INTRODUCTION TO ORAL SOLID DOSAGE (OSD) FORMS MANUFACTURING

Background

Oral Solid Dosage Forms have become the most common route drug delivery or administration. These dosage forms can be produced in a non-sterile environment and the process, equipment, and technology are well-defined and known after decades of development.

With the high volume of products produced in these dosage forms, it is important the unit operations for their production be thoroughly understood. The workshop will focuses on the fundamentals of each discrete processing step (unit operation) required for the manufacture and packaging of tablets and capsules. In addition pharmaceutical facilities and utilities for the manufacture of OSD will be looked at in the workshop.

Learning Objectives

1. Understand guidance on regulatory expectations as it is applied to the design of Oral Solid Dosage (OSD) process systems and facilities.
2. Understand principles for establishing an effective Quality Risk Management Process
3. Understand aspects of technologies, unit operations, and associated equipment pertinent to product quality and facility design.
4. Understand containment considerations for OSD manufacturing.
5. Understanding the requirements for design considerations.

Target group

- Production or Manufacturing
- Research and Development
- Quality Control (QC)
- Quality Assurance
- Regulatory Affairs

- Researchers
- Responsible pharmacists
- Technical support
- Engineering

Programme

The presentation will consist of a presentation emphasizing practical approaches of conducting effective investigations as per regulatory requirements; practical cases studies relating to production and analytical processes emphasizing the following:

- Understand the three main OSD processing methods: Direct Compression, Wet Granulation and Dry Granulation and complete a detailed review of all the major unit operations associated with OSD manufacturing processes including: Ingredient Dispensing/Formulation; Blending; Granulation; Drying; Compression/Encapsulation; Coating; Packaging and Receiving/Warehousing Operations.
- A comparison of technical approaches and the different methods for OSD drug product manufacturing to identify the types of OSD manufacturing equipment and the technology advancements for achieving higher performance.
- An overview of product characteristics and how they dictate the unit operations method.
- The ability to know how to effectively utilize process monitoring techniques during scale-up and technology transfer to advance the delivery of drug products.
- A summary of the principles of QbD in OSD manufacturing processes and how GMPs influence unit operations and subsequent equipment design, production suite design, control and monitoring requirements.

Presenter

Mbonisi is a qualified pharmacist and formulation scientist with a great passion for the pharmaceutical industry with extensive research background and has served in well renowned organizations. His experience includes medicine systems consultancy; technical operations;

operations management; pharmaceutical development; analytical method development; process engineering; research and academia.

Mbonisi holds a postgraduate degree and a vast number of courses from various institutes and thus he well versed with current techniques, skills and standards in the pharmaceutical industry. He holds a Bachelor of Pharmacy (B.Pharm) degree, Master of Science (M.Sc) in Pharmaceutical Chemistry degree from Rhodes University in collaboration with University of Tiaret. Mbonisi is currently pursuing a Doctor of Philosophy (Ph.D) degree at the University of Witwatersrand focusing on the application of mathematical modelling in pharmaceutical development for different drug delivery systems. To date he has published three journal articles and co-authored one book chapter.