Dr AJ van Zyl

t/a Van Zyl GMP International

FACEBOOK: VAN ZYL GMP INTERNATIONAL

Dr AJ van Zyl in association with SAAPI present:

GOOD PRACTICES, CONTAMINATION CONTROL AND HVAC SYSTEMS IN CLEAN ROOMS

Initial and continuous training for those involved in GMP

Date: 11 November 2021

Time: 09:00 to 16:30 (SAT)

Virtual training workshop

BACKGROUND

The basic function of a cleanroom is to protect the product being manufactured, from contamination. Different standards exist addressing clean rooms, production and control environments. Potential sources of contamination, including viable and non-viable particles should be controlled and or eliminated where possible.

In many cases, the Heating, Ventilation and Air Conditioning systems (HVAC) can play an important role to ensure that the environment meets regulatory standards for the production and control of pharmaceutical products.

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Good Manufacturing Practice guidelines describe and refer to international standards for clean rooms, environmental and room classification and monitoring. To achieve compliance with regulatory requirements, HVAC systems should be appropriately designed, installed and qualified.

It is important to consider that the concept of a "clean room" is not only meant for sterile product manufacturing.

OBJECTIVES AND PROGRAM CONTENT:

In this workshop, general concepts of clean rooms will be discussed, including:

- Risk management
- Contamination control
- Clean room expectations for production and control areas
- Elements of draft Annex 1
- HVAC systems
    - GEP and GMP
    - Elements of ISO 14644
    - Qualification, classification, monitoring
    - Regulatory findings and CAPAs

TARGET GROUP

Sterile and non-sterile products

- Management
- Quality assurance
- Quality control
- Production
- Engineering

PRESENTER

Presenter: Dr AJ van Zyl (Andre)

Andre is a consultant, auditor and inspector with almost three decades of international experience. He obtained a B.Pharm, M. Pharm and two Ph.Ds in pharmacy and he has worked for many years in retail pharmacy, clinical research, aseptic processing and medicines

regulation. He was the Head of the Inspectorate in MCC (now SAHPRA). He worked for over 20 years with the World Health Organization in Geneva as Program Manager and Head of inspections for the United Nations Prequalification of Medicines Program) as well as Technical Advisor and Member of the Expert Committee. He is the author of several WHO GxP guidelines. Andre has done audits, inspections and training in many countries for WHO, The Global Fund, USP, UNFPA, various NGOs (e.g. The Clinton Foundation, The Red Cross, Doctors without Borders), as well as for multinational and generic manufacturers around the world. He is the author of the book *Making Medicines Better*.