جامعة الزقازيق

كلية الصيدلة

توصيف برنامج التدريب الاجباري (الامتياز) لبرنامج بكالوريوس الصيدلة (فارم دي-Pharm D)

(2026 – 2025) إلى (2028 – 2027)

توصيف البرنامج التدريبي

اسم البرنامج: برنامج التدريب الإجباري (الامتياز) للصيادلة

المؤسسة: كلية الصيدلة - جامعة الزقازيق

مدة البرنامج: تسعة أشهر (36 أسبوعا)

الوحدة المسئولة عن البرنامج: وحدة التدريب الإجباري (الامتياز) للصيادلة بكلية الصيدلة - جامعة الزقازيق

برنامج تدريب صيادلة الامتياز

- هو مجموعة من الدورات العلمية التطبيقية في المنشآت والمؤسسات الطالبة والمؤسسات والهيئات العلاجية الحكومية والخاصة.
- يشمل البرنامج التدريبي على عدد ست دورات تدريبية تناوبية في مختلف أماكن العمل الطالب، مدة الدورة الواحدة ستة أسابيع بإجمالي ستة وثلاثون أسبوعا (عام أكاديمي)
- يبدأ البرنامج بعد اجتياز الطالب عدد الساعات المنصوص عليها في اللائحة الأكاديمية لبرنامج بكالوريوس الصيدلة (فارم دي – Pharm D) وكذلك اجتياز التدريب الميداني (100 ساعة)
- يؤهل اجتياز برنامج التدريب الإجباري (الامتياز) خريج كليات الصيدلة للعمل بعد الحصول على شهادة التدريب الإجباري (الامتياز) المعتمدة

أهداف برنامج التدريب

يهدف برنامج التدريب الإجباري إلى تنمية قدرات ومهارات خريجي كليات الصيدلة لتلبي احتياجات سوق العمل من كفاءات وجودة الأداء وإعداد صيادلة مؤهلين بأحدث المفاهيم في مجال الرعاية الصحية ومجال اكتشاف وتطوير الدواء، من خلال:

1. إعداد صيدلي قادر على المنافسة في سوق العمل محليًا وإقليميًا ودوليًا.
2. الربط الفعلي بين مواقع العمل الصيدلي (المنشآت والمؤسسات الصيدلية والمؤسسات والهيئات العلاجية) والجامعات.
3. توفير تدريب تطبيقي ينمي كفاءات الخريج كمتعلم ومهني قادر على الارتقاء بالرعاية الصحية.
4. إعداد صيدلي قادر على الإسهام في تطوير وتوطين الصناعات الدوائية في مصر وملم بالشئون التنظيمية للدواء.
5. إعداد كوادر صيدلية قيادية مبتكرة ومطورة وقادره على حل المشكلات والعمل بروح الفريق.

6. مزاولة المهنة في ضوء الأخلاقيات والقيم الحاكمة، مع الالتزام بالحقوق والواجبات والمسئوليات التي تقتضيها المهنة.

7. شرح وإبراز التخصصات المختلفة أمام خريجي كليات الصيدلة وتجهيزهم بالتدريبات الكافية لتحديد أوجه اهتماماتهم.

8. إمداد المنشآت والمؤسسات الصيدلية والمؤسسات والهيئات العلاجية والمراكز البحثية والجامعات بالصيادلة المؤهلين مهنياً للعمل.

شروط الالتحاق بالبرنامج التدريبى :

يشترط الالتحاق ببرنامج تدريب صيادلة الامتياز دراسة واجتياز جميع المقررات الدراسية المنصوص عليها في اللائحة الأكاديمية لبرنامج بكالوريوس الصيدلة (فارم دي – Pharm D) بنجاح وكذلك استكمال التدريب الصيفي (100ساعة)

هيكل البرنامج التدريبى لسنة الامتياز:

- **عدد الدورات التدريبية:** (6) دورات منها أربع دورات إجبارية ودورتين اختياريتين.
- **مدة الدورة :** 6 أسابيع

الدورات الإجبارية:

تشمل أربع دورات تدريبية طبقا للائحة المعتمدة من المجلس الأعلى للجامعات وتوصيفها كالتالى :

1-دورة تدريبية في مجال صيدليات المستشفيات والصيدليات العامة والخاصة .

2-دورة تدريبية في مجال الصيدلة الإكلينيكية .

3-دورة تدريبية في مجال تصنيع وتسجيل المستحضرات الطالبة .

4-دورة مشروع بحثي تطبيقي .

الدورات الاختيارية:

وتشمل دورتين تدريبيتين فى مجالات تصنيع وتنظيم تداول الدواء مثل

- Pharmaceutical Product Development تطوير المستحضرات الصيدلية
- Quality Management in Pharmaceutical Industry دورة إدارة الجودة ف صناعة الدواء

- Pharmacovigilance اليقظة الدوائية
- Pharmaceutical Regulatory Inspection التفتيش الصيدلي
- Drug Discovery and Development دورة اكتشاف وتطو رٌ الدواء
- Pharmaceutical Sales and Marketingا لمبيعات وتسويق الدواء
- Pharmaceutical Productionالتصنيع الدوائي
- Quality by Design and Process Analytical Technology (QbD & PAT) دورة الجودة من خلال التصميم والتكنولوجيا التحليلية للعمليات.

القواعد المنظمة للتدريب

اولا: آلية الإشراف على التدريب

- يقوم بالإشراف على التدريب عن طريق لجنة مشتركة من أحد أعضاء هيئة التدريس تحدده وحدة التدريب بالكلية وعضو من جهة التدريب (تحدده جهة التدريب) للإشراف على التدريب في كل دورة تدريبية .
- يقوم مشرف التدريب بالمتابعة والتأكد من الحضور ومدى الالتزام بالمحتوى التدريبي عن طريق زيارات ميدانية (ان أمكن) او اتصالات او لقاءات افتراضية للتواصل عن طريق جروب على تطبيق الواتساب لضمان اكتساب الجدارات واجتياز التدريب

ثانيا: واجبات ومسئوليات طالب الامتياز

- احترام القوانين واللوائح الخاصة بجهة التدريب والحفاظ على أدأب وأخلاقيات مهنة الصيدلة .
- يلتزم طالب الامتياز بتعليمات وارشادات مسؤول التدريب بالكلية ومشرف التدريب بجهة التدريب ويتم تقييم أداء المتدرب بصفة مستمرة وتوجيهه أثناء فترة التدريب
- الالتزام بالحضور والانصراف في مواعيد العمل الرسمية لجهة التدريب وفقا للوائح المنظمة للعمل بمواقع التدريب
- التعامل مع فريق العمل والزملاء في مواقع العمل بقدر من الخلق والاحترام يعكس صورة الجامعة والكلية التي ينتمي لها
- المحافظة على سرية المعلومات الخاصة بجهات التدريب المختلفة وعدم الإفصاح عنها وفقا للقواعد المقررة في جهة التدريب .
- تسليم نماذج التدريب المعتمدة من جهة التدريب الى وحدة التدريب بالكلية فور انتهاء الدورة التدريبية

التقييم

- يتم تقييم أداء طالب الامتياز أثناء كل دورة تدريبية طبقا لنمازج التقييم في جهات التدريب .
- يتم تسليم كتيب تدريب (Log book) لكل متدرب منذ بدء السنة التدريبية بحيث يحتوي على جميع نماذج التقييم وأيضا جميع الأوراق الخاصة به خلال السنة التدريبية لمتابعة درجة أداء المتدرب أثناء التدريب .
- يتم تسليم الطالب نسخة اليكترونية من كتيب توصيف البرنامج التدريبي للمساعدة في تقييم الدورات التدريبية للاستفادة في التطوير المستمر لبرنامج التدريب وتحقيق اهداف برنامج الفارم دي التعليمي .

شروط الحصول على شهادة اجتياز البرنامج التدريبى الإجبارى (الامتياز) للصيادلة

تمنح شهادة اجتياز برنامج التدريب الإجباري (الامتياز) من الكليات موضحة بها أسماء الدورات وإجمالي عدد ساعات التدريب لكل دورة، وتصدر نسخة باللغة العربية وأخرى باللغة الإنجليزية، وتصدر الشهادة وفقا للشروط الاتية :

1-اجتياز طالب الامتياز ست دورات تدريبية بنجاح

2-الحصول على 60 % من أجمالي درجات او نقاط الدورة كحد أدني لاجتياز الدورة .

3-نسبة حضور لا تقل عن 75 % في كل دورة تدريبية .

4-في حالة عدم اجتياز طالب الامتياز دورة تدريبية او أكثر يتم إعادة الدورات التي لم يجتزها مع بداية التدريب اللاحق

ضوابط عامة لتنفيذ برنامج التدريب الإجباري (الامتياز)

•**استبدال موقع التدريب:** يجوز لطالب الامتياز استبدال موقع **التدريب لدورة تدريبية واحدة فقط** بعد موافقة وحدة التدريب بشرط وجود موافقة الجهة المسئولة عن التدريب .

•**استبدال دورات التدريب:** يجوز لطالب الامتياز في حال عدم اجتياز دورة تدريبية أو أكثر أن يستبدلها في الإعادة بدورة أخرى في نفس المجموعة التدريبية بعد **موافقة وحدة التدريب بالكلية والجهة المسئولة عن التدريب**

•**تأجيل التدريب:** يجوز لطالب الامتياز تأجيل التدريب في دورة تدريبية أو أكثر من دورات التدريب بناء على طلب يقدم لوحدة التدريب بالكلية موضحا أسباب موثقة للتأجيل **يقبلها مجلس الكلية** على أن يتم إعادتها في الموعد الذي **تقرره وحدة التدريب بعد العرض على مجلس الكلية.**

•يجوز لصيادلة **الامتياز الوافدين أو المصريين** بعد موافقة وحدة التدريب قضاء **سنة الامتياز خارج جمهورية**

مصر العربية على أن يقدم المستندات الرسمية التي تفيد اجتيازه جميع الدورات التدريبية المقررة بالبرنامج التدريبي **واعتمادها من هيئة الدواء أو المجلس الأعلى للمستشفيات الجامعية بحسب نوع الدورة محل النظر** .

الاجازات

يجوز منح طالب الامتياز خلال السنة التدريبية الإجازات الآتية بعد التقدم بطلب لوحدة التدريب وموافقة عميد الكلية واعتمادها من مجلس الكلية :

1-اجازة **عارضة لمدة (5) خمسة أيام** خلال سنة الامتياز وذلك لسبب طارئ يتعذر معه الحصول على أجازه أخري

2- اجازة اعتيادية لمدة (15) خمسة عشر يوماً خلال سنة الامتياز بحد اقصى ثلاثة ايام في الدورة التدريبية الواحدة وبما لا يتجاوز النسبة المقررة للغياب .

3-الإجازة المرضية، اجازة الوضع، واجازة رعاية الطفل على ان تعوض بما يماثلها من الوقت قبل منح شهادة السنة السادسة، وإذا تجاوزت الإجازة النسبة المقررة لاجتياز الدورة التدريبة فإنه يلزم اعادة الدورة التدريبية كاملة

يتم تقديم طلب الإجازة إلى وحدة التدريب وبموافقة عميد الكلية ويتم اعتمادها واخطار جهة التدريب بها فورا .

الجزاءات والتظلمات :

إذا أخل طالب الامتياز بواجباته او التزاماته المهنية فعلى جهة التدريب رفع الأمر إلى عميد الكلية لتحويله إلى التحقيق ويجوز توقيع أحد الجزاءات التالية في ضوء نتائج التحقيق وبعد اعتماد العقوبة من مجلس الكلية :

1-الإنذار الكتابي مع وضعة تحت الملاحظة من مشرف التدريب .

2-اعادة الدورة التدريبية او جزء منها .

3-اعادة سنة التدريب

ولا يتم اعادة سنة التدريب الا بقرار من مجلس الكلية ويحق لطالب الامتياز التظلم لعميد الكلية ضد أي جزاء بحقه خلال **ثلاثون يوما من ابلاغه بالجزاء**

A) Obligatory Rotations

1- دورة الصيدليات
1- Pharmacy Based Rotation

Outline:

Item	Design
Rotation Title	Pharmacy Based Rotation
Rotation Type	Obligatory
Rotation Duration	6 weeks
Mode of Delivery	On-site

Pharmacy Based Rotation

During this rotation, the trainee is expected to be exposed to the medication use cycle within one of the pharmacy settings mentioned below (1-3) whether in the community or in the hospital. Trainees can attend any of the following practice sites or a combination of two or three sites for a total of six weeks, taking into consideration that the IV admixing preparation training should not exceed three weeks

Community Pharmacy

Objective:

The community-based advanced pharmacy practice experience is committed to providing trainees with a variety of patient care experiences including technical and clinical services to enhance their skills to become exemplary community pharmacists. During this rotation, the trainee will be exposed to all the important aspects of contemporary community pharmacy practice by working with and under the direction of a registered pharmacist preceptor. The preceptor should evaluate the trainee‟s experience in community pharmacy and establish goals for the rotation which complement and build on the trainee‟s experience and future plans.

Learning Outcomes (LOs):

After the completion of this rotation, the trainee should be able to:

- Demonstrate and provide the appropriate pharmaceutical technical services related to the community practice including:
  - preparation and dispensing medications using appropriate techniques and following applicable professional standards, laws, and regulations and in accordance with patient needs.
  - demonstrating knowledge of commonly used medications, formulations, and drug products in Egypt, in terms of their generic name, trade name, indications, side effects, and counselling messages.
  - compounding non-sterile products and extemporaneous preparations according to the physician order, using appropriate techniques and following applicable professional standards, laws, and regulations.
  - completion of all steps in the final check of filled prescriptions to ensure accuracy.
  - demonstrating understanding of the principles of inventory control,

including cycle counts, audits, physical inventory, turnover rate, handling return of merchandise, drug recalls, and days-on-hand.
  - determination of impact of the pharmaceutical return process.
  - understanding and adherence to coding, billing, and reimbursement regulations.
  - handling of narcotics and psychotropic medications according to the applicable laws and regulation and determining if modifications are needed to improve their security.
  - explaining strategies for ensuring the integrity of the supply chain.
  - adherence to appropriate safety and quality assurance practices and effective promotion of the safety culture.
  - identification of system errors prior to an event.

- Collect relevant information related to patient data and knowledge of disease states to aid in clinical decision making including:
  - receiving the medication order/prescription and obtaining all required information for its processing.

- collecting relevant patient information from different sources (patient interview, and patient chart).
  - interpreting the medication order completely, accurately, and efficiently and perform order entry accurately (if applicable).
  - conducting medication reconciliation thoroughly and effectively
  - dispensing prescription and performing order entry accurately (if applicable).
  - conducting effective and thorough literature search in many resources and utilize appropriate drug information resources.
- Identify drug related problems and adverse drug reactions (ADRs) through:
  - identification of potential and actual medication-related problems and take appropriate actions on identified problems.
  - identifying and reporting ADRs and prevention strategies.

- Develop and implement pharmaceutical care plans pertaining to the community practice through:
  - performing pharmaceutical calculations related to medication orders, based on a patient‟s condition including pediatric medications doses by weight including pediatric medications doses by weight.
  - Identification of patient‟s need and respond according to presented patient‟s symptoms.
  - selecting the most appropriate over the counter medication (OTC) according to the case evaluation.
  - Identification of patients‟ needs for appropriate available services in the practice to facilitate safe and effective use of medications (e.g., compliance packaging, delivery services, compounded formulations).
  - conducting appropriate point of care testing, if applicable.
  - determination of barriers to patient adherence and making appropriate adjustments.
  - taking appropriate actions to refer patients for other health care services or care.

- Communicate effectively and provide competent counselling services through:
    - working effectively as a team member in an efficient and interactive way to perform the required tasks.
    - managing time well and demonstrating an appropriate level of preparedness.
    - employing effective counseling techniques and educating the patient and/or caregiver effectively about both dispensed and self-care medications.
        Counsel patients on prescription/OTC medications. Counsel patients on appropriate use of inhalers.
        Counsel patients on appropriate insulin injections techniques.
    - demonstrating effective communication skills verbally, non-verbally, and in writing with professional health care team, patients, and communities.
    - participating in disease screening or health promotion activities or education of a group of patients, community groups or school trainees on disease/medication use.
    - identifying and clarifying drug information questions.
    - determination of barriers to patient adherence and making appropriate adjustments.
- Demonstrate professionalisms and ethical practice through:
    - applying professional ethics as they relate to the practice of pharmacy.
    - adherence to legal, and regulatory requirements.
    - monitoring effectively and efficiently the accuracy of the work of pharmacy assistants, clerical personnel, and others.
    - accepting constructive criticism; and responding to feedback to modify behaviours

b- Institutional/Hospital Pharmacy

Objective:

In this rotation, the trainee is expected to apply knowledge and advanced experience in the processes and functions carried within the hospital pharmacy services. The main aim of this rotation is to introduce the trainee and develop their knowledge and skills in hospital pharmacy operations and services (e.g., outpatient pharmacy, inpatient pharmacy, supply chain unit, pharmacy administration…etc.). These activities will allow the trainees to recognize the pharmacist‟s technical and administrative services in the hospital. including basic and special drug therapy management in addition to direct patient care activities.

The hands-on exposure of the trainees to all the important aspects of contemporary hospital pharmacy practice is achieved by working with and under the direction of a registered pharmacist preceptor and other pharmacy personnel. The preceptor should evaluate the trainee‟s experience in hospital pharmacy and establish goals for the rotation which complement and build on the trainee‟s experience and future plans.

Learning Outcomes (LOs):

After the completion of this rotation, the trainee should be able to:

- Demonstrate and provide the appropriate pharmaceutical technical services related to the Institutional/Hospital practice including:
  - demonstrating knowledge of commonly used medications, formulations, and drug products in Egypt, in terms of their generic name, trade name, indications, side effects.
  - participation in formulary management.
  - assisting in stock control within the pharmacies and coordinate with warehouse, clinics, nurse stations and physicians to prepare and dispense medications.
  - understanding the different medication distribution systems within the hospital.
  - implementation and working according to the infection prevention and control requirements and standards.
  - explanation of strategies for ensuring the integrity of the supply chain.
  - demonstrating understanding of the principles of inventory control, including cycle counts, audits, physical inventory, turnover rate, handling return of merchandise, drug recalls, and days-on-hand.
  - determination of the impact of the pharmaceutical return process.
  - handling of narcotics and psychotropic medications according to the applicable laws and regulations and determining if modifications are needed to improve their security.
  - performing pharmaceutical/pharmacokinetics calculations related to medication orders, including pediatric medications doses by weight.
  - preparation and dispensing medications using appropriate techniques and following applicable professional standards, laws, and regulations and in accordance with patient needs.
  - practicing intravenous (IV) admixture preparation, IV compatibility checking and compounding of sterile products according to the national and international standards.
  - completing all steps in the final check of medication order to ensure accuracy.
  - appropriately substituting generic products according to formulary system

- Collect relevant information related to patient data and knowledge of disease states to aid in clinical decision making including:
  - receiving medication orders and obtaining all required information for its processing.
  - interpreting the medication order/prescription completely, accurately, and efficiently and performing order entry accurately (if applicable).
  - collecting, retrieving, and reviewing relevant patient information from different sources (patient interview, patient chart, electronic system if available).
  - conducting an effective and thorough literature search in many resources and utilize appropriate drug information resources.
- Identify drug related problems and adverse drug reactions (ADRs) by:
  - identifying potential and actual drug-related problems including, potential interactions with other drug therapy or disease states, contraindications, and duplicate therapy and recognize medication errors and acting according.

- identifying and reporting adverse drug events, and prevention strategies.

- Develop and implement pharmaceutical care plans pertaining to the community practice through:
  - selecting the appropriate dosage form and regimen according to the patient‟s conditions and history.
- Communicate effectively and provide competent counselling services through:
  - communicating effectively (verbally & written) with **p**atients and other healthcare professionals.
  - providing effective medication counseling and patient education showing empathy.
  - Identifying, clarifying, and responding to drug information questions.
  - working effectively as a team member in an efficient and interactive way to perform the required tasks.
- Demonstrate professionalisms and ethical practice through:
  - adherence to legal, and regulatory requirements.
  - applying professional ethics as they relate to the practice of pharmacy.
  - accepting constructive criticism; and responding to feedback to modify behaviours.
  - managing time well and demonstrating an appropriate level of preparedness.

c- Intravenous (IV) Admixing Preparation

Objective:

This rotation will prepare the trainee on the preparation of sterile compounds, hazardous/radiopharmaceutical medications, and all aspects of handling from receiving materials to final examination or disposal.

Learning Outcomes (LOs):

After the completion of this rotation, the trainee should be able to:

- Demonstrate and provide the appropriate pharmaceutical technical services related to the IV admixing practice including:
  - demonstrating appropriate pharmaceutical calculations as required to prepare a variety of sterile compounded preparations (Reconstitution, drug dose, IV flow rate, etc.)
  - describing the various sterile compounding areas: anteroom, buffer room, clean room, and the compounding, storage, and cleaning requirements for each area.
  - recalling the various types of hoods and isolators to determine the appropriate method required for cleaning each.
  - listing the proper methods for documenting environmental quality control in the cleanroom.
  - demonstrating 100% accurate aseptic technique in
    -handwashing,

    -proper gowning and sterile gloving technique,

    - proper horizontal hood cleaning technique,

- proper vertical hood or barrier isolator cleaning technique (when applicable),

- proper powder vial reconstitution technique and

- proper liquid vial and ampoule technique.

  - practicing intravenous (IV) admixture preparation, IV compatibility checking and compounding of sterile products according to the national and international standards
  - Maintenance of sterile compounding and clinical competency in compliance to policy and sufficient to meet pharmacy standards for patient safety and effective therapy.
  - handling of cytotoxic medications and hazardous substances and preparing cancer treatment drugs in a way to maintain a sterile environment, including cleaning procedures and sterilization techniques, the use of appropriate personal protective equipment and procedures for the disposal of cytotoxic materials and supplies used in dealing with them (If available).
  - assisting in stock control within the pharmacies and coordinate with warehouse, clinics, nurse stations and physicians to prepare and dispense prepared medications whenever appropriate.
  - supervising technicians in aseptic compounding including parenteral nutrition.
  - providing all needed interventions, reporting, and discussing medication errors, and adverse drug reaction(s) (ADRs).
  - referring pending and unresolved difficulties to senior level.

- Communicate effectively and provide competent counselling services through:
  - communicating effectively orally and in writing with patients and other healthcare providers.
  - supervising technicians/workers in aseptic compounding areas.
- Demonstrate professionalism and ethical practice through:
  - applying professional ethics as they relate to the practice of pharmacy.
  - adherence to legal, and regulatory requirements.
  - working as an effective member of the patient care team in an efficient and interactive way to perform the required tasks.
  - managing time well and demonstrate an appropriate level of preparedness

2. دورة الصيدلة السريرية في الطب العام للبالغين
2- Clinical Pharmacy Rotation in Adult General Medicine

Outline:

Item	Design
Rotation Title	Clinical Pharmacy Rotation in Adult General Medicine
Rotation Type	Obligatory
Rotation Duration	6 weeks
Mode of Delivery	On-site

Objective:

The purpose of this rotation is to develop the trainees‟ knowledge- based competencies and clinical skills required to deal professionally with a wide range of general medicine-related diseases (endocrine (e.g., endocrine disorders, gastrointestinal disorders, renal disorders, cardiovascular disorders, and other chronic conditions) and provide the required pharmaceutical care for these patients. During this rotation, trainees will spend 6 weeks at any adult general medicine rotation site and work closely with their preceptor and the training will be a dynamic experience to ensure the necessary skills are developed.

Learning Outcomes (LOs):

After the completion of this rotation, the trainee should be able to:

- Collect relevant information related to patient data and knowledge of disease states to aid in clinical decision making including:
  - demonstrating appropriate understanding of disease state, and drug therapy.
  - assessing patient/patient medical history to identify disease/condition, other medical problems and/or therapies or potential drug therapy problems and organize information.
  - ability to review and retrieve information from patient charts.
  - identifying and utilizing appropriate drug information resources and demonstrating ability to research, review, and critically evaluate pertinent drug literature to respond to drug information questions.
  - conducting medication reconciliation and drug use evaluation accurately and in a timely manner.
  - responding proficiently to drug information requests from available resources.
- Identify drug related problems and adverse drug reactions through:
  - consistent and accurate identification of potential and actual drug-related problems including allergies, potential interactions with other drug therapy or disease states, and duplicate therapy and recognizing medication errors and prioritizing the problem list.
  - recognizing and reporting adverse drug reactions (ADRs) on the appropriate

ADR form as directed by the preceptor.

- Develop and implement pharmaceutical care plans pertaining to the internal medicine practice through:
  - participation in the formulation and selection of rational pharmacotherapeutic plan to include drug, route, dose, interval, therapeutic endpoint, and monitoring parameters in assigned patients.
  - evaluating and adjusting doses of different medications and accurate performance of pharmaceutical calculations related to medication orders, including pediatric and renal patient orders (based on ideal body weight (IBW), and creatinine clearance (CrCl)).
  - interpreting vital signs and laboratory values and adjusting medications accordingly.
  - performing therapeutic drug monitoring and pharmacokinetic based dosing.
- Communicate effectively and provide competent counselling services through:
  - effective presentation of patient cases and therapeutic care plans to preceptors and peers.
  - communicating effectively (verbal & written) with patients/carer and healthcare professionals regarding drug therapy.
  - demonstrating sensitivity, respect, and showing empathy during communication with patients.
  - providing effective medication counseling and patient education about safe and proper use of medicines including OTC preparations and medical devices.
  - utilizing technologies and media to demonstrate effective presentation skills.
- Demonstrate professionalisms and ethical practice through:
  - adherence to legal, and regulatory requirements.
  - applying professional ethics as they relate to the practice of pharmacy, and in terms of respecting patients‟ rights and confidentiality of their data.
  - working collaboratively with other healthcare professionals daily in various medical departments and respecting each other‟s roles and responsibilities.
  - managing time well and demonstrating an appropriate level of preparedness.
  - Practicing self-assessment, accepting constructive criticism; and responding to feedback to modify behaviours.
  - implementing consistent scientific method for critical analysis of information and solving problems.
  - accomplishing assignments, tasks and topics research that require independent work and functioning for future professional development.

3- دورة الدواء : من التسجيل الي التسويق
3. Drug Tour: Registration to Market

Outline:

Item	Design
Rotation Title	Drug Tour: Registration to Market

Rotation Type	Obligatory
Rotation Duration	6 weeks
Mode of Delivery	On-site / Online

Description:

This rotation aims to provide an overview of various stages of the pharmaceutical industry. Trainees will be exposed to the regulatory requirements for registration. Multiple stages of the product life-cycle will be covered according to the following pillars:

Pillar 1: Regulatory overview on the registered pharmaceutical and biological products

Pillar 2: Regulation overview of the registration of Medical Devices and in-vitro diagnostic medical devices (IVDs)

Pillar 3: Overview on bioavailability and bioequivalence studies Pillar 4: Overview on Good Manufacturing Practice (GMP)

Pillar 5: Pharmaceutical inspection and knowledge of the application of pharmacy laws and inspection tasks

Pillar 6: Quality Control of Pharmaceutical Products in EDA Labs

Pillar 7: Over- The-Counter Marketing of drugs, Application, Approaches and Principals

Pillar 8: How to Regulate Insert Leaflet and Promotional material

Pillar 9: Regulatory Overview on Pharmacovigilance Practice

PILLAR 1: Regulatory overview on the registered pharmaceutical and biological products

Objectives

This pillar aims to introduce the necessary studies to ensure the quality of pharmaceutical products in reference to the international guidelines followed and highlight on the registration process guidelines.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:

1- Define different pharmaceutical products with their different forms (human, veterinary, herbal and cosmetics).
2- Define biological products and their derivatives.
3- Understand how to register pharmaceutical products according to international guidelines.
4- Comprehend how to prepare registration files of pharmaceutical products according to EDA regulatory guidelines.
5- Know how to register biological products according to the international guidelines.
6- Comprehend how to prepare registration files of biological products according to EDA regulatory guidelines.
7- Know the components of the unified technical file (Common Technical Document – CTD & eCTD files).
8- Identify international institutions regulating the registration and trading of pharmaceutical products such as (WHO, EMA, FDA).

PILLAR 2: Regulation overview of the registration of Medical Devices and in-vitro diagnostic medical devices (IVDs)

Objective:

This pillar aims to introduce the necessary studies to ensure the quality of medical supplies in reference to the international guidelines followed and highlight on the recent guidelines.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:

1- Define the medical device.
2- Recognize how to register the medical device and in-vitro diagnostic medical devices (IVDs) in accordance with international guidelines.
3- Know how to prepare registration files and the current regulatory decrees. 4- Identify medical devices classification.

PILLAR 3: Overview on bioavailability and bioequivalence studies

Objective:

This pillar aims to introduce Egyptian Guidelines for conducting Bioequivalence Studies and in vitro dissolution studies on pharmaceutical products. In addition to discussing the experimental conditions. Also, it will provide the needed information how to make bioequivalence study designs, including subject selection criteria, pharmacokinetics, and statistics evaluation, highlight on the criteria in the exempted pharmaceutical products.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:
1- Identify the importance of Bioequivalence in drug registration. 2- Recognize a brief introduction about bioequivalence study.
3- Recognize a brief introduction about in-vitro dissolution study.
4- Understand the Egyptian guidelines for conducting bioequivalence studies. 5- Know the licensing process of bioequivalence and bioavailability centers approved by EDA.

PILLAR 4: Overview on Good Manufacturing Practice (GMP)

Objective:

This pillar aims to introduce the initial requirements of good manufacturing practice and quality system in pharmaceutical factories according to the latest international references and the scientific and practical experience of trainees.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:
1- Identify basic principles of Good Manufacturing Practices.
2- Recognize Good documentation system (How to control and validate data integrity from regulatory point of view).
3- Understand Good documentation system (Manufacturing point of view).
4- Recognize the guidelines of assurance system for good cleaning and public health (Cleaning Validation).
5- Understand systems for the qualification and verification of equipment and devices.
6- Identify raw material management systems, good storage, and warehouses, ensuring and applying safety measures in every step, and good storage conditions of warehouses.

PILLAR 5: Pharmaceutical inspection and knowledge of the application of pharmacy laws and inspection tasks

Objective:

This pillar aims to introduce the inspection procedures followed to tighten control over the Egyptian drug market. In addition to highlight on the essential requirements for good storage and distribution that must be met in all pharmaceutical entities, stores, warehouses, and distribution companies. To clarify the most common violations in accordance with international Good Storage and Distribution requirements to ensure the availability of safe, effective, and high-quality medical preparations in the Egyptian market.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:
1- Identify licensing procedures for the stores, warehouses, and distribution companies of pharmaceutical and biological products.
2- Recognize pharmaceutical inspection laws and regulations.
3- Understand the controlling method on licensed pharmaceutical entities.
4- Recognize the control over pharmaceutical establishments (factories -stores -pharmacies.).
5- Identify narcotic drugs usage laws and how to apply in market.
6- Practice reports writing for tests and checklists.
7- Prepare regulatory inspection reports, warning letters and recalls.

PILLAR 6: Quality Control of Pharmaceutical Products in EDA Labs

Objective:

This pillar aims to introduce the general principles of Quality Control for Pharmaceutical Products with emphasis on the Safety, Efficacy and Compliance in addition to assessment methods as applicable tests of chemical, physical, and microbiological properties of pharmaceutical products.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:
1- Identify the basic concepts of Total Quality Management (TQM) and Quality Management System (QMS).
2- Perform the physicochemical analysis of Pharmaceutical Products (Basics).
3- Execute the microbiological analysis of pharmaceutical products (Basics).
4- Recognize good laboratory and inspection practices (Basics).
5- Accomplish practical training.

PILLAR 7: Over- The-Counter Marketing of drugs, Application, Approaches and Principals

Objective:

This pillar aims to introduce a number of interesting topics concerning community pharmacy practice aspects as Over the counter (OTC) system, in which, it defines the OTC products criteria and regulations, highlight on the implementation of new system for approving OTC drugs, what are common medication errors and how to report them, in addition to the rational use of antimicrobial agents.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:
1- Define a pharmaceutical product as an OTC.
2- Recognize the approved national list of OTC drugs.
3- Know EDA regulations for the registration of OTC products.
4- Identify the role of outpatient (community) Pharmacist in reporting emergency and medical errors.
5- Understand the restrictions on dispensing antimicrobial agents on the OTC.
6- Realize pharmacy outpatient role in patient counseling on the OTC usage.

PILLAR 8: How to Regulate Insert Leaflet and Promotional material

Objective:

This pillar aims to give an overview on the most important pillars in providing full information about the pharmacological characteristics of drugs. Highlight on the most accreditable reference for data providence of drug internationally. Highlight on the Pharmacy informatics application conducted by EDA. Introduction on the Promat application and prompt and

promotional guidelines as Pillars of information and SmPC. The most important pharmaceutical References, informatics new era for technology and also provide practical session to emphasize on the scientific part.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:

1- Define promotional materials and learn how to prepare and control them.
2- Identify SmPC and PIL: pillars of information.
3- Recognize the most important pharmacological and drug references.
4- Determine pharmacy informatics application.
5- Discern drug information resources and search approaches.
6- State drug regulatory authorities in reference countries.
7- Navigate through pharmaceutical references via practical training.

PILLAR 9: Regulatory Overview on Pharmacovigilance Practice

Objective:

This pillar aims to introduce regulatory process and pharmacovigilance practice in 3 different pillars: Pharmaceutical companies, hospitals and public pharmacies with highlighting the importance of reporting pharmacovigilance in maintaining patient safety and clarifying the methods of adverse effects reporting and its importance.

Learning Outcomes (LOs):

After completion of this pillar, the intern pharmacist should be able to:

1- Understand the importance of Pharmacovigilance regulation system for pharmaceutical companies and the impact on drug registration.
2- Know the importance of Pharmacovigilance regulation to hospitals and health institutes.
3- Recognize Pharmacovigilance regulatory system channels of reporting for the public.
4- Tracking data of Pharmaceutical Products globally (new warnings or precautions).
5- Identify Risk Management Plan (RMP).
6- Recognize emerging safety issues (ESI) / Safety information.
7- Fulfill causality assessment of individual case safety reports (ICSRs). 8- Execute practical training on reporting to national database

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4- المشروع البحثي التطبيقي
4. Applied research Project

Outline:

Item	Design
Rotation Title	Applied research Project
Rotation Type	Obligatory
Rotation Duration	6 weeks
Mode of Delivery	On-site / Online

Description:

The project represents a true test for the trainee, revealing their ability to deal with or solve

problems and innovate new solutions by designing a project using one of the techniques they have studied. The project also provides the student with important practical experience that serves as an introduction to practical life, as the student relies entirely on their creativity in completing the project.

Project Objectives:

1. Qualify the intern pharmacist to be an effective member in various scientific, practical, and research fields.
2. Train the intern pharmacist to utilize their knowledge and writing, public speaking, research, and organizational skills.
3. Provide the intern pharmacist with the opportunity to apply what they have learned and implement it in practice.
4. Provide the intern pharmacist with the opportunity to practice and apply professional ethics and teamwork before actually joining the workforce.
5. Develop the intern pharmacist's innovative capacity.

B) Elective Rotations

الدورات الاختيارية في مجال تصنيع وتنظيم تداول الدواء

Drug Manufacture and Regulations Elective Rotations

دورة تطوير المستحضرات الصيدلانية
Pharmaceutical Product Development Rotation

Outline:

Item	Design
Rotation Title	Pharmaceutical Product Development
Rotation Type	Elective
Rotation Duration	6 weeks
Mode of Delivery	On-site / Online

Objective:

This rotation aims to expose the trainees to various aspects of research and development in the pharmaceutical industry. Topics include intellectual property rights, literature search and multiple stages of pharmaceutical product development; formulation, analytical method development and validation as well as various studies required for quality assessment of the pilot and production batches of finished pharmaceutical products such as stability and bioequivalence studies. The program will also cover the regulatory requirements for the registration of pharmaceutical products and the preparation of a dossier in CTD format.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Review the specifications of raw materials and pharmaceutical products according to the latest editions of pharmacopoeias.
2- Know and follow references and guidelines for conducting performance, stability, comparative dissolution, and bioequivalence studies on pharmaceutical products.
3- Recognize the development process stages for new formulations, from initial planning to production.
4- Participate in the design and conduct of laboratory experiments on different pharmaceutical dosage forms, for example, dissolution, disintegration, friability, hardness, content uniformity, weight variation, etc.…
5- Engage in conducting stability studies on finished products, follow-up them in stability chambers, and conduct the required stability tests.
6- Participate in designing and conducting comparative dissolution and/or bioequivalence studies for pharmaceutical products (Generic *versus* Innovator).
7- Collaborate in the analytical method development and validation.
8- Investigate any problem that appears during the production of new pharmaceutical products and take preventive measures (Troubleshooting).
9- Apply Good Laboratory Practices (GLP) and Good Pharmaceutical Manufacturing Practices (cGMP).
10- Participate in recording, analyzing, and interpreting test results and processing them statistically.
11- Identify and prepare the Common Technical Document (CTD & eCTD files) and their components.
12- Demonstrate responsibility, cooperate, and integrate effectively with research team members.
13- Demonstrate effective communication skills verbally, non-verbally with research team members.

دورة إدارة الجودة في صناعة الدواء
Quality Management in Pharmaceutical Industry Rotation

Outline:

Item	Design
Rotation Title	Quality Management in Pharmaceutical Industry
Rotation Type	Elective
Rotation Duration	6 weeks
Mode of delivery	On-site / Online

Objective:

This rotation aims to provide the trainees with the basic concepts of total quality management (TQM), quality management systems (QMS), various elements of quality assurance (QA) and quality control (QC), good documentation practice, … etc. Trainees will be able to review and evaluate models of standard operating procedures (SOPs),

perform audits, identify nonconformities, and propose the necessary corrective actions. The concepts of pharmaceutical record management systems and data integrity will be also discussed. Qualifications and authorities for the person in charge of batch release operations will be explained through a series of case studies. Trainees will be introduced also to the relevant ISO standards for the pharmaceutical industry and requirements for accreditation.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

- *Quality Control (QC):*

1- Identify and participate in QC tests of raw materials: procedures, significance, and troubleshooting.
2- Recognize and collaborate in QC tests of finished products: procedures, significance, and troubleshooting.
3- Prepare quality control (QC) reports.
4- Engage in the analytical method development and validation.
5- Identify and apply standard operating procedures (SOPs) for operation, validation and calibration of different instruments and devices.
6- Apply Good Laboratory Practices (GLP) and data integrity in QC.

- *Quality Assurance (QA):*

7- Monitor different production lines.
8- Recognize Good Documentation Practice and Data Integrity.
9- Understand the basic concepts of Total Quality Management (TQM), Quality Management System (QMS) and the risk management system (RMS).
10- Apply standard operating procedures (SOPs) for deviation, complaint, recall, and change control.
11- Prepare operating records for manufacturing products (Batch Records).
12- Perform Process Validation: protocol, sampling, and final report.
13- Perform Cleaning Validation: protocol, sampling, and final report.
14- Participate in Room Qualification or Machine Qualification: protocol and final report.
15- Execute internal auditing and prepare quality reports.
16- Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
17- Demonstrate effective communication skills verbally, non-verbally with teamwork members.

دورة اليقظة إلدوائية
Pharmacovigilance Rotation

Outline:

Item	Design
Rotation Title	Pharmacovigilance
Rotation Type	Elective

Rotation Duration	6 weeks
Mode of delivery	On-site / Online

Objective:

This rotation aims to provide profound knowledge to the trainees on the importance of pharmacovigilance in monitoring the safety of pharmaceutical products and medical devices that have been launched in the market. Reflection on the international vigilance guidelines and good pharmacovigilance practice (GVP) will be presented. Detection & evaluation of medicines that cause serious adverse drug reactions (ADRs) including lack of efficacy, and subsequent removal from the market to protect public health. The importance of Pharmacoeconomics in developing pharmacovigilance activities as a working tool to guide the process of decision-making in the healthcare sector will be also discussed. The rotation will focus also on the tools for receiving follow-up reports on the quality of pharmaceutical products, taking the appropriate actions and good communication with members of the healthcare team.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Determine, measure, and compare the costs, risks, and benefits of different treatment programs.
2- Monitor the serious adverse drug reactions (ADRs) of drugs by following-up on marketed pharmaceutical products.
3- Ensure the safety, quality, and efficacy of marketed pharmaceutical products.
4- Receive and inspect follow-up reports on the quality of pharmaceutical products with decision-making in case of the occurrence of ADRs.
5- Prepare the Risk Management Plan (RMP) document
6- Prepare periodic safety update reports (PSUR) for pharmaceutical products.
7- Understand the international vigilance guidelines and apply good pharmacovigilance practices (GPvP).
8- Recognize the procedures of regulatory inspections and audits.
9- Demonstrate responsibility, cooperate, and integrate effectively with healthcare team members.
10- Demonstrate effective communication skills verbally, non-verbally with healthcare team members.

دورة التفتيش التنظيمي الصيدلى
Regulatory Inspection Rotation

Outline:

Item	Design
Rotation Title	Pharmaceutical Regulatory Inspection

Rotation Type	Elective
Rotation Duration	6 weeks
Mode of Delivery	On-site / Online

Objective:

This rotation aims to cover the regulatory inspection requirements as per the WHO requirements. Trainees will be introduced to the parameters, approaches, and concerns of inspectors, and the tools for preparing, coping, and managing inspections in pharmaceutical facilities. The following topics will be covered: GMP overview, expectations of regulatory inspections, warning letters, recalls, and other potential actions, preparation of response to inspection findings and preparation/execution of remediation plans.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Identify the international institutions concerned with the registration and circulation of pharmaceuticals, such as WHO, EMA, FDA, EUDRA.
2- Recognize current registration procedures of pharmaceutical and biological products, nutritional supplements, medical supplies, and cosmetics.
3- Understand the pharmaceutical inspection process in compliance with WHO requirements, and pharmacy laws.
4- Receive pharmaceutical products with physical examination and their certificates of analysis.
5- Prepare, cope, and manage the audit and inspection tools over pharmaceutical and biological products, nutritional supplements, medical supplies, and cosmetics, and their significance.
6- Prepare, cope, and manage the audit and inspection tools over pharmaceutical establishments (companies – drug distribution stores – pharmacies, etc...).
7- Prepare regulatory inspection reports, warning letters, recalls and follow them up.
8- Prepare and execute remediation plans.
9- Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
10- Demonstrate effective communication skills verbally, non-verbally with teamwork members.

دورة إكتشاف وتطوير إلدواء
Drug Discovery and Development Rotation

Outline:

Item	Design
Rotation Title	Drug Discovery and Development
Rotation Type	Elective
Rotation Duration	6 weeks

Mode of Delivery	On-site / Online

Objective:

This rotation aims to give the trainees an overview of the drug discovery and development process in compliance with the legal and regulatory requirements. Topics include lead compound discovery and preparation using chemical / biochemical synthesis, extraction from natural sources, fermentation technology as well as other innovative tools such as cell culture. Various in vitro experimental techniques required to evaluate safety and efficacy will be explained. Relevant tools intended to reduce possible side effects, enhance efficacy and reduce production costs such as computer-aided drug design, protein engineering and other advanced tools will be explored. The trainees will participate in designing and conducting experiments within preclinical & clinical settings. The basics of literature search, preparation of experimental protocols, obtaining the required ethical committee approvals, scientific interpretation and statistical analysis of the results and writing of reports and scientific papers will be also explained.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Understand the drug discovery and development process in the light of legal and regulatory requirements.
2- Discover and prepare lead compounds *via* chemical/biochemical synthesis, extraction from natural sources, fermentation, cell cultures, etc.
3- Apply computer-aided drug design or other suitable tools to enhance the safety and efficacy of potential drugs, and to reduce the production costs.
4- Design and conduct *in vitro* experiments, preclinical and clinical studies on potential drugs.
5- Participate in recording, analyzing, and interpreting test results and processing them statistically.
6- Practice literature search and writing of scientific reports and/or research articles.
7- Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
8- Demonstrate effective communication skills verbally, non-verbally with teamwork members.

دورة المبيعات والتسويق الدوائي
Pharmaceutical Sales & Marketing Rotation

Outline:

Item	Design
Rotation Title	Pharmaceutical Sales & Marketing
Rotation Type	Elective
Rotation Duration	6 weeks

Mode of delivery	On-site / Online

Objective:

The rotation aims to provide the trainees with the fundamentals of pharmaceutical business administration. Understanding market research data and forecasting tools, developing marketing strategies and tactics as well as market segmentation and targeting will be explored. Trainees will be also introduced to the concepts of communication skills, concepts of customer value satisfaction, pricing models, and budgeting. Regulatory guidelines for the preparation of promotional materials and marketing campaigns will be explained. Managing retailing, wholesaling, and logistics of good distribution practice (GDP) will be also explained.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Understand the basics of pharmaceutical business administration.
2- Identify the marketing strategies and tactics.
3- Understand the art of medical advertising, and medicinal sales.
4- Recognize the concepts of individual and group communication skills.
5- Understand the concepts of customer value satisfaction, pricing models, and budgeting.
6- Understand the work of scientific offices in medical advertising.
7- Know and identify clients and customers in the healthcare system.
8- Understand market research data and forecasting tools.
9- Develop market segmentation and targeting
10- Identify the types of economic analyses and studies used in the field of Pharmacoeconomics.
11- Participate in recording, analyzing, and interpreting collected data and processing them statistically.
12- Understand managing retailing, wholesaling, and logistics of good distribution practice (GDP).
13- Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
14- Demonstrate effective communication skills verbally, non-verbally with teamwork members.

دورة التصنيع الدوائي
Pharmaceutical Production Rotation

Outline:

Item	Design
Rotation Title	Pharmaceutical Production
Rotation Type	Elective
Rotation Duration	6 weeks
Mode of delivery	On-site / Online

Objective:

This rotation aims to give the trainees an overview of the current technology to produce various pharmaceutical dosage forms through scenario-based exercises. Workflow involving the relationships between various departments in pharmaceutical production facilities will be presented. Visual demonstration of the current manufacturing and engineering practices through site visits and video illustrations will be performed. Real-time demonstrations of production key steps such as mixing, blending, drying, sizing, tableting, encapsulation, coating … etc will be experienced. Case studies for production-related issues and concerns will be presented. Analyzing the problems to identify the root cause and present solutions will be carried out.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Identify the various production areas in the pharmaceutical manufacturing company: solid preparations (such as tablets and capsules), non-solid preparations (such as ointments, creams, and syrups), sterile preparations (such as ampoules and vials), gelatin capsules, and other products.
2- Recognize the layout of production areas, and the workflow in different production facilities.
3- Determine the production process operations starting from receiving the raw materials through the various manufacturing stages until reaching the finished product.
4- Apply product control during manufacturing (in-process control 'IPC' Tests), and the significance of each test.
5- Examine production-related problems that may occur during manufacturing (Troubleshooting) and how to overcome them.
6- Apply good manufacturing practices (cGMP) and data integrity in production.
7- Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
8- Demonstrate effective communication skills verbally, non-verbally with teamwork members.

دورة الجودة من خلال التصميم والتكنولوجيا التحليلية للعمليات
Quality by Design and Process Analytical Technology (QbD & PAT) Rotation

Outline:

Item	Design
Rotation Title	Quality by Design and Process Analytical Technology (QbD & PAT)
Rotation Type	Elective
Rotation Duration	6 weeks

Mode of delivery	On-site / Online

Objective:

This rotation aims to expose the trainees to the most advanced trends in product and process development in the pharmaceutical industry. Basic concepts of good manufacturing practice (GMP) and good laboratory practice (GLP) will be revisited. The value of the implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) in ensuring final product quality will be addressed. The favorable impact of QbD and PAT on production cost/efficiency and speed of batch release processes will be demonstrated through case studies.

Learning Outcomes (LOs):

After completion of this rotation, the intern pharmacist should be able to:

1- Recognize the concept of pharmaceutical quality by design (QbD) and describes its objectives.
2- Identify the ICH guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality System).
3- Design a quality product and its manufacturing process to consistently deliver the intended performance of the product to meet patient needs.
4- Describe that critical material parameters (CMP) and critical process parameters (CPP) linked to the critical quality attributes (CQAs) of the product.
5- Increase process capability and reduce product variability and defects by enhancing product and process design, understanding, and control.
6- Analyze, evaluate, and interpret problems associated with the design of pharmaceutical products.
7- Understand the quality risk management across the product lifecycle for drug products.
8- Illustrate the principles and tools of quality risk management that can be applied to different aspects of pharmaceutical quality.
9- Understand and analyze case studies related to Quality by design (QbD) approach for product development

توافق دورات الصناعة مع جدارات البرنامج

Industrial Rotations NARS Competencies

A) Obligatory Rotations

Drug Tour: Registration to Market Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	Please rate the trainee's performance according to the mentioned activity
PILLAR 1: Regulatory overview on the registered pharmaceutical and biological products			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1**	1	Define different pharmaceutical products with their different forms (human, veterinary, herbal and cosmetics).
		2	Define biological products and their derivatives.
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**2-5-1**	3	Understand how to register pharmaceutical products according to international guidelines.
		4	Comprehend how to prepare registration files of pharmaceutical products according to EDA regulatory guidelines.
		5	Know how to register biological products according to the international guidelines.
		6	Comprehend how to prepare registration files of biological products according to EDA regulatory guidelines.
		7	Know the components of the unified technical file (Common Technical Document – CTD & eCTD files).

1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-6** **2-5-1**	8	Identify international institutions regulating the registration and trading of pharmaceutical products such as (WHO, EMA, FDA).
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**			
PILLAR 2: Regulation overview of the registration of Medical Devices and in-vitro diagnostic medical devices (IVDs)			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1**	9	Define the medical device.
		10	Identify medical devices classification.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **2-3-2** **2-5-1**	11	Recognize how to register the medical device and *in-vitro* diagnostic medical devices (IVDs) in accordance with international guidelines.
		12	Know how to prepare registration files and the current regulatory decrees.
PILLAR 3: Overview on bioavailability and bioequivalence studies			

1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with**	**1-1-1** **1-1-3** **1-1-6** **2-2-4** **2-3-2** **2-5-1** **2-5-2** **2-5-3**	13	Identify the importance of Bioequivalence in drug registration.
		14	Recognize a brief introduction about bioequivalence study.
		15	Recognize a brief introduction about *in-vitro* dissolution study.
respect to relevant laws and legislations. **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**		**16**	**Understand the Egyptian Guidelines for Conducting Bioequivalence Studies.**
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**2-5-1**	**17**	**Know the licensing process of bioequivalence and bioavailability centers approved by EDA.**
PILLAR 4: Overview on Good Manufacturing Practice (GMP)			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical**	**1-1-1** **1-1-3** **2-2-2** **2-3-2** **2-5-1**	18	Identify basic principles of Good Manufacturing Practices.
		19	Recognize the guidelines of assurance system for good cleaning and public health (Cleaning Validation).

products, and participate in systems for dispensing, storage, and distribution of medicines. **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **2-2-2** **2-2-3** **2-3-2** **2-5-1**	20	Understand systems for the qualification and verification of equipment and devices.
		21	Identify raw material management systems, good storage, and warehouses, ensuring and applying safety measures in every step, and good storage conditions of warehouses.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-5** **Contribute in pharmaceutical research studies** **and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **2-2-2** **2-5-1**	22	Recognize Good documentation system (How to control and validate data integrity from regulatory point of view).
		23	**Understand Good documentation system (Manufacturing point of view).**
PILLAR 5: Pharmaceutical inspection and knowledge of the application of pharmacy laws and inspection tasks			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and**	**1-1-1** **2-3-2** **2-5-1**	24	Identify licensing procedures for the stores, warehouses, and distribution companies of pharmaceutical and biological products.

deliver population and patient-centered care. **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-4** **2-3-2** **2-5-1**	25	Identify narcotic drugs usage laws and how to apply in market.
	1-1-1 **1-1-6** **1-1-7** **2-3-2** **2-5-1** **2-5-2**	26	Recognize pharmaceutical inspection laws and regulations.
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**2-5-1** **2-5-2**	27	Understand the controlling method on licensed pharmaceutical entities.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-2** **1-1-6** **1-1-7** **2-2-2** **2-3-2** **2-5-1** **2-5-2**	28	Recognize the control over pharmaceutical establishments (factories - stores - pharmacies ...).
	1-1-1 **1-1-3** **1-1-7** **2-2-2** **2-3-2** **2-5-1**	29	Practice reports writing for tests and checklists.
		30	**Prepare regulatory inspection reports, warning letters and recalls.**
PILLAR 6: Quality Control of Pharmaceutical Products in EDA Labs			

1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **1-1-7** **2-2-2** **2-3-2** **2-5-1**	31	Identify the basic concepts of Total Quality Management (TQM) and Quality Management System (QMS).
	1-1-1 **1-1-3** **2-2-1** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	32	Perform the physicochemical analysis of Pharmaceutical Products (Basics).
		33	Execute the microbiological analysis of pharmaceutical products (Basics).
	1-1-1 **1-1-3** **2-2-2** **2-3-2** **2-5-1**	34	Recognize good laboratory and inspection practices (Basics).
PILLAR 7: Over- The-Counter Marketing of drugs, Application, Approaches and Principals			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-1** **Work collaboratively as a member of an inter- professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **3-1** **Handle and dispose biological and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research**	**1-1-1** **1-1-4** **1-1-5** **1-1-6** **2-1-1** **2-1-2** **2-1-3** **3-1-1** **3-1-2** **3-2-1** **3-2-2** **3-2-3** **3-2-5**	35	Define a pharmaceutical product as an OTC.
		36	Recognize the approved national list of OTC drugs.
		37	Know EDA regulations for the registration of OTC products.
		30	**Prepare regulatory inspection reports, warning letters and recalls.**

studies and clinical trials needed to authorize medicinal products.			
PILLAR 6: Quality Control of Pharmaceutical Products in EDA Labs			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **1-1-7** **2-2-2** **2-3-2** **2-5-1**	31	Identify the basic concepts of Total Quality Management (TQM) and Quality Management System (QMS).
	1-1-1 **1-1-3** **2-2-1** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	32	Perform the physicochemical analysis of Pharmaceutical Products (Basics).
		33	Execute the microbiological analysis of pharmaceutical products (Basics).
	1-1-1 **1-1-3** **2-2-2** **2-3-2** **2-5-1**	34	Recognize good laboratory and inspection practices (Basics).
PILLAR 7: Over- The-Counter Marketing of drugs, Application, Approaches and Principals			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-1** **Work collaboratively as a member of an inter- professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **3-1** **Apply the principles of body functions to participate in improving health care**	**1-1-1** **1-1-4** **1-1-5** **1-1-6** **2-1-1** **2-1-2** **2-1-3** **3-1-1** **3-1-2** **3-2-1** **3-2-2** **3-2-3** **3-2-5**	35	Define a pharmaceutical product as an OTC.
		36	Recognize the approved national list of OTC drugs.
		37	Know EDA regulations for the registration of OTC products.
		38	Identify the role of outpatient (community) Pharmacist in reporting emergency and medical errors.

services using evidence-based data. **3-2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**		39	Understand the restrictions on dispensing antimicrobial agents on the OTC.
3-2 **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**3-2-1** **3-2-2** **3-2-3** **3-2-4** **3-2-5** **3-2-6**	40	Realize pharmacy outpatient role in patient counseling on the OTC usage.
PILLAR 8: How to Regulate Insert Leaflet and Promotional material			
2-6 **Perform pharmacoeconomic analysis and develop promotion, sales, marketing, and business administration skills.**	**2-6-1** **2-6-2**	41	Define promotional materials and learn how to prepare and control them.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-5** **1-1-6**	42	Identify SmPC and PIL: pillars of information.
		43	Recognize the most important pharmacological and drug references.
		44	Discern drug information resources and search approaches.
		45	State drug regulatory authorities in reference countries.
		46	Navigate through pharmaceutical references *via* practical training.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-1** **Work collaboratively as a member of an inter- professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **2-4** **Actively share professional decisions and**	**1-1-1** **1-1-2** **1-1-4** **1-1-5** **1-1-6** **2-1-1** **2-1-2** **2-1-3** **2-4-3** **3-1-1** **3-1-2** **3-1-3**	**47**	**Determine pharmacy informatics application.**

proper actions to save patient's life in emergency situations including poisoning with various xenobiotics, and effectively work in forensic fields. **3-1** **Apply the principles of body functions to participate in improving health care services using evidence-based data.** **3-2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**3-1-4** **3-2-1** **3-2-2** **3-2-3** **3-2-4** **3-2-5** **3-2-6**		
PILLAR 9: Regulatory Overview on Pharmacovigilance Practice			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.** **3-2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**1-1-1** **1-1-2** **1-1-4** **1-1-5** **1-1-6** **1-1-7** **2-5-1** **2-5-2** **3-2-1** **3-2-2** **3-2-3** **3-2-4**	48	Understand the importance of Pharmacovigilance regulation system for pharmaceutical companies and the impact on drug registration.
		49	Know the importance of Pharmacovigilance regulation to hospitals and health institutes.
		50	Recognize Pharmacovigilance regulatory system channels of reporting for the public.
		51	Tracking data of Pharmaceutical Products globally (new warnings or precautions).
		52	Identify Risk Management Plan (RMP).
		53	Recognize emerging safety issues (ESI) / Safety information.
		54	**Fulfill causality assessment of individual case safety reports (ICSRs).**
		55	**Execute practical training on reporting to national database.**
GENERAL			
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	56	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.

4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	57	Demonstrate effective communication skills verbally, non-verbally with teamwork members.

Pharmacy Based Rotation

Hospital Pharmacy rotations

Competencies	**Key elements**	**Performance Evaluation Elements**	
		No	**Objectives**
1.1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-2** **1-1-4** **1-1-5** **1-1-6**	1.	receive the medication order/prescription and obtain all required information for its processing.
		2.	interpret the medication order/prescription completely, accurately, and efficiently and perform order entry accurately (if applicable).
2.1 **Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.**	**2-1-1** **2-1-2** **2-1-3**	3.	adhere to legal, and regulatory requirements.
		4.	prepare and dispense medications using appropriate techniques and follow applicable professional standards, laws, and regulations and in accordance with patient needs.
2.2 **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines. 2.3 Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2.6.** **Perform pharmacoeconomic analysis and develop promotion, sales, marketing, and business**	**2-2-2** **2-3-2** **2-6-1**	5.	assist in stock control within the pharmacies and coordinate with warehouse, clinics, nurse stations and physicians to prepare and dispense medications.
		6.	demonstrate understanding of the principles of inventory control, including cycle counts, audits, physical inventory, turnover rate, handling return of merchandise, drug recalls, and days-on-hand.
		7.	understand the different medication distribution systems within the hospital
		8.	explain strategies for ensuring the integrity of the supply chain.
		9.	determine impact of the pharmaceutical return process

administration skills.		10.	practice intravenous (IV) admixture preparation, IV compatibility checking and compounding of sterile products according to the national and international standards
	2-2-3	11.	complete all steps in the final check of medication order to ensure accuracy.
	2-2-4	12.	perform pharmaceutical calculations related to medication orders, including pediatric medications doses by weight.
		13.	select the appropriate dosage form and regimen according to the patient"s conditions and history.
1.1 Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient- centered care. **2.5 Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-6** **2-5-2**	14.	conduct an effective and thorough literature search in many resources and utilize appropriate drug information resources
		15.	Identify, clarify and respond to drug information questions.
2.4 Actively share professional decisions and proper actions to save patient's life in emergency situations including poisoning with various xenobiotics, and effectively work in forensic fields. **3.1 Apply the principles of body functions to participate in improving health care services using evidence-based data.**	**2-4-1** **3-1-1** **3-1-2**	16.	handle narcotics and psychotropic medications according to the applicable laws and regulation and determine if modifications are needed to improve their security.
		17.	implement and work according to the infection prevention and control requirements and standards.
3.1 Apply the principles of body functions to participate in improving health care services using evidence-based data. **3.2 Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**3-1-1** **3-1-2** **3-2-1** **3-2-2**	18.	collect, retrieve, and review relevant patient information from different sources (patient interview, patient chart, electronic system if available).
		19.	substitute appropriate generic products according to the formulary system

3.2 **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**3-2-1** **3-2-2** **3-2-3** **3-2-5** **3-2-6**	20.	identify potential and actual drug-related problems including, potential interactions with other drug therapy or disease states, contraindications, and duplicate therapy and recognize medication errors and act accordingly.
		21.	identify adverse drug events including drug allergies and prevention strategies.
		22.	provide effective medication counseling and patient education showing empathy.
		23.	demonstrate knowledge of commonly used medications, formulations, and drug products in Egypt, in terms of their generic name, trade name, indications, and side effects.
4.1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1**	24.	manage time well and demonstrate an appropriate level of preparedness.
	4-1-2	25.	work effectively as a team member in an efficient and interactive way to perform the required tasks.
4.2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	26.	communicate properly verbally, non-verbally, and written being an active listener.
4.3 **Express self-awareness and be a life-long learner for continuous professional improvement.**	**4-3-1**	27.	accept constructive criticism; and respond to feedback to modify behaviors.

Clinical Pharmacy Rotation in Adult General Medicine (and other rotations viz. Cardiology and Cardiovascular/ Gastroenterology and Hepatology/ Nephrology and Urology/ Infectious Diseases/ Pediatrics and Neonates/ Geriatrics/ Neuropsychiatric/ Obstetrics and Gynecology Rotations

Competencies	**Key elements**	**Performance Evaluation Elements**	
		No	**Objectives**
1.1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-2** **1-1-4** **1-1-5**	1.	demonstrate appropriate understanding of disease state in terms of disease terminology, pathophysiology, symptomatology, and drug therapy.

2.1 **Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.**	**2-1-1** **2-1-2**	2.	work collaboratively with other healthcare professionals daily in various medical departments and respect each other‟s roles and responsibilities.
		3.	apply professional ethics as they relate to the practice of pharmacy, in terms of respecting patients‟ rights and confidentiality of their data.
		4.	adhere to legal, and regulatory requirements.
2.4 **Actively share professional decisions and proper actions to save patient's life in emergency situations including poisoning with various xenobiotics, and effectively work in forensic fields.** **3.1** **Apply the principles of body functions to participate in improving health care services using evidence-based data.** **3.2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**2-4-2** **2-4-3** **3-1-4** **3-2-1** **3-2-2**	5.	review and retrieve information from patient charts.
		6.	interpret vital signs and laboratory values and adjust medications accordingly.
		7.	assess patient/patient medical history to identify disease/condition, other medical problems and/or therapies or potential drug therapy problems and organize information.
		8.	participate in the formulation and selection of rational pharmacotherapeutic plan to include drug, route, dose, interval, therapeutic endpoint and monitoring parameters in assigned patients.
2.2 **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2.4** **Actively share professional decisions and proper actions to save patient's life in emergency situations including poisoning with various xenobiotics, and effectively work in forensic fields.** **3.2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**2-2-4** **2-4-3** **3-2-2** **3-2-1** **3-2-2**	9.	evaluate and adjust doses of different medications and accurately perform pharmaceutical calculations related to medication orders, including pediatric and renal patient orders (based on ideal body weight (IBW), and creatinine clearance (CrCl)).
		10.	perform therapeutic drug monitoring and pharmacokinetic based dosing.
		11.	consistently and accurately identify potential drug- related problems including potential interactions with other drug therapy or disease states, and duplicate therapy and recognizing medication errors and prioritizing the problem list.
		12.	recognize and report adverse drug reactions (ADRs) on the appropriate ADR form as directed by the preceptor.
		13.	conduct medication reconciliation and drug use evaluation accurately and in a timely manner.

1.1 **Integrate knowledge from basic and applied pharmaceutical and clinical sciences to standardize materials, formulate and manufacture products, and deliver population and patient- centered care.** **2.5** **Contribute to pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-6** **2-5-2**	14.	identify and utilize appropriate drug information resources and demonstrate ability to research, review, and critically evaluate pertinent drug literature to respond to drug information questions.
		15.	respond proficiently to mruf information requestsfrom available resources.
3.2 **Provide counseling and education services to patients and communities** **about safe and rational use of medicines and medical devices.**	**3-2-5** **3-2-6**	16.	provide effective medication counseling and patient education about safe and proper use of medicines including OTC preparations and medical devices.
4.1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	17.	manage time well and demonstrate an appropriate level of preparedness.
		18.	implement consistent scientific method for critical analysis of information and solving problems
4.2 **Effectively communicate verbally, non- verbally and in writing with individuals and communities.**	**4-2-1** **4-2-2**	19.	communicate properly verbally, non-verbally, and in written being an active listener.
		20.	demonstrate sensitivity, respect, and show empathy during communication with patients
		21.	utilize technologies and media to demonstrate effective presentation skills
4.3 **Express self-awareness and be a life-long learner for continuous professional improvement.**	**4-3-1** **4-3-2**	22.	practice self-assessment, accept constructive criticism; and respond to feedback to modify behaviors.
		23.	accomplish assignments, tasks and topics research that require independent work and functioning for future professional development

B) Elective Rotations

Pharmaceutical Product Development Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	Please rate the trainee's performance according to the mentioned activity
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**1-1-3** **1-1-6** **2-2-1**	1	Review the specifications of raw materials and pharmaceutical products according to the latest editions of pharmacopoeias.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-3** **1-1-6** **2-2-4** **2-3-2** **2-5-1** **2-5-2** **2-5-3**	2	Know and follow references and guidelines for conducting performance, stability, comparative dissolution, and bioequivalence studies on pharmaceutical products.
2-2 **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for** **dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and**	**1-1-1** **1-1-3** **1-1-6** **1-1-7** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	3	Recognize the development process stages for new formulations, from initial planning to production.
		4	Investigate any problem that appears during the production of new pharmaceutical products and take preventive measures (Troubleshooting).

synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations. **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	5	Participate in the design and conduct of laboratory experiments on different pharmaceutical dosage forms, for example, dissolution, disintegration, friability, hardness, content uniformity, weight variation, etc.…
		6	Engage in conducting stability studies on finished products, follow-up them in stability
		7	Participate in designing and conducting comparative dissolution and/or bioequivalence studies for pharmaceutical products (Generic versus Innovator).
		8	Collaborate in the analytical method development and validation.
	1-1-1 **1-1-3**	9	Apply Good Laboratory Practices (GLP) and Good Pharmaceutical Manufacturing Practices (cGMP).
	2-2-2 **2-3-2** **2-5-1**	10	Identify and prepare the Common Technical Document (CTD & eCTD files) and their components.
2-2 **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**2-2-4**	11	Participate in recording, analyzing, and interpreting test results and processing them statistically.
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	12	Demonstrate responsibility, cooperate, and integrate effectively with research team members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	13	Demonstrate effective communication skills verbally, non-verbally with research team members.

Quality Management in Pharmaceutical Industry Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	Please rate the trainee's performance according to the mentioned activity
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient- centered care.** **2-2** **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **2-2-1** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	1	Identify and participate in QC tests of raw materials: procedures, significance, and troubleshooting.
		2	Recognize and collaborate in QC tests of finished products: procedures, significance, and troubleshooting.
		3	Engage in the analytical method development and validation.
	1-1-1 **1-1-3** **2-2-2** **2-3-2** **2-5-1**	4	Apply Good Laboratory Practices (GLP) and data integrity in QC.
	1-1-1 **1-1-3** **1-1-7** **2-2-2** **2-2-3** **2-3-2** **2-5-1**	5	Monitor different production lines.
	1-1-1 **1-1-3** **1-1-7** **2-2-2**	6	Understand the basic concepts of Total Quality Management (TQM), Quality Management System (QMS) and the risk management system (RMS).
		7	Apply standard operating procedures (SOPs) for deviation, complaint, recall, and change control.
		8	Execute internal auditing and prepare quality reports.
	1-1-1 **1-1-3** **2-2-2**	9	Perform Process Validation: protocol, sampling, and final report.

	2-2-3 **2-3-1** **2-3-2** **2-5-1** **2-5-3**	10	Perform Cleaning Validation: sampling, and final report.
		11	Participate in Room Qualification or Machine Qualification: protocol and final report.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient- centered care.**	**1-1-1** **1-1-3** **2-2-2**	12	Prepare quality control (QC) reports.
		13	Recognize Good Documentation Practice and Data Integrity.
2-2 **Standardize pharmaceutical materials, formulate, and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**2-5-1**	14	Prepare operating records for manufacturing products (Batch Records).
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **2-2-3** **2-5-3**	15	Identify and apply standard operating procedures (SOPs) for operation, validation and calibration of different instruments and devices.
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	16	Demonstrate responsibility, cooperate, and integrate effectively with research team members
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	17	Demonstrate effective communication skills verbally, non-verbally with research team members.

Pharmacovigilance Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	Please rate the trainee's performance according to the mentioned activity
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-2** **1-1-4** **1-1-6** **1-1-7**	1	Determine, measure, and compare the costs, risks, and benefits of different treatment programs.
2-1 **Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.** **3-2**	**2-1-1** **2-1-2** **2-1-3** **2-5-1** **2-5-2** **3-2-1** **3-2-2** **3-2-3** **3-2-4**	2	Monitor the safety, quality, and efficacy of marketed pharmaceutical products.
Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.	**1-1-2** **1-1-4** **1-1-6** **2-1-1** **2-1-2** **2-1-3** **2-5-1** **2-5-2** **3-2-1** **3-2-4**	3	Monitor the serious adverse drug reactions (ADRs) of drugs by following-up on marketed pharmaceutical products.

1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.** **3-2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**1-1-1** **1-1-2** **1-1-4** **1-1-5** **1-1-6** **1-1-7** **2-5-1** **2-5-2** **3-2-1** **3-2-4**	4	Receive and inspect follow-up reports on the quality of pharmaceutical products with decision-making in case of the occurrence of ADRs.
	1-1-1 **1-1-2** **1-1-4** **1-1-5** **1-1-6** **1-1-7** **2-5-1** **2-5-2** **3-2-1** **3-2-2** **3-2-3** **3-2-4**	5	Prepare the Risk Management Plan (RMP) document.
		6	Prepare periodic safety update reports (PSUR) for pharmaceutical products.
		7	Understand the international vigilance guidelines and apply good pharmacovigilance practices (GPvP).
	1-1-1 **1-1-4** **2-5-1** **3-2-2**	8	Recognize the procedures of regulatory inspections and audits.
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	9	Demonstrate responsibility, cooperate, and integrate effectively with healthcare team members.

4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	10	Demonstrate effective communication skills verbally, non-verbally with healthcare team members.

Regulatory Inspection Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	**Please rate the trainee's performance according to the mentioned activity**
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-6** **2-5-1**	1	Identify the international institutions concerned with the registration and circulation of pharmaceuticals, such as WHO, EMA, FDA, EUDRA.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **2-3-2** **2-5-1**	2	Recognize current registration procedures of pharmaceutical and biological products, nutritional supplements, medical supplies, and cosmetics.
2-3	**1-1-1**		

Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations. **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products**	**1-1-6** **1-1-7** **2-3-2** **2-5-1** **2-5-2**	3	Understand the pharmaceutical inspection process in compliance with WHO requirements, and pharmacy laws.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-2** **1-1-3** **1-1-6** **1-1-7** **2-2-2** **2-5-1** **2-5-2**	4	Receive pharmaceutical products with physical examination and their certificates of analysis.
	1-1-1 **1-1-2** **1-1-3** **1-1-6** **1-1-7** **2-2-2** **2-3-2** **2-5-1** **2-5-2**	5	Prepare, cope, and manage the audit and inspection tools over pharmaceutical and biological products, nutritional supplements, medical supplies, and cosmetics, and their significance.
		6	Prepare regulatory inspection reports, warning letters, recalls and follow them up.
		7	Prepare and execute remediation plans.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical**	**1-1-1** **1-1-2** **1-1-6** **1-1-7** **2-2-2** **2-3-2** **2-5-1** **2-5-2**	8	Prepare, cope, and manage the audit and inspection tools over pharmaceutical establishments (companies – drug distribution stores – pharmacies, etc...).

products, and participate in systems for dispensing, storage, and distribution of medicines. **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**			
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	9	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	10	Demonstrate effective communication skills verbally, non-verbally with teamwork members.

Drug Discovery and Development Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	**Please rate the trainee's performance according to the mentioned activity**
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-5**	**1-1-1** **2-5-1**	1	Understand the drug discovery and development process in the light of legal and regulatory requirements.

Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.			
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **1-1-6** **2-2-1** **2-2-2** **2-2-3** **2-3-1** **2-3-2** **2-5-2** **2-5-3**	2	Discover and prepare lead compounds via chemical/biochemical synthesis, extraction from natural sources, fermentation, cell cultures, etc.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture**	**1-1-1** **1-1-3** **1-1-4** **1-1-5** **1-1-6**		

products, and deliver population and patient-centered care. **2-1** **Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**2-1-1** **2-1-2** **2-1-3** **2-2-1** **2-2-2** **2-2-3** **2-2-4** **2-5-2** **2-5-3**	3	Design and conduct *in vitro* experiments, preclinical and clinical studies on potential drugs.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**1-1-1** **1-1-3** **1-1-4** **1-1-5** **1-1-6** **2-2-1** **2-2-2** **2-2-3** **2-5-2** **2-5-3**	4	Apply computer-aided drug design or other suitable tools to enhance the safety and efficacy of potential drugs, and to reduce the production costs.
2-5 **Contribute in pharmaceutical research studies and clinical trials needed to**	**1-1-1** **1-1-6** **2-2-3**	5	Participate in recording, analyzing, and interpreting test results and processing them statistically.

authorize medicinal products.	**2-2-4** **2-5-2** **2-5-3**	6	Practice literature search and writing of scientific reports and/or research articles.
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	7	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	8	Demonstrate effective communication skills verbally, non-verbally with teamwork members.

Pharmaceutical Sales & Marketing Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	**Please rate the trainee's performance according to the mentioned activity**
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-6** **Perform pharmacoeconomic analysis and develop promotion, sales, marketing, and business administration skills.**	**1-1-1** **2-6-1** **2-6-2**	1	Understand the basics of pharmaceutical business administration.
		2	Identify the marketing strategies and tactics.
		3	Recognize the concepts of individual and group communication skills.
		4	Understand the concepts of customer value satisfaction, pricing models, and budgeting.
		5	Know and identify clients and customers in the healthcare system.
			Understand market research data and

		6	forecasting tools.
		7	Develop market segmentation and targeting.
		8	Identify the types of economic analyses and studies used in the field of Pharmacoeconomics.
		9	Participate in recording, analyzing, and interpreting collected data and processing them statistically.
		10	Understand managing retailing, wholesaling, and logistics of good distribution practice (GDP).
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-1** **Work collaboratively as a member of an inter- professional health care team to improve the quality of life of individuals and communities, and respect patients' rights.** **2-6** **Perform pharmacoeconomic analysis and develop promotion, sales, marketing, and business administration skills.** **3-2** **Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.**	**1-1-1** **1-1-2** **1-1-4** **2-1-1** **2-1-2** **2-1-3** **2-6-1** **2-6-2** **3-2-1** **3-2-2** **3-2-5**	11	Understand the art of medical advertising, and medicinal sales.
		12	Understand the work of scientific offices in medical advertising.

4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	13	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	14	Demonstrate effective communication skills verbally, non-verbally with teamwork members.

Pharmaceutical Production Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	**Please rate the trainee's performance according to the mentioned activity**
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**1-1-1** **1-1-3** **2-2-2** **2-2-3**	1	Identify the various production areas in the pharmaceutical manufacturing company: solid preparations (such as tablets and capsules), non-solid preparations (such as ointments, creams, and syrups), sterile preparations (such as ampoules and vials), gelatin capsules, and other products.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**			

2-2 **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.**	**1-1-1** **1-1-3** **2-2-2** **2-2-3** **2-3-1** **2-3-2**	2	Recognize the layout of production areas, and the workflow in different production facilities.
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.** **2-2** **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.**	**1-1-1** **1-1-3** **2-2-1**	3	Determine the production process operations starting from receiving the raw materials through the various manufacturing stages until reaching the finished product.
	2-2-2 **2-2-3** **2-2-4** **2-3-1** **2-3-2** **2-5-1** **2-5-3**	4	Apply product control during manufacturing (in-process control „IPC“ Tests), and the significance of each test.
2-3 **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5**	**1-1-1** **1-1-3** **1-1-6** **1-1-7** **2-2-1** **2-2-2** **2-2-3**	5	Examine production-related problems that may occur during manufacturing (Troubleshooting) and how to overcome them.

Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.	**2-2-4** **2-3-1** **2-3-2** **2-5-1** **2-5-3**		
	1-1-1 **1-1-3** **1-1-6** **2-2-2** **2-3-2** **2-5-1**	6	Apply good manufacturing practices (cGMP) and data integrity in production.
4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	7	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	8	Demonstrate effective communication skills verbally, non-verbally with teamwork members.

Quality by Design and Process Analytical Technology (QbD & PAT) Rotation

NARS Competencies	Key elements	Performance Evaluation Elements	
		No	Please rate the trainee's performance according to the mentioned activity
1-1 **Integrate basic and applied pharmaceutical and clinical sciences knowledge to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.**	**1-1-1** **1-1-3** **2-2-2** **2-2-3** **2-3-2** **2-5-1**	1	Recognize the concept of pharmaceutical quality by design (QbD) and describes its objectives.
		2	Identify the ICH guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality System).
2-2 **Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.** **2-3** **Handle and dispose biologicals and synthetic/natural pharmaceutical materials/products effectively and safely with respect to relevant laws and legislations.** **2-5** **Contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.**	**1-1-1** **1-1-3** **1-1-6** **1-1-7** **2-2-2** **2-2-3** **2-3-2** **2-5-1** **2-5-2** **2-5-3**	3	Design a quality product and its manufacturing process to consistently deliver the intended performance of the product to meet patient needs.
		4	Describe that critical material parameters (CMP) and critical process parameters (CPP) linked to the critical quality attributes (CQAs) of the product.
		5	Increase process capability and reduce product variability and defects by enhancing product and process design, understanding, and control.
		6	Analyze, evaluate, and interpret problems associated with the design of pharmaceutical products.
		7	Understand the quality risk management across the product lifecycle for drug products.
		8	Illustrate the principles and tools of quality risk management that can be applied to different aspects of pharmaceutical quality.
		9	Understand and analyze case studies related to Quality by design (QbD) approach for product development.

4-1 **Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.**	**4-1-1** **4-1-2**	10	Demonstrate responsibility, cooperate, and integrate effectively with teamwork members.
4-2 **Effectively communicate verbally, non-verbally and in writing with individuals and communities.**	**4-2-1**	11	Demonstrate effective communication skills verbally, non-verbally with teamwork members.