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Dr AJ van Zyl, trading as Van Zyl GMP International in association with SAAPI present:

Training Workshop: Navigating through cGMP guidelines

Initial and continuous training for those involved in GMP

Date: 5 December 2019

Registration: 08:00 to 08:30

Workshop: 08:30 to 16:30

Venue: Glenhove Conference Center, 52 Glenhove Rd, Melrose Estate, Johannesburg

LEARNING OBJECTIVES

To get a better understanding of:

- current Good Manufacturing Practices (GMP) and regulatory requirements and expectations;
- current developments and expectations in current GMP

- how to ensure compliance with the regulatory requirements
- … and many more

BACKGROUND

Good Manufacturing Practices requirements have evolved significantly over recent years. From an often referred to "secundem Artem" approach in many areas of production to a more scientific, risk based approach for ensuring safety, efficacy and quality of pharmaceutical products - quality by design, design of experiments, transfer of technology, process capability and process validation approaches based on risk management principles are now the talk of the day. With the change in GMP for the 21st century, and the focus on identifying and assessing risks, the regulatory expectations for risk assessment and implementing controls to eliminate the risks (or at least reduce the risks to an acceptable level) have become a focus area of inspections and audits.

In addition, focus is placed on ensuring the integrity of data. Data integrity lapses identified in several manufacturing facilities around the world in the last 2 decades have led to mistrust of data and information presented by companies, to regulators. This resulted in stringent requirements and guidelines on data integrity. With the inherent risk of human error and linked to the data integrity concern, more and more expectations are placed on automation and computerized systems to be used in production and quality control. A renewed emphasis has been placed on regulatory compliance for computerized systems.

As many companies manufacture several products in shared facilities, the risk of cross-contamination remains real. Although cGMP refers to the use of separate, dedicated facilities for certain products such as penicillin and sex hormones – it is often not clear what is expected for other products. Setting health based exposure limits (HBEL) for products in shared facilities is now becoming an increased focus point in cGMP. No longer is cleaning validation considered as sufficient proof of prevention of cross-contamination and prevention of carry over from one product to another, in the same equipment train.

The life cycle approach and quality by design in production and quality control with continuous improvement have further placed additional responsibilities on pharmaceutical manufacturers.

In an attempt to navigate through the latest current GMP requirements, an overview of regulatory requirements and expectations of stringent regulatory authorities, the World Health Organization (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) will be given. If there is one training workshop that you should attend, it is this one!

TARGET GROUP

- Senior Management
- Quality assurance
- Quality control
- Production
- Information Technology (IT)
- Engineering
- Regulatory Affairs
- Personnel at all levels, who should be aware of policies, procedures and how to do risk assessment

PROGRAMME

The workshop will consist of presentations, discussion and a case study or two relating to good manufacturing practices, with specific emphasis on:

- cGMP (International requirements e.g. USA, EU, WHO)
- Quality Risk Management
- Product Quality Review
- Data Integrity
- Quality by design, life cycle approach
- Computerized systems
- Setting HBEL in shared facilities (including organizational and functional controls, risk management and cleaning validation)
- Case study and assessment

PRESENTER

Presenter: Dr Andre van Zyl

Andre is a well-known inspector and consultant with over two decades of international experience. He has worked for many years as the Head of the Inspectorate in MCC; Program Manager and Head of Inspections for the United Nations Prequalification of Medicines Program in the World Health Organization HQ (Geneva); as a consultant, auditor and technical

adviser for WHO, The Global Fund, USP, UNFPA, The Clinton Foundation, various NGOs as well as Multinational and Generic manufacturers around the world.

He was an appointed member of the Legal Committee, the Pharmaceutical and Analytical Committee; and a member of the Medicines Control Council until January 2017. He is a member of the Panel of Experts and the Expert Committee of the WHO, Geneva.

He has presented several training workshops over the years and is the author of various GMP guidelines, and the book “Making Medicines Better”.