



Pharmine

Workpackage 5



Recommendations on competency curricula for pharmacy specialisation (Industrial)

1. Definitions of competencies at Master level
2. Definitions of competences at specialisation level (postgraduate)



WP5 programme

1. EIPG: European Industrial Pharmacy Group
= pharmacists working in Pharmaceutical Industry
(Jane Nicholson, Gino Martini)
2. Set of competences
3. Main question : do you consider an Advanced Master in Industrial Pharmacy would be a positive tool in your country ?



Milestones

1. Set of competences
2. Amendments
3. Approval General Assembly EIPG Milano,
14-15 May 2010
4. Approval by EUFEPS, IMI, FIP



Knowledge Competencies needed by the Pharmacist for a career in the Pharmaceutical Industry



General:

Knowledge related to the different areas of employment of the Industrial Pharmacist in the Pharmaceutical Industry



Knowledge related to the development, production, analysis and distribution of pharmaceutical products.

- Understands the design, manufacture and performance of dosage forms and is able to critically appraise the inter-relationship between formulation, drug delivery and therapeutic effectiveness.
- Has an integrated vision of the role of the various disciplines that are involved in the development of a medicinal product.
- Understands the quality requirements for manufacturing procedures for pharmaceutical products on both small and industrial scale, including Standard Operating Procedures and the supervision standards necessary to achieve these quality levels.
- Understands the relative importance of quality control testing and manufacturing controls for product quality.
- Understands the organisation and monitoring of the distribution of medicinal and other healthcare products including the regulations related to pharmaceutical marketing.
- Has knowledge of the production, quality assurance and applications of biotechnology, nanotechnology and genomic medicines.



Knowledge related to the analysis and quality control of pharmaceutical products.

- Understands the main sources of active drug substance and the major excipients and the ways in which they are purified, characterised and analysed.
- Understands the role and appropriate application of the various techniques for the analysis of pharmaceutical products.
- Understands the role and responsibilities of the Qualified Person
- Understands and can explain the quality management systems applied to pharmaceutical products.
- Understands the theory and practice of analytical method validation of drugs



Knowledge of management, legislation and economics applied to the pharmaceutical industry.

- Has an understanding of leadership and project management skills
- Understands the principals of business economics. and intellectual property rights including the basics of patent interpretation.
- Understands the steps needed to bring a medicinal product to the market including the safety, quality, efficacy and pharmaco-economic assessments of the product.
- Understands the role of Regulatory Affairs and the key aspects of pharmaceutical registration and legislation.
- Has an understanding of the Quality Systems including GxP and ISO, applied to the pharmaceutical industry.
- Understands the role and function of the marketing and sales departments.



Knowledge in pre-clinical, clinical and experimental clinical-pharmacological research.

- Understands the assessment of benefit/risk in relation to animal /clinical studies.
- Has knowledge of the purpose, organisation and running of clinical studies, from “first in human” trials to post-marketing phase 4 studies
- Has an understanding of appropriate research methodology as applied to scientific and practice related problems.
- Is able to find and interpret relevant scientific and clinical information available in current data bases.
- Understands the relationship between pharmacological science and the detection, assessment and prevention of adverse events.



Milestone 5

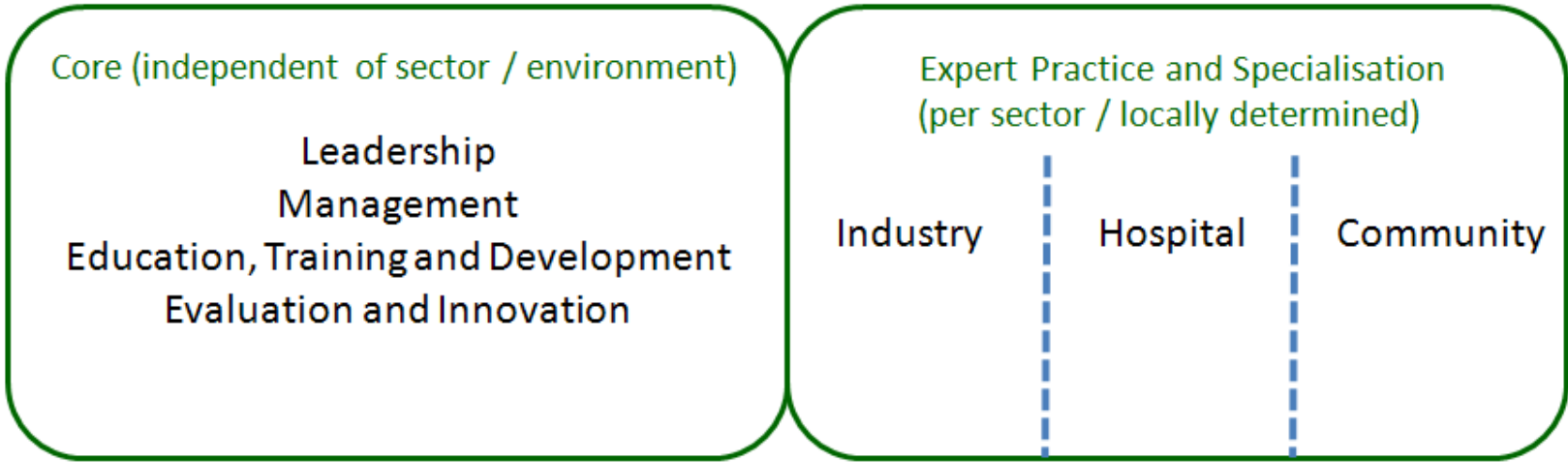
Integrations of this set of competences
with WP3 and WP4



IDENTIFYING AND DEFINING COMPETENCIES

A clear map for scientific and professional competencies as applied to industrial pharmacy

2011



Clusters	starting with → moving towards			Setting	Job descriptions
	L M ET RE	Spectrum / scope of practice			Industry Hospital Community



Specialisation level

Survey of existing postgraduate courses for industrial pharmacists

Ex. UK -> Manchester School of Pharmacy, PIAT course



- Master in Industrial Pharmacy ?
- Master classes in Industrial Pharmacy ?

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