# DEVIATION AND CHANGE CONTROL MANAGEMENT DURING ROUTINE/COMMERCIAL MANUFACTURING

**Background**

Change is inevitable in a pharmaceutical manufacturing operation. Vendors change processes, sources, and specifications for raw materials, equipment requires repair, service, or replacement, manufacturing locations are changed, batch sizes are increased or decreased and advancements in technology are made that dictate changes to the operations. After issuing of Marketing Authorization and/or manufacturing, many changes occur across the Product lifecycle, i.e. Scaling up of pilot batch into commercial batch and variation in manufacturing processes, excipients and manufacturing sites. All these changes are considered as post approval changes or variations. These variations need to be approved by the respective regulatory authorities of a country. If not, it puts the marketing authorization holder and/or license holder at risk. Proper management of changes is critical and proper change management reduces the risk of suspension of licenses and the warning letter from the regulatory authorities.

This training programme aims to provide an industry perception on Deviation and Change Control management and importance of the Quality Management System.

**Learning Objectives**

1. Understand importance of change management
2. Define quality management system for reporting data
3. Build robustness into processes based on good deviation and change management
4. Understand documentation applicable to deviation and change management

**Target group**

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

- Researchers (Clinical and Academia)

**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:

1. Comparison between change control and deviations
2. Importance of a pharmaceutical quality system
3. Deviation Management
4. Principles of change control
5. Practical application of change management
6. Documentation

**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; process engineering; analytical method development; 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.