Dr AJ van Zyl

t/a Van Zyl GMP International

FACEBOOK: VAN ZYL GMP INTERNATIONAL

Dr AJ van Zyl in association with SAAPI present:

GMP FOR PHARMACEUTICAL WATER SYSTEMS

Initial and continuous training for those involved in GMP

Date: 20 May 2021

Virtual training workshop

OBJECTIVES:

To obtain a better understanding of:

- the latest GMP requirements for pharmaceutical water systems
- the regulatory approach to utilities
- the importance of risk management in utilities
- design, qualification, monitoring and management of these systems

Topics and questions under discussion will include e.g.:

- Introduction to GMP requirements

- Application of risk management in water systems
- Drinking water and purified water
- Water for injection and steam
- Maintenance and calibration
- Inspection findings – lessons to be learnt

Considerations:

- Which water purification system is needed? RO? Ultrafiltration?
- Do we need purified water for washing equipment?
- Can we have plastic piping in the water loop?
- Is a slope needed?
- Manual or orbital welding?
- What is Passivation?
- Where can you use ball valves?
- In line, on line and off line monitoring

.....and many more....

BACKGROUND

New GMP guidelines have been published for water systems. In addition, WFI can now be produced by means, other than distillation.

In the workshop, we will explore:

- The new guidelines and requirements, what is needed and why
- How to approach risk assessment in these areas
- Calibration
- Principles of preventive maintenance
- What engineers need to know
- What QA need to know
- What production need to know
- What QC need to know
- What management need to know
- How to meet GMP requirements

TARGET GROUP

- This workshop is designed to help management, quality assurance, quality control, engineers and production personnel to better understand the latest GMP requirements for pharmaceutical water systems
- It is strongly recommended that personnel from different departments attend this workshop. It is not focusing only on engineering aspects, but approaches the topic from different angles to ensure that QA, production, QC, Validation and engineering understand the regulatory approach and GMP expectations.

It is important that these systems are appropriately designed, installed, controlled, maintained and monitored to meet current GMP expectations.

QA should not sign off all the required protocols, reports, trends, charts, change controls if they do not fully understand these systems.

Production should equally accept their responsibility in ensuring that these systems are appropriately calibrated, qualified, maintained, and monitored – and data collected where appropriate for trending, quality reviews and management review.

PROGRAMME

Morning session:

- Introduction to GMP requirements
- Quality Risk Management in water systems
- Purified water, Water for Injection and steam
- Storage and distribution
- Calibration
- Preventive Maintenance
- Regulatory findings
- Case study and assessment
- Discussion

PRESENTER

Presenter: Dr AJ van Zyl (Andre)

Andre is a consultant, auditor and inspector. He has almost three decades of international experience. He has worked for many years as the Head of the Inspectorate in MCC (now SAHPRA); for over 20 years with the World Health Organization HQ (Geneva) as Program Manager and Head of inspections for the United Nations Prequalification of Medicines Program and as a consultant and inspector. He has done audits and training in many countries for The Global Fund, USP, UNFPA, The Clinton Foundation, various NGOs as well as Multinational and Generic manufacturers around the world. He will present these topics and facilitate case studies to allow for "hands on" experience in understanding these GMP requirements.