# TURNING QUALITY BY DESIGN (QbD) INTO A PRACTICAL REALITY


**Background**

Substantial business benefits are emerging from industry when **Quality by Design (QbD) principles** are used for new and existing drug products yielding reduced operational costs, enabling significantly more efficient manufacturing processes and better positioning pharmaceutical companies to meet the increasing regulatory expectations.

The completion of ICH Guidelines, **Q8 (R2): Pharmaceutical Development**, **Q9: Quality Risk Management** and **Q10: Pharmaceutical Quality System**; and the recent FDA guidance on Process Validation, contain recommendations for building and capturing process knowledge and understanding and establishing a strategy for process control during process design. There is increasing evidence (i.e. warning letters) that regulators are citing unacceptable levels of process understanding, like an unidentified and lack of control of factors which result in process variability. Additionally, FDA appears to be accelerating the QbD push, suggesting that abbreviated new drug application (ANDAs) for generic drugs should have QbD elements.

**Learning Objectives**

1. Understand and apply QbD terminology including the principles of a science and risk based approach
2. Understand importance of product and process understanding and patient requirements
3. Use tools and techniques provided to understand the application of Quality Risk Management
4. Understand the relationship between Pharmaceutical Quality Systems and GMP and how they link to control strategy
5. Understanding the considerations when implementing a control strategy derived from enhanced QbD approaches
6. Examine opportunities for continuous improvement arising from QbD and statistical analysis

**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:

1. Introduction to QbD and its benefits
2. QbD roadmap
3. Quality risk management
4. Control strategy
5. Pharmaceutical Quality Systems and GMP – linking to control strategy
6. Process validation
7. Continuous improvement and statistical process monitoring (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.