



## Course Syllabus

<b>Course Code</b>	<b>Course Title</b>	<b>ECTS Credits</b>
PHAR-626	Product's Life Cycle Activities	10
<b>Prerequisites</b>	<b>Department</b>	<b>Semester</b>
None	Health Sciences	Fall
<b>Type of Course</b>	<b>Field</b>	<b>Language of Instruction</b>
Elective	Pharmacy	English
<b>Level of Course</b>	<b>Lecturer(s)</b>	<b>Year of Study</b>
2 <sup>nd</sup> Cycle	Dimitris Zampatis, Thelma Koulourou	2 <sup>nd</sup>
<b>Mode of Delivery</b>	<b>Work Placement</b>	<b>Corequisites</b>
e-learning	--	none

### Course Objectives:

A product lifecycle, including drugs, is the success outcome of stages from the product's birth until its final withdrawal from the market. For drugs, three different periods are present: an extensive early development phase; a highly competitive mid-life interval; and a significant late post-patent period which constitute the real life of a drug. Drugs have a lengthy, closely regulated, and complex developmental pre-marketing phase usually lasting a decade. During this time interval a number of factors are involved that can dramatically alter the conditions of access, utilization, pricing, and sales.

While each stage brings significant changes, a succession of strategies for the management of product lifecycle is required. The product lifecycle management creates and manages a company's product-related intellectual capital starting from an idea to its final retreat. In pharmaceutical industry, the main applications of product lifecycle management involve enhancing the lifespan of patent and pricing strategies. Improved patient compliance, revenue growth, expanded clinical benefits, life extension exclusivity and quicker market launch.

To devise an effective and fruitful product lifecycle management program many attributes are considered including early start; strategic planning clear leadership, supporting knowledge and skills, preparedness for changing rules of government and organizations.

Accordingly, the aim of the course is on product lifecycle management, its applications and the key considerations for a successful product lifecycle management. The course aims to provide an in depth understanding and analysis of product life cycle management and the key challenges with implementing the strategies to improve product pipelines, shorten the time for the introduction of

products into the market and enhance profits. Armed with these knowledge students should be able to devise a successful strategy to improve a pharmaceutical product's life cycle.

### Learning Outcomes:

After completion of the course students are expected to be able to:

- Upon completion of this course the attendees will be able to:
- Analyse the products life cycle stages, and the drugs PLC curves.
- Summarize and asses regulatory, scientific and technical options for optimizing brand life cycle, by introducing the drug in the market early, minimize development cost all aiming at maximizing revenues
- Familiarize with the process of developing appropriate Life Cycle Management strategies for maximizing the performance of a brand throughout its life cycle
- Rate the commercial options for optimizing brand life cycle, taking into consideration the challenges, competition and regulatory issues and other hurdles
- Develop strategies to cope with late stage Life Cycle Management and drive the value in PLM
- Interpret the process in creating and managing portfolio

### Course Content:

- **Lifecycle Management business environment I: Introduction to LCM and the pharmaceutical environment**
  - The Life Cycle of Industries
  - Introduction to Product Life Cycle Management
  - Overview of Current Pharmaceutical Environment
  - Lifecycle Phases
  - Development, Introduction, Growth, Maturity and Decline Phases
- **Lifecycle Management business environment II: Life cycle of industries, brands and services and branded pharmaceuticals**
  - The Life Cycle of a Pharmaceutical Brand
  - Lifecycle Curve of Pharmaceuticals
  - Slow Rate of Growth during the Growth Phase
  - Lack of a True Maturity Phase
  - Precipitous Decline Phase
  - Factors Affecting Rate of Conversion to Generics
  - Government Policy
  - Size of Brand
  - Active Substance and Other Barriers to Entry

- **Life Cycle Management: Regulatory and Legal Environment**
  - The Generic Approval Process
  - Patents and Other Intellectual Property Rights
  - Patenting, Patent Enforcement and Patent Strategy
- **Developmental LCM I: Strategic Principles of Developmental LCM**
  - Provide a Meaningful Improvement in Clinical Profile
  - Increase the Potential Real-World Patient Potential for the Brand
  - The Ability to Generate an ROI
  - The Ability to Enhance Market Exclusivity of the Brand Franchise
  - Categories of indication expansion
- **Developmental LCM II: Different Developmental strategies**
  - Patient subpopulations: personalised medicine
  - New dosage strengths and regimens
  - Reformulation: New routes of administration
  - Second generation products
- **Commercial LCM I**
  - The Ability to Drive Widespread and Preferential Patient Access to the Brand
  - The Ability to Defend Market Access and Formulary Position
  - The Ability to Optimize Profitability of the Brand Franchise
- **Commercial LCM II: Geographical Expansion and Optimization OTC**
  - Geographic expansion
  - Choosing the Best Approach
  - Dealing with Intermarket Variability
  - Balancing the Product Life Cycle?
  - How to Make the Switch Successful
- **Commercial LCM III: Brand Loyalty and Service Programs Strategic Pricing Strategies**
  - Pricing Strategy and Tactics in the Launch and Growth Phases
  - Pricing Strategy and Tactics Following Patent Expiry
  - Generic Strategies and Tactics
  - Exit Strategies
- **Biologics & Biosimilars**
  - Emergence of Biotech
  - Uptake and value of biologics
  - Next generation biologics
  - Indication expansion
  - Why are biosimilars a big deal?
- **The integrated brand LCM strategy and its implementation I: strategic goals of LCM**
  - Position to market
  - Comparative clinical profile vs. gold standard

- Level of market unmet need
- **10 Keys to Successful LCM**
  - Excellent Functional Expertise
  - Patent Attorneys
  - Regulatory Affairs
  - Clinical Development
  - Formulation Scientists
  - Marketing and Sales
  - Manufacturing
  - Organizational Structures and Systems for Ensuring Successful LCM
  - The LCM Process: Description, Timing, and Participants
- **Integrating LCM with portfolio management**
  - Principles of Portfolio Management LCM Projects in the Development Portfolio Managing Established Brand Portfolios

**Learning Activities and Teaching Methods:**

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and ebooks), access to additional videos related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies, wikis, and major assignments.

**Assessment Methods:**

Continuous Assessment (major assignments and weekly activities), Final Exam

**Required Textbooks / Readings:**

Title	Author(s)	Publisher	Year	ISBN
Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand	Tony Ellery, Neal Hansen	John Wiley	2012	978-0-470-48753-2

Product Lifecycle Management for the Pharmaceutical Industry	Todd Hein, Michael Winkler, Hardeep Gulati, Arvinth Balakrishnan	Oracle Life Sciences		
Product Lifecycle Management: Marketing Strategies for the Pharmaceutical Industry	Dennis Z. Kvesic D.Z	Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing	2008	vol. 8, no. 4, pp. 293-30
Product lifecycle management in pharmaceuticals', Journal of Medical Marketing: Device, Diagnostic and	Prajapati V.and Dureja H	Pharmaceutical Marketing	2012	vol. 12, no. 3, pp. 150-158