Insights to the Industrial Pharmacist role for the future:

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Introduction and Scope

Purpose

This paper is an update of the previous EIPG paper and intends to raise awareness of the changing requirements of the professional profile of Industrial Pharmacists for Pharmacists at any stage of their career who intend to pursue careers in the Pharmaceutical Industry and those involved in the education of Pharmacists to update the education provided accordingly.

Scope

This paper is aimed at Pharmacists at all stages of their careers, including Pharmacy students, early career Pharmacists and Pharmacists working in a sector other than the Pharmaceutical Industry [collectively referred to as "Pharmacists" throughout]. The considerations presented are based on the collective expertise of the group. Therefore, this paper should be consulted as a starting point and is not a complete discussion of Pharmacist knowledge, competencies and skills nor a comprehensive overview of the Pharmaceutical Industry.

Introduction to the 2023 Paper

The EIPG with responsibility for the Pharmaceutical World, decided to continue the Project of the Advisory Group of Competencies. They used as a baseline document the first version of the position paper from 2020, in order to update the missing or outdated areas in the Pharmaceutical Industry. By examining some new trends and evolutions in drug science and technology, they explained the opportunities and challenges that are likely to arrive. All this information is intended for those at any stage of their Pharmacy career who want to understand their potential within the Pharmaceutical Industry.

The target of the project is to evaluate and determine the roles where the Industrial Pharmacist will work in the future and what knowledge, competencies and skills are needed to fulfill the requirements in these future roles. It is a shared understanding that there are gaps in the current curricula, but academia cannot cover all the needs of the Pharmaceutical Industry. For this reason, the Advisory Group have made some recommendations and proposals to recognize and fill those gaps. Hence, Pharmacists will have a clear view of the various roles in the pharmaceutical life cycle, and will be able to identify areas to develop on order to secure selected roles in the industry. This document may also be helpful in differentiating Pharmacists from other professions when applying for these roles.

Background

Pharmacists have played a critical role in the design, development, production and distribution of medicinal products and medicinal knowledge since ancient times. They have contributed significantly to the transition away from the compounding of medicines in local Pharmacies or apothecaries towards the large-scale industrial manufacture of medicinal products. More specifically, Industrial Pharmacists have been instrumental in the Pharmaceutical Industry in Europe ever since, bringing a unique set of skills and knowledge built on the novel combination of pharmaceutical science and clinical pharmacy practice education.

The training of Pharmacists is uniquely recognized in European law with the Pharmacy undergraduate program being one of the recognised programs providing the requisite

knowledge and competencies to undertake the role of the Qualified Person as defined in Directive 2001/83/EC. The robust educational foundation as both a scientist and a healthcare professional has allowed Pharmacists to provide valuable input in a variety of roles across a medicine's lifecycle at all levels in the Pharmaceutical Industry and affiliated organizations.

The Pharmaceutical Industry, like most industries, is deluged from various challenges that are likely to influence the future of our planet as a whole. Unpredictable conditions, such as the pandemic period and geopolitical instability, as well as novel introductions in personalized medicines and advanced manufacturing technologies will continue to shape the healthcare environment. Pharmacists, as professionals in healthcare, must continually update their professional performance and develop new knowledge, competencies and skills in order to effectively support patient care.

Method

Following the decision to update the previous publication, interested Industrial Pharmacists and academics were invited to apply to be members of the Advisory Group, those with relevant experience and knowledge were selected to form the final group to develop this publication.

The topics to be covered were identified in the initial brainstorming sessions between members of the Advisory Group. Smaller groups self-formed around areas of expertise and/or interest to revise the previous concept paper, collect updated data, policy documents, and shared experiences to compile the individual sections. To ensure accuracy and relevance, a meticulous approach was taken, involving comprehensive review, incorporation of latest insights, and extensive collection of information from relevant publications. Valuable insights from experts were gained through active participation in meetings and discussions. Rigorous revisions and evaluations were conducted to validate the gathered information.

The Advisory Group met regularly (a total of six times) to discuss the information presented by the smaller groups, to agree technical points and revise the contents of the paper. Feedback from all Advisory Group members enhanced the quality and reliability of the document.

Consistent usage of terms like "knowledge," "competency," and "skill" is ensured throughout the paper as follows, knowledge is the understanding of information and concepts, a skill is the ability to perform a specific task, and competency is the holistic capacity to effectively apply skills and knowledge in a particular context.

The final paper was agreed by consensus of the Advisory Group.

The Graduated Pharmacist today

In the European Union (EU), a Pharmacist is a highly qualified healthcare professional who has completed a university degree in Pharmacy and has acquired knowledge, competencies and basic skills necessary to practice and, in some cases, passed an additional qualification in their country of practice to perform the duties of Pharmacist. This may include, but is not limited to, practice in a community or hospital Pharmacy or within a number of different positions in the pharmaceutical, health or biomedical products industry. However, across the EU and even within member states, there is remarkable heterogeneity in Pharmacy curricula, ranging from more clinical- to industrial-oriented ones[3,4,5]. In some countries, such as Italy,

Pharmacy students may opt for a different curriculum, purposely designed for the community/hospital pharmacy practice or to hold positions in an industrial or academic environment, when enrolling in university. In other countries, an option to specialize for a specific sector within the course of study or at registration is not available. Upon completing registration, Pharmacists can pursue further study or qualifications within their chosen sector to enhance their practice, for example, Independent Prescribing in community Pharmacy or Nominated Signatory in the Pharmaceutical Industry.

Standard Curricula

Irrespective of the existing differences, based on the provisions of Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications (Art. 44 and 45), graduated Pharmacists in the EU should be trained to gain access and pursue a range of professional activities. To this end, they typically possess the following:

- Solid background knowledge of basic disciplines, including mathematics, statistics, computer science, physics, general, inorganic, organic and analytical chemistry, biology, microbiology, biochemistry, anatomy, physiology, pathology.
- Deep knowledge of:
    - pharmaceutical sciences, including medicinal chemistry, pharmaceutical analysis, pharmaceutical technology, biopharmaceutics, pharmaceutical legislation and professional ethics. Fundamental knowledge in industrial manufacturing of drug products with regulatory aspects is also acquired.
    - pharmacological sciences, including pharmacognosy, pharmacology and pharmacotherapy, toxicology.
- Skills for compounding and dispensing pharmaceuticals, including prescription and non-prescription drugs, as well as sterile injectable preparations.
- Competencies in clinical pharmacy, to identify, prevent and manage drug-related problems, and to provide patient counselling on the safe and effective use of medications.

In addition, registered Pharmacists acquire practical skills such as business skills, for efficient inventory, marketing and financial management of a Pharmacy, and communication skills, to interact effectively with patients, healthcare professionals and other stakeholders in cross-cultural settings.

All of these knowledge, skills and competencies are normally acquired through core courses and a compulsory vocational traineeship of at least six months in a community or hospital pharmacy, under the supervision of a professional tutor.

Elective courses

Alongside the required core courses and vocational traineeship, elective courses falling under a degree requirement are intended to complement knowledge, competencies and skills in light of preferred career paths, personal preference or particular ambitions. Such courses may cover, but would not be limited to, the following:

- Formulation of biotech drugs, including monoclonal antibodies
- Intellectual property and patents
- Quality by Design (QbD) and Design of Experiments (DoE)

- Continuous Manufacturing
- Advanced manufacturing techniques (microfluidics, 3D printing, 4D printing, electrospinning, etc.)
- Marketing authorization procedures in EU
- Health Technology Appraisal and pharmacoeconomics
- Market access principles
- Nanobiotechnology products
- Green processing
- Pharmaceutical process engineering and informatics
- Advanced Therapy Medicinal Products (ATMP)

These and other knowledge, competencies and skills may also be acquired as "micro-credentials" through specific classes offered by other faculties or through training courses held by accredited non-formal education providers (Recommendation on a European approach to micro-credentials for lifelong learning and employability, adopted by the Council of the European Union in 2022).

Additional desirable skills

In addition to the above, a range of different soft skills may be desirable, such as:

- Critical and analytical thinking
- Written, oral communication and presentation ability
- Team spirit and capability in leading multidisciplinary teams and managing conflicts
- Building, managing and training teams
- Planning, organizing and project management

These soft skills would particularly be developed during the vocational traineeship, any optional laboratory internships and drafting of the graduation thesis for final dissertation. In some universities, they may even be acquired through dedicated cross-curricular courses.

As all healthcare professionals, a graduated Pharmacist in the EU would be committed to lifelong learning and continuing professional development, to keep up with scientific and technical advances that have occurred after successfully obtaining her/his degree.

The Pharmacist today in the industry

There is a wealth of opportunity afforded to those who complete the Pharmacy degree, within the Pharmaceutical Industry. Currently the most common roles for Pharmacists include:

- Formulation Scientists
- Process Development Scientists
- Quality Assurance
- Regulatory Affairs
- Chemistry and Manufacturing Controls (CMC)
- Responsible Person
- Qualified Person
- Medical Information/ Medical Science Liaison
- Health Economics, Market Access & Reimbursement
- Pharmacovigilance

The sections below give an overview of the key elements of the job descriptions of roles that are relevant to Pharmacy education. Please note that these are an estimation of the authors, and role titles and job descriptions can vary significantly from one country and company to another. For examples, please see Appendix 1.

Pharmacists in Research and Development (R&D) Functions

Pharmacists can add value to various roles in the pharmaceutical industry R&D department. In the R&D functions, the candidate is often expected to have a PhD. The educational background of Pharmacists is competitive when compared to other university backgrounds, in particular, the experience of dispensing products to a patient which can inform important aspects such as the formulation. The academic studies of a PhD can have a significantly guiding impact on the role when the person transfers from academia to the industry and will often be very specific to the portfolio or ambitions of the particular company.

Pharmacists in Commercial Manufacturing & Supply Organizations

Pharmacists can add value to various roles in the commercial supply chain. Unlike in the R&D organization where PhD degrees are more common, the pharmacists working in commercial manufacturing are often Bachelor of Sciences or Master of Sciences. Pharmacy is a competitive educational background especially in the roles of quality and supply chain organization.

Pharmacists in Wholesale, Commercial Sales & Marketing Organizations

Pharmaceutical education also provides sound knowledge to pursue careers in wholesale, marketing and sales of medicines. Typically, Pharmacists have a good understanding of the legal and ethical frameworks for marketing, which is an asset.

The changing environment and new signals in the Pharmaceutical Industry

The role of the Industrial Pharmacist will need to adapt to the pressures of the evolving healthcare and scientific environment in which the Pharmaceutical Industry exists. For instance, the pharmaceutical production environment has been relatively stable, as the principles in small molecule manufacturing processes have been similar for decades. However, as the technology develops, the Pharmaceutical Industry cannot follow the development as an outsider without implementing improvements to its different processes. Most importantly, the Pharmaceutical Industry has an essential role to develop and manufacture more innovative medicinal products for patients in need. As described in the Method, the Advisory Group identified agreed key areas of interest which were then explored by self-formed teams. Therefore, these topics are intended to be a starting point for further discussions and not a comprehensive list. For examples of knowledge, skills and competence generated by the Advisory Group, please see Appendix 2.

Developing medicinal products

Biologicals

Biological medicines continue to be at the forefront of scientific and clinical innovation[8]. With the identification of new targets, molecular pathways in disease states and genetic markers, there continues to be a strong demand for biological medicines that offer greater precision and specificity over the traditional chemical based medicines.

Advanced Therapy Medicinal Products (ATMPs)

ATMPs are medicines based on genes, tissues or cells (ATMP Regulation 1394/2007). High unmet medical needs and scientific advances have seen an increase in cell and gene-based therapies which continue to gain traction across the healthcare sector with increasing numbers of regulatory approvals year on year. An example of ATMPs in clinical use are Chimeric Antigen Receptor (CAR)-T therapies which utilize the patient's own immune cells to treat their cancer[6]. ATMPs are complex in nature, requiring special consideration for manufacture, regulation and administration. Industrial Pharmacists have the scientific and healthcare professional background to be able to navigate these complexities in production, registration and healthcare professional education[16].

Personalized Medicines[22]

As the 'omics' wave continues to gain momentum in clinical and translational research, the advent of personalized medicines continues to grow. With improved diagnostics, there is an ever-increasing trend towards personalized, target specific therapies particularly in oncology. In addition, personalized medicine relies increasingly on the ability to understand genetic reports and translate them into clinical action. Treatment personalization may also require customized dosage forms or delivery systems having tunable drug content and/or release kinetics.

Orphan drugs

Rare diseases present challenges for pharmaceutical organizations due to small patient populations and limited reimbursement. Governments offer incentives to develop therapies for high unmet medical needs, leading to increased investment in rare diseases[21]. Industrial Pharmacists can add value with their clinical background, informing development decisions and engaging with stakeholders in an ethical and empathetic way[1,18].

Combination Products (Medical Devices):

Patients are increasingly showing a preference to self-administer medicines for chronic conditions like rheumatoid arthritis and psoriasis. Devices like auto-injectors and pre-filled syringes have become popular for administering biologics, eliminating the need for hospital visits. Combination products of medicines within administration devices present new challenges in product design, regulation, and user experience outside clinical settings[14,28,34].

Social Challenges

Reimbursement[8]

Healthcare in the 21st century increasingly involves complex, high-cost medicines like biologics or ATMP. Aging populations and increasing average lifetimes are putting pressure on National health authorities and their health budget watchdogs who in turn are calling for increased levels of demonstrated health outcomes as a caveat to reimbursement.

Real World Evidence (RWE)

Evidence based decision making Manufacturers face reimbursement challenges, needing to justify cost-benefit despite regulatory approval to demonstrate patient outcomes and that the estimated cost:benefit is being realized for patients in the real world, outside of controlled

clinical trial settings[19]. The demonstration of RWE requires new ways of working with regards to data collection and interpretation. The future may rely on personal health/companion apps and sensors to collect patient data to demonstrate patient compliance and demonstrated benefit.

Access to medicines

Patient access to medicines continues to be a hot-topic in public health circles with developing nations in particular struggling to meet the high costs associated with new and more complex medicines[35]. The COVID-19 pandemic was an acute example where global outcomes and variant minimization may have been achieved by having common access to vaccines[33]. The need for patient access is also becoming more visible through the advocacy of patient groups and social media providing a platform for patients without access. As healthcare professionals employed by private, for profit organizations patient access continues to be an ethical dilemma that will remain despite the intentions of all stakeholders involved.

Environmental Sustainability

Within the Pharmaceutical Industry, there has been an on-going movement towards clean industry, green chemistry, organic food stocks and a circular economy[12]. Environmental sustainability has become a key part of many organizations' short and long-term goals. This has included the development of private solar/wind farms at manufacturing sites, reduction and recycling in the use of organic solvents and minimizing electrical and water consumption where possible[14]. This will increasingly involve the use of statistical optimization tools to reduce the number of screening trials and use of raw materials[9].

Supply Chain - On-going geopolitical and health crises[12]

Europe in particular has been front and center of a number of crises in the last 15 years, from the financial crisis in 2008 and its knock-on impact which continues to be felt to the most recent war in Ukraine which began in February 2022. Other large challenges included the migrant crisis in 2015, Brexit in 2016 and finally the COVID-19 pandemic between 2020-2022. These crises have created profound shocks on our supply chains leading to increased delays and cost of goods through delayed or lack of raw materials, energy shortages, labor shortages and general transportation delays. The patient impact can be clearly seen through widespread drug shortages at both hospital and community pharmacy level. The only certainty is further uncertainty in the short-term as the Ukraine war continues without end in sight, geopolitical tensions across the pacific continue to rise e.g. Taiwan, and the EU and Britain continue to define their post-Brexit relationship.

Technology

The 4th industrial revolution is upon us with the development of cyber physical systems with the 5th industrial revolution on the horizon with the advancement of artificial intelligence (AI) in partnership with humans to enhance processes in the workplace. The factory of the future is here with digitalization, AI, Big data, robotics and advanced manufacturing becoming the norm rather than the exception in the pharmaceutical industry[30].

The technology development has enabled new approaches to various parts of the pharmaceutical industry. The industry is moving towards widespread adoption of process

analytical technologies (PAT) for in-line and on-line testing as part of in-process control and a push towards full implementation of ICH Q8 Quality by design. This includes the use of various analytical technologies such as UV, IR, NIR and Raman spectroscopy as well as light scattering techniques such as Multi-Angle Light scattering[7].

We believe that there is an increasing need for Industrial Pharmacists to understand and master statistical principles and parts of basic engineering. As the commercial manufacturing should be based on RWE, we propose examples of knowledge, competencies and skills in the following areas.

Digitalization

The modern pharmaceutical manufacturing plant is tending towards being devoid of paper forms, physical archives and physical documents with IT systems replacing physical documentation leading to the streamlining of processes and remote access. In addition, the need to be physically present on sites is being replaced by IT systems providing remote access to physical equipment and associated manufacturing and testing data in real-time i.e. Delta V. This move to digital systems allows for vendors to provide remote support and troubleshooting, and digitalization also allows for remote approval of documents such as batch records using manufacturing execution systems (MES) for remote access that limit the need to visit the site and special permissions to view the batch record in document control. The use of automation systems to collect data and control processes from outside the manufacturing suite is another example of digitalization and Pharma 4.0.

Statistics - multivariate analysis - Artificial Intelligence (AI) - Big data - Machine Learning (ML)

The digitalization of manufacturing processes has resulted in an exponential increase in in-process data available to pharmaceutical scientists. This data availability enables the deployment of advanced computing and statistical techniques such as AI, big data and ML. These techniques are also being employed in drug design and formulation development and medical affairs. The access to large data sets allow for models to be developed with training sets and validated with additional data in ML. In addition, supercomputing allows for previously impossible relationships to be defined with big data. AI has been used in automated visual inspection systems for drug product release.

Robotics

The 3rd industrial revolution ushered in the use of robotics and automation in the industrial environment in the 1970s. However, there has been sparse and variable deployment in the Pharmaceutical Industry with many processes remaining highly manual until the turn of the century. With the rise of more sophisticated technology, well-defined business cases robotics are gaining traction within the Pharmaceutical Industry, with unit operations such as packaging, visual inspection moving towards robotic systems in lieu of manual, human-executed processes. This will continue and gain traction in highly manual operations such as laboratory testing. In sterile manufacturing, humans are widely accepted as the greatest risk to introducing microbial contamination and there is a concerted effort to move towards robotics isolators that do not require any human intervention.

Advanced Manufacturing

The pharmaceutical industry is moving towards the use of new and novel manufacturing technologies such as continuous manufacturing, 3D printing, inkjet printing, electrospinning, microfluidics and creation of amorphous solid states through hot-melt extrusion for oral solid dosage forms. There are also new advanced manufacturing technologies to be discovered, as even the current advanced technologies have their limitations.

Regulatory and legislation changes

Despite the significant level of well-established regulatory requirements in the Pharmaceutical Industry, regulatory updates continue to occur as the industry strives for continuous improvement and enhanced patient safety, and in response to new technologies such as continuous manufacturing and emerging therapeutic challenges. In Europe there has been significant regulatory upheaval with the release of a new revision of Annex 1 detailing the requirements for sterile manufacturing. The Medical Device Regulation (MDR) went live in 2021 updating the standards expected for medical device supply in the EU. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has in the last number of years also been busy globally with the update and release of revision 2 of ICH Q9 on quality risk management, first publication of ICH Q12 on life-cycle management and ICH Q13 on continuous manufacture of drug products and drug substances in July 2023.

Additionally, the Commission is proposing to revise the EU's pharmaceutical legislation[(14)] - the largest reform in over 20 years - to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU. The revision will make medicines more available, accessible and affordable. It will support innovation and boost the competitiveness and attractiveness of the EU Pharmaceutical Industry, while promoting higher environmental standards. In addition to this reform, the Commission proposes a Council Recommendation to step up the fight against antimicrobial resistance (AMR).

The regulatory framework is constantly developing to be more precise and relevant. Good knowledge and understanding of the guidelines is key in mastering multiple roles in the Pharmaceutical Industry. Below we present some example guidelines that have been recently changed or implemented, and where the industry has a high need for competent personnel:

- Awareness of ICH guidelines and in particular the newest publications by ICH i.e. ICH Q9 Revision, ICH Q12 and ICH Q13.
- Describe the updates to EU Annex 1 for sterile manufacturing
- Describe the EU Medical Device Regulations (MDR)
- Define rolling-review and how it was applied in the case of covid-19 pandemic.
- Define ICH Q7 & Q3 impurity requirements with a particular focus on nitrosamines case study

Regulatory harmonization & Rolling-Review

The rapid development and implementation of the COVID-19 vaccine portfolio was enabled by rolling regulatory reviews with many vaccines not receiving full approval until 2022/23. This new, pandemic enforced way of working of rolling regulatory approvals may offer a new pathway for faster access to medicines. While it is not known whether rolling regulatory

approvals will become commonplace in the future, when combined with existing practices such as breakthrough designation, the regulatory approval process may not return to pre-pandemic methodology.

How can Pharmacists build their knowledge, skills and competence to succeed in the Pharmaceutical Industry?

Pharmacists should engage in lifelong learning by staying updated with the latest advancements in pharmaceutical sciences, clinical practice guidelines, and regulatory changes. They can attend conferences, seminars, workshops, and webinars, as well as pursue postgraduate education, certifications, and specialty training programs.

Actively participating in professional organizations, such as pharmacy associations and societies, provides opportunities for networking, knowledge sharing, and staying informed about industry trends. Pharmacists can attend meetings, join online communities, and connect with colleagues to expand their professional network and gain valuable insights.

Participating in work experience in the Pharmaceutical Industry or work-shadowing a colleague can enhance pharmacists' knowledge and practical skills. These placements offer hands-on experience in different practice settings, exposure to diverse environments, and opportunities to work collaboratively with different teams.

Pharmacists can engage in research activities to contribute to the advancement of pharmaceutical knowledge. This may involve participating in clinical trials, conducting observational studies, or collaborating with researchers and academia. Involvement in research can deepen their understanding of evidence-based practice and critical appraisal of scientific literature.

Serving as preceptors for pharmacy students or mentoring less-experienced colleagues can foster the development of teaching and leadership skills. Sharing knowledge, guiding others, and providing feedback can help pharmacists refine their communication skills and expand their professional influence.

Pursuing specialized areas of pharmacy practice through certifications, such as board certifications or additional training, can demonstrate expertise in specific domains. Specializations can include areas like ambulatory care, critical care, geriatrics, oncology, or informatics. These certifications enhance pharmacists' credibility and open up opportunities for advanced roles and responsibilities.

Collaborating with other healthcare professionals, such as physicians, nurses, and allied health professionals, strengthens pharmacists' teamwork and communication skills. Engaging in interdisciplinary discussions, case conferences, and collaborative patient care initiatives improves patient outcomes and expands pharmacists' knowledge beyond their specific domain.

Building leadership skills equips pharmacists to take on managerial roles, lead teams, and drive innovation within the pharmaceutical industry. Seeking opportunities for leadership training, taking on project management roles, or participating in quality improvement initiatives can enhance leadership capabilities.

Staying updated with the latest technology trends in pharmacy practice is crucial. Pharmacists should familiarize themselves with pharmacy management systems, electronic health records, medication-related software, and digital health tools. Embracing technology and understanding its implications can optimize pharmacy workflows, patient care, and medication safety.

Regularly reflecting on professional practice, identifying areas for improvement, and setting goals for personal and career development are essential. Self-assessment tools, performance evaluations, and seeking feedback from colleagues or supervisors can provide valuable insights and facilitate professional growth.

By actively pursuing these strategies, Pharmacists can continuously build their knowledge, competencies and skills, positioning themselves for success in the dynamic and evolving Pharmaceutical Industry.

Conclusion

Knowledge forms the foundation of a Pharmacist's understanding, skills represent their practical abilities, and competencies showcase their potential to apply knowledge and skills in practice. The professional accountability of Pharmacists means that they are ideally placed to bridge the gap between pharmaceutical science and the commercialization of safe, effective and high quality pharmaceutical products while complying with regulatory requirements and industry standards.

The Pharmaceutical Industry is constantly responding to the environment and predicting shifts to keep pace with healthcare needs. In addition to the development needs raised within industry, the world around the industry will urge for changes. The Industrial Pharmacist must keep their knowledge current and continue to build their skills beyond their university education. The education of Pharmacists must also develop in line with progression of the sector for the future industrial Pharmacists.

In conclusion, the Advisory Group of gathered experts sought to demonstrate that the Pharmacist education is a competitive advantage for many roles in the Pharmaceutical Industry. Those who have ambitions to become and those who are already Industrial Pharmacists must be aware that, like most industries, the Pharmaceutical Industry is subject to pressures to evolve in order to meet healthcare needs. This paper has demonstrated some of the key knowledge, skills and competencies for Pharmacists now and in the future to ensure the Pharmaceutical Industry can continue to provide for patients in need.

Appendices

Appendix 1: Roles in the Pharmaceutical Industry by Department

The sections below give an overview of the key elements of the job descriptions of roles that are relevant to Pharmacy education. Please note that these are an estimation of the authors, and role titles and job descriptions can vary significantly from one country and company to another.

Research & Development

Role	Group	Key elements of the Job Description
Target Identification	Research	Identify therapeutic targets of interest
Drug Discovery	Research	Identify compounds that can target biological target
Candidate Optimization	Research	Optimize compounds to maximize efficacy, minimize toxicity
Formulation Scientists	Early Stage Development	Pre-, early and advanced formulation studies to develop products for toxicology and clinical studies and commercial supply.
Process Development Scientists	Early Stage Development	Develop manufacturing process at small and pilot scale
Analytical Development Scientist	Early Stage Development	Develop analytical techniques to characterize and release batches and perform stability testing
R&D Program Management	CMC	Manage all program elements i.e. clinical supply, tech transfer, commercialization
Chemistry & Manufacturing Controls (CMC)	CMC	Write and submit dossiers
Clinical Trial Management	Clinical Trials	Manage clinical trials

Clinical Trials Associate	Clinical Trials	Execute clinical trials at local level
Clinical Packaging	Clinical Trials	Package and label clinical drug product & placebo before clinical trial usage
R&D Quality	R&D Operations	Ensure quality assurance of clinical manufacture & testing
R&D Manufacturing	R&D Operations	Manufacture clinical batches.

Commercial Manufacturing and Supply Organizations

Role	Group	Key elements of the Job Description
Process Development Scientists	Technical Operations	Develop commercial manufacturing processes
Analytical Development Scientist	Technical Operations	Develop commercial testing processes
Validation	Technical Operations	Validate commercial equipment & processes
Tech Transfer	Technical Operations	Transfer manufacturing process e.g. from clinical site to commercial site(s)
QC Analyst	Quality	Test commercial product as part of release testing
Quality Assurance	Quality	Ensure quality assurance of commercial batches, testing & processes
Quality Systems	Quality	Internal auditing, supplier management
Qualified Person	Quality	Batch release

Sterility Assurance	Quality	Ensure compliance with sterile manufacturing requirements
Regulatory Affairs	Quality	Liaise with health authorities and file marketing authorisation applications and post-marketing changes
Engineering	Engineering	Process, Mechanical, Utility, Maintenance
Planning & Buying	Supply Chain	Plan manufacturing schedule and manage inventory
Procurement	Supply Chain	Manage vendor supply contracts
Logistics & Warehouse	Supply Chain	Receipt, storage and shipping of raw materials and finished products
Operations & Production	Operations	Manufacture of commercial batches
Automation & IT	Support	Manage Manufacturing site automation and IT infrastructure and processes
External Manufacturing	Supply Chain	Management of external manufacturing supply

Wholesale, Commercial Sales and Marketing Organizations

Role	Group	Key elements of the Job Description
Distribution	Supply Chain	Distribution of finished product to wholesalers or end users (final mile). Could also include the distribution of raw materials or semi-finished products
Warehousing/ Storage	Supply Chain	Storage of (semi-)finished product at (pre)wholesalers. Could also include GMP-licensed product alterations and site of (physical) importation for products from outside the EU/EEA

Responsible Person	Supply chain	Ensures Good Distribution Practices are employed
Medical Sales	Sales	Sales of API/finished product to third party/wholesalers
Medical Marketing	Marketing	Marketing of medicinal product to consumers/HCPs
Medical Director	Medical Affairs	Management of Medical Affairs function
Medical Affairs Manager	Medical Affairs	Creation of Medical Strategy
Medical Science Liaison	Medical Affairs	Supply of detailed medical information to HCPs, involved with Phase IV/Real World Evidence studies
Medical Information	Medical Affairs	Supply of medical information to HCPs and consumers
Scientific Communications	Medical Affairs	Dissemination of product information
Post-Marketing Clinical Research	Medical Affairs	Phase IV clinical trial management
Health Economics, Market Access & reimbursement	Medical Affairs	Pharmacoeconomic evaluation to support pricing model
Innovation & Digital Health	Medical Affairs	Development of digital healthcare solutions
Pharmacovigilance	Medical Affairs	Collection, detection, assessment, monitoring, and reporting of adverse effects signals

Appendix 2: Examples of knowledge, skills and competence in the Pharmaceutical Industry

Key Industry Focus Areas	Knowledge	Skill	Competency
Access to Medicines	Awareness of the local access to medicines routes e.g. national reimbursement, compassionate use schemes, named patient supply	Training on company procedures for medicines access	Supporting access via a compassionate use scheme or similar e.g. post-trial access
Advanced Manufacturing	Understanding the basics of different manufacturing technologies and their applications	Training on the use of the different advanced manufacturing technologies	Supporting the integration of an update in technology to optimize the manufacturing process
ATMPs	What gene therapy is and the disease area of interest High level overview of ATMP manufacturing and distribution and the critical quality attributes associated with different ATMP classes	Upskilling colleagues on the requirements of ATMPs at each stage of development	Supporting the design, registration and on-going monitoring of an ATMP
Biologics	The design, formulation, manufacture, analysis and administration of biological medicines	Explaining the differences between biologics and biosimilars	Supporting the Regulatory approval of a Biologic/Biosimilar
Combination Products (Medical Devices)	Knowledge of combination products	Training on the local regulatory requirements for Combination devices	Supporting the marketing of a Combination device
Digitalization	Awareness of evolving digital trends like MES, IoT and AI.	Use of cloud platforms for secure data storage,	Managing and leading organizational change during

		management, and collaboration	digital transformation initiatives
Environmental Sustainability	Awareness of environmental sustainability challenges for the Pharmaceutical Industry	Company and health and safety training on environmental impact	Participation in environmentally focused initiatives such as a Company's Environmental club
Orphan Drugs	Disease, existing treatment landscape, how the product works	How to navigate the local orphan-drug designation requirements	Provision of disease/product education to HCPs and Patients
Personalized Medicines	High level overview of personalized medicine, understanding the impact of genetic differences on the action of pharmaceuticals	How to test for genomic differences that could affect pharmaceutical treatment, how read a genomic report	How to interpret a genomic report to appropriately treat patients
Regulatory and Legislation Changes	Understanding the basics of marketing authorisation procedures and investigating the foreseen legislation changes.	Legal research and interpretation capability, scientific understanding, regulatory awareness, communication skills, data analyzing skills	Regulatory expertise to be able to navigate in the jungle of changing regulatory requirements. Additionally project management and analytical skills and thinking
Regulatory Harmonisation and Rolling Review	Capability to review and assess the marketing authorisation related data while the clinical trial is on-going.	Comprehend the regulatory complexity with speed and flexibility	Data-analysis, risk assessment, adaptability, technical writing and ethical judgment
Reimbursement	Understanding the local processes for reimbursement	Applying models used to determine cost-effectiveness e.g. QALYs	Supporting a reimbursement application to the local authority

Robotics	Knowledge of GMP requirements and regulations to ensure that automated processes comply with industry standards	Integrating, programming and configuring robotics seamlessly into existing pharmaceutical processes while maintaining quality and compliance	Identifying opportunities to optimize processes through the integration of robotics and automation
RWE	Understanding the potential and limitations of RWE	Interpretation of Real World Data (RWD) into RWE	Support the set up of a RWD study Application of RWE in clinical setting
Statistics - multivariate analysis - Artificial Intelligence (AI) - Big data - Machine Learning (ML)	Understanding the foundational principles and their potential applications in the pharmaceutical industry	Utilizing Statistics, multivariate analysis, AI and ML algorithms to analyze complex pharmaceutical data sets for predictive insights	Identifying and executing on opportunities for Statistics, multivariate analysis, AI, ML, and big data applications
Supply Chain	Awareness of Local and Global supply chain issues	Training on company procedures to notify local Authorities on product shortages	Participation on a task force dedicated to dealing with a shortage issue

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