maintenance team; pitfalls)
- Job competence (job descriptions, training programs; practical issues)
- Food vs. Pharmaceutical GMPs

SHORT COURSE AGENDA: DAY TWO

GMP Principles 7 – 8 (with examples and case studies)

- Cleanliness (strategies for equipment; overall facility issues; monitoring and control)
- Biological cleanliness (people as sources of contamination; monitoring and control strategies)
- Validation (instrument calibration, IQ/OQ/PQ, cleaning validation, prospective and retrospective validation)
- Metrology and statistics review to support validation

GMP Principles 9 – 10 (with examples and case studies)

- Process control (general principles; vesting of control; compliance strategies)
- Three compliance requirements (raw materials; in process testing; final product specifications; applicability)
- Auditing for compliance (self-inspections, third party inspections, inspectional standards)
- HACCP vs. GMP

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.

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.