Dr AJ van Zyl

t/a Van Zyl GMP International

FACEBOOK: VAN ZYL GMP INTERNATIONAL

Dr AJ van Zyl in association with SAAPI present:

WHO PREQUALIFICATION:

HOW TO GET APPROVED FOR GLOBAL SUPPLY OF MEDICINES

Initial and continuous training for those involved in GMP

Date: 29 July 2021

Virtual training workshop and webinar

OBJECTIVES:

The objectives of this workshop and webinar is to:

- Explain the principles of the WHO Prequalification program (PQ)
- Understand how to apply for WHO Prequalification
- Understand how to get your API prequalified
- Understand how to get your finished pharmaceutical product (FPP) prequalified

- Understand the latest norms and standards WHO apply in prequalification, including GMP for APIs and FPPs
- Get a brief overview of GxP applied in PQ

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

- Introduction to PQ
- What are Expressions of Interest (EOIs)?
    - Can we apply for prequalification for any product?
- APIMF and Product dossiers
    - What should be submitted for PQ?
- Assessments
    - How does the assessment work?
    - Who assesses the dossiers?
- Inspections – API, Bioequivalence studies, FPP, Quality control laboratories
    - How does the inspection section work?
    - Who are the inspectors?
    - Does my supplier of API have to be inspected?
    - We have been inspected by SAHPRA and US FDA. Will WHO still need to inspect us?
    - Will there be an inspection of the bio-equivalence study data and site?
    - If we fail the WHO inspection, what happens to my dossier?
- What are the norms and standards WHO will apply?
    - Which GMP guidelines will be used for assessment?
    - Does WHO have its own GCP guidelines?
    - Will be CRO be inspected?
    - What about the site design, premises, equipment, computers, HVAC and water systems?
- If we get prequalification, is it for the dossier, the site or for what?
- How long does it take? And how long does the prequalified status last?
- Once prequalified, what is my guaranteed sales income from supplying WHO, UNICEF, or countries around the world?

……..and many more

BACKGROUND

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In 2001, the United Nations started a program for prequalification of medicines. The aim was to ensure the safety, efficacy and quality of medicines used in the treatment of HIV/AIDS. In addition, the objective was to bring down the price of anti-retroviral products to make medicines accessible to all countries.

The programme expanded to include the treatment of tuberculosis and malaria. With the success of the programme, it was further expanded to include reproductive health products, treatment of neglected tropical diseases, prequalification of APIs and biosimilars.

Today, the program includes also vaccines, vector control products and pesticides.

In the workshop, we will discuss the history, objective and process of prequalification. We will explore how to apply, what to expect and discuss how your company can become a player in the international supply of medical products.

TARGET GROUP

- This workshop is designed to help manufacturers understand:
    - how to apply for prequalification
    - what can be applied for
    - what the requirements are
    - what the possibilities are to supply products internationally through the UN prequalification program.
- Management, quality assurance, quality control, production and engineering personnel will benefit from this workshop
- Personnel will get a better understanding of the latest GxP requirements from WHO PQ
- Personnel from different departments should attend this workshop as it is not focusing only on GxP, but will cover which products are eligible, what happens after prequalification, and what are the rules in terms of supplies and sales.

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TENTATIVE PROGRAMME

- Background and introduction to the United Nations Prequalification programme, managed by WHO
- Scope of the PQ programme
- Expressions of interest

Break

- Active Pharmaceutical Ingredients
    - GMP for APIs

Lunch break

- Finished Pharmaceutical Products
- Good Practices
    - GMP for FPPs
    - GCP
    - Other GxPs
- Quality Control Laboratories

Break

- Vaccines, pesticides, nets and other products
- Prequalification life cycle
- Procurement, supply, storage and distribution
- Discussion

PRESENTER

Presenter: Dr AJ van Zyl (Andre)

Andre is a consultant, auditor and inspector. He has almost three decades of international experience. He obtained his Ph.Ds in pharmacy and he has worked for many years in retail pharmacy, clinical research, aseptic processing and as the Head of the Inspectorate in MCC (now SAHPRA). He has 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) and technical advisor, and author of 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 will present these topics and facilitate questions based on his "hands on" experience as the first person employed by WHO to establish the prequalification program in 2001.