

DEXP5.2

IDENTIFYING AND DEFINING COMPETENCIES

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

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Education and Culture DG

Lifelong Learning Programme

PHARMINE
*Pharmacy Education
in Europe*

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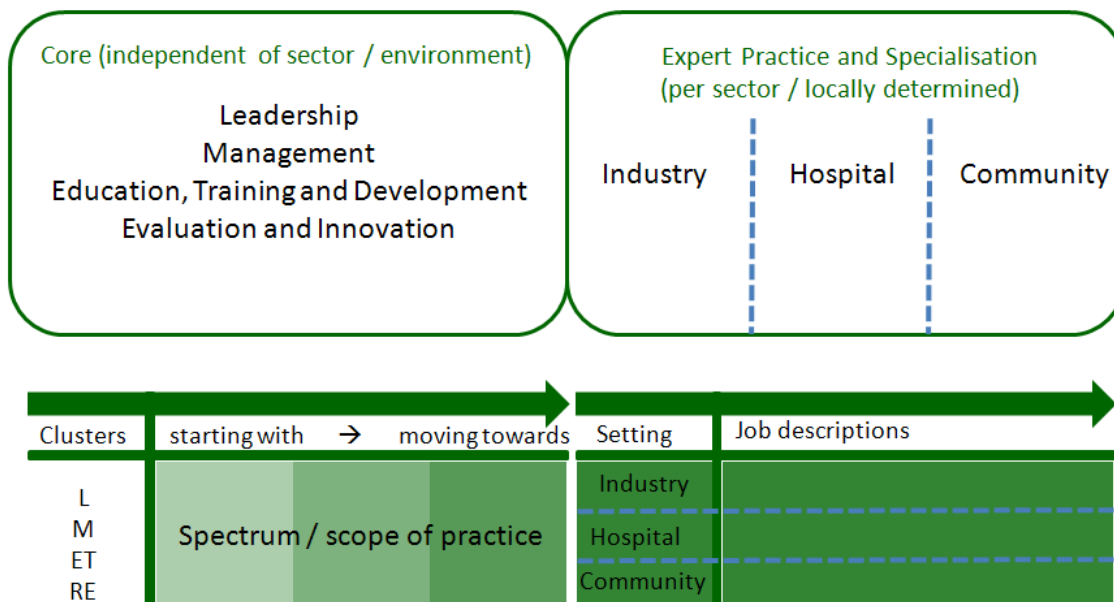
ABPI	Association of the British Pharmaceutical Industry
ALF	Advanced Level Framework
CAP	Community-acquired Pneumonia
CE	Continuing Education
CPD	Continuous Professional Development
CTA	Clinical Training Agreement
CTD	Common Technical Document
CV	Cardiovascular
DH	Department of Health
EAFP	European Association of Faculties of Pharmacy
EAHP	European Association of Hospital Pharmacists
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHEA	European Higher Education Area
EIPG	European Industrial Pharmacists Group
EMA	European Medicines Agency
EPP	Expert Professional Practice
EPSA	European Pharmacy Students' Association
ESCP	European Society of Clinical <i>Pharmacy</i>
ET	Education and Training
ETD	Education Training and Development
EU	European Union
FIP	International Pharmaceutical Federation
FLF	Foundation Level Framework
FLO	Foundation Level Outcomes
GCP	Good Clinical Practice
GHTF	Global Harmonisation Task Force
GLF	General Level Framework
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HEI	Higher Education Institution
HIV	Human Immunodeficiency Virus
ICU	Intensive Care Unit
IMPD	Investigational Medicinal Product Dossier
ISO	International Standards Organization

IT	Information Technology
ITU	Intensive Therapy Unit
IV	Intravenous
L	Leadership
LLL	Life Long Learning
M	Management
MA	Marketing Authorization
MEDDEV	Medical Devices
MRSA	Methicillin-resistant Staphylococcus Aureus
NHS	National Health Service
NPC	National Prescribing Centre
OTC	Over The Counter
PGEU	Pharmaceutical Group of the European Union
PICU	Postoperative Intensive Care Unit
PIL	Patient Information Leaflet
PIPA	Pharmaceutical Information and Pharmacovigilance Association
QP	Qualified Person
QRD	Quality Review of Documents
RD	Research and Development
RE	Research and Evaluation
REACH	Registration, Evaluation and Authorisation of Chemicals
REI	Research Evaluation and Innovation
RFID	Radio Frequency Infrared Device
RIP	Research Implementation Projects
SALF	Specialist and Advanced Level Framework
SOP	Standard Operating Procedures
SPC	Summary of Product Characteristics
TDM	Therapeutic Drug Monitoring
TOPRA	The Organisation for Professionals in Regulatory Affairs
TPN	Total Parenteral Nutrition
UK	United Kingdom
UKMI	United Kingdom Medicines Information
WP	Work Package

1. WP5 AIM

To provide recommendations on competency curriculum for industrial pharmacy. Specifically aims to reach consensus on a core set of scientific and expert practitioner competencies based on establishing the requirements for modern practice.

Figure 1. WP4 and WP5 Diagram



The aim of WP5 is to produce an EU consensus on the scientific and professional competencies for pharmacists ready to function in the industry. Evidently, focus will be on the pharmaceutical industry, but also chemical and cosmetic industry will be taken in account.

Three issues will be dealt with in detail:

What competencies are required at the Master level? In other words what competencies are required for a pharmacist entering the pharmaceutical industry and what is the position of this pharmacist?

Is there a need for a specialisation in Industrial Pharmacy? Could such a specialisation be provided by an Advanced Master in Industrial Pharmacy? Should such an Advanced Master be associated with a title of "Industrial Pharmacist"?

If there is no need for such a broad specialisation in Industrial Pharmacy, what are then the post-graduate needs of the industrial pharmacist and what are the Advanced level competencies of an industrial pharmacist. What is the relation between these post-graduate needs of the industrial pharmacist and the academia?

What are the professional needs and how can they be achieved in Doctoral pharmacy programmes, in other words how is the relation between pharmaceutical industry and a Doctor in Pharmacy? This last issue will be dealt in DEXP5.3

2.WP5 CONTEXT

The Pharmaceutical Industry is evolving at a rate that has never before been seen and which will demand more from the Industrial Pharmacist.

A brainstorming session by industrial pharmacists in Belgium on the changes in the pharmaceutical industry and the impact of these changes on the work of industrial pharmacists highlighted the following 4 points:

1. The increased importance of pharmacovigilance/risk-benefit analysis/regulatory affairs and strategy/electronic documentation management
2. The need for knowledge of economics/management/finance/process analysis/communication and customer liaison skills
3. The need for knowledge of intellectual property rights/project management/pharmaco-economics
4. The requirement for specialization in the various functions of industry is indispensable

In project management, key areas of change are that pharmacists will be dealing with projects that are being developed across national borders.

There will be greater emphasis on developing medicines which show marked clinical differentiation and thus are readily reimbursable.

There will be medicines which will require a greater degree of pharmacist intervention due to the impact of diagnostics, personalised medicine and need for specialist handling and cold chain supply.

The ideal industrial pharmacist must have the necessary technical competencies but in addition must have good communication skills, have the ability to manage global projects, have knowledge of global registration requirements and be able to understand the move from 'one size fits all' mode of drug development to developing medicines which are delivered at the right dose, at the right time and at the right rate for individual patients. The pharmacist will be comfortable in handling technical and regulatory projects with people whose first language is not English and in different time zones because this will be the norm. Working in a virtual team, the pharmacist will be the locus for technical exchange of data, information and advice.

3.WP5 DEVELOPMENTS, EVIDENCE and OUTCOMES. The Specialist and Advanced Level Framework (SALF)

1. Working method

Data acquisition: the first step was the data gathering on what is available on courses in industrial pharmacy for pharmacists (at any level) in the European countries. What data are available on competences required for industrial pharmacists in the Schools of Pharmacy, or in the professional associations of industrial pharmacists at country level and European level?

Each of the partners in WP5, takes a central role in industrial pharmacy. P8 is the European Industrial Pharmacists Group; the E.I.P.G. is a European association representing the national professional organisations of pharmacists employed in the European pharmaceutical industry. The main objective of EIPG is to promote and uphold the importance and role of the industrial pharmacist within the pharmaceutical industry. Thus, the various aspects of education and training for industrial pharmacists are of major concern and are key points for discussion at every EIPG General Assembly. EIPG is the main stakeholder for pharmacists entering the Pharmaceutical Industry. P1 and P2 represent the European Association of Faculties of Pharmacy (EAFP, president and past-president). EAFP

is the association of all Schools of Pharmacy in Europe. Using the backbone of both organisations, the data acquisition could be successfully organised.

Discussion forums: at national level and at European level several forums were started to discuss the issues raised in the Aims and Objectives.

Consensus meetings at European level. These consensus meetings were the working party meetings held during the EIPG General Assemblies in Riga, Latvia (2009) and Milan, Italy (2010).

2. Data acquisition

As described previously, this WP5 started with a data acquisition via EIPG and EAFP. Where no direct data were available, they were gathered via the electronic survey, described in WP2.

Already in 2008, during the EIPG General Assembly in Malta, the competences & skills needed to become an industrial pharmacist in the different EU countries were discussed. It was noted that in France and Finland there is a specialized cycle for industrial pharmacists. EIPG delegations agreed that there cannot be more than minimal specialization unless the basic course is at least 6 years as in France. Hungary is looking to expand the education for all pharmacists to be 6 years. In most countries, including the Netherlands and Great Britain there is no specific education for Industrial Pharmacists but rather a general education to become a pharmacist with some orientation in the later years such as in Spain and Czech Republic. Some countries have Pharmaceutical Technology PhD programmes for pharmacists going into industry. Other relevant data were from France where the Conseil National de L'Ordre des Pharmaciens funded by the French Government has undertaken an extensive review of the job expectations, expertise, skills and “know how” required from pharmacists to produce competency guidelines. The French member of EIPG, Section B of the Ordre des Pharmaciens, reviewed the draft document written by Professor P. Tchoreloff (Faculté de Pharmacie de Châtenay-Malabry), who was responsible for elaborating the industrial pharmacy guidelines. During the meeting in Malta EIPG stated that the training of pharmacists should produce an individual with a unique profile: an applied scientist with patient focus, who can lead or work within a team and someone who can bridge the medical and natural sciences, regulatory and technical processes. Another document taken in account was a survey of the main areas of employment of pharmacists in the pharmaceutical industry was conducted amongst EIPG members prior to a General Assembly in Prague 2007. The breakdown was found to be as follows:

- Research and Development
- Quality Assurance and Analysis
- Manufacture and Wholesale Distribution
- Regulatory Affairs including Product Registration
- Clinical Trial Management
- Marketing and Sales and Sales Training
- Product Information, Patient Safety and Pharmacovigilance
- General Management, Project Management and Business Development

The proportion of pharmacists working in the various functions of industry was found to differ between both companies and countries.

Issue 1: Competences for pharmacists entering the Pharmaceutical Industry

Using the data acquisition, WP5 stated that the competences of pharmacists were different in the several countries of Europe, but that it should be possible to harmonize and formulate a set of minimum competences required for pharmacists to enter the Pharmaceutical Industry. The goal of this issue was to formulate these competences and

to have them validated by a maximum of delegates of stakeholders. These competences will be proposed to Working Party 3 for incorporation into the foundation level scientific and professional competences for all pharmacists.

A draft list of “knowledge competences” required on Day 1 of registration as a pharmacist was first produced in Belgium by an ad hoc working group of members of WP1 and WP8. This draft list was then circulated to EIPG (WP8) delegations of different European countries in December 2009. Comments and amendments were received from 17 member delegations of EIPG and an observer (Switzerland). In addition, the draft was circulated for comment to the Industrial Section of the International Pharmaceutical Federation (FIP), the European Trade Association (EFPIA), the European Pharmaceutical Sciences Federation (EUFEPS) and EAFP. The document was made available to member delegations for distribution and discussion on a national basis. The final document (see Appendix 3) was not only approved by the 2010 EIPG General Assembly in Italy, the main stakeholder of the pharmaceutical Industry for pharmacists, but also by all other stakeholders mentioned above.

The conclusions were that a polyvalent first degree is considered essential for patient safety. Whether pharmacists work in community, hospital or industry, they need to communicate with one another on the basis of a common scientific and clinical background. A Masters in Pharmacy produces an applied scientist with patient focus who is an ideal professional for the industry.

This document was presented to WP3 for incorporation into the foundation level scientific and professional competencies for all pharmacists.

Issue 2: Advanced level competences and the post-graduate needs of industrial pharmacists

Using the same strategy as for pharmacist level, advanced level competences and the post-graduate needs of industrial pharmacists were formulated (see section 3.3.).

Moreover, a survey of existing postgraduate courses was undertaken during 2008 and presented at the EAFP Conference in Norway 2009. In this survey responses were included from Belgium, Bulgaria, Czech, Denmark, France, Germany, Greece, Great Britain, Italy, Latvia, Malta, Netherlands and Sweden. All country delegates reported company sponsored training courses and most commented on postgraduate Master or Diploma courses in aspects of industrial pharmacy ranging from qualification, validation, audit and inspection of quality systems to PK/PD training in drug discovery. Although many are organised by University Schools of Pharmacy, these postgraduate courses are not specific to pharmacy graduates. A summary of responses is as shown in Appendix 4:

At the 2010 General Assembly in Milano (Italy), there was a discussion of a pre-circulated questionnaire on Advanced level training. It was noted that most of the delegations did not consider a broadly based Advanced Masters in Industrial Pharmacy was a positive tool. It was confirmed by all present that an Advanced Masters should definitely not be associated with the title of “Industrial Pharmacist”. The reason for this is that after 1-3 years post-registration (the time will vary between individuals) the foundation level competencies will be met at a higher level of “knows and shows how” either through “on the job training” whilst working in industry when the young pharmacist moves departments and undertakes courses provided by the company and overseen by the professional body or through an Advanced Masters course (typically provided in Belgium and Italy as a 1 year university course or in Malta as part- time distance learning whilst working in industry.) After the early years, industrial pharmacists will normally specialize in a job function of industry and attain more specific competencies at an “advanced practice level” such as specialist in regulatory affairs, clinical trials management or quality assurance. The most popular courses are supervised by the Universities in collaboration with the professional bodies and staff working in industry. Delegations were asked whether part-time or full-time postgraduate courses were considered most popular

and if studies were appropriate before or during employment in industry. The optimum blend of conditions seemed to be the ability to be exposed simultaneously to an industrial environment and the higher level of University training i.e. part- time modular courses arranged by the Universities with input from the professional associations were favoured.

As industrial pharmacists will normally specialise in a particular area and in consideration of the 8 main areas of employment of pharmacists, a search was made for existing competencies in these specialist areas. Examples of two sets of specialist competencies are as shown in Appendix C. One is from the European organisation for Professionals in Regulatory Affairs (TOPRA) entitled Key Regulatory Competencies and the second for Medical Information Professionals (PIPA) which are competencies for those working in pharmaceutical information and pharmacovigilance. For those working in Quality Assurance the attached Qualified Persons study guide contains the required competencies. Competencies for other areas are in the throes of being established such as a list of sales and marketing competencies being put together by a European Marketing Group.

Conclusions

The main conclusion of this issue is that the pharmacists working in industry do not consider that a broad Advanced Master in Industrial Pharmacy and a title of Industrial Pharmacist is appropriate for pharmacists working in the pharmaceutical Industry. However, a set of short Master or Diploma Courses (such as Regulatory Affairs, Quality Assurance) should be organized by experts in the field and should be under the supervision of academia. Preferentially, these short Master courses should be organized by e-learning and distance learning, with eventually a residential seminar. The way these courses should be organized could be the topic of another European project.

During their career, industrial pharmacists may move into a number of specialist areas of work in the pharmaceutical and allied industries. In addition to their technical knowledge, a range of management, leadership, analytical and communication skills and an understanding of health policy and economics are needed as exemplified by the competencies listed in Appendix 1.

There are a large variety of post-graduate courses currently available but these need to be mapped against the range of competencies from all areas of the pharmaceutical and allied industries. There would appear to be opportunities for joint ventures between Schools of pharmacy and Departments of Business Studies, Law and Health Economics so that pharmacists can better relate these specialist post-registration courses to their role in pharmacy.

3.3. WP5 Work in parallel with WP3 and WP4

The developments on WP5 were carried out in parallel with the developments taking place in WP3 and WP4.

Following the concept of behavioural (educational) driven competence, a pilot version that describes competencies for advanced level practice for specialisation was drafted (Appendix 1). Consultations agreed that specialisation should map across all scopes/sectors of practice. The logical base for this resides in a framework that is educational (and not related to functional tasks or job descriptions) and hence must be intellectually applicable across all sectors of practice, must be cognitive and must be generic. After a period of consultations,

meetings and iterations (n=8 meetings; n=230 emails) the Specialist and Advanced Level Framework (SALF) was developed for pharmacists progressing to advanced levels of practice (Appendix 2).

Using previous evidence and research, regular meetings and consulting with partners ((n=8 meetings; n=230 emails) the identified professional competencies were arranged in two sections: Core Clusters (Competencies which are common to all sectors of practice) and Specialisation or Expert Professional Practice Clusters (Sector specific and locally determined); and after a period of meetings and iterations (Appendix 1) consensus was reached and the Specialist and Advanced Level Framework was developed (Appendix 2).

Core Clusters include competencies referred to the areas of 'Leadership', 'Management', 'Education, Training and Development' and 'Innovation and Evaluation' whereas Specialisation Clusters focus on Expert Professional Practice, Specialisation and Building Working Relations

The SALF is made up of the following components:

1. **Core clusters** which include four main areas of practice-based competence (competency clusters), which are:

Leadership

Management

Education, training and development

Evaluation and Innovation

Each of the Core clusters contains closely related competencies. Using the Leadership Competencies cluster as an example, the competencies in this area pertain to:

Patient Consultation

1. Leadership

-Strategic Context

-Contributes to the organisational governance

-Creates Vision for Service Development

-Innovation

-Motivational

Each of these competencies is related to an explanation of the scope of practice for that particular competency. This section of the developmental framework provides the individual with a tool to progress within her/his sector, starting within a specialized position and slowly acquiring more responsibilities and moving towards a mastery level in each of the domains. Using the 'Strategic Context' competency in the Leadership cluster:

1. Leadership

-Strategic Context



- *Demonstrates understanding of the needs of stakeholders and practice reflects both local and national health care policy.*
- *Demonstrates ability to incorporate national healthcare policy to influence local strategy.*

- *Demonstrates active participation in creating national health care policies.*

2. Specialisation Clusters which include:

Expert Professional Practice

Specific Competencies for Hospital Pharmacy (Appendix 2)

Specific Competencies for Industry Pharmacy
(Appendix 2, in FULL in Appendix 5)

Expert Professional Cluster is structured the same way as the Core Clusters with the difference being sector specific and locally determined. A list of specific competencies necessary for the specialized practices of hospital or industry pharmacy is included in this section of the framework. The competencies listed build upon basic pharmacy skills and are intended for intermediate level pharmacists who have completed a period of work experience or training in hospital or industry setting.

With this kind of structure, harmonization in all sectors is possible and, at the same time, professional autonomy is protected. This structure allows specialisms, sectors and individual practitioners to translate their own practice context.

Appendix 1. Specialist and Advanced Level Framework (SALF) developments

CORE CLUSTERS
1. Leadership 2. Management 3. Education, Training & Development 4. Evaluation & Innovation
1. Leadership -Strategic Context -Contributes to the organisational governance -Creates Vision for Service Development -Innovation -Motivational 2. Management -Implementing organisational priorities in line with National policy -Resource utilisation -Standards of practice -Managing Risk - if applicable to your country -Managing Performance including Service Development -Project Management -Managing Change -Strategic Planning -Working Across Boundaries (including Cultural, societal, professional) 3. Education, Training & Development -Role Model -Mentorship -Conducting Education & Training within organisational and working environments -Continuing Professional Development -Links Practice and Education -Educational Policy 4. Evaluation & Innovation -Critical Evaluation -Identifies Gaps in The Evidence Base (creativity, innovation, environmental scanning) -Develops and Evaluates Research Protocols -Creates Evidence -Research Evidence Into Practice -Supervises Others Undertaking Research -Establishes Research Partnerships / Novel ways of working

1. Leadership

-Strategic Context

- Demonstrates understanding of the needs of stakeholders and practice reflects both local and national health care policy.
- Demonstrates ability to incorporate national healthcare policy to influence local strategy.
- Demonstrates active participation in creating national health care policies.

-Contributes to the organisational Governance

- Demonstrates understanding of the pharmacy role in clinical governance.
Implements this appropriately within the organisation.
- Influences clinical governance agenda for the team.
- Shapes and contributes to the clinical governance agenda at a higher level.

-Creates Vision for Service Development

- Demonstrates understanding of, and contributes to, the department and corporate vision.
Reviews last year's progress and develops clear plans to achieve results within priorities set by others.
- Creates vision of future and translates this into clear directions for staff and supervisors.
Develops clear understanding of priorities and formulates practical short-term plans in line with department strategy.
- Convinces others to share the vision at a higher level.
Relates goals and actions to strategic aims of organisation and profession.

- Innovation

- Demonstrates ability to improve quality within limitations of service.
Requires limited supervision.
- Recognises and implements innovation from the external environment. Does not require supervision.
- Takes the lead to ensure innovation produces demonstrable improvement in service delivery.

- Motivational

- Demonstrates ability to motivate self to achieve goal.
- Demonstrates ability to motivate individuals in the team.
- Demonstrates ability to motivate individuals at a higher level.

2. Management

-Implementing Organisational priorities in line with National policy.

SPECIALISATION CLUSTERS

- 1. Expert Professional Practice, Specialisation and Building Working Relationships**
- 2. Specific competencies for hospital pharmacy (Specialisation Stream Hospital)**
- 3. Specific competencies for industrial pharmacy (Specialisation Stream Industry)**
- 4. Specific competencies for community pharmacy (Specialisation Stream Community)**

1. Expert Professional Practice, Specialisation and Building Working Relationships

-Expert Skills and Knowledge

- Demonstrates general pharmaceutical knowledge in core areas. Is able to plan, manage, monitor, advise and review general pharmaceutical care programmes in core areas.
- Demonstrates specialist pharmaceutical knowledge in a defined area (s). Is able to plan, manage, monitor, advise and review specialist pharmaceutical care programmes in defined area(s).
- Advances the knowledge base in the defined area. Advances specialist pharmaceutical care programmes in the defined area(s).

-Service / Patient Care Responsibilities

- Is accountable for the delivery of a pharmacy service to which they themselves directly provide pharmaceutical care.
- Is accountable for the delivery of a pharmacy service to a defined group.
- Is accountable for the direct delivery of the pharmacy service for the defined area(s).

-Reasoning and Judgment. Including: Analytical Skills, Judgmental Skills, Interpretational Skills, Option Appraisal

- Demonstrates ability to use skills in a range of routine situations requiring analysis or comparison of a range of options. Recognises priorities when problem-solving and identifies deviations from the normal pattern.
- Demonstrates ability to use skills to make decisions in complex situations where there are several factors that require analysis, interpretation and comparison. Demonstrates an ability to see situations holistically.
- Demonstrates ability to use skills to manage difficult and dynamic situations. Demonstrates ability to make decisions in the absence of evidence or data or when there is conflicting evidence or data.

-Professional Autonomy

- Is able to follow legal, ethical, professional and organisational policies/procedures and codes of conduct
- Is able to take action based on own interpretation of broad professional policies/procedures where necessary
- Is able to interpret overall health service policy and strategy, in order to establish goals and standards for others within the defined area(s).

-Communication. Including ability to: Persuade, Motivate, Negotiate, Empathise, Provide Reassurance, Listen, Influence. Networking and Presentation Skills.

- Demonstrates use of appropriate communication to gain the co-operation of individual patients, colleagues or clinicians. Demonstrates ability to communicate where the content of the discussion is

Appendix 2. Specialist and Advanced Level Framework (SALF)

Framework Part 1. Core Clusters (independent of sector or environment)

Leadership				
Inspires individuals and teams to achieve high standards of performance and personal development				
Competency		Spectrum / Scope of Practice		
		Starting with	Moving Towards	
1	Strategic Context	Demonstrates understanding of the needs of stakeholders and practice reflects both local and national health	Demonstrates ability to incorporate national healthcare policy to influence local strategy.	Demonstrates active participation in creating national health care policies.
2	Clinical Governance (ie. Pharmacovigilance)	Demonstrates understanding of the pharmacy role in clinical governance. Implements this appropriately within the organisation.	Influences the clinical governance agenda for the team.	Shapes and contributes to the clinical governance agenda at a higher level.
3	Vision	Demonstrates understanding of, and contributes to, the department and corporate vision.	Creates vision of future and translates this into clear directions for staff and supervisors	Convinces others to share the vision at a higher level.
4	Innovation	Demonstrates ability to improve quality within limitations of service. Requires limited supervision	Recognises and implements innovation from the external environment. Does not require supervision	Takes the lead to ensure innovation produces demonstrable improvement in service delivery.
5	Service Development	Reviews last year's progress and develops clear plans to achieve results within priorities set by others.	Develops clear understanding of priorities and formulates practical short-term plans in line with department	Relates goals and actions to strategic aims of organisation and profession.
6	Motivational	Demonstrates ability to motivate self to achieve goals	Demonstrates ability to motivate individuals in the team.	Demonstrates ability to motivate individuals at a higher level.

Management				
Organises and delivers service objectives in a timely fashion				
Competency		Spectrum / Scope of Practice		
		Starting with	Moving Towards	
1	Implementing National Priorities	Demonstrates understanding of the implications of national priorities for the team	Shapes the response of the team to national priorities.	Accountable for the direct delivery of national priorities at a higher level.
2	Resource Utilisation	Demonstrates understanding of the process for effective resource utilisation	Demonstrates ability to effectively manage resources.	Demonstrates ability to reconfigure the use of available resources.
3	Standards of practice	Demonstrates understanding of, and conforms to, relevant standards of practice	Accountable for the setting and monitoring of standards of practice at team level	Accountable for the setting and monitoring of standards at a higher level
4	Managing Risk - if applicable to your country	Demonstrates ability to identify and resolve risk management issues according to policy/protocol	Is accountable for developing risk management policies/protocols for the team, including identifying and resolving new risk management issues	Is accountable for developing risk management policies/procedures at a higher level, including identifying and resolving new risk management issues
5	Managing Performance	Follows professional and organisational policies/procedures relating to performance management. Refers appropriately to colleagues for guidance.	Is accountable for performance management for the team	Is accountable for performance management at a higher level..
6	Project Management	Demonstrates understanding of the principles of project management.	Demonstrates ability to successfully manage a project at team level.	Demonstrates ability to successfully manage a project at a higher level
7	Managing Change	Demonstrates understanding of the principles of change management	Demonstrates ability to manage a process of change for the team	Demonstrates ability to manage a process of change at a higher level.
8	Strategic Planning	Demonstrates ability to think 4-12 months ahead within a defined area. Plans the work programme to align with strategy. Demonstrates understanding of formal structures	Demonstrates ability to think over a year ahead within a defined area. Demonstrates understanding of culture and climate and ability to plan with the whole of the organisation in mind	Thinks long term and sector wide. Takes the long-term perspective. Demonstrates understanding of organisational politics changes in the external environment.
9	Working Across Boundaries	Demonstrates ability to extend boundaries of service delivery within the team	Demonstrates ability to extend the boundaries of the service across more than one team	Demonstrates the value of extending boundaries across professions/in the external environment.

Education, Training & Development				
Supports the education, training & development of others. Promotes a learning culture within the organisation.				
Competency		Spectrum / Scope of Practice		
		Starting with		Moving Towards
1	Role Model	Understands and demonstrates the characteristics of a role model to members of the team	Demonstrates the characteristics of an effective role model at a higher level	Is able to develop effective role model behaviour in others
2	Mentorship	Demonstrates understanding of the mentorship process	Demonstrates ability to effectively mentor others within the team	Demonstrates ability to effectively mentor outside the team.
3	Conducting Education & Training	Demonstrates ability to conduct teaching efficiently according to a lesson plan with supervision from a more experienced colleague	Is able to assess the performance and learning needs of others. Demonstrates ability to plan a series of effective learning experiences for others	Demonstrates ability to design and manage a course of study, with appropriate use of teaching, assessment and study methods
4	Continuing Professional Development	Demonstrates self-development through routine continuing professional development activities available in your country with facilitation	Acts as a continuing professional development facilitator (eg. Acts as a mentor or focus for other practitioners to develop)	Shapes and contributes to the continuing professional development strategy at a local (outside of discipline) or external (within discipline) levels.
5	Links Practice and Education	Participates in the formal education of undergraduate and postgraduate students	Participates in the education and training of formal specialist interest groups in the external environment	Shapes, contributes to or is accountable for the creation or development of higher education qualification(s)
6	Educational Policy	Demonstrates an understanding of current educational policies in health services	Demonstrates ability to interpret national policy in order to design strategic approaches for local workforce	Shapes and contributes to national educational policy.

Innovation & Evaluation

Uses research to deliver effective practice. Identifies and undertakes research to inform practice.

Competency		Spectrum / Scope of Practice		
		Starting with		Moving Towards
1	Critical Evaluation	Demonstrates ability to critically evaluate medical and review pharmacotherapeutic literature	Demonstrates application of critical evaluation skills in the context of specialist practice	Is recognised as undertaking peer review activities within the speciality.
2	Identifies Gaps in The Evidence Base	Demonstrates ability to identify instances where there is a gap in the evidence base to support practice	Demonstrates ability to formulate appropriate and rigorous research questions within the speciality	Demonstrates ability to design a successful strategy to address research questions within the speciality.
3	Develops and Evaluates Research Protocols	Demonstrates ability to describe the core features of research protocols	Demonstrates ability to design a rigorous protocol to address previously formulated research questions	Demonstrates active involvement in the critical review of research protocols.
4	Creates Evidence	Demonstrates ability to generate evidence suitable for presentation at local level	Demonstrates ability to generate new evidence suitable for presentation at research symposium	Demonstrates authorship of primary evidence and outcomes in peer reviewed media.
5	Research Evidence Into Practice	Demonstrates ability to apply research evidence into own practice	Demonstrates ability to apply evidence-based practice within the team	Is able to use research evidence to shape organisational policy/procedure.
6	Supervises Others Undertaking Research	Demonstrates understanding of the principles of research governance	Is able to contribute to research supervision in collaboration with research experts.	Is a research project supervisor for postgraduate students
7	Establishes Research Partnerships	Demonstrates ability to work as a member of the research team	Demonstrates ability to establish new multidisciplinary links to conduct research projects	Demonstrates ability to show leadership within research teams concerning the conduct of specialist research.

DRAFT

Framework Part 2. Specialisation (per sector / locally determined)

To enable evidence gathering for portfolio

To enable curriculum development. For example, “knowledge and skills” states (ie Spain, France, etc)

1. Expert Professional Practice / Specialisation and Building Working Relationships / Professional Curricula

Improving standards of pharmaceutical care. Is able to communicate, establish and maintain working relationships and gain the co-operation of others

Competency		Starting with	Moving Towards	
1	1a Expert Skills and Knowledge for those who are patient facing	Demonstrates general pharmaceutical knowledge in core areas. Is able to plan, manage, monitor, advise and review general pharmaceutical care programmes for patients in core areas	Demonstrates specialist pharmaceutical knowledge in a defined area(s). Is able to plan, manage, monitor, advise and review specialist pharmaceutical care programmes for patients in defined area(s)	Advances the knowledge base in the defined area. Advances specialist pharmaceutical care programmes for patients in the defined area(s)
	1b Expert Skills and Knowledge for those who are not patient facing	Demonstrates general pharmaceutical knowledge in core areas. Is able to plan, manage, monitor, advise and review general pharmaceutical care programmes in core areas	Demonstrates specialist pharmaceutical knowledge in a defined area(s). Is able to plan, manage, monitor, advise and review specialist pharmaceutical care programmes in defined area(s)	Advances the knowledge base in the defined area. Advances specialist pharmaceutical care programmes in the defined area(s)
2	2a Patient Care Responsibilities	Is accountable for the delivery of a pharmacy service to patients to whom they themselves directly provide pharmaceutical care	Is accountable for the delivery of a pharmacy service to a defined group of patient	Is accountable for the direct delivery of the pharmacy service for the defined area(s)

	2b Service Responsibilities for those who are not patient facing	Is accountable for the delivery of a pharmacy service to clients to whom they themselves directly provide pharmaceutical care	Is accountable for the delivery of a pharmacy service to a defined group of clients	Is accountable for the direct delivery of the pharmacy service for the defined area(s)
3	3 Reasoning and Judgment (Analytical, Judgmental Interpretational Skills, Option Appraisal)	Demonstrates ability to use skills in a range of routine situations requiring analysis or comparison of a range of options. Recognises priorities when problem-solving and identifies deviations from the normal pattern	Demonstrates ability to use skills to make decisions in complex situations where there are several factors that require analysis, interpretation and comparison. Demonstrates an ability to see situations holistically	Demonstrates ability to use skills to manage difficult and dynamic situations. Demonstrates ability to make decisions in the absence of evidence or data or when there is conflicting evidence or data
4	4 Professional Autonomy	Is able to follow legal, ethical, professional and organisational policies/procedures and codes of conduct	Is able to take action based on own interpretation of broad professional policies/procedures where necessary	Is able to interpret overall health service policy and strategy, in order to establish goals and standards for others within the defined area (s).
5	5a Communication for those patient facing (Persuade, Motivate, Negotiate, Empathise, Provide Reassurance, Listen, Influence. Networking and Presentation Skills)	Demonstrates use of appropriate communication to gain the co-operation of individual patients, colleagues and clinicians. Demonstrates ability to communicate where the content of the discussion is explicitly defined	Demonstrates use of appropriately selected communication skills to gain co-operation of small groups of patients, colleagues, senior clinicians and managers within the organisation. Demonstrates ability to communicate where the content of the discussion is based on opinion	Demonstrates ability to present complex, sensitive or contentious information to large groups of patients, clinicians and senior managers. Demonstrates ability to communicate in a hostile, antagonistic or highly emotive atmosphere

	5b Communication for those not patient facing (Persuade, Motivate, Negotiate, Empathise, Provide Reassurance, Listen, Influence. Networking and Presentation Skills)	Demonstrates use of appropriate communication to gain the co-operation of colleagues. Demonstrates ability to communicate where the content of the discussion is explicitly defined	Demonstrates use of appropriately selected communication skills to gain co-operation of colleagues, senior and managers within the organisation. Demonstrates ability to communicate where the content of the discussion is based on opinion	Demonstrates ability to present complex, sensitive or contentious information to senior managers. Demonstrates ability to communicate in a hostile, antagonistic or highly emotive atmosphere
6	6 Teamwork and Consultation	Demonstrates ability to work as a member of the pharmacy team. Recognises personal limitations and is able to refer to more appropriate colleague	Demonstrates ability to work as an acknowledged member of a multidisciplinary team. Accepts consultation for specialist advice from within the organisation	Works across boundaries to build relationships and share information, plans and resources. Sought as an opinion leader both within the organisation and in the external environment

2a. Specific Competencies for Hospital Pharmacy

2b. Specific Competencies for specialist areas of Industrial Pharmacy

2c. Specific Competencies for Community Pharmacy

Appendix 3. Knowledge Competencies needed by all Pharmacists on Day 1 of graduation

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 principles 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 pharmacoeconomic 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.

APPENDIX 4. Survey of existing postgraduate courses for industrial pharmacists

In Belgium, for the title of “industrial pharmacist” the Schools of Pharmacy run full-time Advanced Masters courses in industrial pharmacy. These seem to be more popular than the training given by companies for their staff to achieve the title “industrial pharmacist”.

In Bulgaria, post-graduate diplomas are offered in industrial pharmacy, pharmaceutical technology or pharmaceutical analysis. These are 3 year courses and the interest for any specialization is extremely low because the diplomas are not considered an advantage or benefit to the pharmacist and the courses are not free.

In the Czech Republic, a post-graduate course in industrial pharmacy leads to a PharmDr. qualification

In Denmark, the Faculty of Pharmacy in Copenhagen runs part-time Masters Courses in industrial drug development, drug management and regulatory affairs.

In France, there are many post-graduate courses offered by Schools of Pharmacy,

In Germany, there are many post-graduate specialist courses arranged by University Schools of Pharmacy in subjects such as pharmaceutical technology, pharmaceutical analysis, toxicology and product information. The courses are mostly 120 seminar hours in length to be undertaken within 3 years. In addition, Schools run short courses in specialist subjects such as pharmacoeconomics.

In Great Britain, a number of Universities run full and part-time post-graduate courses in various aspects of industrial pharmacy and the pharmaceutical sciences. As an example, the Pharmaceutical Industry Advanced Training Course at Manchester School of Pharmacy was developed with the pharmaceutical industry as a modular distance learning course. For each module students complete exercises from workbooks, a written assignment, attend workshops and an examination session at the University. MSc students must complete a dissertation. A range of modules can be studied covering subjects such as clinical trials, business development, licensing, pharmaceutical microbiology and toxicology.

In Greece, Athens University has a full time 2 year Masters course in industrial pharmacy including a 6 month research project whilst Thessaloniki runs a Masters in pharmaceutical sciences. Patras University runs post-graduate diploma courses in industrial pharmaceuticals and analysis, pharmaceutical chemistry of natural products, molecular pharmacology, pharmaceutical biotechnology and biomedicine and pharmaceutical marketing. In addition, specialist courses are available in subjects such as total quality management, pharmacoeconomics and pharmaceutical marketing.

In Italy, several Universities, in conjunction with the EIPG member, AFI (Associazione Farmaceutici Industria) run Masters Courses in pharmaceutical technology and regulatory affairs, industrial pharmaceutical technology, pre-formulation and pharmaceutical development. At the request of the Health Authorities, specialist training courses for their inspectors are arranged through AFI.

In Latvia, there are no post-graduate courses for industrial pharmacists and those working in technical areas such as the qualified person will be trained abroad

In Malta, the Department of Pharmacy offers an MSc in Pharmacy with industrial pharmacy as one of the areas of specialization. It is a 15 month full- time taught masters (60 ECTS taught/30 ECTS research). The other major degree of interest to industrial pharmacists is the M.Sc. in Applied Chemistry, offered by the Department of Chemistry. This is a 3 year

part-time course designed specifically for the pharmaceutical industry. Both courses have PgDip exit points after the taught study units.

In the Netherlands, the National Post-academic Education in Pharmacy (PAO-pharmacy) organize on behalf of the Royal Dutch Pharmacy Association (KNMP) a registration phase for pharmacists working in industry. The course consists of 4 x 2 day modules in research and development, drug safety, regulatory affairs and marketing and sales.

In Sweden, a modular training course in clinical trials is available with an examination resulting in a qualification of Clinical Trials Manager. The post-graduate student working in industry must have undertaken a minimum of three years, full or part time (minimum 75%) work in clinical trials including active participation in a series of planning, design, monitoring and management activities.



pharmaceutical information professionals association

Competency Areas for Medical Information Professionals

Information management skills

- Knowledge of relevant information sources including: printed publications, unpublished sources, databases, web sites, company departments, external bodies
- Understanding of the principles of information storage and retrieval, and skill in their application
- Ability to search a range of relevant information sources
- Effective use of word processing, spreadsheet and other office software programs
- Effective use of web systems

Scientific knowledge

- Ability to understand in detail clinical, biomedical and scientific reports about pharmaceutical products and related subject areas

Analytical skills

- Ability to analyse and appraise clinical, biomedical and scientific reports in a systematic, fair and balanced way
- Makes informed decisions after finding the relevant facts
- Appreciates the potential risk of inaccurate or inappropriate information to the enquirer and the company

Communication skills

- Ability to communicate information effectively and clearly in written form and orally, and at levels appropriate to the needs of different customers

Understanding the wider context

- Knowledge of the business and of the pharmaceutical industry
- Understanding of the external environment: the NHS, Government policy, regulatory requirements

Understanding of relevant legal and related issues

- Medicines Act and Statutory Instruments
- Copyright
- Codes of Practice
- Data Protection legislation
- Liability

Ethics

- Understanding of and compliance with company policies, legal requirements, the ABPI Code of Practice and industry guidelines that are relevant to medical information
- Application of sound professional judgement to ethical issues

Workload Management

- Delivers work within agreed timelines
- Is able to prioritise, plan and organise work with the appropriate sense of urgency based on customer's and business needs

Management skills

- Team management and leadership skills (for team leaders and managers)
- Strategic planning (especially for managers)
- Interpersonal skills
- Understands the needs and priorities of the customer
- Uses questioning effectively to establish and understand requests
- Actively listens
- Team work
- Networking
- Courteous manner and considers others' views

Proactivity

- Providing alerts about news and new publications
- Keeping customers up to date with subjects of key interest to them
- Informing management of important issues as they arise which require their attention
- Actively promoting medical information services to colleagues and customers in appropriate ways

Accountability

- Setting and fulfilling objectives
- Use of appropriate performance measures
- Compliance with appropriate standards, using PIPA guidelines as minimum standards
- Compliance with standard operating procedures and company policies

Continuous development

- Developing and improving knowledge and skills
- Keeping abreast of developments in relevant therapeutic areas
- Keeping abreast of developments in information systems
- Developing role in line with company's and customers' needs
- Identifying and implementing improvements in ways of working - for self and for team/department

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Appendix 5. Specific Competencies for Specialists areas in Industry Pharmacy

Competency Areas for Medical Information Professionals

Information management skills

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- Understanding of the principles of information storage and retrieval, and skill in their application
- Ability to search a range of relevant information sources
- Effective use of word processing, spreadsheet and other office software programs
- Effective use of web systems

Scientific knowledge

- Ability to understand in detail clinical, biomedical and scientific reports about pharmaceutical products and related subject areas

Analytical skills

- Ability to analyse and appraise clinical, biomedical and scientific reports in a systematic, fair and balanced way
- Makes informed decisions after finding the relevant facts
- Appreciates the potential risk of inaccurate or inappropriate information to the enquirer and the company

Communication skills

- Ability to communicate information effectively and clearly in written form and orally, and at levels appropriate to the needs of different customers

Understanding the wider context

- Knowledge of the business and of the pharmaceutical industry
- Understanding of the external environment: the NHS, Government policy, regulatory requirements

Understanding of relevant legal and related issues

- Medicines Act and Statutory Instruments
- Copyright
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- Data Protection legislation
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- Strategic planning (especially for managers)
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- Keeping customers up to date with subjects of key interest to them
- Informing management of important issues as they arise which require their attention
- Actively promoting medical information services to colleagues and customers in appropriate ways

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- Setting and fulfilling objectives
- Use of appropriate performance measures
- Compliance with appropriate standards, using PIPA guidelines as minimum standards
- Compliance with standard operating procedures and company policies

Continuous development

- Developing and improving knowledge and skills
- Keeping abreast of developments in relevant therapeutic areas
- Keeping abreast of developments in information systems
- Developing role in line with company's and customers' needs
- Identifying and implementing improvements in ways of working - for self and for team/department



TOPRA: Key Regulatory Competences

Human Medicines: Regulatory Competences

1. Knowledge about the discovery and development of pharmaceutical products
2. Knowledge about emerging technologies for dosage form design, delivery systems
3. Knowledge and application of current procedures for obtaining approval to carry out clinical trials in the European Union (CTAs, IMPDs and other supporting documentation)
4. Knowledge and application of current procedures for obtaining approval in other countries as appropriate to carry out clinical trials
5. Knowledge and application of principles of Good Clinical Practice (GCP)
6. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
7. Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals
8. Knowledge and application of the registration procedures in other markets as appropriate for approvals, changes and updates
9. Knowledge and application of the technical, chemical, pharmaceutical and biological requirements for registration of chemical entities
10. Knowledge and application of the technical requirements for registration of biological and biotechnological products
11. Knowledge and application of the nonclinical requirements for registration of chemical, biological and biotechnological products
12. Knowledge and application of the clinical requirements for registration of chemical, biological and biotechnological products
13. Knowledge and application of the content and format of registration files (Common Technical Document and eCTD)
14. Knowledge and application of Pharmacovigilance and the qualified person
15. Knowledge and application of requirements for information for promotion, labelling (SPC, PIL, user acceptance testing, Braille labelling)

16. Knowledge and application of requirements for risk management (clinical, quality)
17. Knowledge and application of regulatory compliance with the approved registration file/change control
18. Knowledge and application of environmental risk assessment for human medicinal products
19. Knowledge and application of reimbursement and economic assessment (for prescribability)
20. Knowledge and application of advertising and promotional material clearance

Human Medicines: OTC Products

- 21. Knowledge and application of legislation for changing legal supply classification (e.g. prescription to pharmacy sale)
- 22. Knowledge and application of advertising and promotional material clearance

Medical Devices

- 23. Knowledge and application of the Medical Devices legislation (EU Directives) and guidelines (MEDDEVs), awareness of Global Harmonisation Task Force (GHTF) documents
- 24. Knowledge and application of emerging technologies for medical devices
- 25. Knowledge and application of Device Vigilance

Cosmetics and Borderline Products

- 26. Knowledge and application of the Cosmetics Directive (76/68/EC) and associated legislation
- 27. Knowledge and application of the borderline between Cosmetics, Medicines and Medical Devices

Chemicals

- 28. Knowledge and application of the new proposed EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH), and the transition Research Implementation Projects (RIPs)

Food Additives

- 29. Knowledge and application of legislation and submissions for authorisation of additives permitted in foodstuffs

Pesticides and Biocides

- 30. Knowledge and application of requirements under 91/414/EEC (or as amended) The Plant Protection Products Directive and 98/8/EC (The Biocidal Products Directive) and how to apply them.

Veterinary Medicines

- 31. Knowledge and application of principles of Good Laboratory Practice (GLP) and its application in clinical studies used in veterinary medicinal product applications
- 32. Knowledge and application of the requirements for veterinary feed additives for farm animals
- 33. Knowledge and application of the clinical requirements for veterinary medicinal products for large animals
- 34. Knowledge and application of the clinical requirements for veterinary medicinal products for companion animals

- 35. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
- 36. Knowledge and application of user safety requirements for veterinary products
- 37. Knowledge and application of environmental risk assessment of veterinary medicinal products
- 38. Knowledge and application of advertising and promotional material clearance

Competences specific for Regulatory Affairs Professionals working in National Competent Authorities (Agencies) and the EMEA

- 39. Knowledge and application of regulatory legislation and the legal implications of regulatory decisions
- 40. Knowledge and application of the management of regulatory procedures
- 41. Knowledge and application of preparation of Assessment Reports (quality, non-clinical, and clinical)
- 42. Knowledge and application of the review of Product Information translations
- 43. Knowledge and application of the principles of Quality Management Systems
- 44. Knowledge and application of regulatory guidance and regulatory precedents
- 45. Knowledge and application of QRD rules on leaflets and readability

IT Competences will include knowledge and application of:

- 46. Word processing
- 47. Spreadsheets
- 48. Presentations
- 49. Project management
- 50. Document Management Systems
- 51. Publishing/eCTD etc

Competences may include knowledge and application of some of the following 'Soft Skills':

- 52. Negotiation and influencing skills
- 53. Presentation skills for regulators
- 54. Team working in a global environment
- 55. Project management and strategic thinking
- 56. Time management
- 57. Leadership Skills
- 58. Performance Management
- 59. Marketing for regulators
- 60. Crisis Management

Contact us: http://www.topra.org/sites/default/files/topra_key_regulatory_competences_2011.pdf or for further advice on life long learning contact tony.cartwright@globalregulatorysolutions.co.uk

**Royal Pharmaceutical Society
Royal Society of Chemistry
Society of Biology**

Qualified Persons in the Pharmaceutical Industry

Study Guide

**Guide to the Knowledge and Practical Experience
required by Qualified Persons in the
Pharmaceutical Industry**

March 2008

Updated September 2010

Guide to the Knowledge and Practical Experience Required by Qualified Persons in the Pharmaceutical Industry Study Guide

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Preface

The three UK professional bodies administering the Qualified Persons scheme, The Society of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry, first introduced a Study Guide for Qualified Persons in 1978 based on Article 23 of 75/319/EEC. A revised version (Study Guide 2000) was issued in 2000 and revised in 2004. The Study Guide 2006 came into effect on 1 May 2006, and this revision, Study Guide 2008, was effective from **1 January 2008**.

The three professional bodies require an applicant for certification as a Qualified Person to demonstrate foundation knowledge and to be able to apply his or her knowledge of QMS principles, and will also be expected to demonstrate understanding of the additional knowledge requirements. The applicant will be required to demonstrate this by reference to the products and processes for which he or she is claiming his or her qualifying experience, which will apply wholly or in part to the Manufacturer's Licence(s) detailed on the application.

The three professional bodies have determined that the foundation knowledge elements are:

- pharmaceutical law and administration;
- the role and professional duties of the Qualified Person;
- quality management systems (i.e. the basic philosophy and principles of Quality Assurance); the latter applies to all sections of this guide.

Certification of eligibility for nomination as a Qualified Person on a Manufacturer's Licence is dependent upon the demonstration of both an appropriate knowledge of those activities and disciplines relevant to pharmaceutical manufacturing and Quality Assurance (QA), and appropriate practical experience.

1.0 The Qualified Person in the Pharmaceutical Industry: Background

The Medicines and Healthcare products Regulatory Agency (MHRA) of the UK Department of Health, and the Veterinary Medicines Directorate (VMD), have interpreted the requirements of the Pharmaceutical Directive 2001/83/EC and the Veterinary Directive 2001/82/EC through a Study Guide, drawn up by a panel of experts, and have given authority to three professional bodies, the Society of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry, to operate an assessment procedure for their members. The assessments seek to determine an applicant's suitability for being named on a company Manufacturer's licence.

The professional bodies' role is to certify the eligibility of the applicant for nomination as a Qualified Person on a Manufacturer's Licence. The applicant must be able to demonstrate that he or she can satisfy the knowledge and experience requirements of Articles 49 and 50 of the "Pharmaceutical Directive" 2001/83/EC (amended by Directive 2004/27/EC), Articles 53 and 54 of the "Veterinary Directive" 2001/82/EC (amended by 2004/28/EC), or Article 13 of the "Clinical Trials Directive" 2001/20/EC. Acceptance of a person, certified as eligible for nomination, on a Manufacturer's Licence is a matter for the Licensing Authority.

The certification process includes submission of a completed application form, the sponsorship of an applicant by a Qualified Person who is also a member of the Society of Biology, the Royal Pharmaceutical Society or the Royal Society of Chemistry, the payment of an application fee, and for applications under the permanent provisions, an oral assessment of the applicant's knowledge and experience.

Applications under the transitional provisions of Article 50 of 2001/83/EC do not normally involve an oral assessment. Since the change in veterinary legislation in 2005, applications can no longer be made under the transitional provisions of 2001/82/EC. The VMD has the capacity to appoint QPs independently of the Tripartite bodies.

Since 1992 the oral assessments have been conducted jointly by the three professional bodies. The oral assessment is carried out by a panel of assessors drawn from all three professional bodies, who are themselves well-acquainted with the role of a Qualified Person. The three professional bodies have agreed with the MHRA and VMD that, in principle, an individual who has been certified as eligible for nomination as a Qualified Person is also potentially eligible for transfer from one Manufacturer's Licence to another, although the final decision for accepting a person as a Qualified Person on a licence rests with the Licensing Authority in the UK. In consequence the assessors must be satisfied that an applicant, after a suitable induction period, will be able to function as a Qualified Person in any licensed undertaking.

Appeals can be made by applicants to their professional body as appropriate.

A guide to the body of knowledge required by the Qualified Person is set out in the following pages. This document should be studied in conjunction with the current edition of the Medicines and Healthcare products Regulatory Agency's (MHRA) "Rules and Guidance for Pharmaceutical Manufacturers and Distributors (known as "the Orange Guide").

The Joint Professional Bodies no longer issue a "Sources of Reference" document. Frequent legislation changes result in the document rapidly becoming out-of-date. Applicants are reminded that a thorough understanding of current legislation is required to meet the requirements of this Study Guide.

2.0 The three foundation knowledge elements

a Pharmaceutical law and administration

To assure patient safety the manufacture and distribution of pharmaceutical products is highly regulated within the European Union. The Qualified Person, in particular, must ensure that all legislative obligations are fully satisfied before any product is released for sale.

A Qualified Person must have a comprehensive knowledge of all European and National legislation relating to the manufacture, storage and supply of licensed medicinal products and the interpretation of the law as exemplified in the current edition of the MHRA's "Rules and Guidance for Pharmaceutical Manufacturers and Distributors ", ("the Orange Guide").

Applicants will be expected to demonstrate a thorough understanding of the following:

- European pharmaceutical directives (including but not limited to 2001/83/EC, 2001/82/EC, 2001/20/EC, 2003/94/EC, 2004/24/EC, 2004/27/EC, 2004/28/EC);
- the UK Medicines Act (1968) and other UK national medicines legislation, and the Veterinary Medicines Regulation, including amendments;
- Marketing, Manufacturing and Wholesaler Authorisation requirements and responsibilities;
- the role, legal status and structure of both the European and British Pharmacopoeias, including the Certification procedure of the EDQM;
- the organisation of the UK MHRA, the role of the European Agency for the Evaluation of Medicinal Products (EMA), and the role of the Veterinary Medicines Directorate (VMD);
- procedures for dealing with complaints and product recalls and the role of the MHRA's Defective Medicines Reporting Centre, CHMP and CVMP guidelines on quality;
- The International Conference on Harmonisation (ICH and VICH) guidelines;

- Mutual Recognition Agreements (MRAs);
- Pharmaceutical Inspection Co-operation Scheme (PICS);

b The role and professional duties of a Qualified Person

It is incumbent upon all Qualified Persons, whether or not members of one of the three professional bodies, that they discharge their professional duties in accordance with the Code of Practice for Qualified Persons, which the three professional bodies (SB, RPS and RSC), in collaboration with the MHRA and VMD, have produced.

It is the responsibility of the Qualified Person to certify that a product has been manufactured in accordance with its Marketing Authorisation, and with Good Manufacturing Practice (GMP).

The Qualified Person might not have direct line responsibility for many of the activities which could affect compliance with GMP or the Marketing Authorisation. However, they must be aware of any incidents or deviations which may influence their decision to release a batch for sale.

Applicants will be expected to demonstrate a thorough understanding of the following:

- batch review and decision making on disposition.
- the principles and practice of current GMP and QA as given in European Directives and Guides on Good Manufacturing Practice including relevant Regulations made under the Medicines Act 1968 and the current edition of the MHRA's Rules and Guidance for Pharmaceutical Manufacturers and Distributors, ("the Orange Guide");
- the conduct and obligations of MA and MAA holders;
- the preparation for and management of Regulatory Inspections.

c Quality management systems

The manufacture of pharmaceutical products requires the establishment and implementation of an effective 'quality management system' (QMS). The concepts of QA, GMP and Quality Control (QC), which are inter-related, form the basis of such a system for the manufacture of pharmaceutical products.

Applicants will be expected to demonstrate a thorough understanding of the following:

- the philosophy and basic principles of QA;
- the design criteria for an effective QMS;
- auditing and self inspections;
- deviations and change control;
- documentation and record keeping;
- the interpersonal skills (leadership, delegation, communication, etc) necessary to implement an effective QMS;
- the concepts associated with risk management;
- the principles of design, selection, qualification and maintenance of premises, equipment, utilities, and services;
- calibration, preventative maintenance and training;
- the principles of purchasing and supplier certification, including knowledge of supply chains and material control and the roles of brokers, distributors and repackagers;
- production planning, scheduling, and inventory control;
- annual product quality reviews;
- the interface between QA and the Development, Regulatory Affairs, and Marketing Departments;
- the skills and competences needed to provide effective Good Pharmaceutical

- Manufacturing Practice training;
- organisational structures and reporting relationships;
- technical agreements and auditing in contract giving and acceptance.

3.0 Additional knowledge requirements for the Qualified Person

d Mathematics and statistics

The practical application of basic statistical tools in pharmaceutical production and QA is essential in demonstrating the capability of processes or the acceptability of materials.

Applicants will be expected to demonstrate an understanding of the following:

- Statistical Process Control;
- BS6000-6001 (Sampling plans);
- Process Control Charts;
- Acceptable Quality Levels (AQLs) (subset of 6001/2);
- statistics applied during analytical method validation.

e Medicinal chemistry and therapeutics

The Qualified Person must have an understanding of the actions and uses of medicines in clinical

practice in order to judge their significance for the manufacture of sales material or clinical trial supplies. Evaluating the significance of cross-contamination hazards or product complaints are examples where such knowledge is important.

Applicants will be expected to demonstrate an understanding of the following:

- basic physiology;
- outline knowledge of the autonomic nervous system and some general aspects of chemical structure/pharmacological action relationships;
- summary of key therapeutic drug classifications with examples;
- examples of disease states and their treatment with medicinal products;
- general absorption, distribution, metabolism and excretion of drugs;
- principal routes of drug administration;
- role of the company medical department;
- pharmacovigilance related to quality monitoring;
- general implications of clinical knowledge of drugs upon facility design, plant segregation/isolation, cleaning verification and production scheduling.

f Pharmaceutical formulation and processing

The formulation and processing conditions employed in the manufacture of medicinal products have a significant effect upon their safety, quality and efficacy. Even subtle changes to the input materials and/or processing conditions can have a profound adverse effect on content uniformity, stability, bioavailability, and other attributes which are not detectable by routine QC testing.

It is vitally important that the Qualified Person understands the principles of formulation and pharmaceutical processing to ensure that informed release decisions are made.

Applicants will be expected to demonstrate an understanding of the following:

- the major processing techniques, their limitations and critical control parameters;
- the factors that could potentially affect content uniformity, stability (chemical, physical and microbiological) and bioavailability in manufacture;
- the principles of process validation and control;
- the principles of technology transfer and production scale-up;
- pre-formulation studies and product development;
- the storage and distribution of materials and finished products.

g Pharmaceutical microbiology

The Qualified Person must understand the significance of the presence of bacteria, yeasts, moulds, viruses and toxins in pharmaceutical raw materials, products and production environments. In addition, they must understand how to prevent contamination by good product design, GMP and control over starting materials, intermediates, finished products, production plant and processes, people and the environment.

Applicants will be expected to demonstrate an understanding of the following:

- sources and types of micro-organisms as related to pharmaceutical production;
- production of sterile and non-sterile products and associated environmental controls;
- bacterial endotoxins and pyrogens, their sources, removal and testing;
- microbiology of water, its production and distribution systems;
- sterilisation and disinfection methods;
- interpretation of microbiological data;
- validation of microbiological test methods;
- microbiological specifications;
- selection and use of preservatives;
- microbiological test methods used in routine manufacture and product development;
- rapid methods of microbiological testing.

h Analysis and testing

The sampling and testing of materials does not by itself assure product quality. It must be seen as one part of a comprehensive 'Quality management system', including QA and GMP, which must be correctly implemented and controlled.

The data generated by laboratory testing of samples must be evaluated before materials are released for sale.

Applicants will be expected to demonstrate an understanding of the following:

GCLP (Good Control Laboratory Practice);

- quality control of sterile and non-sterile dosage forms;
- interpretation of analytical data and non-conforming results;
- the principal qualitative and quantitative analytical methods in common use;
- analytical chemistry as relevant to the properties of medicinal products and materials;
- the principles of method selection and validation;
- the design of sampling regimes;
- biological test methods and interpretation of results;
- physical and organoleptic testing;
- stability testing (protocols & methods);
- the significance of degradation, contamination and adulteration of pharmaceutical materials;
- the types, purpose, significance and management of systems of in-process control;
- the International Conference on Harmonisation (ICH) guidelines for method validation, impurities and stability testing;

i Pharmaceutical packaging

It is a requirement of GMP that holders of Manufacturing Authorisations establish procedures for their packaging operations to minimise the risk of cross-contamination, mix-up or substitutions. The Qualified Person must understand the importance of controlling packaging components (both primary and printed materials) throughout the supply chain to assure the quality of finished products.

Applicants will be expected to demonstrate an understanding of the following:

- control of packaging components by suppliers and throughout production;
- the chain of systems which ensure the integrity and accuracy of textual information from originator to routine production;

- the layout and organisation of packaging operations;
- causes of label and other printed component mix-ups;
- packaging and labelling processes and equipment;
- the testing of packaging materials including pack integrity testing;
- product security (automated systems, reconciliation, line clearance etc);
- in-process controls;
- effects of packaging materials on product stability;
- selection of packaging materials;
- tamper-evidence and anti-counterfeiting measures.

j Active pharmaceutical ingredients

The Qualified Person must understand the influence of manufacturing pathways and associated physical and physico-chemical attributes, of both active pharmaceutical ingredients and major excipients, on the quality of the finished dosage form.

Applicants will be expected to demonstrate an understanding of the following:

- the steps commonly taken in the manufacture of active pharmaceutical ingredients and excipients (including biopharmaceuticals), their purpose and limitations;
- the generation of impurities, their identification, quantification, and elimination;
- the physico-chemical and biological properties of active pharmaceutical ingredients, and excipients, and their effect on the attributes of the final dosage form;
- the specific requirements for bulk materials intended for sterile products;
- the nature of controls for the manufacture of bulk biological and biotech products;
- auditing of API manufacturers.

k Investigational medicinal products

The manufacture, packaging and distribution of investigational medicinal products must be controlled. There are significant differences between the manufacture of IMPs and licensed dosage forms. The Qualified Person must understand these differences together with the safeguards required to assure the quality of IMP supply.

Applicants will be expected to demonstrate an understanding of the following:

- specific GMPs associated with the manufacture of investigational medicinal products;
- the control of active and placebo forms;
- the control of packaging operations and blinding;
- the control and release of imported IMPs;
- the control and release of comparators;
- effective batch documentation, sampling and batch release;
- change control and material traceability;
- controls surrounding the procurement of Clinical Trial (CT) supplies;
- the principles of clinical trial design and Good Clinical Practice (GCP).

4.0 The Qualified Person: practical experience requirements

The precise wording used in Article 49 of the Pharmaceutical Directive 2001/83/EC is as follows:

"The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorised to manufacture medicinal products, in the activities of

qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products”.

The three professional bodies have interpreted this legal obligation as requiring the applicant to have had at least #one or two years of relevant practical experience in assuring the quality of medicinal products during their manufacture, including Good Manufacturing Practice, as defined

in the current edition of the MHRA’s “Rules and Guidance for Pharmaceutical Manufacturers and Distributors (“the Orange Guide”).

(#In the UK, the MHRA and VMD have approved one year of practical experience for pharmacists).

4.1 Illustration of requirements

1. The applicant must have had at least #one/two years relevant practical experience in one or more of those activities embraced by the term QA (as defined and detailed in the EC Good Manufacturing Practice Guide, and the EC Directive 2001/83/EC) gained in premises licensed for the manufacture of medicinal products.

(#In the UK, the MHRA and VMD have approved one year of practical experience for pharmacists).

The MHRA advises that experience obtained in an establishment that has only a Specials Licence, or experience of the manufacture of active pharmaceutical ingredients, cannot contribute to the practical experience requirement (unless the site holds a manufacturer’s licence) (Article 40 of 2001/83/EC).

The applicant must demonstrate a thorough core competence in the manufacturing processes and the quality management systems involved in the production, testing, batch release and approval for sale of the products made under the Manufacturer’s Licence(s) under which he or she is claiming his or her qualifying experience.

2. In addition, it is important that the applicant can demonstrate an ability to translate and extrapolate the working knowledge and understanding gained from his or her experience. In particular, scenario questions may be used to determine whether an applicant is able to articulate a logical approach to a practical situation with which he or she may be unfamiliar, thereby demonstrating his or her ability to apply his or her knowledge and experience.

The applicant can expect detailed questioning on his or her knowledge of QMS principles, and will be required to demonstrate this by reference to the products or processes operating under the Manufacturer’s Licence(s) under which he or she is claiming his or her qualifying experience. The assessors may ask questions pertinent to other activities or functions which they consider relevant. The assessors must satisfy themselves that the applicant, after a suitable induction period, will be able to function as a Qualified Person in any licensed undertaking.

5.0 Role of the Qualified Person

5.1 Directives 2001/83/EC and 2001/82/EC

The functions of a Qualified Person as set out in the UK Statutory Instruments and EU Directives 2001/83/EC and 2001/82/EC are as follows:

- to ensure that each batch of the medicinal product to which the licence relates has been manufactured or assembled and checked in compliance with the provisions of the Act and Regulations made there under, the provisions of the Manufacturer's Licence and the provisions of the Product Licence or Marketing Authorisation which relates to the product;
- to certify in a register, or other record appropriate for the purpose, whether each production batch of the medicinal product to which the licence or authorisation relates satisfies the requirements set out above and to ensure that such register or other record is regularly maintained, in particular that the appropriate entries in such register or other record are made as soon as practicable after each such batch has been manufactured;
- for medicinal products manufactured outside the European Community, the Qualified Person must ensure that each imported batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the Marketing Authorisation (although it should be recognised that there are exemptions to this requirement: batches of medicinal products which have undergone such controls in a Member State shall be exempt from the above controls);
- in the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the medicinal product applies standards of GMP at least equivalent to those laid down by the Community and to ensure that the controls referred to above have been carried out in the exporting country, the Qualified Person may be relieved of responsibility for carrying out those controls.

5.2 Directive 2001/20/EC

The functions of a Qualified Person as set out in the Clinical Trials Directive 2001/20/EC are as follows:

For IMP manufactured in the Member State concerned, that each batch of medicinal product has;

- been manufactured and checked in compliance with the requirements of Directive 2003/94/EC laying down the principles of good manufacturing practice for medicinal products for human use and investigational medicinal products for human use, the product specification file and the information notified pursuant to article 9(2) of Directive 2001/20/EC;
- in the case of an investigational medicinal product manufactured in a third country, that each production batch of product has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Directive 2003/94/EC, in accordance with the product specification file and that each production batch has been checked in accordance with the information notified pursuant to article 9(2) of Directive 2001/20/EC;
- in the case of an investigational medicinal product which is a comparator product from a third country and which has a Marketing Authorisation, where the documentation certifying that each production batch has been manufactured in conditions at least equivalent to those laid down in Directive 2003/94/EC, that each production batch has undergone all relevant analyses, test or checks necessary to confirm its quality in accordance with information notified pursuant to article 9(2) of Directive 2001/20/EC.

The role of the Qualified Person is thus of considerable importance within the industry and this should be reflected in the calibre of applicant appointed to such a position. Although every person included in the Register meets, in the opinion of the professional body concerned, the statutory requirements to become a Qualified Person, it is up to individual companies to satisfy themselves of the suitability of any individual applicant for a particular post.

The Licensing Authority is the final arbiter of who can be named as a Qualified Person on a Manufacturer's Licence.

6.0 Other European Member States

Applicants from other EU Member States, who are not members of either of the three aforementioned

Article 49 of 2001/83/EC, will be considered by the Licensing Authority on nomination by a company, as a QP for a Manufacturer's licence.

The Royal Society of Chemistry (RSC) has an agreement with the Institute of Chemistry of Ireland (ICI) that Irish applicants will be assessed by a team of assessors that will include an Irish assessor, who is a member of both the RSC and ICI.

7.0 Summary

In Summary, the applicant must demonstrate:

- the relevant practical experience in one or more licensed facilities;
- an in-depth working knowledge and understanding, allied to practical experience;
- a thorough understanding of the principles and requirements laid out in "the Orange Guide";
- an ability to translate those principles and requirements to other situations currently outside his or her direct experience;
- an endorsement of his or her credentials, including qualifications and experience, from a sponsor.

Appendix 6. List of documents - PHARMINE Catalogue

PHARMINE Catalogue

ACLF	Framework / Word doc	CoDEG_09
Advanced and Specialist Practice Project Report_GLF_terminology	Word doc	CoDEG_09
Advanced Service Competency Framework	PDF	DoH_05
Application form 2008: Lifelong Learning Programme Sub-programmes - Multilateral Projects, Networks, Accompanying measures -	PDF	Pharmine_08
ARS Agences Régionales de la Santé	PDF	Laroque_07
Assessments V8 Aug 09	Word doc	CoDEG_09
Australia Competency Framework	Word doc	SHPA_03
Australia_news_Shpa announces work on a national competency project	Word doc	SHPA_09
BachReport	PDF	Bach_08
Bibliography	Word doc	Obiols_09
Big picture diagram (WP3/WP4)	PowerPoint	Obiols_09
Canada competency framework (Models standards of practice for Canadian pharmacists)	Word doc	NAPRA_03
Clinical topics resource pack V5	Word doc	CoDEG_09
Competencies for Chlamydia (doc 1) Screenings and Treatment Enhanced Service using the GLF	Word doc	CoDEG_09
Competencies for Chlamydia (doc 2) Screenings and Treatment Enhanced Service using the GLF	Word doc	CoDEG_09
Content guide final amend re HAG	Word doc	CoDEG_09
DAP guide V3	Word doc	CoDEG_09
Denmark_Copenhagen	PDF	Fjalland_Apr09
Dummy Form FLF	Word doc	Obiols_09
Easy_to_understand	Excel	JamesDavies_09
E Directive prof recog 2005_36_EC_05.09.07	PDF	EU Parliament_07
Farmacia Hospitalaria	PDF	ComisionNacionalFarmaciaHospitalaria_99
First Output	SPSS	Svarcaite_09
FLF	Word doc	Obiols_09
France competences for Pharmacien Ind	PowerPoint presentation	Tchoreloff_07
FrenchSystem_Luc's_emails	Word doc	Obiols_09
GLF	Framework / Word doc	CoDEG_05

GLF_ACLF_TLF_terminology	Word doc	CoDEG_09
GLF Functional Requirements	Word doc	Svarcaite_09
GLF Language Sensitive	Excel	Svarcaite_09
GLF Taskforce meeting Oct 09	Word doc	CoDEG_09
Glossary of terms	Word doc	Obiols_09
Higher Level Practice in Clinical Pharmacy Specialities. Application of the ACLF and Implications for Consultant Pharmacists	Word doc	Obiols_09
Initial education	PDF	Ordre National des Pharmaciens_05
James_work	Word doc	Obiols_09
JPBclincurric guide 2008 with learning support	Word doc	CoDEG_08
Kick-off_Minutes_Feb09	Word doc	Pharmine_Feb09
LarcherReport	PDF	Larcher_08
ListAttendance	Word doc	Pharmine_09
Mapping of Advanced Services to GLF final	Word doc	CoDEG_05
MicrobiologiaParasitologia	PDF	BOE_06
Minutes HEI Leads 27 th Aug	Word doc	CoDEG_09
Mucklow_02	PDF	Mucklow_02
Outline for PHARMINE Project	Word doc	JamesDavies_09
PAYMENTformTRAVEL	PDF	Pharmine_09
Pharmacien industriel - Elaboration du eferential de compétences	PDF	Tchoreloff_07
Pharmacy Practitioner Development Across Europe	Word doc	JamesDavies_09
Pharmine Catalogue	Excel spreadsheet	Obiols_Oct09
PHARMINE newsletter French competency frameworks for Pharmacy 1208	PDF	Pharmine_08
PHARMINE newsletter French LMD Santé 1208	PDF	Pharmine_08
PHARMINE presentation	PowerPoint presentation	Pharmine_09
PHARMINE presentation. Practicalities	PowerPoint presentation	Rombaut_09
Pharmine_WP3	PowerPoint presentation	Bates_09
Pharmine_WP4	PowerPoint presentation	Bates_09
Plan_frances	Word doc	Obiols_09
ProgressReport_Pharmine	PDF	Pharmine_Jan09
ProgressReport for Pharmine	PDF	Pharmine_08
Questionnaire on Pharmacists Activities	Word doc	IvanaSilva_Jun09
Raw data	SPSS	Svarcaite_09

Responses from FIP Global Pharmacy Workforce Survey	Word doc	Bruno_09
Recognition of professional qualifications	PDF	EU Parliament_05
SALF - Specialist and Advanced Level Framework	Word doc	Obiols_09
Slides_for_Roberto	PowerPoint presentation	Bates_09
Spanish System	PowerPoint Slide	Obiols_09
Spanish_System	Word doc	Obiols_09
Summary_Spanish System Specialisation in Hospital Pharmacy	Word doc	Obiols_09
Summary_French	Word doc	Obiols_09
Surveying Pharmacy Practice in Europe_MScThesis	Word doc	Svarcaite_09
Surveying Pharmacy Practice in Europe_MScThesis	PDF	Svarcaite_09
TLF	Framework / Word doc	CoDEG_09
Translation industry competencies FRANCE	Word doc	Tchoreloff_07
Working	SPSS	Svarcaite_09
Working_recoded	SPSS	Svarcaite_09
Working towards educational consensus_WP3_WP4	PowerPoint presentation	Bates_09
What is CPD and when to begin	PowerPoint presentation	Silva_Sep09

Appendix 7. Glossary of Terms

Glossary of Terms

Behavioural competency: Typical behaviour observed when effective performers apply motives, traits or skill to job relevant tasks.

Clinical Governance: A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Competence: Ability to carry out a job or task.

Competency: A quality or characteristic of a person related to effective or superior performance. It is made up of many things such as motives, traits and skills.

Continuing Education (CE): A structured process of education designed or intended to support the continuous development of pharmacists to maintain and enhance their professional competence. CE does not necessarily equate to adequate learning to attain the competence of the professional. Hence continuing professional development (CPD) is increasingly adopted by the profession world-wide as the way to ensure professional competence.

Continuing Professional Development (CPD): Self-directed, ongoing, systematic and outcomes-focused approach to learning and professional development.

Evidence-Based Practice: Using good quality evidence to make sound clinical decisions

Facilitator: One who encourages self-directed learning.

Higher Level: A greater level of organisational complexity than that of the pharmacist's team (as defined above).

Hospital: Licensed establishment primarily engaged in providing medical, diagnostic, and treatment services that include physician, nursing, and other health services to in-patients and the specialized accommodation services required by in-patients.

Life Long Learning: All learning activity throughout life, with the aim of improving knowledge, skills and competence, within a personal, civic, social and/or employment-related perspective.

Mentor: One who advises on how skills should be performed in the workplace.

National Priorities: Health care priorities identified in the Government's Public Service Agreement.

Outcome: Performance indicator based on standards that are measurable; often demonstrated through products or behaviours.

Peer Review Activities: Expert opinion is sought to undertake a review of published work(s) in the pharmacist's area of practice.

Pharmaceutical Care : The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

Qualified Person: The Qualified Person (QP) is essential to the safe control of medicines and needs to have extensive training and in-depth critical understanding of all the aspects associated with pharmaceutical manufacturing. The primary legal responsibility of the Qualified Person (QP) is to certify batches of medicinal products prior to use in a clinical trial (human medicines products only) or prior to release for sale and placing on the market (human and veterinary medicinal products).

Role Model: One whose behaviour is copied by a learner Specialist Pharmaceutical
Sector: Major field of professional activity in a defined environment such as community, industry, hospital, administration and academia.
Team: The staff (pharmacy or multidisciplinary) or care group with which the pharmacist works most closely.

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