








SHORT REPORT

# Upgrading pharmacy education to produce practice-ready pharmacists in Lebanon

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## Abstract

**Background:** Pharmacy is a steadily evolving profession that brings about changes in practice, where the pharmacist should fulfil novel expanded roles. As such, pharmacy education has to adapt to these local and international changes and follow scientific progress to graduate practice-ready pharmacists. The authors' objective is to suggest a roadmap with practical solutions to scale-up pharmacy education in Lebanon and produce practice-ready pharmacists with specialised competencies while curbing the number of non-specialised graduates. **Methods:** To reach this objective, the Order of Pharmacists of Lebanon (OPL) has considered adopting the post-graduate training system to meet the needs of the country, based on scientific and social development. **Results:** The Board of the Order of Pharmacists of Lebanon agreed on the concept of the post-graduate training system for all pharmacists registering with the OPL. Consequently, the scientific committee at the OPL, in collaboration with relevant stakeholders, developed post-graduate competencies and related activities in two parts (general core competencies and advanced specific competencies), to be applied by academia and pharmaceutical institutions. This project would raise the level of the profession, improve readiness to practice in different fields, and indirectly reduce the number of non-specialised pharmacy graduates. **Conclusion:** This paper suggests a road map with practical solutions, including core and specialised competencies acquired in post-graduate training and assessed through a licensure examination, to scale-up pharmacy education in Lebanon and produce practice-ready pharmacists. Further work is necessary to explore the applicability of these documents and confirm their validity in different fields of practice.

## Introduction

Pharmacy is a constantly evolving profession that brings about practical changes, where the pharmacist is expected to fill new and expanded roles. Consequently,

pharmacy education must adapt to local and international changes and progress to graduate pharmacists who are ready to practice. Worldwide, five years of general pharmacy study is becoming insufficient for good quality

of care, potentially affecting patients' health that remains a priority to all healthcare professionals. Thus, several countries have extended general pharmacy education to six years and adopted the Doctor of Pharmacy (Pharm.D.) degree as the entry-level for any field of practice, such as the United States of America (USA) (Knoer *et al.*, 2016), France (Bourdon *et al.*, 2008), the Netherlands (Mason, 2000), Chile (Universidad De Chile, 2017), Canada (starting 2020) (The Canadian Council for Accreditation of Pharmacy Programs, 2014), and Egypt (Akhbarak, 2014).

In addition to the general pharmacy education, a large number of pharmacy specialisations are available to pharmacists after graduation (e.g. clinical pharmacy in a hospital or a community setting, industrial pharmacy, medical laboratory, etc.) (Sholy & Zeenny, 2013). Most require at least six years before enrolling, with the 6th year being part of the pre-graduate curriculum or post-graduate studies, according to the field of practice, and becoming practice-ready.

Countries that have adopted post-graduate training are producing practice-ready pharmacists in different fields, according to additional required skills per specialty and the needs of each country. Examples include France (Bourdon *et al.*, 2008), Japan (Zamami *et al.*, 2016), South Africa (Bradley *et al.*, 2015), and Brazil (Melo *et al.*, 2017). In Arab countries, the trend is towards specialisation in clinical pharmacy (such as Pharm.D. programmes in Saudi Arabia and Kuwait) or postgraduate training in Syria (Alkhateeb *et al.*, 2018; Ministry of Health, 2017).

Whatever the method adopted by the local authority to improve pharmacy practice, a clear vision of the needed competencies is crucial to help educational institutions achieve the required learning outcomes in general and specialised studies and graduate more practice-ready pharmacists.

This paradigm is now globally accepted. Indeed, international organisations have suggested core competencies for general pharmacy (International Pharmaceutical Federation [FIP], 2012), in addition to some national organisations, such as the Centre for the Advancement of Pharmacy Education (Medina *et al.*, 2013) and the National Association of Pharmacy Regulatory Authorities (NAPRA), (NAPRA, 2017), and specialised pharmacy societies in developed countries that have created their specific required competencies (Atkinson *et al.*, 2015; Saseen *et al.*, 2017).

In the Eastern Mediterranean Region, several researchers have issued a call for action to develop strategic plans for workforce and education development, based on the 'adopt and adapt' approach to national transformation

needs and the FIP roadmap (FIP, 2017; Mukhalalati *et al.*, 2019). Stakeholders outlined a mismatch between the competencies of graduates, the supply of pharmacists, and the national demand, highlighting the need for competency-based frameworks specific to each country to circumvent an oversupply of pharmacists with no career options (Bajis, Moles, & Chaar, 2017). The main reason underlying this problem is training inadequacy (Kheir *et al.*, 2008; Al-Ghananeem *et al.*, 2018).

In Lebanon, the situation is no different from the rest of the region. Indeed, each year, around 500 non-specialised pharmacy graduates register with the Order of Pharmacists of Lebanon (OPL), the official pharmacists association in Lebanon, far exceeding the national needs. The absence of an official core competencies framework leads to discrepancies in these graduates' skills; for experiential education, pharmacy students must complete a 12-month training with no supervision of the content from any authority. Thus, some pharmacists may graduate with the required duration of academic training, by the end of the fifth year, without going through all the needed rotations to practice the profession properly, such as clinical and hospital pharmacy training. Furthermore, since the entry-level in the country is still the five-year pharmacy degree, fresh graduates shall probably need a postgraduate training period to gain experience and reduce potential errors resulting from lack of exposure in any field of practice, which can have a detrimental impact on the patient.

Based on all these factors, Lebanon is facing a mismatch between the competencies of pharmacy graduates and the labor market needs. Therefore, the OPL decided to act on elaborating pharmacy education recommendations to optimise pharmacy practice; after defining the core competency framework for pharmacy in Lebanon (Sacre *et al.*, 2020), it further developed specialised competencies and postgraduate training. The authors' objective is to suggest a roadmap with practical solutions to scale-up pharmacy education in Lebanon and produce practice-ready pharmacists with advanced competencies, while indirectly curbing the number of non-specialised graduates. This work is a continuum of the one describing the Lebanese Pharmacy Core Competencies Framework (Sacre *et al.*, 2020)

## Methods

To reach the set goal, the OPL considered adopting a post-graduate training system to meet the needs of the country, based on scientific and social development.

### **Contact with academic institutions and rejected suggestions**

During the meetings of the Academic Board (composed of representatives of the faculties of pharmacy in Lebanon, in addition to members of the OPL scientific committee), the OPL presented several suggestions in 2017 (that were rejected by some universities), aimed at scaling up education and reducing the oversupply of non-specialised pharmacists. Among the most important rejected suggestions:

1. Extend the pharmacy education to six years, as in developed and some neighbouring countries. The practice of pharmacy in Lebanon is subject to Law No. 367, which defines in its first section the conditions for obtaining a license to practice in Lebanon, without specifying the duration of studies (which maintains the entry-level at five years, until today).
2. Adopt measures to reduce the oversupply of general practice pharmacists, such as: a) adopting a specific average grade at the Lebanese baccalaureate or its equivalent for admission to any university teaching pharmacy in Lebanon or registration with the OPL; b) organising a national examination with the collaboration of the Ministry of Education and Higher Education (MEHE), accredited Lebanese universities, and the OPL to determine the number of pharmacy graduates according to the needs of the country; or c) committing to a fixed number of graduates by Gentlemen's Agreement under the auspices of the MEHE.
3. Extend the training period to 20 months and at least six hours a day, during pharmacy studies. Thus, the student would acquire the necessary professional skills and experience to engage in professional work, which will reduce errors during practice in the interest of the patient's health and the pharmacist.

The motives underlying the rejection of these suggestions were not always clear. The main declared reason was the need to reshuffle current curricula, admission, and graduation procedures, which was considered a heavy workload and highly expensive task.

### **The Order of Pharmacists of Lebanon – Board decision**

When the above suggestions did not attain the acceptability of all stakeholders and could not be implemented, the OPL Board (composed of pharmacists elected by the General Assembly of Registered Pharmacists in Lebanon including community, hospital, academia, industrial, and marketing fields pharmacists), decided to

take action in March 2018. It decided to move on with the postgraduate training concept that would upgrade pharmacy education and indirectly curb the number of non-specialised pharmacists, and delegated to the OPL Scientific Committee the responsibility of elaborating implementation documents.

### **Developing postgraduate competencies**

The OPL Scientific Committee developed a series of postgraduate competencies, based on the previous work of a group of Lebanese Academic Pharmacists (2015-2016). It updated the previously drafted document and sent it to different stakeholders to seek their opinion, including academia (two members from each university), one pharmacy student from each university, and one representative from other stakeholders, i.e. the industry, importers, scientific offices, community pharmacists, hospital pharmacists, non-governmental organisations (NGOs), and public authorities.

The finalised document was run over two rounds to reach a consensus regarding postgraduate competencies, using the Delphi method, a forecasting process framework based on the results of multiple rounds of questionnaires sent to a panel of experts. After each round, the anonymous responses were aggregated and shared with the group until a consensus was reached over the list of suggested competencies, i.e. core (common to all specialties and recommended by the majority of stakeholders) and advanced specific (specialised) postgraduate competencies.

### **Developing activities matching postgraduate competencies**

Afterward, in-depth semi-structured interviews were held with the representatives of these stakeholders to confirm their feedback regarding the needed core and specialised competencies, related to their respective fields in the job market. They were asked to suggest required matching specific activities, in addition to recommended general activities, considered essential to prepare graduates for their future roles.

Additionally, stakeholders defined their current needs and expected difficulties in implementing the suggested postgraduate training. Their answers were taken into account to shape the final document that included competencies and matching activities approved by the OPL Scientific Committee.

In parallel, the OPL Scientific Committee drafted an official document clarifying the process and needed steps to implement the suggested training adequately. It was issued in May 2018 and sent to the MOPH for approval.

**Results**

**Content of the decision of the OPL Board**

In its meeting held on 15th March 2018, the OPL Board adopted the concept of the postgraduate training system to all pharmacists registering with the OPL. According to the Board decision, students registered at the University, and who will be joining the OPL starting 2019, are required to enrol for a nine-month postgraduate training after registering with the OPL with the status of trainee (postgraduate) pharmacist. Students can opt to replace this duration with a Pharm.D. degree or an additional year of study in any pharmacy-related domain, such as research or professional master’s degrees, where they would gain experience in the field of the intended work.

Students starting their first academic year of pharmacy in 2018-2019 would be required to apply for post-graduation training of 20 months after registering with the OPL as trainee pharmacists. They can replace this training with advanced studies; the OPL would determine the duration of the exemption, depending on the field of studies. This decision applies to students graduating from Lebanon and abroad. In parallel, the OPL drafted legislation to create the status of postgraduate pharmacists for fresh graduates registered with the OPL and sent it to the MOPH for approval.

**Postgraduate competencies**

Postgraduate (PG) competencies were divided into general core competencies (PG-GCC) and advanced specific competencies (PG-ASC) and presented with related indicators.

The PG-GCC eventually linked to PG core training included the following competency domains (Table I):

1. Professional Practice: Continuing Professional Development (CPD). PG trainees apply principles of CPD, assessing own learning needs, and developing a plan to meet these needs.
2. Personal Skills: PG trainees have leadership skills; they demonstrate leadership abilities in the team processes. They also have Information Technology (IT) skills, applying a minimum of IT in work.
3. Safe and Rational Use of Medicines: PG trainees monitor the use of medicines and the progress of patients and assess therapeutic outcomes. They monitor and prioritise medication safety and act accordingly.
4. Pharmaceutical Public Health Competencies: PG trainees engage in health promotion activities with the patient to promote population health.

**Table I: General (core) competencies (PG-GCC) and activities for core PG training**

Competency	Indicators	Required Activity
<b>1. Professional Practice</b> <b>Continuing Professional Development (CPD)</b>  Applies principles of continuing professional development including assessing own learning needs and developing a plan to meet these needs.	1.5.1 Understands and accepts the importance of life-long learning for pharmacists 1.5.2 Demonstrates the ability to critically reflect on their own practice and skills to identify learning and development needs 1.5.3 Takes personal responsibility for engaging in CPD and achieving learning and professional development goals 1.5.4 Undertakes appropriate learning activities that meet identified learning needs 1.5.5 Keeps knowledge and skills up to date 1.5.6 Commits to the continual improvement of the profession	- Has to complete the required 15 annual CE credits of which five at least must be live - Creates all the needed accounts to be able to start the CE program - Starts doing online sessions using Swank healthcare system - Starts attending OPL CE program sessions, the annual congress and pharmacist day - Attends other live sessions offered by academic institutions or accredited by the OPL - Completes evaluation forms that are required by the OPL - Should present a statement of account from Swank with the detailed credits earned
<b>2. Personal Skills</b> <b>2.1 Leadership Skills</b>  Demonstrates leadership abilities in the team processes.	2.1.1 Applies assertiveness skills as appropriate and inspires confidence 2.1.2 Provides leadership in the workplace to ensure quality and patient safety in the pharmacy 2.1.3 Builds credibility and portrays the profession in a positive light by being professional and well informed 2.1.4 Demonstrates determination and initiative to achieve and improve patients’ service 2.1.5 Inspires and motivates others to work to high standards by being enthusiastic about the profession and the service provided 2.1.6 Provides appropriate supervision 2.1.7 Identifies characteristics that reflect leadership versus management 2.1.8 Identifies the history of a team before implementing changes 2.1.9 Develops relationships, values diverse opinions, and understands individual strengths and weaknesses to promote teamwork 2.1.10 Persuasively communicates goals to the team to help build consensus 2.1.11 Empowers team members by actively listening, gathering input or feedback, and fostering collaboration	- Attends soft skills sessions organized by the OPL or any other academic institution - Participates to workshops and related discussions organized by the OPL or any other academic institution - Participates to all OPL initiatives that are related to patient services and collaboration with other health care professionals - Helps junior trainees fulfilling their own assigned training activities - Minimum required: 5 credits

<p><b>2. Personal Skills</b> <b>2.2 Information Technology (IT) Skills</b></p> <p>Applies a minimum of IT in daily work.</p>	<p>2.5.4 Knows how to use OPL online platforms (Medication Safety, Patient Profile...) related to the training site</p>	<ul style="list-style-type: none"> <li>- Uses OPL online platforms, as requested by the OPL in training sites:                             <ul style="list-style-type: none"> <li>◦ E-prescription &amp; Barcoding,</li> <li>◦ Drug Shortage</li> <li>◦ Lebanese Advanced Patient Profile</li> </ul> </li> <li>- Minimum required: 1 activity of each per week</li> </ul>
<p><b>3. Safe and Rational Use of Medicines</b> <b>3.1. Monitors medicines use</b></p> <p>Monitors the patient's progress and assess therapeutic outcomes.</p>	<p>4.3.6 Enters all relevant data collected in the OPL Advanced Patient Profile Platform</p>	<ul style="list-style-type: none"> <li>- Enters all relevant data collected in the OPL Advanced Patient Profile Platform</li> <li>- Provides the patient with adequate counseling</li> <li>- Minimum required: 1 intervention per week</li> </ul>
<p><b>3. Safe and Rational Use of Medicines</b> <b>3.2. Monitors Medication Safety</b></p> <p>Prioritizes medication safety and acts accordingly.</p>	<p>4.4.1 Identifies medication safety as a priority 4.4.2 Maintains a reporting system of pharmacovigilance using the OPL Medication Safety Platform 4.4.3 Encourages patients to be knowledgeable about their medication 4.4.4 Document and act upon dispensing errors 4.4.5 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system 4.4.6 Implements and manages risk management to avoid adverse events with medication 4.4.7 Documents and acts upon errors to include clear and open communication with patients 4.4.8 Learns from and acts upon previous 'near misses' and 'dispensing errors' 4.4.10 Identifies, prioritizes and resolves medicines management problems 4.4.11 Takes action to prevent, minimize, resolve and follows up medicines related problems 4.4.12 Takes steps to improve the safe use of medicines for patients in all practice settings</p>	<ul style="list-style-type: none"> <li>- Enters all relevant data collected in the OPL Platforms related to safety:                             <ul style="list-style-type: none"> <li>- Medication Safety platform</li> <li>- Medication Therapy Management (medication error reporting)</li> </ul> </li> <li>- Minimum required: 1 intervention of each per week</li> </ul>
<p><b>4. Pharmaceutical Public Health Competencies</b> <b>Population Health</b></p> <p>Engages in health promotion activities with the patient.</p>	<p>5.1.6 Engages in research related to health care and population health</p>	<ul style="list-style-type: none"> <li>- Helps the OPL in conducting professional, institutional and patient related research by filling out questionnaires and collecting data</li> <li>- Minimum required: as needed by OPL</li> </ul>
<p><b>5. Specific areas of training</b></p> <p>Applies knowledge to specific training sites.</p>	<p>Specific indicators to training sites (see appendices 1 to 5)</p>	<ul style="list-style-type: none"> <li>- Community Pharmacy management</li> <li>- Hospital Pharmacy management</li> <li>- Generating and applying a marketing plan and application</li> <li>- Quality control application (industry)</li> <li>- Other activities</li> </ul>

The PG-ASC were developed according to specific areas of training within selected fields of pharmacy, including community/ambulatory care, hospital pharmacy, clinical pharmacy, industrial pharmacy, and sales and marketing pharmacy. PG trainees apply advanced knowledge at specific training sites, based on specific competencies. Competencies and indicators were presented for each field (Appendices 1 to 5).

**Postgraduate (PG) related activities**

The representatives of stakeholders suggested activities that matched the competencies document. Table I presents activities matching PG-GCC and indicators, and Table II activities for specific training sites, to be coupled with PG-ASC in appendices 1 to 5.

**Table II: Required activities for specific post-graduate training according to training site \***

Training Site	Required Activities
Community/ Ambulatory Care	<ul style="list-style-type: none"> <li>- Unified prescription/Barcoding</li> <li>- Medication safety</li> <li>- Drug shortage</li> <li>- Lebanese Advance Patient Profile</li> <li>- Medication Therapy Management</li> <li>- Research assistance</li> <li>- Pharmacy management</li> <li>- Other trainings agreed upon</li> </ul>
Hospital Pharmacy	<ul style="list-style-type: none"> <li>- Unified prescription/Barcoding</li> <li>- Medication safety</li> <li>- Drug shortage</li> <li>- Lebanese Advance Patient Profile</li> <li>- Medication Therapy Management</li> <li>- Medication reconciliation</li> <li>- Research assistance</li> <li>- Management</li> <li>- Other trainings agreed upon</li> </ul>
Importers and Scientific Offices (Sales and Marketing)	<ul style="list-style-type: none"> <li>- Medication safety</li> <li>- Drug shortage</li> <li>- Research assistance</li> <li>- Marketing plan</li> <li>- Other trainings agreed upon</li> </ul>
Pharmaceutical Industries	<ul style="list-style-type: none"> <li>- Medication safety</li> <li>- Drug shortage</li> <li>- Research assistance</li> <li>- Quality control</li> <li>- Other trainings agreed upon</li> </ul>
Clinical Pharmacy	<ul style="list-style-type: none"> <li>- Medication safety</li> <li>- Drug shortage</li> <li>- Lebanese Advance Patient Profile</li> <li>- Medication Therapy Management</li> <li>- Medication reconciliation</li> <li>- Research assistance</li> <li>- Other trainings agreed upon</li> </ul>

\*These activities are to be coupled with Advanced Specific Competencies (Appendices 1 to 5)

**Practical and logistic details**

All activities would be carried out according to the process elaborated by the OPL that emphasises the use of electronic platforms developed by the OPL, such as the unified prescription/barcoding, medication safety, drug shortage, Lebanese Advance Patient Profile (LAPP), and Medication Therapy Management (MTM). Additionally, the student and the training supervisor would be responsible for specific activities in every field of work. Table III presents practical and logistic details of the training process: both PG-GCC (nine months) and PG-ASC (eleven months) related activities are required to consider that the graduate has fulfilled the PG training.

**Table III: Postgraduate training process practical details**

<b>CORE TRAINING</b>	
<b>Duration:</b>	9 months
<b>Sites:</b>	Community and/or Hospital Pharmacy
<b>Candidates:</b>	All newly registered pharmacists at the OPL starting 2019
<b>Pre-requisite:</b>	An official academic portfolio (certified by the university) including all acquired competencies and activities during the university trainings
<b>Deliverable:</b>	A self-constructed portfolio where the candidate shows his acquirement of the core postgraduate competencies and all conducted activities
<b>Outcome:</b>	General core training certificate delivered by an academic institution and/or OPL
	<ul style="list-style-type: none"> <li>The core training is mandatory to all BS Pharm graduates who are required to complete these activities to acquire the necessary post-graduate core competencies.</li> <li>A special emphasis is put on the use of electronic platforms developed by the OPL</li> <li>Graduates with a Pharm.D. or a Master’s degree will have to present an official proof of completion of these activities to be exempted from the core training.</li> <li>Holders of degrees requiring 3+ years post-graduation (PhD, Medical lab...) are exempted</li> </ul>
<b>SPECIFIC TRAININGS</b>	
<b>Duration:</b>	11 months
<b>Sites:</b>	Specific according to field of pharmacy
<b>Candidates:</b>	All newly registered pharmacists at the OPL starting 2024
<b>Pre-requisite:</b>	Core Training Certificate
<b>Deliverable:</b>	A self-constructed portfolio where the candidate shows his acquirement of the competencies and all conducted activities
<b>Outcome:</b>	Advanced specific training certificate delivered by an academic institution and/or OPL
	<ul style="list-style-type: none"> <li>Specific advanced training-related competencies enclosed as appendices (Appendices 1 to 5).</li> <li>A special emphasis is put on the use of electronic platforms developed by the OPL</li> <li>The training institution will decide which additional activities might lead to the required competencies</li> <li>Holders of degrees requiring 3+ years post-graduation (PhD, Medical lab...) are exempted</li> </ul>

**Stakeholders’ noteworthy opinions**

Moreover, the semi-structured interviews with the various stakeholders confirmed the suggested document (competencies and activities of Tables I & II), and generated a set of feedback thoughts about current needs and expected difficulties in the application of the PG system, summarised hereafter:

1. Academia: They highlighted a lack of training sites, especially in the case of universities that do not have affiliated hospitals, and difficulty to recruit specialised preceptors or educators in several fields of practice.
2. Industry: They described a lack of post-graduate studies related to the industry, and when available, it did not meet actual needs. Thus, graduates have to study abroad to complete their education, and those who do not do so are trained onsite for several months.
3. Importers and scientific offices: These employ pharmacists in their sales or marketing workforces mainly. Even graduates from universities that include management in their curriculum lack the basics in this topic and need to be well-trained for several months before they can be autonomous and ready to practice.
4. Pharmacy students: All interviewed 5th-year pharmacy students were not sure they were able to start practicing. Even those who had more than 6-month community pharmacy clerkship declared being unable to run and manage their own community pharmacy.
5. Community pharmacists: They confirmed that fresh graduates are not prepared enough to run a community pharmacy in terms of management and advanced pharmacy services, including patient care. They also agreed that graduates with a Pharm.D. are better prepared than those with BSc. Pharm. and require less training to be in charge of a community pharmacy from both perspectives.
6. Hospital pharmacists: They insisted on not confusing between clinical and hospital pharmacy, which requires higher management skills. Therefore, Pharm.D .graduates that have clinical skills may not meet the job criteria of hospital pharmacists.
7. NGOs and public authorities: They confirmed that pharmacists applying to NGOs and public institutions lack the basic knowledge of public health required in such positions. They also lack soft skills and basic writing and critical thinking skills.

**Postgraduate training process**

Based on the OPL Board decision, the document of competencies and activities, and interviews of stakeholders, the OPL Scientific Committee developed the process of the PG training as follows:

**Step 1:** Pharmacists graduate from the university, get the equivalence of the pharmacy degree from the MEHE, and the license to practice pharmacy from the MOPH.

**Step 2:** Graduates register with the OPL as trainee pharmacists. The duration of their post-graduate training is calculated according to the number of years of study completed.

**Step 3:** Training is performed according to the required activities (as detailed in Tables I, II, and III) in pharmaceutical institutions licensed by the MOPH. Trainees should present to OPL portfolios of all activities upon completion of training.

**Step 4:** The OPL Board monitors training through its inspection department.

**Step 5:** At the end of the training, a Licensure Examination confirms the acquisition of the PG competencies; the status of the pharmacist is then changed from trainee pharmacist to registered pharmacist.

**Final document to be distributed**

The final suggested document would be distributed to all academic institutions to help them optimise their curricula, meeting international standards and national needs: it consists of a folder that includes Appendices A to E, Tables I to III, and the detailed training process.

**Discussion**

This article presents a road map with practical solutions to scale-up pharmacy education in Lebanon and produce practice-ready pharmacists with optimised PG general core competencies (PG-GCC) and added advanced specific competencies (PG-ASC) while curbing the number of non-specialised graduates who are not yet ready to enter the labour market. This system would raise the level of the pharmacy profession, improve readiness to practice in different sectors of work, and effectively reduce the number of non-specialised pharmacy graduates in light of the dramatically growing number of pharmacists and reduced work opportunities. It would also improve patient care in all professional sectors.

Moreover, newly graduated pharmacists must acquire the necessary experience that will enable them to use the

tools developed by the OPL, which will raise the level of the services offered to the patient in pharmacies, hospitals and other pharmaceutical institutions. Pharmacists would implement medication risk management policies through the unified e-prescription, the electronic patient profile, the pharmacovigilance platform, the drug shortage platform, and other online tools that the OPL has developed in collaboration with the MOPH. All these require that pharmacists have completed their studies and gained all the necessary information and training.

The OPL initiative simulates what happened decades ago in developed countries and is currently considered a success story. For example, in the USA, the year 2000 witnessed a change in the pharmacy curriculum, as starting from this year, Pharm.D. became the entry-level degree for all graduating pharmacists in 2004. It consists of didactic and experiential education that includes Introductory Pharmacy Practice Experiences (IPPE) and Advanced Pharmacy Practice Experiences (APPE). These undergraduate experiences can be completed with PG training, PG Year One (PGY-1), and PG Year Two (PGY-2). PGY-1 allows pharmacists to work within acute hospital and ambulatory clinic settings, while PGY-2 enables them to practice in a specialised area and prepares them to pursue Board certification if it exists in that specialty (Knoer *et al.*, 2016). In 2015, *Pharmacotherapy* published two commentaries regarding PG training and readiness to work (Murphy, 2015; Robinson & Speedie, 2015). In the first, Murphy argued that Pharm.D. might not be enough to generate practice-ready pharmacists and that PG residencies and/or certification programmes are advisable for the provision of direct patient care (Murphy, 2015). Oppositely, Robinson and Speedie (2015) suggested that Pharm.D. programmes can and are preparing practice-ready graduates. However, they agreed that the lack of assessment of pharmacists' specialised skills makes it difficult to confirm it. They proposed to create a skill-based assessment test that would complete the North American Pharmacy Licensure Exam (NAPLEX) prior to licensure (Robinson & Speedie, 2015). In all cases, clinical pharmacy education in the USA had positive outcomes; it improved patient care and provided cost-effective services (Touchette *et al.*, 2014; Taylor *et al.*, 2015).

Other developed countries have applied specialised pharmacy education to other fields. For example, in France, pharmacists willing to become medical laboratory specialists or hospital pharmacists should complete the first five years of the pharmacy programme, followed by four years of internship and specialisation (Bourdon *et al.*, 2008). In Japan, many pharmacists are part of medical

teams in emergency hospitals. Indeed, students in their 5th or 6th year of pharmacy can opt for additional training to acquire specific pharmaceutical lifesaving skills enabling them to perform relevant emergency interventions within a multidisciplinary care team (Zamami *et al.*, 2016).

Developing countries took similar steps and conducted studies on PG training and advanced pharmacy services to cope with the changes and align with international standards. In Thailand, where the Pharm.D. degree is not mandatory, among pharmacists enrolled in the public service programme, Pharm.D. graduates reported higher competencies than BSc. Pharm. graduates, particularly in acute care services, medication reconciliation services, and primary care services (Sumpradit *et al.*, 2014). In 2010, the College of Pharmacy Practice was established in Hong Kong to grant specialty status to pharmacists, similarly to the US Board of Pharmacy Specialties (BPS). Pharmacists must complete the local practice experience in addition to other criteria adopted from the US BPS to earn the specialty status and perform continuing education to maintain it (Lee, 2018).

In the neighbouring countries, pharmacy education follows the American system mainly, focusing on clinical pharmacy and Pharm.D. programmes. Indeed, in Saudi Arabia, new pharmacy schools offer Pharm.D. programmes only. Universities in Kuwait started phasing out their B.Pharm. programmes and will be implementing standalone Pharm.D. programmes in 2020. In the United Arab Emirates (UAE), both Bachelor of Science (BSc.) and Pharm.D. programmes exist. The requirement to practice clinical pharmacy is a Pharm.D. and a two-year experience in a related field in a hospital setting or a PGY-2 accredited programme, while to practice community pharmacy, pharmacists should have a B.Pharm. or a Pharm.D. degree plus two years of experience in a related field (Alkhateeb, *et al.*, 2018; Ministry of Health, 2017).

In Syria, the Syrian Board for Medical Professions, established in 2012, regulates specialisations and credentials of pharmacy and other healthcare professions (Syrian Republic, 2012). According to a ministerial decision of April 2018 updated in December 2018, a strict PG training programme of four - five years (depending on the specialty) is required to earn the title of a specialised pharmacist (Syrian Board for Medical Professions, 2018; Syrian Ministry of Health, 2018).

As for practice preparedness, since the pharmacy profession shifted from a product-based model of care to a patient-centred model of care, studies focusing on the readiness and the willingness of pharmacists to engage in MTM and direct patient care are multiplying. Some suggested that a Pharm.D. degree is not enough to

provide such services, without specifying the prerequisites, which can be a PG training or a residency programme (Murphy *et al.*, 2006; American Society of Health-System Pharmacists, 2019). In Lebanon, pharmacists are aware of their growing role and ready to engage in MTM and other services but have never received training regarding this matter (Okamoto, & Brock, 2009; Consortium, 2010; Domiati *et al.*, 2018; Law,). A study in Lahore, Pakistan, revealed low awareness of pharmacy extended services (such as MTM, patient profile, and other available modern services) among community pharmacists who, nevertheless, showed a positive attitude towards this shift in the pharmacy practice and a willingness to engage in those services after receiving the necessary training to use these tools (Hashmi *et al.*, 2017).

Consequently, the academic sector should offer more extensive innovative educational paradigms to reinforce a value-based health care environment, optimise pharmacy education, fill skills gaps, and adapt advanced training to local needs. Strengthening partnerships between schools of pharmacy and local healthcare organisations is of utmost importance, specifically through training and experiential education, to ensure local communities benefit from valuable services provided by pharmacists (Taylor *et al.*, 2015). Furthermore, academic partners should contribute to the Licensure Examination by using modern evaluation methods, such as Objective Structured Clinical Examination (OSCE) and Multiple Mini-Interviews (MMI).

Finally, future studies should complement **this** work by exploring the applicability of this framework and confirming its internal and external validity in different fields of practice.

## Conclusion

This paper presented a road map with practical solutions, including core and specialised competencies to be acquired in PG training and assessed through a licensure examination. The suggested framework is expected to scale-up pharmacy education in Lebanon and produce practice-ready pharmacists while indirectly curbing the number of non-specialised graduates. Further work is necessary to explore the applicability of this framework and confirm its validity in different fields of practice.

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**Appendix A**

**Community/Ambulatory Care Pharmacists Minimal Competencies**

Area	Competency	Indicators
0 Fundamental Skills	0.1 Legal Considerations	0.1.1 Apply laws and regulations that impact pharmacy practice 0.1.2 Identify issues, pending legislation and regulations across all levels of government
0 Fundamental Skills	0.2 Product Procurement	0.2.1 Select and acquire products through appropriate supply chain 0.2.2 Anticipate, identify and troubleshoot problems with the supply chain 0.2.3 Manage inventory
0 Fundamental Skills	0.3 Compounding	0.3.1 Compound extemporaneous preparations 0.3.2 Perform basic, non-sterile compounding
0 Fundamental Skills	0.4 Pharmacy Operation	0.4.1 Apply typical pharmacy dispensing workflow 0.4.2 Comprehend and adopt a given set of pharmacy operating procedures 0.4.3 Comprehend and adopt an existing collaborative drug therapy management system 0.4.4 Evaluate prescription for legitimate medical use 0.4.5 Describe the roles and responsibilities of each pharmacy staff member 0.4.6 Implement dispensing processes when pharmacy automation is utilized
0 Fundamental Skills	0.5 Quality Improvement	0.5.1 Optimize the concepts of quality measurement and improvement 0.5.2 Apply national standards/guidelines/best practices 0.5.3 Develop a plan for quality/performance improvement
0 Fundamental Skills	0.6 Pharmacy Automation	0.6.1 Describe the role of computerized pharmacy management systems in dispensing 0.6.2 Dispense prescriptions utilizing technology-assisted workflow when applicable

## Appendix A (continued)

## Community/Ambulatory Care Pharmacists Minimal Competencies

1 Safe and Rational Use of Medicines	1.1 Clinical skills	1.1.1 Demonstrate and routinely apply clinical skills and provide patient care services 1.1.2 Individualize therapy through the implementation of a patient's profile to the selection and modification of a medication regimen 1.1.3 Describe and apply clinical practice guidelines to patient care 1.1.4 Demonstrate knowledge of appropriate administration technique for dosage forms commonly dispensed in community pharmacy 1.1.5. Describe common doses of drugs requiring monitoring and collaborative drug therapy management 1.1.6 Proactively perform counseling and education which complies with current guidelines
1 Safe and Rational Use of Medicines	1.2 Medication Therapy Management	1.2.1 Define and appropriately document comprehensive MTM services 1.2.2 Conduct a patient interview and provide education 1.2.3 Conduct comprehensive medication review 1.2.4 Identify and resolve medication therapy problems, manage drug interactions, and resolve gaps in care 1.2.5 Recommend therapeutic alternatives and generic substitutions 1.2.6 Document services and follow-up with other health professionals 1.2.7 Use multiple MTM platforms as required by third party payers and OPL
1. Safe and Rational Use of Medicines	1.3. Compliance and Adherence	1.3.1 Support and assist patient behavior change 1.3.2 Identify and resolve patient-specific barriers to medication adherence 1.3.3 Facilitate patient self-administration of medications and disease monitoring
1 Safe and Rational Use of Medicines	1.4 Problem solving/ Referrals	1.4.1 Make appropriate recommendations or referrals 1.4.2 Assess and resolve issues related to medication safety
1 Safe and Rational Use of Medicines	1.5 Over the counter Medicine	1.5.1 Assist with patient self-care, including helping patients make appropriate selections of OTC medications 1.5.2 Assist with patient self-care, including helping patients make appropriate selections of dietary supplements 1.5.3 Assist with patient self-care, including helping patients make appropriate selections of herbal supplements
2 Pharmacy Management	2.1 Functions	2.1.1 Manage inventory costs and inventory levels or order points 2.1.2 Identify cash flow problems and apply solutions to address 2.1.3 Develop a business plan for clinical service programs 2.1.4 Describe basic finance terms and analyze a financial statement 2.1.5 Apply healthcare economics and pharmaco-economics 2.1.6 Describe strategies for asset protection and safety 2.1.7 Use pharmacy technology effectively
2 Pharmacy Management	2.2 Managed care /Drug Coverage Policies	2.2.1 Explain the general concept of managed care, associated with the benefit structure of a health plan 2.2.2 Adapt best treatment strategies to patient socioeconomic status 2.2.3 Provide guidance to patients seeking assistance to apply for drug payment programs 2.2.4 Troubleshoot denied claims 2.2.5 Discuss the concept of drug utilization review, formulary management and provide functional definitions of key managed care strategies (e.g., prior authorizations, step therapy, quantity limits) 2.2.6 Identify major factors that contribute to prescription drug related fraud and abuse 2.2.7 Identify the major factors influencing drug costs for a managed care organization (e.g., pharmacy costs, drug pricing methodologies, contracts/rebates, discounts)
3 Professional Skills	3.1 Health Literacy	3.1.1 Determine patient level of health literacy by observation or interview, 3.1.2 Adjust counseling delivery and communicate at all levels of health literacy 3.1.3 Solve adherence challenges created by low health literacy
3 Professional Skills	3.2 Patient communication	3.2.1 Support patient behavior change through skills such as motivational interviewing 3.2.2 Demonstrate a respect for patient confidentiality and privacy rights 3.2.3 Demonstrate patient compassion and empathy
3 Professional Skills	3.3 Health professional communication	3.3.1 Function as part of a team engaged in team-based care 3.3.2 Document appropriate therapeutic recommendations related to medication therapy
3 Professional Skills	3.4 Team communication	3.4.1 Identify and manage conflict at all levels 3.4.2 Supervise and motivate employees, staff, students, interns, residents 3.4.3 Delegate appropriate tasks 3.4.4 Articulate team objectives and measure and report team performance
3 Professional Skills	3.5 Leadership Abilities	3.5.1 Display confidence in the patient care skills 3.5.2 Demonstrate professional behavior (attitude, dress, appearance, etc.) in practice settings 3.5.3 Embrace and advocate changes that improve patient care
3 Professional Skills	3.6 Drug information skills	3.6.1 Access and utilize appropriate drug information resources and provide an accurate and credible solution in both written and oral forms 3.6.2 Utilize a variety of drug-related reports, monographs, reviews and policies using drug literature evaluation skills 3.6.3 Evaluate appropriateness of clinical trials and other study designs, including validation of methodology and assessment of data credibility 3.6.4 Access appropriate drug information resources required for patient education 3.6.5 Implement career advancement through continuous professional development
3 Professional Skills	3.7 Ethical Considerations	3.7.1 Understand professional ethics as they apply to the practice of pharmacy 3.7.2 Apply knowledge and understanding of ethical aspects of pharmacy practice required to evaluate a patient care decision

4 Public health Fundamentals	4.1 Clinical Applications of Public Health	<p>4.1.1 Participate in education and intervention in public health initiatives applicable to pharmacy practice</p> <p>4.1.2 Be knowledgeable about immunization schedules and requirements and actively involved in vaccination campaigns</p> <p>4.1.3 Collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests</p> <p>4.1.4 Promote healthy lifestyle and nutrition and describe how it impacts drug therapy and overall health</p> <p>4.1.5 Describe the role of a pharmacist in emergency situations</p> <p>4.1.6 Participate in population-based provision of care (as distinguished from direct patient care).</p>
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**Appendix B**

**Hospital Pharmacists Minimal Competencies**

Area	Competency	Indicators
0 Fundamental Skills	0.1 Regulations	<p>0.1.1 Apply pharmaceutical statutory regulations</p> <p>0.1.2 Apply hospital regulations pertaining to the operations of the hospital pharmacy</p>
0 Fundamental Skills	0.2 Drug Procurement	<p>0.2.1 Select and acquire drug selection and acquisition</p> <p>0.2.2 Manage drug inventory management</p> <p>0.2.3 Manage backorders and recalls</p> <p>0.2.4 Handle drug waste</p> <p>0.2.5 Handle drug shortages</p>
0 Fundamental Skills	0.3 Medication Preparation and Delivery	<p>0.3.1 Optimize the medication use process in health systems, including how pharmacy impacts the safety of storage/preservation, prescribing, preparation, transcription, dispensing, administration and monitoring steps</p> <p>0.3.2 Perform activities within a typical hospital drug distribution system, including order receipt, evaluation and review, and describe the appropriate roles of pharmacy staff and pharmacists in these processes</p> <p>0.3.3 Supervise pharmacy staff in their work in medication preparation and delivery</p>
0 Fundamental Skills	0.4 Aseptic Techniques	<p>0.4.1 Follow aseptic technique and describe processes and facilities needed to provide sterile compounded parenteral solutions, including the basic requirements of hospital accreditation standards</p> <p>0.4.2 Apply knowledge of hospital hygiene and infection prevention control (IPC).</p>
0 Fundamental Skills	0.5 Pharmaceutical and Hospital Technology/ Automation	<p>0.5.1 Outline the basic functionality of commonly used automated systems related to medication use (such as automated dispensing cabinets, computerized prescriber order entry systems, bar code medication administration systems, programmable infusion devices, and robotics)</p> <p>0.5.2 Understand their appropriate and safe use as well as unintended consequences</p>
0 Fundamental Skills	0.6 Pharmaceutical/ Medical Skills	<p>0.6.1 Implement the appropriate use of injectable medications, including intravenous, intrathecal, intraocular, intradermal and other routes. Description should include unique preparation techniques, concentration considerations, rates of administration, special infusion devices, and compatibility considerations</p> <p>0.6.2 Integrate and interface the clinical and distributive functions, including the synergy that translates into safe and effective medication therapy</p> <p>0.6.3 Participate in designing and implementing pharmaceutical/therapeutic protocols and algorithms</p> <p>0.6.4 Integrate of pharmaceutical oncology, nutrition and other fields when applicable</p> <p>0.6.5 Demonstrate knowledge of pharmaceutical radiotherapy: therapeutic and diagnostic applications (e.g. contrasts) when applicable</p> <p>0.6.6 Describe the use of medical devices, prostheses and implants when applicable</p>
0 Fundamental Skills	0.7 Business Management Skills	<p>0.7.1 Perform accounting activities</p> <p>0.7.2 Perform financial management</p> <p>0.7.3 Set budgeting proposals/plans</p>
1 Safe and Rational Use of Medicines	1.2 Patient Safety	<p>1.2.1 Understand patient safety culture that relates to medication use, pharmaceutical care and pharmacy's role</p> <p>1.2.2 Reconcile effectively the medications of a patient transitioning from one care setting to another and make appropriate communications to involved pharmacy providers</p> <p>1.2.3 Employ performance improvement techniques used in health systems and describe how they are used to appropriate communications to involved pharmacy providers</p> <p>1.2.4 Describe the impact of pharmacist involvement on medication safety and quality using appropriate literature</p> <p>1.2.5 Develop and implement pharmacovigilance activities</p>
1 Safe and Rational Use of Medicines	1.3 Quality Assurance	<p>1.3.2 Describe how the accreditation organizations such as the Joint Commission strive to assure quality of healthcare through the accreditation process, giving examples of relevant standards related to safe and appropriate medication use</p> <p>1.3.3 Apply national standards, guidelines, best practices and established principles and process related to quality and safe medication use (e.g. storage of look-alike/sound-alike medications, high alert medications, storage of concentrated potassium in patient care areas, dangerous abbreviations, leading decimal points and trailing zeros, quality measure related to medications, etc.)</p>
2 Patient Centered Care	2.1 Literature Evaluation /Search / Trials	<p>2.1.1. Access appropriate drug information resources, including primary literature</p> <p>2.1.2 Analyze a recently published study</p> <p>2.1.3 Provide an accurate and evidence based answer</p> <p>2.1.4 Present the answer successfully in both written and oral forms</p> <p>2.1.5 implement methodologies for clinical trials and observational studies</p>

2 Patient Centered Care	2.2 Pharmacokinetic Based Assessment	2.2.1 List the medications that need pharmacokinetic evaluation 2.2.2 Apply dosing principle 2.2.3 Evaluate drug-response and monitor patients 2.2.4 Evaluate medication-use patterns in a specified patient population
2 Patient Centered Care	2.3 Drug Use Optimization	2.3.1 Demonstrate an appropriate level of clinical knowledge related to medications and therapeutics in making decisions or recommendations 2.3.2 Contribute to the establishment of medication use policies, including anti-microbial stewardship, criteria and maintenance of the formulary as a member of the Pharmacy and Therapeutics Committee 2.3.3 Provide quality care through best use of resources 2.3.4 Draft and distribute information and recommendations related to the clinical use of drugs when appropriate 2.3.5 Optimize use of drugs including: addition, deletion, dose adjustment, IV to Po switch, renal dosing, dose reduction...
3 Professional Skills	3.1 Written and Oral Communication	3.1.1. Demonstrate effective verbal and written communications 3.1.2 Communicate with pharmacy, and healthcare team members 3.1.3 Respond to questions with the appropriate level of detail necessary to ensure proper patient care and communication with other relevant parties 3.1.4 Document appropriate therapeutic recommendations related to medication therapy
3 Professional Skills	3.2 Behavior & Ethical	3.2.1 Demonstrate professional behavior (attitude, dress, appearance, etc.) in practice settings 3.2.2 Apply ethical principles
3 Professional Skills	3.3 Management	3.3.1 Demonstrate project and team management skills 3.3.2 Prioritize multiple patient care and triage in times of high activity and workload 3.3.3 Demonstrate effective problem solving skills

**Appendix C**

**Sales and Marketing Pharmacists Minimal Competencies**

Area	Competency	Indicators
<b>0. Pharmaceutical Knowledge</b>	0.1 Pharmaceutical knowledge	0.1.1 Provide information on drugs/products and services 0.1.2 Answer questions of healthcare professionals on drugs/products and services (characteristics, contraindications, incremental benefits, etc.), as part of a comprehensive care of patients 0.1.3 Provide information and answer questions as part of therapeutic regimens associated with a pathology linked to the concerned drugs 0.1.4 Link scientific and medical knowledge to drug/product arguments 0.1.4 Exchange with healthcare professionals on scientific topics
<b>1. Professional communication skills</b>	1.1 Communication	1.1.1 Explain the characteristics and the proper use of drugs/products based on the needs of the healthcare professionals and market demands 1.1.2 Take ownership of the content of the information prepared by the scientists responsible of the pharmaceutical company 1.1.3 Use the information, arguments, business aids developed by the pharmaceutical company 1.1.4 Maintain and develop product knowledge through training
<b>1. Professional communication skills</b>	1.2 Data processing analysis skills	1.2.1 Collect and process of information on drugs/products, from documentation and training sessions to prepare for visits and communication actions 1.2.2 Collect, analyze and transmit questions to the concerned departments of the company 1.2.3 Collect and transmit pharmacovigilance information 1.2.4 Apply competitive intelligence and report information to its hierarchy 1.2.5 Monitor actions and professional communication during visits
<b>1. Professional communication skills</b>	1.3 Negotiation	1.3.1 Establish a quality relationship with healthcare professionals 1.3.2 Identify/address the healthcare professionals' concerns/needs and their patient care practices by using appropriate probing/questioning 1.3.3 Apply active listening techniques with the healthcare professional. 1.3.4 Adapt to different communication styles 1.3.5 Process requests for information and objections 1.3.6 Conclude the call/visit & Prepare reports 1.3.7 Analyze the call/visit (SWOT analysis) and plan the next step 1.3.8 Animate professional communication gatherings and develop long-term professional relationships/partnership with healthcare professionals
<b>1. Professional communication skills</b>	1.4 Information technology	1.4.1 Save and transmit calls/visits reports to the company database 1.4.2 Inform and update files 1.4.3 Master research of information via electronic databases. 1.4.4 Optimize the use of computerized/electronic devices to prepare presentations, reports, charts, etc, and manage business and information processing 1.4.5 Manage of prescribers/customers files

<b>1. Professional communication skills</b>	1.5 communication and language	1.5.1 Use effective verbal, non-verbal, listening and written communication skills to communicate clearly, precisely and appropriately 1.5.2 Communicate effectively with physicians, other healthcare professionals, other support staff, and other relevant third parties 1.5.3 Use appropriate language and checks understanding 1.5.4 Demonstrate respect, cultural awareness, sensitivity and empathy when communicating
<b>2. Organization and management skills</b>	2.1 Self-management skills	2.1.1 Demonstrate organization and efficiency in carrying out the work 2.1.2 Organize visits according to the predefined objectives and through teamwork 2.1.3 Ensure work time and processes are appropriately planned and managed 2.1.4 Demonstrate the ability to prioritize work appropriately 2.1.5 Take responsibility as appropriate in the workplace 2.1.6 Ensure punctuality and reliability 2.1.7 Reflect on and demonstrate learning from critical incidents
<b>2. Organization and management skills</b>	2.2 Internal management skills	2.2.1 Demonstrate an understanding of the principles of organization and management 2.2.2 Work effectively with the documented procedures and policies within the workplace 2.2.3 Work effectively with the company hierarchy 2.2.4 Provide regular feedback on the drugs/products and the market 2.2.5 Convey any useful information from the market with all the company's concerned people/departments (medical representatives, direct manager, product manager, medical manager, medical science liaison, CRA...) 2.2.6 Apply the company's compliance, procedures and safety rules (road, IT, etc...) 2.2.7 Organize round tables, expert meetings, advisory boards, lectures, CME conferences, staff meetings, awareness campaigns, etc. in coordination with different departments within the company and service providers 2.2.8 Apply the international code of ethics guidelines when organizing any of the scientific events mentioned above
<b>3. Professional practice</b>	3.1 Standard Practice	3.1.1 Carry out duties as a medical representative in a professional manner 3.1.2 Demonstrate awareness of the position of trust in which the profession is held and practices in a manner that upholds that trust 3.1.3 Treat others with sensitivity, empathy, respect and dignity 3.1.4 Take responsibility for their own actions 3.1.5 Recognize their scope of practice and the extent of their current competency and expertise and works accordingly 3.1.6 Maintain a consistently high standard of work
<b>3. Professional practice</b>	3.2 Ethical Practice	3.2.1 Understand obligations under the principles of the statutory Code of Conduct for Pharmacists and acts accordingly 3.2.2 Make and justify decisions in a manner that reflects the statutory Code of Conduct for pharmacists and pharmacy law 3.2.3 Recognize ethical dilemmas in practice scenarios and reasons through dilemmas in a structured manner 3.2.4 Implement standard operating procedures and code of ethics
<b>3. Professional practice</b>	3.3 Legal Practice	3.3.1 Demonstrate an awareness of and adheres to professional indemnity requirements 3.3.2 Use and take into account the drug related pharmaceutical and economic regulation and its evolution to inform and answer questions from healthcare professionals 3.3.3 Integrate into business the rules of advertising, promotion, distribution and delivery of the drug and their changes 3.3.4 Raise awareness and provide information on regulatory changes 3.3.5 Use tools related to the product (SPC, product file, Transparency Commission opinion, validated data, etc.) 3.3.6 Drive up pharmacovigilance information by following the internal procedures and regulations
<b>4. Personal skills</b>	4.1 Role Modeling	4.1.1 Inspire confidence and applies assertiveness skills as appropriate 4.1.2 Build credibility and portrays the profession in a positive light by being professional and well informed 4.1.3 Contribute to the initiation, development and continuous improvement of business plans
<b>4. Personal skills</b>	4.2 Team working skills	4.2.1 Recognize the value of transversal teamwork 4.2.3 Recognize when it is appropriate to seek advice from experienced colleagues, refer decisions to a higher level of authority or to include other colleagues in the decision

## Appendix D

### Industrial Pharmacists Minimal Competencies

Area	Competency	Indicators
<b>0 Research and Development</b>	0.1 Process implementation	0.1.1 Identify the different phases of a research process 0.1.2 Integrate the input requirements and objectives of the process
<b>0 Research and Development</b>	0.2 Mastering analytical and extraction techniques	0.2.1 Implement experimental conditions for synthesizing a chemical entity 0.2.2 Use a technique for extraction and purification of a natural origin molecule 0.2.3 Use a technique for gene expression
<b>0 Research and Development</b>	0.3 Mastering characterization techniques	0.3.1 Use molecule characterization techniques (separation techniques, spectroscopic techniques, capillary electrophoresis...) 0.3.2 Implement experimentation protocols to characterize the interaction target-molecules 0.3.3 Design and validate a technique for obtaining or characterization of a molecule 0.3.4 Organize a scientific monitoring process

<b>1 Pharmaceutical and Industrial development</b>	1.1 Drug formulation expertise	<p>1.1.1 Use the established physicochemical characteristics of active molecules by using appropriate analytical techniques (X-ray diffraction, solubility, etc.)</p> <p>1.1.2 Develop formulations and routes of administration (including controlled of modified release systems) according to the characteristics of the molecules and the marketing objectives</p> <p>1.1.3 Set a process to optimize a formulation</p> <p>1.1.4 Remain up to date with and applies pharmaceutical knowledge on the requirements of formulating and compounding of medicines</p> <p>1.1.5 Demonstrate the ability to perform pharmaceutical calculations accurately</p> <p>1.1.6 Apply pharmaceutical knowledge to select appropriate ingredients and excipients of the required quality standard for the manufacture and compounding of medicines</p> <p>1.1.7 Demonstrate an understanding of the legislative framework and requirements that govern the manufacture of medicinal products, including GMP</p>
<b>1 Pharmaceutical and Industrial development</b>	1.2 Packaging expertise	<p>1.2.1 Develop packaging characteristics from the properties of the molecules and the developed dosage form</p> <p>1.2.2 Elaborate packaging characteristics according to container-content interactions and physicochemical stability</p>
<b>1 Pharmaceutical and Industrial development</b>	1.3 Industrial scale transposition	<p>1.3.1 Evaluate the feasibility, reliability and reproducibility of a method or an equipment and implement the concept of risk management</p> <p>1.3.2 Elaborate the product characteristics through the test results by integrating the regulatory and commercial data</p> <p>1.3.3 Translate test results in instructions and procedures</p>
<b>1 Pharmaceutical and Industrial development</b>	1.4 Process development and optimization	<p>1.4.1 Design and implement improvements in the formulation development techniques</p> <p>1.4.2 Use experimental designs to master the process</p> <p>1.4.3 Analyze the economic feasibility of a formulation and industrial development plan</p>
<b>2 Analytical Development</b>	2.1 Analytical protocols and techniques expertise	<p>2.1.1 Identify the physicochemical variables to point to an analytical technique of a molecule, impurities and end-product</p> <p>2.1.2 Set an experimental context to point to an analytical, separation or dosing technique depending on the characteristics of the formulation, the regulatory and commercial constraints</p> <p>2.1.3 Implement analytical tests and dosing techniques using protocols</p>
<b>2 Analytical Development</b>	2.2 Analytical project development and implementation	<p>2.2.1 Evaluate the feasibility, reliability and reproducibility of an analysis by integrating the concept of risk management and analytical validation</p> <p>2.2.2 Translate test results in instructions and procedures</p> <p>2.2.3 Design and implement improvements in analytical development techniques</p> <p>2.2.4 Analyze the economic feasibility of an analytical development project</p>
<b>3 Industrial Pharmaceutical Production</b>	3.1 Process engineering and equipment technology	<p>3.1.1 Analyze critical steps of a manufacturing and a packaging process</p> <p>3.1.2 Analyze the critical specific steps of the biotechnology products processes</p> <p>3.1.3 Analyze the expected return of each step and the deviations</p> <p>3.1.4 Design a protocol of equipment qualification</p> <p>3.1.5 Design a validation protocol of a manufacturing and a packaging process</p> <p>3.1.6 Determine and implement process control tools (Monitoring Statistical Process control -MSP)</p> <p>3.1.7 Use the statistical tool and interpret results to analyze the capability and robustness of processes and identify areas for improvement</p> <p>3.1.8 Determine the follow-up and control set up according to these results</p> <p>3.1.9 Propose and argue for technical improvements in production methods and processes according to the follow-up results</p>
<b>3 Industrial Pharmaceutical Production</b>	3.2 Organization and production management	<p>3.2.1 Driving the steps of industrial transposition to larger scales</p> <p>3.2.2 Organize and plan various activities of production in compliance with regulations, quality, hygiene and safety rules, cost and defined deadlines</p> <p>3.2.3 Use production management tools</p> <p>3.2.4 Organize and control the movement of products as well as documentary flows</p> <p>3.2.5 Identify and assess the conditions of storage, transport and distribution of products</p> <p>3.2.6 Optimize the organization of work, work processes and means</p>
<b>3 Industrial Pharmaceutical Production</b>	3.3 Health, Safety and Environment (HSE)	3.3.1 Deploy a system of environmental risk management (an ISO 14001 type) and make it live alongside the other management systems (quality, etc.)
<b>3 Industrial Pharmaceutical Production</b>	3.4 Continuous improvement	<p>3.4.1 Define and implement tracking indicators of the activity of a department and productivity indicators</p> <p>3.4.2 Analyze the results of production and productivity monitoring indicators</p> <p>3.4.3 Propose and implement corrective actions to reduce costs and delays in conjunction with other departments and evaluate the results</p> <p>3.4.4 Use methods to improve production organization</p> <p>3.4.5 Establish continuous improvement conditions and follow-up the improvement of the industrial processes</p>
<b>3 Industrial Pharmaceutical Production</b>	3.5 Cross disciplinary functions	3.5.1 Animate an action plan within a team
<b>3 Industrial Pharmaceutical Production</b>	3.6 Quality Assurance	<p>3.6.1 Define sampling plans and compliance</p> <p>3.6.2 Define and organize batch stability monitoring</p>

<b>3 Industrial Pharmaceutical Production</b>	3.7 Quality control	<p>3.7.1 Identify and assess the constitution of the sample library</p> <p>3.7.2 Analyze the causes of a malfunction, a drift or a non-compliance related to a process or an equipment, and identify corrective measures</p> <p>3.7.3 Assess the compliance of activities, premises/facilities and equipment with the quality standards (GMP, ISO) and safety rules</p> <p>3.7.4 Assess the compliance of a batch record</p> <p>3.7.5 Analyze the causes of non-compliance related to quality and safety</p> <p>3.7.6 Propose and implement corrective actions to address the non-compliance related to quality and safety in conjunction with other departments</p> <p>3.7.7 Assess the compliance, implement the analysis (quality control of raw material, finished or semi-finished products), interpret and validate the results</p> <p>3.7.8 Assess the compliance of products from the analytical and manufacturing files</p> <p>3.7.9 Identify maintenance operation of quality control equipment</p> <p>3.7.10 Estimate the authenticity of the results to generate the certificate of analysis</p>
<b>4 Quality management</b>	4.1 Program management and implementation	<p>4.1.1 Define the Quality policy elements of the company</p> <p>4.1.2 Implement a global Quality approach including the concepts of quality control, quality assurance and quality management</p> <p>4.1.3 Develop and implement general and transversal quality systems deployed in all business sectors: research, development, production, distribution, marketing, promotion, information, operations...</p> <p>4.1.4 Define the conditions of the relation of the customer-supplier relationship: establish the quality aspect in the implementation of the customer-supplier relationships</p> <p>4.1.5 Design procedures for complaints handling, batch follow-up, batch recall and traceability</p>
<b>4 Quality management</b>	4.2 Program quality assurance	<p>4.2.1 Design a procedure for process validation and equipment qualification</p> <p>4.2.2 Define a method of audit, an audit program; achieve audits and make audit follow-up</p> <p>4.2.3 Develop, implement and evaluate quality training programs</p>
<b>4 Quality management</b>	4.3 Documentation and traceability expertise	<p>4.3.1 Organize and document annual reviews</p> <p>4.3.2 Organize and manage the traceability of all industrial operations</p> <p>4.3.3 Organize a document management mode, archiving procedures, use of electronic document management systems</p>
<b>4 Quality management</b>	4.4. Financial analysis	<p>4.4.1 Analyze the costs of non-quality</p> <p>4.4.2 Understands the principles of pharmacoeconomic assessment and medicines cost benefits analysis</p> <p>4.4.3 Demonstrates the ability to effectively analyze and manage financial data and budgetary information</p>
<b>4 Quality management</b>	4.5 Risk management expertise	<p>4.5.1 Use methods of Risk Management; define risks and hazards, identify critical points and design approaches that put them under control</p> <p>4.5.2 Integrate the environmental risk management in the Quality Management System</p>