INTRODUCTION TO PHARMACEUTICAL DEVELOPMENT

Background

Developing a new chemical entity (NCE) for human use can take up to 15 years. It is a highly costly process (approx. US$2.15 bn) and a vast number of steps are involved so as to bring NCEs to commercial manufacturing. There are a lot of pitfalls along the way as less than 10% of pharmaceutical development projects will lead to FDA approval, and even though odds are very steep, it is not impossible. The development of new medicines is a long and complicated process. Each success is built on many prior failures. Advances in understanding human biology and diseases are opening up existing new possibilities for breakthrough medicines. This course provides a background and in-depth understanding on processes required to move a potential drug candidate from a concept to the market. Emphasis on how various functional areas contribute at each stage of development and how they are recognized. Furthermore, an insight of regulatory environment in which these activities occur shall be discussed.

Learning Objectives

1. Describe the use of a target drug profile (TPP) as a tool in designing pharmaceutical development program
2. Describe the phases of pharmaceutical development
3. Identify the sources of pharmaceutical development regulators
4. List the functional areas involved in the pharmaceutical development process
5. Describe the workflow for bringing a new product into the market

Target group

- Production or Manufacturing
- Research and Development
- Quality Assurance
- Regulatory Affairs
- Researchers (Clinical and Academia)
- Pharmaceutical Business Support
- Project Management

Programme

The presentation will consist of a PowerPoint presentation demonstrating critical aspects of pharmaceutical development; extensive practical cases studies relating to pharmaceutical development emphasizing the following:

1. Principles of quality by design
2. Discovery process
3. Lead optimization (molecular)
4. Development process
5. New drug application (NDA) and approval
6. Manufacturing
7. Ongoing studies and phase IV trials
8. Product lifecycle management

Presenter

Mbonisi Ncube 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 with use of Instrumental Analysis; regulatory affairs; 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 Philology (Ph.D) degree at the University of Witwatersrand focusing on the application of mathematical modelling and artificial intelligence in pharmaceutical development for different drug delivery systems. To date he has published three journal articles and co-authored one book chapter.