

## A PRACTICAL APPROACH TO TECHNOLOGY TRANSFERS



### Background

Developing effective protocols for technology transfer is essential for addressing current industry challenges and evolving business needs. As the industry continues to experience changes; technology transfer for active pharmaceutical ingredients (APIs), finished dosage forms and analytical methods between development and manufacturing sites and contract manufacturing organizations (CMOs) has become increasingly important. This workshop on Pharmaceutical Technology Transfer identifies criteria for successful technology transfer and provides 'how to' examples which can be individually tailored, depending on the type and scope of transfer.

### Learning Objectives

1. Understand principles of conducting technology transfers
2. Development of a transfer proposal and plan
3. Execution of a technology transfer
4. Development of robust qualification and validation procedures and protocols
5. Build compliance (as per regulatory standards) into the technology transfer process

### Target group

- Production or Manufacturing
- Research and Development
- Quality Control (QC)
- Quality Assurance
- Regulatory Affairs
- Researchers (Clinical and Academia)
- 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:

- a) Introduction to technology transfer
- b) Planning and success criteria
- c) Quality risk management
- d) Phases of the transfer process including qualification and validation
- e) Analytical procedures transfer
- f) Pharmaceutical product transfer
- g) API transfer (overview)

## 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.