

Module 10: Business & Technology Innovation in the Pharmaceutical Industry

Stage	1						
Semester	1						
Module Title	Business and Technology Innovation in the Pharmaceutical Industry						
Module Number/Reference	MSC-IPM-BTI						
Module Status (Mandatory/Elective)	Mandatory						
Module ECTS credit	10						
Module NFQ level (only if applicable)	9						
Pre-requisite Module Titles	n/a						
Co-requisite Module Titles	n/a						
Is this a capstone module? (Yes or No)	n/a						
List of Module Teaching Personnel	Annette Shinnars, Ruth McCarthy, Dr Abina Crean						
Contact Hours				Non-contact Hours			Total Effort (Hours)
Lecture	Practical	Tutorial	Seminar	Assignment	Placement	Independent work	
60		12		28		150	250
Allocation of Marks (Within the Module)							
	Continuous Assessment	Project	Practical	Final Examination	Total		
Percentage contribution	60%			40%	100%		

Intended Module Learning Outcomes

On successful completion of this module, the learner will be able to:

1. Expertly apply the concepts of lean 6 σ to pharmaceutical business management.
2. Critically appraise the benefits and impact of lean 6 σ , 5S on global pharmaceutical & biotechnology organisations

3. Critique the use of the DMAIC methodology and toolbox within management of the pharmaceutical organisation.
4. Evaluate how integrated process applications & technology benefits organisations and contributes to continuous improvement business strategies
5. Distinguish between Programme Management and Project Management; understand the key elements of the Hoshin Planning process
6. Critically assess the role of Human Performance Excellence in enabling business transformation and delivering continuous improvement
7. Evaluate and debate the role of business transformation in delivering high performance, integrated, innovative organisations.

Module Objectives

This module aims to introduce learners to the general subject of continuous improvement and business transformation as applied in the pharmaceutical & biotechnology industry. The continuous improvement framework is a fundamental aspect of the module and its deployment/application is demonstrated to the learner through integrated process application, human performance excellence, business transformation, and program management. The main purpose of the module is to explore the principles of continuous improvement in the global Pharmaceutical and Biotechnology industry. This module demonstrates the relevance of continuous improvement; and identifies key elements in which learners can apply as leaders to transform their business.

Module Aims

This module aims:

- To demonstrate the role which continuous improvement and business transformation play in global pharmaceutical and biotechnology organisations
- To enable learners to review their current improvement processes and change management approach; identify ways to integrate process applications and technology; and create or contribute to an environment that supports innovation and human performance excellence
- To investigate how managers and leaders can review their program management structure; consider how to effectively create and communicate program objectives; techniques to aid stakeholder Management and Program Risk Management

Module Curriculum

Section 1: Continuous Improvement

- **Lean 6 σ Manufacturing**
 - Understand the Definitions and concepts of lean manufacturing and 6 σ
 - Lean sigma structure
 - Understand the project lifecycles: Yellow Belt, Green Belt, Black Belt
 - Describe the 5 Lean Principles
 - Understand 5s
 - The benefits of 6 σ and impact of lean 6 σ on global pharmaceutical & biotechnology organisations
 - Case study 1

- **Statistics for Management**
 - DMAIC Methodology
 - DMAIC toolbox
 - Introduction to statistics
 - Multi Vari Charts
 - Statistical Process Control
 - Variable and attribute control charts
 - Introduction to Design of Experiments

- **Integrated Process applications and technology**
 - Understanding alignment of business application and technology plans with business strategy
 - Integration of data sources & business intelligence (business processes and functionality)
 - Analysis & reporting - Leveraging Multiple Perspectives
 - Benefits of Integrated Process Applications and Technology
 - Impact of Integrated Process Applications and Technology on business continuous improvement strategies

Section 2: Human Performance Excellence & Business Transformation

- **Human Performance Excellence**
 - Understanding how human factors contribute to errors, and the source of those factors
 - Human Error theory & models e.g. Talsico
 - Analysing human factors as part of systematic investigation process
 - Human Error Prevention Strategies & Hierarchy
 - Benefits of Human Performance excellence to an organisation
 - The role of Human Performance excellence in Continuous Improvement deployment and success; an enabler to Business Transformation
 - Regulatory expectations regarding human error elimination

- **Business Transformation & Change Management**
 - The role of business transformation in delivering high performance, integrated, innovative organisation
 - Transformation Phases
 - Engagement
 - Diagnostics
 - Solution Development/Pilot
 - Implementation Roll out
 - Continuous Improvement
 - Value Stream Mapping
 - Elements of Innovation Culture
 - Knowledge Management

- **Programme Management & Hoshin Planning**
 - Programme Management vs Project Management – understanding the elements of both and roles within
 - CI deployment & Strategic Planning
 - Deploying Objectives
 - Cascading Objectives
 - Shortlisting Projects
 - Programme Stakeholder Management and Program Risk Management

- **Assignment Workshop**
 - Review activities introduced in Lectures 1 – 5.
 - Relate theoretical concepts to practice.
 - Assess the case study.

Teaching plan

Week 1&2	Lean 6σ manufacturing
Weeks 3&4	Statistics for management
Weeks 5,7&7	Integrated process applications and technology
Week 8&9	Human performance excellence
Week 10	Business transformation & change management
Week 11	Programme management & Hoshin planning
Week 12	Assignment Workshop

Reading lists and other learning materials

Gassmann, O. et al. 2010. *Leading pharmaceutical innovation: trends and drivers for growth in the pharmaceutical Industry*. Berlin: Springer.

Goodman, E. and Riddell, J. 2014. *Knowledge management in the pharmaceutical industry*. Surrey: Gower.

Harpum, P. ed. 2010. *Portfolio, program, and project management in the pharmaceutical and biotechnology industries*. N.J: Wiley-Blackwell.

Jungmittag, A. et al. 2011. *Changing innovation in the pharmaceutical industry: globalization and new ways of drug development*. London: Springer.

Nunnally, B.K. and McConnell, J.S. 2007. *Six sigma in the pharmaceutical industry: understanding, reducing, and controlling variation in pharmaceuticals and biologics*. Boca Raton: CRC Press.

Journals

Total Quality Management & Business Excellence

International Journal of **Innovation Management**

Module Learning Environment

A classroom setting is used for the delivery of the module through a series of 10 lectures and 2 assessment-based workshops. Supports for learners include a set of printed notes incorporating syllabus, lecture notes, activities, short self-administered questionnaires, a case study and related assessment tasks. These are supplemented with a module set book and online reading materials, PowerPoint presentations, and other activities using Moodle, the College's Virtual Learning Environment (VLE) provide additional support materials to help with self-study.

Module Teaching and Learning Strategy

This module demonstrates the relevance of continuous improvement; and identifies key elements in which learners can apply as leaders to transform their business. Section 1 (Lectures 1 – 4) deals with key concepts of continuous improvement as applied in the pharmaceutical & biotechnology industry. These lectures provide information and background that help learners to make sense of the continuous improvement subject matter (Week 1) and toolkit (Week 2). The deployment/application of these concepts is demonstrated to the learner through integrated process application (Week 3), human performance excellence (Week 4), business transformation (Week 5) and program management (Week 6). Workshop 1 (Week 7) helps learners to complete the continuous assessment element of the module. This assessment is worth 60% of the overall mark.

Module Assessment Strategy

Element Number	Weighting	Type	Description
1	60%	Written report	Case study based assessment
2	40%	Examination	End of semester examination

Learners are required to work on a 60% weighted assignment. This is a Work Based Activity (WBA) which requires learners to identify areas of Continuous Improvement and develop a comprehensive written plan to deploy the tools in a case study organisation, their own workplace or a context in which they play to work in the future.

Learners sit an end of semester examination which contributes 40% towards their final mark for this module. The exam paper has three sections focusing on the concepts of lean 6 σ , Statistics for management, Hoshin Planning, Human Performance Excellence and Business Transformation.

Constructive Alignment of Assessment

Module Learning Outcomes	Assessment Strategy	
	Element 1	Element 2
1. MLO 1	Yes	Yes
2. MLO 2		Yes
3. MLO 3	Yes	Yes
4. MLO 4	Yes	Yes
5. MLO 5	Yes	Yes
6. MLO 6	Yes	Yes
7. MLO 7	Yes	Yes