EIPG ADVISORY GROUP ON COMPETENCIES
CONCLUSIONS

Table of Contents

Advisory Group

Anni Svala	Chair of the Group, industrial pharmacist (Finland)
Maurizio Battistini	Industrial pharmacist (Switzerland)
Carla Caramella	Professor at University of Pavia (Italy)
Piero Iamartino	Industrial pharmacist (Italy)
Susan Kilby	Industrial pharmacist (Great Britain)
Harriet Lewis	Industrial pharmacist (Great Britain)
Michael Morris	Pharmacist at Regulatory Authorities (Ireland)
Giorgos Panoutsopoulos	Industrial pharmacist (Greece)
Dimitrios Rekkas	Professor at University of Athens (Greece)
Astrid Thorissen	Industrial pharmacist (Netherlands)

Scope

The pharmaceutical industry is continually evolving and needs new Knowledge, Skills and Competencies (KSCs) to compete effectively in a commercial and highly regulated environment.

It is for the above reasons that the EIPG has decided to explain the opportunities for pharmacists in the pharmaceutical industry and to provide information which may be of use to Schools of Pharmacy when considering course content and advising students on careers.

Process

The process included the following steps:

1. Setting up a working group which included EIPG members and academics from across Europe who were working in different areas of the Pharmaceutical Industry
2. Identifying the current and future roles and opportunities within the pharmaceutical industry for pharmacists
3. Considering the KSCs pharmacists require for the above roles
4. Defining the relevant KSCs which it would be reasonable to expect a pharmacy student to have acquired by the time they have completed their undergraduate degree

And the following steps to be done:

5. Understand what is currently covered in the undergraduate courses in order to identify the gaps in KSCs
6. Make recommendations on how the gaps in KSCs can be addressed

Background

The pharmaceutical Industry is changing which is due to a number of factors including globalization and regulatory framework. This has resulted in centralization of functions such as research and development (R&D), manufacturing, supply chain and logistics so that companies will no longer have sites in all countries. New approaches such as Quality by Design (QbD), Pharmaceutical Quality System (PQS), Quality Risk Management (QRM), Artificial Intelligence (AI), Big Data, Precision Medicine and Digitalization shaped a totally new regulatory framework. Within this context pharmacists urgently need a new, modern and flexible curriculum ensuring the new KSCs required to successfully address these major changes.

The product pipeline for companies is also changing and this has resulted in the movement from small molecules to biologics and gene cell therapy. Products may require biomarkers to identify appropriate patients, be launched with devices and digital applications. This means pharmacists need to develop new KSCs which will include a knowledge of the regulatory processes for medicines, devices, diagnostics digital applications and an understanding of pharmacogenomics.

In a number of countries there is significant pressure by the healthcare system to control the increasing costs of medicines which has resulted in the growth of health economics, Quality of Life (QoL), Patient Reported Outcome Measures (PROMs) and health technology assessments (HTAs) to justify the value of medicines.

While some roles and opportunities in the pharmaceutical industry may be disappearing in some countries, within the industry there are still opportunities in Regulatory Affairs (RA), Medical Affairs, Pharmacovigilance (PV), Market Access, Commercial and to become a Qualified Person (QP). There is also a growing need for pharmacists to work in Distribution which will include homecare to ensure Good Distribution Practice (GDP).

Knowledge, Skills and Competencies expected of a pharmacist

A pharmacist should develop their KSCs throughout their career, however, individuals will develop at different rates depending on aptitude, willingness to learn and opportunities for development they encounter.

It was agreed that while there is variation in the pharmacy undergraduate course across Europe it was reasonable to expect certain key KSCs that all pharmacists would have.

Pharmacy Graduate	Post registration and additional learning	Experience, additional qualification and life ling learning
Understanding	Proficient	Expert
Has the ability to undertake task with guidance, additional learning and under supervision	Is able to take responsibility for complex task with guidance and additional learning	Is able to lead, advise and be countable for delivery of complex tasks and programmes with the lifelong learning and autonomy
Continuous development of soft skills, communication, multidisciplinary working professional integrity and personal qualities		

Table 1. Competency and skill progression framework

At the 2019 EIPG General Assembly in Budapest, a working group focused on to discuss the KSCs a pharmacy student would need in the future, working in different sectors of the pharma industry. Working group lively discussion ended up that they would expect a pharmacist to have the following KSCs:

- Soft skills (communication, leadership skills)
- Critical appraisal skills (ability to assess and evaluate information from different sources)
- Analytical skills, relevant scientific and technical knowledge
- Ability to think strategically and implement decisions
- Project management skills
- Risk-management skills
- Able to work in multi-professional teams and across functions
- PC literacy skills
- Have a basic knowledge and understanding of the regulatory processes for medicines, devices and digital technologies
- Knowledge and understanding of Good Manufacturing Practice (GMP)
- Knowledge and understanding of Good Distribution Practice (GDP)
- Knowledge and understanding of Good Clinical Practice (GCP)
- Basic knowledge of the healthcare environment at a National and European level

Current and Future Competencies and Skills

Based on the changing environment as described above, the following new competencies and skills are expected to be developed in the different areas where industrial pharmacists can operate.

R&D Area

The R&D area is the most changing environment where scientific discoveries open continuously new opportunities for the development of revolutionary medicinal products. The most promising trends are represented by biological products, including both biotech products and advanced products (ATMPs) based on the use of cells, tissues and MAb derivatives. The manufacture of these new products implies the development and the industrial transfer of specific processes which are characterized by the use of small size batches and aseptic conditions, preventing any contamination, without the application of terminally sterilized processes. The use of big data management is also modifying the approach to the evaluation of R&D findings opening new opportunities for searching areas. The development work trends are mainly focused on the adoption of the best time-to-market process and on the identification of innovative delivery systems suitable for the best administration of the new active substances.

The competencies requested can be described as follows:

- Talent for research activity, based on an excellent scientific background and a good aptitude for continuous learning
- Acquisition of specific and deep scientific knowledge according to the R&D area of activity
- Full understanding of the whole pharmaceutical discovery process
- Ability to work in a multidisciplinary team, interacting with scientists of other disciplines

Quality Area

Next to efficacy and safety, quality is an essential element of a medicinal product. Growing attention has been put on quality over the last few years, with the introduction of new principles, requiring changes in the approach in quality management. A constant increase in resources has also been seen as a need to meet all new requirements and to add specific competencies in quality assurance and control.

The following main expectations are envisaged:

- Acquisition of knowledge about the quality risk management principles, which represent the basis of the required quality culture to be broadly implemented in the pharmaceutical industry
- Good understanding of the QbD approach in the development of formulations and processes (analytical and manufacturing), including sufficient knowledge on statistical multivariate models, which are used as indispensable tools in the development work
- Updated knowledge about modern analytical instrumentations and techniques which are broadly used in quality assessment in order to meet the GMP requirements

Manufacture and GMP Area

As described above, a profound transformation of manufacturing processes is expected as a consequence of the development of new biopharmaceutical products (biotech and ATMPs) and the adoption of advanced technological solutions, with the introduction of automation, and AI systems.

These changes require to consider the following competencies to be present:

- Understanding of the introduction of digitalization in manufacturing processes, taking into account its impact on operation management and specialisation requirements
- Awareness of the increasing complexity in managing manufacturing operations, which require more and more interactions with different specialists
- Knowledge about the manufacturing process which is applied to biological products, considering their specific requirements and critical issues
- Adequate knowledge of the GMP requirements which are applied to ATMPs, considering the increasing importance of these products

Additional Skills

The acquisition of the above competencies and knowledge should be accompanied by the development of some soft skills, in terms of:

- Good communication skills for better interaction with people in an increasingly complex organization
- Open mind attitude and problem-solving capabilities
- The willingness of an interdisciplinary collaboration

Qualified Person (QP)

Qualified Person is a unique role, present only in the pharmaceutical industry, which can be assigned to an industrial pharmacist.

The QP takes full responsibility of batch certification and release for sale on the market, by ascertaining that each batch is manufactured controlled and distributed according to GMPs and GDPs, in full compliance with the Common Technical Document, submitted to the Competent Authority of the country where the product will be put on the market.

In a changing environment, the QP role is expected to face new challenges in terms of duties and responsibilities, taking into account the increasing complexity of the manufacturing processes in relation to the increasing development of biopharmaceutical products.

The following main expectations are envisaged:

- Knowledge of quality principles and their application in medicinal products development, manufacturing and control, with particular focus on quality risk assessment and CAPA plan management
- More extensive cooperation with the other key positions of the pharmaceutical industry i.e. quality, regulatory affairs and manufacturing departments to ensure a multidisciplinary approach in problem-solving always taking the patient safety as a driver
- Presence of adequate knowledge and experience in relation to the specific quality and manufacturing requirements as determined by the category of medicinal products being produced.
- Competencies in data management and data integrity
- Leadership skills
- Good communication skills
- Teamwork management and problem-solving techniques application

Medical Information and Clinical Development

Within a Medical Department of pharmaceutical companies, there are various roles where a background as a pharmacist is highly valuable.

Pharmacists could work in a job focussed on Medical Information, in these kinds of functions you would be responsible to answer various queries originating from Health Care Professionals (HCPs). Pharmacists are trained to provide in-depth explanations about mechanisms of action, interactions, clinical research etc.

Medical Science Liaison (MSL) or Medical Advisor (MA) is another role where pharmacists can show their potential. Where an MSL is more outward-facing, an MA would be more involved with internal strategies. An MSL is in close contact with various HCPs, like other (clinical) pharmacists, but also doctors of all disciplines.

Because of their hybrid scientific culture, pharmacists can easily take the positions as described above.
However, it is recommended that:

- During the Pharmacy degree, all pathologies are covered, which would give a wide general knowledge among all medical specialities.
- Good knowledge of all stages of clinical drug development is required, which makes it easy to comprehend how and why drugs are studied in certain ways, as an MSL or MA could be involved with the setup of phase IV clinical studies.
- Good understanding of the regulatory requirements (GCP guidelines) is essential for performing the roles in clinical trials management

Regulatory Affairs

The Regulatory Affairs (RA) function in pharmaceutical industries can be considered of key importance for obtaining approval for new pharmaceutical products and ensuring that approval is maintained for as long as the products are placed on the market.

RA professionals usually have responsibility for the following areas:

- Keep abreast of current legislation, guidelines and other regulatory intelligence to ensure compliance with all the regulations and laws pertaining to the marketing of pharmaceutical products
- Working with government and local regulatory agencies and personnel on specific issues affecting the life-cycle maintenance (including pricing and reimbursement) of pharmaceutical products
- Advise MAHs on the regulatory aspects and climate or how to best interpret them to their business activities

RA departments are growing within companies or due to the changing resources necessary to fulfil the regulatory requirements, some companies also choose to outsource or out task RA to external service providers. There are many aspects to consider when looking to the future in RA.

As the pharmaceutical market searches for that next blockbuster and as R&D pushes scientific frontiers, the regulations will have to change to keep pace, not only with more complex therapies but also with the drive to develop individualised or personalised medicines.

National Competent Authorities (NCAs) find it difficult to keep pace with the volume and the technical content of novel submissions or to meet their own targets for processing regulatory submissions and responding to the industry in a timely manner. Regulatory expertise could be centralized and shared globally. This model already works to some extent in Europe through the European Medicines Agency (EMA).

Based on the above scenario, the new main competencies and skills are listed as follows:

- Ability to understand in detail complex scientific data reports about pharmaceutical products at a level to allow review, compile and submit them in the form of pharmaceutical dossier modules to Regulatory Authorities
- Ability to comprehend and follow relevant RA information sources including regulation, guideline and directive publications and databases as well as healthcare professionals and external bodies regulatory libraries, in the geographic region of interest
- Good knowledge of the business and of the pharmaceutical industry

- Project management and organization
- Ability to prioritise, plan and organise work with the appropriate sense of urgency based on regulatory requirements and business needs.
- Team management and leadership skills (for team leaders and managers).

Soft skills

- Ability to communicate information effectively and clearly in written form to allow sharing of regulatory intelligence data within the company and to regulatory bodies as required
- Actively increasing awareness of Regulatory requirements to colleagues and third parties in appropriate ways
- Negotiation and communication skills to serve as the interface between the Authority and the pharmaceutical company

Pharmacovigilance

This area is expected to evolve due to the extensive use of tools for monitoring the efficacy and side effects of medicinal products. At the same time, form a regulatory point of view, new requirements are being issued with the final purpose of improving patients' safety based on a detailed clinical data collection allowing prompt evaluation of any therapeutic regimen.

The following main competencies and skills are and will be more and more required:

- Ability to understand in detail clinical, biomedical and scientific reports about pharmaceutical products at a level to allow appropriate capture, review and processing of safety data
- Ability to analyse and appraise safety data as part of the ongoing benefit-risk assessment of the company’s products
- Effective understanding and use of the principles of information capture, storage, searching and retrieval, IT systems and programs
- Use of effective questioning to accurately record safety data
- Understanding of, and compliance with, legal requirements, the European Good Pharmacovigilance Practice Modules
- Data Protection legislation
- Team Working and leadership skills
- Ability to communicate information effectively and clearly in written form to allow sharing of safety data within the company and to regulatory bodies as required.

Supply Chain and GDP

Pharmacists are not so often employed yet within supply chain functions, although they could be highly valuable in such jobs. A pharmacist is completely aware of all the requirements to

keep medicines in their best shape and to keep them effective. For instance, if medicines are handled and shipped without precautions they might actually freeze or experience very high temperatures during their transit, which might cause degradation into ineffective - or even harmful substances. This is in particular important for cold chain products like biologics, that are continuously increasing in the market. This kind of excursions will cause many challenges for the pharmaceutical industry, they need to go through a sometimes extensive CAPA-process to evaluate whether the medicines are still safe to use.

Traceability is also another important challenge to insure Good Distribution Practices (GDP) compliance and the recent introduction of unique identifiers per single packs will help, also if for the moment only in an end to end process, to control the flow along the supply chain.

Within the supply chain for medicines many third parties are being used (trucking companies, forwarders, air and ocean carriers etc.), until recently these parties were often a 'black box' for pharmaceutical companies. These third parties would now have to be assessed for their capabilities to comply with GDP, this would also include auditing these third parties.

By working as a pharmacist within the supply chain you are trained to identify risks and eliminate or at least minimize these. As a pharmacist, you also understand what the actual effects on the medicinal product and product availability are and how this would translate to the clinical practice.

- Understanding of external factors' influence on the stability and compliance of medicines.
- Understanding of, and compliance with, legal requirements, the European Good Distribution Practice
- Quality management systems expertise
- Ability to identify and assess risks (temperature, damage, security, compliance) and apply appropriate mitigating measurements.
- Auditing (internal and external)
- Implementation of quality agreements and service level agreements with external parties
- External communication with customers and/or suppliers

Sales, Marketing, Market research, Business information, Health economics and outcomes, Pricing and reimbursement

- Knowledge and understanding of the health systems they are operating in (i.e four health care systems in UK) which would include structure, function, policy and funding flows
- Ability to communicate effectively with team members, individuals from other departments within the company and healthcare professionals including doctors, nurses, pharmacists, commissioners/payers

- Able to demonstrate effective team working as part of a cross functional team
- IT skills
- Ability to rapidly get up to speed on the different treatment/management options for therapy areas
- Ability to critically appraise clinical papers
- Understanding regulatory process for medicines, devices, diagnostics and technologies (Apps)
- Understanding of systems and processes for health technology appraisals, Quality of Life (QoL) and Patient Reported Outcome Measures (PROMs)
- Understanding of basic health economic techniques for economic evaluations and cost impact modelling
- Medical writing skills (for writing de novo and assessment of outputs from Agencies)

Role Specific

Sales

- Knowledge of in licence indications, side effects etc. and trials supporting claims
- Presentation skills
- Able to work on their own and as part of a team
- Follow relevant procedures and regulations including pharmacovigilance requirements
- Able to plan and prioritise work
- Able to develop and sustain networks of contacts, identify the decision makers and influencers
- Project management skills to roll out value added services
- Good understanding of therapy area and different treatment/management options, current competitors and potential changes to market
- Develop mentoring and coaching skills
- Ability to manage and motivate a team, undertake appraisals, manage human resource issues etc.
- Budgetary management
- Increased cross functional team working

Marketing

- Understand the principles of marketing and the different channels of marketing
- Good understanding of market, current therapy management, competitors and potential new entrants
- Ability to relate and motivate a sales team
- Ability to work with agencies, develop clear briefs
- Manage a budget

- Develop marketing strategies
- Understanding of clinical trial, HTA and regulatory process
- Project management skills
- Understand the different types of market research and what it will deliver
- Work with patient groups or link to company individual leading on patient interactions
- Ability to work across functions and link to global
- Understanding of manufacturing process and logistics to ensure stock is available

Market access/Healthcare development

- In-depth understanding of healthcare environment, structure, function, financial flows, policy and drivers for change
- Understand and interpret different healthcare data sources
- Ability to interpret and use budget impact models with payers
- Knowledge of products, positioning and therapy area
- Project management skills for delivery of value-added services
- Able to work on their own and as part of a team
- Follow relevant procedures and regulations including pharmacovigilance requirements
- Able to plan and prioritise work
- Able to develop and sustain networks of contacts, identify the decision makers and influencers
- Ability to communicate effectively with healthcare decision makers and influencers
- Ability to perform in cross functional teams

Health Economist

- Data analysis
- Economic modelling
- Literature review/network meta-analysis
- Understanding and interpreting clinical trial data
- Real-world evidence generation: understanding governance processes
- Strategic thinking
- Project management
- Vendor management
- Communication
- Collaboration

Pricing and reimbursement

- Understand reimbursement processes and financial flows for different countries
- Understand assessment and evaluation processes for different countries

- Understand payer needs and perspective
- Ability to commission meaningful payer research
- Economic modelling

Medical Scientific Liaison (MSL)

- Understanding of clinical trials
- In depth knowledge of therapy area including use of product outside of licence
- Understanding of biostatistics
- Ability to communicate effectively with a range of healthcare professionals including doctors, nurses and pharmacists
- Able to present clinical data and answer relevant questions
- Able to perform in cross functional teams
- Ability to develop training programmes for healthcare professionals and sales team
- Follow relevant procedures and regulations including pharmacovigilance requirements
- Able to plan and prioritise work

Medical Managers Final Signatories

- Extensive knowledge of national and international pharmaceutical codes of practice (i.e ABPI, EFPIA, IFPMA)
- Ability to review detailed technical and scientific copy review
- Ability to interpret clinical data and rapidly assimilate new therapy areas
- Strong attention to detail
- Excellent verbal and written communication skills
- Project/time management and organisational skills
- Able to work independently and comfortable working with high volumes of work and to tight deadlines

The need for an updated educational profile

The current Pharmacy curricula reflect the traditional roles of the Pharmacist and more or less are falling into two categories, i.e. the ones which are more focused on the so-called "hard science" courses and the ones which address in a more adequate manner the clinical competencies of the Pharmacist. However, in the light of the new regulatory and scientific developments presented before, both of them need major revisions to assure new skills which are advanced technology and science oriented.

The following list briefly describes the **main features** of the new working environment and the **new competencies** to be acquired by the Industrial Pharmacists:

- The faster transition from the bench to the bedside
- Precision medicine and personalized therapy
- Extensive use of IT tools
- Statistical approach and use of data-driven decision-supporting tools
- Pharmaceutical requirements in lifecycle management
- Advanced manufacturing methods (Lean, Continuous, Fast and Flexible Manufacturing)
- Smart factories design and operations
- Quality by Design and Quality Risk Management
- Statistical Process Control
- Environmental Engineering
- Systems Theory
- Automatic Control
- Artificial Intelligence and Machine Learning
- Robotics
- Big Data and evidence-based medicine
- Understanding of the supply chain complexity and its critical issues, including a particular focus on the qualification process which is to be applied to all actors involved

In addition to the specific technical competencies as described above, the presence of personal skills is also to be considered an essential requirement for industrial pharmacists to face the changing environment.
Though part of these skills has already been reported above when describing the areas of activity, the most important skills can be listed as follows:

- Teamwork, including:
  - ability to actively listen
  - ability to learn from the experience of others, both inside and outside the organization
- Leadership in the multidisciplinary team management
- Ability to apply problem-solving techniques

- Positive attitude towards continuous professional development
- Knowledge management and dissemination

All the above features should be highlighted and promoted in developing new Pharmacy Curricula and/or postgraduate courses.

Challenges and opportunities

The changes in the pharmaceutical industry are mainly due to the scientific advances in the development of new medicinal products and the constant progress of technological solutions which can be applied to the pharmaceutical area. The speed of these changes seems to increase over time and requires industrial pharmacists increasing efforts in keeping pace with the scientific and technical knowledge for their constantly updated professional performance. Taking advantage of its position in representing all industrial pharmacists in Europe, EIPG has realized the importance and the urgency of actions with the aim of promoting adequate interventions for upgrading the competencies of a pharmacist at the graduate level.

Now a very detailed list of key skills and competences requested to play any future role in the pharma world is available. This text is to be read as a stimulus for further discussion either within EIPG and with other associations of professionals and academics which would share the same goal of improving the preparedness of pharmacists entering the pharmaceutical industry.

Though EIPG is fully aware of the difficulties which are present in achieving this goal, it firmly believes that through a constructive collaboration among professionals and academics, solutions can be identified, in the interest of all parties concerned.

It is worth remembering that a pharmacist is a professional having a unique hybrid culture, receiving education in different subjects ranging from chemistry to technology, pharmacology and clinical treatment, so acquiring broad scientific competencies which make a pharmacist able to interact easily with other professionals working within the pharmaceutical industry.

This unique professional profile must be maintained and further developed by means of an adequate and urgent upgrade of the knowledge required due to the changing environment in the pharmaceutical industry

Annex I: Members of the EIPG Advisory Group

Anni Svala (chair, facilitator)
Anni Svala graduated 2009 from the University of Helsinki and has been working in Pharma Industry thereafter within regulatory affairs and quality-related tasks. Now she works as a Quality Director at Tamro Oyj and also acts as a Vice-President for Education and Careers in EIPG.

Susan Kilby FRPhamS, MBA, MSc, BPharm
Sue has worked across healthcare having held senior positions in the NHS, Royal Pharmaceutical Society, pharmaceutical industry and consultancy. Over the last 20 years, she has worked for several pharmaceutical companies in business development, marketing, health policy and market access which included managing the NICE HTA process. Currently, Sue is providing consultancy services to a range of customers including a start-up molecular diagnostic company

John Michael Morris, Ph.D., MPSI,
Obtained a degree in Pharmacy and a Ph.D. from the University of Manchester (UK) and worked briefly in industry in the UK. He then worked as a QA pharmacist in a number of hospital-based manufacturing plants in the UK over the next 10 years. In 1987 Michael moved to Ireland to work for NDAB/IMB/HPRA and became Director Scientific Affairs at the Health Products Regulatory Authority (HPRA) of Ireland in 2004 until he retired at the end of 2015.
Michael was formerly Pharmaceutical Director, IMB, responsible for the assessment of quality data (CMC data) and before that Senior Pharmacist at the Irish National Drugs Advisory Board. Dr. Morris was the EU member of the ICH Q6A Expert Working Group, and subsequently became EU topic leader and then Chair of ICH Q4B -pharmacopoeial harmonisation. In 2004 he was elected to the position of Chairman of the European Pharmacopoeia Commission until 2007 and he remained a member of the Ph. Eur.Commission until 2016. He is chair of Ph. Eur. Working Party PAT and a member of Group 12, pharmaceutical dose forms. Michael has also served on a number of committees of PSI, advisory committee of IIOP and the dissolution testing focus group of FIP. He has also been very active in the Ireland chapter of PDA since its inception in 2006 and has just recently stepped down after two years as President of that organization.

Astrid Thorissen
In 2014 Astrid graduated from Utrecht University and immediately started working in the pharmaceutical industry within a Global Quality Department. Afterwards, she has pursued her career in the Medical direction as a Medical Science Liaison. Now in the last 1,5 years, she is back in a global Quality Department at Yusen Logistics, focussing on implementing European GDP standards worldwide.

Harriet Lewis

I am based in Greater Manchester in the UK where I have spent most of my pharmacy career. My patient facing pharmacy roles have included NHS hospital, community and primary care pharmacy, followed by four years with NICE as Associate Director for Medicines Advice Guidelines. As part of these roles I have been actively involved in external advisory boards for pharmacist education and skills development, convened by Department Health and a number of University Schools of Pharmacy.
In 2012 I joined the Association of British Pharmaceutical Industry (ABPI) as Medicines Optimisation and Policy lead, providing policy advice and NHS pharmacist insight to the pharmaceutical industry.
I have long been an advocate of expanding the insights of pharmacy students and newly qualified pharmacists regarding opportunities in industry beyond the traditional and well documented R&D/Regulatory.
I am now the External Affairs Lead for Chiesi UK (a medium sized pharmaceutical company with HQ in Italy). As a result of concerted focused recruitment and training support we now have a group of pharmacists working across Market Access, Medical Information and Marketing. Our pharmacists bring a distinct and unique set of skills, knowledge and expertise that are now highly valued by our company. We regularly meet as a peer group to ensure we continue to provide exceptional insights for the business. I am keen that our next generation of pharmacists have the opportunities to see that there is a rewarding career within the Industry that draws on a range of skills and competencies beyond R&D/Regulatory functions.

Carla M.Caramella
Carla M. Caramella after graduation in Pharmaceutical Chemistry and Technology joined the Academy and became a professor in Pharmaceutical Technology and Biopharmacy at the University of Pavia. As professor emeritus, she is presently responsible for postgraduate educational activities including international student mobility programmes. She has been appointed quality expert at EMA.

Dimitrios Rekkas
is Associate Professor of Pharmaceutical Technology and Head of the Dpt. of Pharmacy at the National and Kapodistrian University of Athens, Greece.

Giorgos Panoutsopoulos
Holds a degree in Pharmacy with postgraduate studies in Pharmacognosy and in Public Health Policies. Since 2008 he works as an industrial pharmacist with Regulatory Affairs, Pricing & Reimbursement, Market Access and Pharmacovigilance duties.

Maurizio Battistini
Graduated in Pharmaceutical Chemistry and Technology and in Pharmacy, with more than 25 years' experience in Pharmaceutical Industry in several areas of competencies (CEO, QP, Operation Director, Global Quality Assurance Director, Research and Development Manager)

Piero Iamartino

After working for 40 years in the pharmaceutical industry, gaining experience in dosage form development and manufacture, then taking responsibility for quality and plant management (including API manufacture), he acts now as an independent consultant.

Annex II: References to other documents

EIPG has been involved in three important projects about education.

The **PHARMINE project** has been funded with support from the European Commission, the Lifelong Learning Programme of the European Union.

The aim was to put forward an EU standard for pharmacy education and training to be adopted by both the older and newer member states as well as candidates for EU membership and countries in non-EU areas such as Africa, China, India and South America.

EIPG was an active partner of the PHARMINE consortium, based on the collaboration of four members of EAFP /the European Association of Faculties of Pharmacy (belonging to universities of Brussels, Nancy, London and Lisbon) with representatives of a few European professional associations of pharmacists (community/PGEU, hospital/EAHP) and the contribution of representative of students (European Pharmacy Students' Association) and other interested bodies.

Taking into account the need for basic pharmaceutical competences (and mutual recognition of pharmacy qualifications) and the specialization needed in the three main areas of pharmaceutical expertise (community, hospital and industry), the consortium made a survey on existing EU pharmacy curricula, in the view of adaptation to the Bologna process. A common competency curriculum, as well as curricula for specialized pharmacy practice, were then developed and submitted to the EU Commission, national authorities and professional pharmacy associations.

PHAR-IN was a consortium funded by the European Commission via its Education, Audio-visual and Culture Agency (EACEA).

The partners of this consortium were from countries of the European Higher Education Area (EHEA), members of the European Association of Faculties of Pharmacy (EAFP), together with the European Industrial Pharmacists' Group (EIPG).

The aim of the project was to define the requirements for education in biotechnology for current and future employees in the pharmaceutical industry.

For this purpose, a panel of industrialists and educationalists with expertise in biotechnology were recruited and a list of education requirements was identified by representatives from EIPG and EAFP. Using several rounds of the Delphi process, a consensual, hierarchical list of competencies and outcomes was produced. The final list was then proposed for adoption in the education and training of biotechnology given at HEIs.

PHAR-QA was another important project funded within the LLP (Life Learning Project) at European level. The main focus of this project was on the way in which Quality Assurance principles are developed in the education courses for pharmacists considering the evolution of the role of the pharmacist in the healthcare system and Europe.

In this context, a study on how industrial pharmacists rank competencies for pharmacy practice was carried out. EIPG members gave their contribution to a survey which was developed for all European pharmacists.

Industrial pharmacists ranked competences centring on research, development and production of drugs higher, and those centring on patient care lower. Competences centring on patient values, communication skills, were ranked similarly by all groups of pharmacists. The results allowed to discuss on the existence or not of an “industrial pharmacy” specialization