



جامعة الفيصل
Alfaisal University

كلية الصيدلة
College of Pharmacy

ADVANCED

PHARMACY PRACTICE EXPERIENCE ROTATIONS

MANUAL

2020-2021

APPE MANUAL

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Contact Information

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KFSH Pharmacy Training Coordinator

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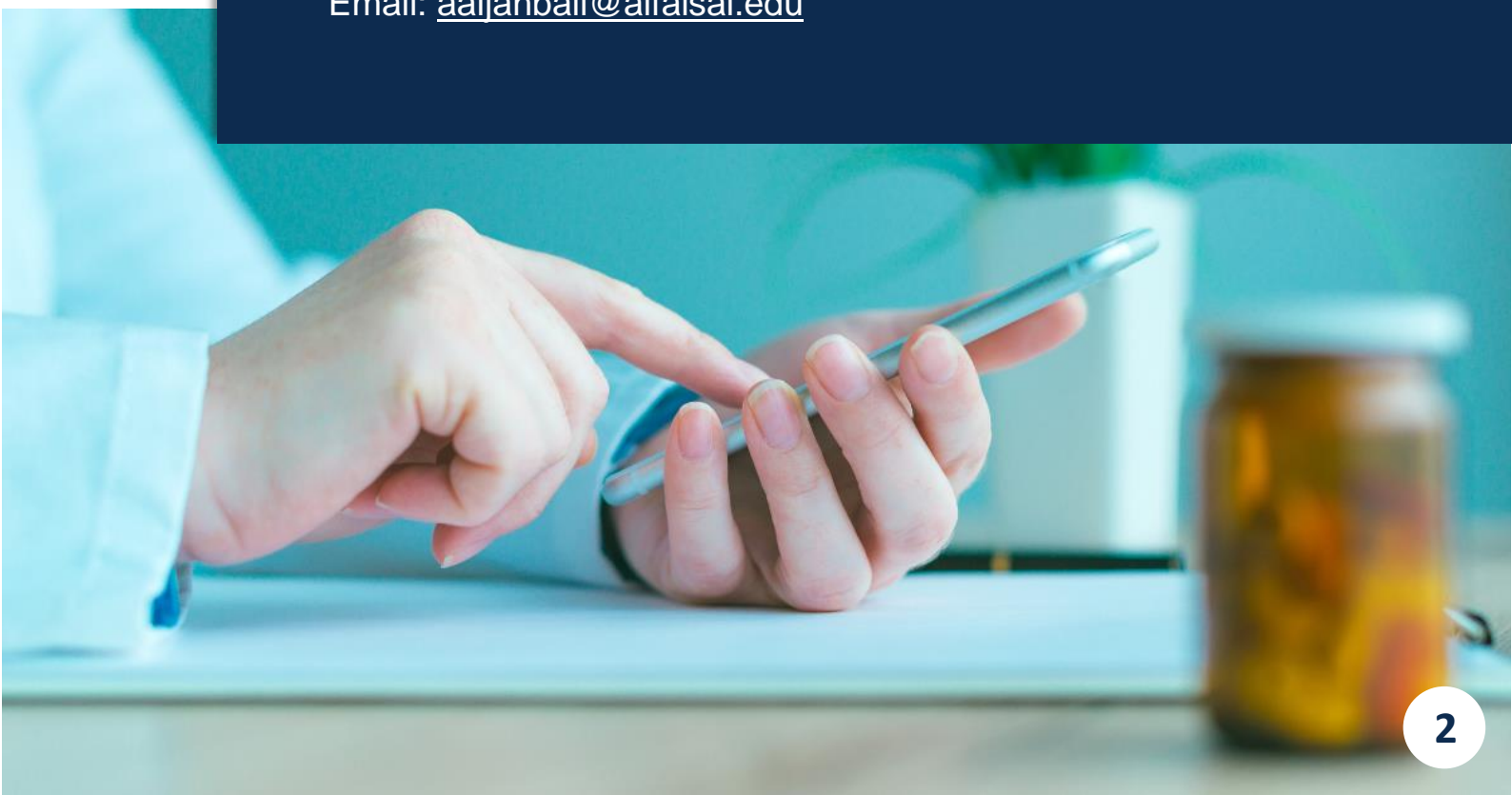
Email: hmuawad@kfshrc.edu.sa

COP Administrative Assistant

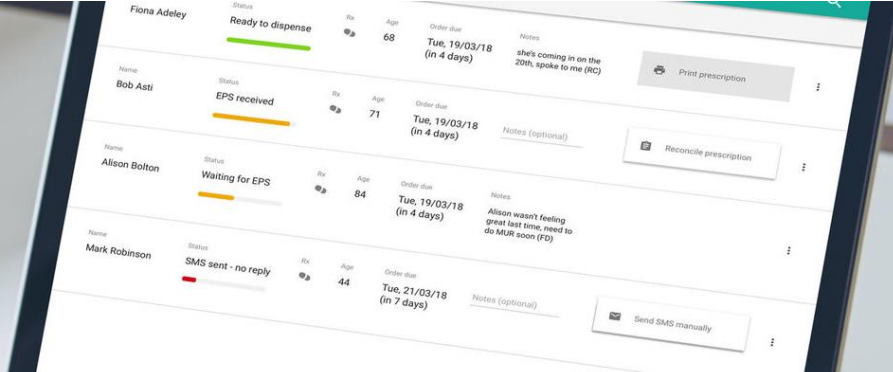
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APPE CALENDAR



APPE Calendar

Rotation Number	Start	End	Number of Weeks
1	21-June (2020)	23-July (2020)	5
Hajj Break	26-July (2020)	6-August (2020)	2
2	9-August (2020)	3-September (2020)	4
3	6- September (2020)	8-October (2020)	5
4	11- October (2020)	12-November (2020)	5
5	15- November (2020)	17-December (2020)	5
6	20- December (2020)	21-January (2021)	5
7	24- January (2021)	25-February (2021)	5
8	28- February (2021)	1-April (2021)	5
9	4-April (2021)	6-May (2021)	5

APPE Overview

College of Pharmacy focuses on the importance of experiential education in its curriculum plan. If a student has reached this stage successfully, it means he/she has already accomplished three introductory practice experience courses to start the next stage with nine advanced pharmacy practice experience rotations.

The advanced pharmacy practice experience plays an important role through combining knowledge learned during the programme and the introductory pharmacy practice experience. In addition, students practicing in a different variety of settings will help them in choosing their future career. These experiences also allow the student to develop further their communication skills with different patient populations and health care professionals.

During the advanced pharmacy practice experiences, students should be under a close supervision of the pharmacist/preceptor role models. The Advanced Pharmacy Practice Experience (APPE) Program at Alfaisal University College of Pharmacy provides an environment for the students in their sixth and final year, to combine their didactic knowledge, pharmacy practice skills, self-learning, with more responsibility. All will contribute greatly to develop their professional attitude for the future. The students will spend approximately 1800 hours in pharmacy practice areas including primary, acute and chronic care settings where pharmacists are delivering patient care services to diverse populations. Also, elective non-clinical areas are offered including pharmacy administration and management, medication safety, automation and quality improvement.

APPE program begins in the summer following the completion of fifth year, and continues for 45 weeks. The APPE series consists of four core rotations given over twenty weeks (4×5) plus three selective rotations given over fifteen weeks (3×5) plus two elective rotations given over ten weeks (2×5).

Core Rotations	Selective/Elective Rotations
APP 001: Ambulatory care APP 002: General internal medicine APP 003: Institutional pharmacy practice APP 004: Community pharmacy practice	APP 005: General paediatrics APP 006: Infectious diseases APP 007: Cardiology APP 008: Adult critical care APP 009: Paediatric/ neonatal critical care
Elective Rotations (APP 010- APP021)	
Organ transplant Adult haematology/oncology Nephrology Acute care TPN Pharmacy administration and management	Pharmacy automation and informatics Surgery Drug information Investigational drug services Medication safety Pharmacy quality improvement



APPE Policies and Regulations

PREREQUISITES

1. Successful completion of all the 3 introductory practice experiences (IPP 489, IPP 596, IPP 5X5)
2. Completion of required immunizations
3. Certification in basic life support
4. Completion of the pre-rotation online rotations through the WHO website:
 - Standard precautions: Hand hygiene
 - COVID-19: How to put on and remove personal protective equipment

DOCUMENTS REQUIRED

Each student must submit a clear copy of their civil ID card or a copy of the passport

ROTATION SCHEDULING

Students are given a two-week time period to rank their preferences for the selective and elective rotations. The students are placed according to the availability of the rotation/preceptor. A copy of the schedule will be distributed to students at least one month prior to the internship.

SCHEDULE CHANGES

From the day the schedule is available, students have 1 week to make changes to their schedule according to the process outlined in APPE orientation. After this 1-week period, rotation changes will only be made in the case of medical or family emergencies or cancelled rotations.

STUDENT ATTENDANCE

- Attendance is MANDATORY.
- If the student is being late due to a transportation issue, the student MUST call the site or the preceptor as soon as possible prior to the scheduled arrival time to the site.
- Students are required to spend a minimum of 40 contact hours per week at the site (200 hours per rotation). Students are not permitted to work “ahead” hours to shorten their rotation.
- Students must notify the preceptor, as soon as possible, of any excuse for absence, any absence must be approved by the preceptor BEFORE YOU COMMIT
 - Student should be prepared to provide documentation to verify reasons for absence. All absences requests and documentation should be included with the student evaluation.
- Any missed time must be made up prior to the end of the current experience. The make-up time will be coordinated with the preceptor’s schedule and approved by site education coordinator.
- Student should be aware that repetitive tardiness or non-compliance with the attendance policy may result in an incomplete (I) grade until all APPE requirements have been completed or failing the rotation.
- Summer holiday DO NOT APPLY while on APPE.

- Students are expected to be punctual and document all his/her hours. The attendance sheet for each rotation should be emailed to malfagih@alfaisal.edu and aaljahbali@alfaisal.edu at the end of each rotation (signed by the student and the preceptor/institution training office).

ABSENCES TYPES

1. Emergency Absence

- Sickness or a family emergency (death of a close family member)
- Students should make a sincere effort to notify the preceptor as soon as possible on that day, and on every day they will be absent thereafter
- Student MUST provide documentation from a health care provider (signed and stamped) or relevant third party for these types of absences. Student should make up days of absence at the discretion of the preceptor.

2. Planned Absence

- Students planning to attend a professional meeting or schedule residency or career interviews during internship should request this time off from the preceptor.
- Student must submit a request for leave of absence to KFSH Pharmacy training coordinator at least 2 weeks before the planned date of leave (see Appendix B)
- Time off for personal or social reasons should not be planned during rotations and therefore will not be approved.

3. Unexcused Absences

- **Any** failure to be present on a scheduled rotation day(s), failure to notify the preceptor of an illness or emergency in a reasonable period of time, or any absence that was not approved by the preceptor
- Unexcused absences are NOT tolerated by any means and student may be dismissed from the rotation in such event with a FAIL grade. Preceptors should immediately notify the university if such absences occur.

CORONA AND EPIDEMICS

- **In the unfortunate case where flu or Corona epidemic occur, students need to follow site specific policy. No suspension from training is permitted unless instructed by the site. Please ask your site education coordinator if such situation occur.**
- **Students should always consider standard precautions to prevent and minimize transmission of infectious microorganisms through the following simple steps:**
 - Hand hygiene
 - The use of disposable gloves where appropriate
 - The use of face mask where appropriate
 - Complete necessary vaccination (if applicable)

If you have any questions, always ask your preceptor.





Student Responsibilities

1. Observe dates for registration schedule. Register for APPE courses and initiate contact with the university if any problem arises during registration.
2. Contact the site education coordinator at least 2 weeks prior to the start of the rotation to help plan for the first day and discuss expectations of the experience. Inquire about introductory or review readings and site policies that they would need to know prior to orientation
3. Exhibit professionalism in manner and dress. Demonstrate a level of maturity required in a professional practice environment. White lab jackets are required of all students while on their assigned APPEs.
4. Punctuality is essential. Notify the preceptor, as soon as possible, of any excuse for absence. Schedules will be determined by the preceptor. Any missed time must be made up prior to the end of the current experience. The preceptor may, at their discretion, deduct 10 points from a final grade for repeated absence.
5. Keep in mind that the primary objective of these courses is learning. Learning is not a passive process; it occurs actively and requires ongoing commitment by the student.
6. Recognize that the optimum learning experience requires mutual respect and courtesy between the preceptor and the student.
7. Wear a nametag, identifying student as a pharmacy student at all times in their assigned practice environment. The dress code will be determined and enforced by the assigned preceptor as each site may have different requirements.
8. Respect any and all confidences revealed during the practice experiences, including pharmacy records, professional policies, patient data, patient charts, etc.
9. Encourage clear, concise and effective communication with all persons involved at the assigned sites, including pharmacists, physicians, other health professionals, patients and other students.
10. Be responsible for all transportation, housing and other incidental expenses associated with APPEs
11. Do not make professional decisions without prior discussion with the preceptor, particularly when filling prescriptions or medication orders, or advising patients and other health care providers on therapeutic and drug related matters.
12. Take the initiative in communicating with physicians and patients, but do not step beyond the bounds of professional courtesy or common sense.
13. Be constantly alert to the laws, regulations and policies that govern the practice of pharmacy, and seek clarification of any points that are not clear.

STUDENT

14. Be responsible for adhering to his/her predetermined schedule. It may be necessary to devote more than the scheduled time to take advantage of certain experiences and exposures.
15. Master the basic pharmacy procedures as soon as possible so that time can be devoted to those aspects of the practice of pharmacy which involve professional judgment and the decision-making process.
16. Do not accept or receive any form of payment, financial or otherwise, from the assigned preceptor during any APPEs
17. Be responsible for submitting the evaluation form to the site preceptor.
18. The student is responsible for maintaining confidentiality in accordance with the policies of the practice site. Inappropriate disclosure of protected health information or other related information could result in a student's dismissal from the practice site. The Confidentiality Statement must be signed and dated by the student prior to participating in the experiential program.
19. Evaluation forms are due on or before 12:00 PM on the Sunday after the end of the experience.
20. Be responsible for evaluating your preceptor on or before 12:00 PM on the Sunday after the end of the experience. Evaluations must be completed to receive a final grade.
21. Be responsible for keeping copies of all submitted activities in a portfolio. Portfolios should be submitted on or before 12:00 PM on the Sunday after the end of the experience. Portfolios must be completed to receive a final grade.
22. Letters of guidance will be issued to students upon a complaint from a preceptor regarding the students' lack of compliance with the above guidelines. Copies of the letters will be sent to the student, Dean's office, and preceptor. Letters of guidance may be cause for disciplinary action.
23. Students are prohibited from contacting current or potential preceptors to whom they are not assigned for the purpose of obtaining placement for themselves for any APPEs
24. Students violating this policy will be referred to the appropriate college committee for review.
25. Students are responsible for all material in this manual





Preceptor Responsibilities

1. The preceptor should encourage the principles of professional ethics and serve as a role model.
2. The preceptor should expose student(s) to all aspects of professional practice and serve to facilitate learning experiences.
3. The preceptor should ensure objectives of the student experience are discussed with all employees to avoid misunderstanding and conflict about the students' role.
4. A preceptor must be willing to mentor student(s).
5. The preceptor must supervise the students' activities at all times; however, the preceptor may delegate this responsibility to another pharmacist or health care professional.
6. The preceptor should conduct or should arrange for an orientation for student(s) assigned. Topics to cover during orientation should include, but are not limited to preceptor expectations, standard operating procedures, and expected activities for student participation.
7. The preceptor is responsible for evaluation of student progress. Critique should be in the form of constructive feedback, and conveyed to the student in private, whenever possible. Feedback should be given on an ongoing basis. The preceptor must provide the student with a midpoint evaluation during the experience (approximately at week 3) and the final evaluation upon completion of the experience.
8. Preceptors are expected to maintain a representative portfolio of student work completed at the site.
9. The preceptor may use his/her discretion in allowing off-site experiences such as continuing education seminars, pharmacy conferences, etc. to count toward the experience requirements.
10. Preceptors must have email addresses and internet access.
11. The preceptors must assist Alfaisal University, College of Pharmacy in the achievement of the educational goals, objectives, and outcomes set forth and to provide a professional environment for the training of the students.
12. The preceptors must provide evidence of a desire to continue the broadening of his/her professional education and of an active involvement in a patient-oriented practice.
13. The preceptor helps and guides college of pharmacy regarding the need for letters of guidance if required to be issued

Preceptor Guidelines for Orientation Meeting

1. Schedule an orientation for students on day 1 of the APPE.
2. Develop a schedule with the student that is agreeable.
3. Provide the student with safety information about the area and site, including the facility safety office phone and emergency number (if applicable).
4. Provide information regarding preceptor expectations and expected activities the student should participate in.
5. Provide the student with other general information about the facility.
6. Discuss the student's previous pharmacy experiences.
7. Tour the facility and introduce the student to those individuals with whom they will be interacting.
8. Orient the student to the general operation of the pharmacy and facility. Orient the student to your policy and procedures.
9. Orient the student to the duties of other personnel in the facility.
10. Orient the student to the communication system within the facility (telephones, computers, messenger service, etc). Provide the student with information about emergency numbers on site.
11. Orient the student to cafeteria, personal care areas and library facilities (if available). Include guidelines on the use and availability to students for each of these areas.
12. Explain the facility's record keeping system if applicable.
13. Explain the facility's inventory control system if applicable.
14. Explain the guidelines for patient contact in the facility if applicable.





Practice Site Responsibilities

1. The practice site must meet all standards set by appropriate governmental, regulatory, and accrediting agencies.
2. All practice sites must reflect a professional image.
3. The experience sites should have facilities to provide a wide range of pharmaceutical services such as, but not limited to:
 - a) Dispensing services or a contemporary drug distribution system: The pharmacy should employ and maintain an inventory system (regular and systematic means of reviewing stock levels; system for ordering direct from manufacturer and/or from wholesaler; method of determining most economical turnover of stock for various sections of the pharmacy; etc).
 - b) Patient profile review mechanisms: The pharmacy must maintain and utilize patient or family medication record systems for drug therapy monitoring purposes and, in addition, should have an area set aside for patient consultation.
 - c) Learning and information resources: Appropriate reference materials must be available for use in supplying drug information to the patient, physician or allied professionals. The pharmacy should supply drug and health related information for the needs of its patients, perhaps by literature or brochure displays, mailings to clients, workshops, etc. Recommended computer resources: Access to the Internet, Microsoft Office and Excel, or equivalent is recommended, as well as access to scientific periodicals.
 - d) Clinical pharmacy services: The pharmacy should strive to achieve outcomes that improve patients' quality of life and optimise disease control. The scope of which should include:
 - Participating in drug therapy decisions
 - Selecting the drug product dosage form
 - Determining the dose and dosage schedule
 - Monitoring the patient to maximize compliance with therapy instructions
 - Monitoring the patient to detect adverse drug reactions and drug interactions
 - Monitoring the patient to enhance the probability that therapy proceeds with established therapeutic objectives
 - Providing patients with effective transitions of care, thus playing an active role in minimizing adverse drug events from occurring when patients transition from one level of care to another
4. Where applicable, the pharmacy should have procedures to provide for the appropriate handling of pharmaceutical waste.
5. Where applicable, the site should utilize and actively maintain a formulary system.

Policy for Using Computing Resources at Experiential Sites

The computing resources of your experiential site are intended to be used for programs of instruction, research and to conduct legitimate business. Students are responsible for seeing that these computing resources are used in an effective ethical and legal manner. Students must be aware of the legal and moral responsibility for ethical conduct in the use of computing resources. Students have a responsibility not to abuse the network and resources, and to respect the privacy, copyrights, and intellectual property rights of others.

Computing Resource Policy Violations:

- For purposes other than the experiential site's program of instruction, research and legitimate business of the site
- To harass, threaten or otherwise cause harm to specific individuals or classes of individuals
- To impede, interfere with or otherwise cause harm to the activities of others
- To download, post or install to experiential site computers or transport across experiential site network, material that is illegal, proprietary or violates copyrights or otherwise damaging to the experiential site
- To recklessly or maliciously interfere with or damage computer or network resources or computer data, files or other information

Examples of Policy Violations:

- Using computer resources for personal reasons
- Sending email on matters not concerning legitimate business or the experiential site
- Sending an individual or group repeated or unwanted (harassing) email
- Accessing or attempting to access another individual's data or information without authorization



Assessment and Evaluation

Grading System

APPE rotations are graded on a PASS/FAIL System. The evaluation system focuses on the students' ability to demonstrate competent performance of the curricular outcomes and successful completion of the program. The rotation minimum passing score is 70%

Student's required activities are to be graded separately; completion of such activities is a REQUIREMENT to pass the rotation. Even though activities grade are not showing in the final calculation of the grade, not fulfilling this part will risk the student having an INCOMPLETE grade.

Incomplete Grading: A student receiving an incomplete for a justified reason will be provided with instructions as well as a timetable from their preceptor as to how the incomplete will be changed to a passing grade. The preceptor will inform the university when the student training has been completed.

Evaluations

- Preceptors should fill a final evaluation at the end of the rotation
- Students should fill an evaluation of the site and preceptor at the end of the rotation

Required Activities

Clinical Rotations

- Observe/shadow the preceptor in performing clinical pharmacy practice duties.
- Perform clinical pharmacy practice duties under the supervision of the preceptor.
- Conduct at least 3 SOAP notes
- Conduct at least 5 of the following: medication history/patient interview/ patient counseling/medication reconciliation
- Answer at least 5 drug information queries
- Perform at least one formal presentation (e.g.: patient case, journal club, topic review or in-service education)

Non-Clinical Rotations

- Observe/shadow the preceptor in performing duties.
- Perform rotation duties under the supervision of the preceptor.
- Perform at least 1 assignment related to the rotation type
- Perform at least one formal presentation

Ambulatory Care Rotation

- Observe/shadow the preceptor in performing ambulatory care duties.
- Perform ambulatory care duties under the supervision of the preceptor.
- Conduct at least 2 patient counseling sessions

Institutional Pharmacy Rotation

- Observe/shadow the preceptor in performing inpatient pharmacy practice duties.
- Perform inpatient pharmacy practice duties under the supervision of the preceptor.



Portfolio Checklist

- ✓ Student CV and career objectives
- ✓ Patient care documentation:
 - Direct patient interaction – e.g. medication history, med reconciliation, patient counseling and/or MTM evaluation
 - Patient care notes – e.g. SOAP, pharmacokinetic, renal dosing, anticoagulation management, therapy monitoring, IV to PO switches
 - ADR/ Medication Error reports
- ✓ Presentations preformed
- ✓ Educational materials (brochures, flyers.)
- ✓ Any of the following documentations
 - Formulary Management (P&T Committee) Material – e.g. drug monograph, therapy protocol review/development, QA activity
 - Newsletter article
 - Medication Use Evaluation (MUE)
- ✓ Reflection paper (at least one page, single spaced, 12-pt font) explaining:
 - ✓ APPE experience with appropriate detail and specific examples (i.e. expectations vs. reality, ability to complete objectives, etc)
 - ✓ What you learned from the experience
 - ✓ Evaluate yourself and your role in the practice of pharmacy at this point
 - ✓ Examples of how the experience ties to past didactic work and/or previous healthcare/service/life experiences
 - ✓ Interactions with other healthcare professionals and pharmacists' roles on the healthcare team
 - ✓ Impact of the experience on your pharmacy career/care of future patients

Rotations Description

Rotations		Description
Clinical Rotations		<p>In a clinical rotation, the student should actively participate in the delivery of patient centred care according to the setting and type of patients (hospitalized, acute care, ambulatory).</p> <p>Appropriate pharmaceutical care should be delivered through: patient assessment, drug therapy assessment and development, implementation, and monitoring drug therapy plans</p>
Non-Clinical Rotations	Drug Information	This rotation aims to develop and refine student's ability to find, analyse, and communicate appropriate medication information to healthcare professionals and the public in a verbal or a written manner.
	Pharmacy Administration and Management	This rotation gives the student an opportunity to acquire first-hand experience in the managerial and administrative aspects of pharmacy practice.
	Pharmacy Automation and Informatics	This rotation exposes students to the evolution of organizations' medication-use systems by applying pharmacy informatics principles, standards, and best practices.
	Medication Safety	This rotation will give the student chances to develop his/her understanding of medication safety issues in hospitals and clinics.
	Pharmacy Quality Improvement	This rotation enhances the students understanding of QI concepts, their familiarity with the pharmacy QI, and to gain practical experience with root-cause analysis and QI initiatives.



APPENDIX A: PLANNED ABSENCE FORM

I am requesting to be absent during the following date/period for the following reason(s):

- ☐ Health related absence (include the hospital report/appointment)
- ☐ Attending a pharmacy conference in Riyadh (include registration if possible –unpaid, until approval)
- ☐ Attending a pharmacy conference abroad (Include registration)
- ☐ Job Interview (Include a copy of the email you received from the site)
- ☐ Residency interview (include a copy of the email you received from the site)
- ☐ Attend a college meeting
- ☐ Other: (please attach a detailed document)

I made arrangement with my preceptor (name) to make up the time I missed as follows:

- ☐ Attend on Saturday(s) on the following date(s):
- ☐ Staying late for hours on the following days:
- ☐ Other arrangement, please describe in details: (attach a document)

I understand that this form must be completed and emailed to HMuwad@kfshrc.edu.sa AT **LEAST 2 WEEKS PRIOR TO THE PLANNED LEAVE.**

Submitting this form does not guarantee approval of the absence from the rotation. Students should not proceed until approval has been provided by the KFSH pharmacy training office.

Student Name: Student Signature:
Preceptor Name: Preceptor Signature:

Forward completed form to: HMuwad@kfshrc.edu.sa

FOR KFSH PHARMACY TRAINING OFFICE USE

☐ Request Approved ☐ Request Denied, Reason: :

Signature: :

Date: :

APPENDIX B: HELPFUL RESOURCES FOR STUDENTS

Preceptor may use different evaluation forms specific to their site. These forms are included to guide and help students.

Appendix C-1: Case Presentation Evaluation Criteria

Appendix C-2: Journal Club Evaluation Criteria

Appendix C-3: Example of Drug Monograph

Appendix C-4: Patient Encounter Data Collection Form

Appendix C-5: Helpful Online Information Resources

APPENDIX B-1: CASE PRESENTATION EVALUATION CRITERIA

#	Criteria	Points Earned
1	Patient Presentation <ul style="list-style-type: none"> • Patient identification, CC, HPI, histories, ROS, VS, PE and lab/test results clearly presented • Detail of chronology of events 	
2	Discussion of patient-specific disease states/pathophysiology <ul style="list-style-type: none"> • Etiology, Epidemiology • Identification of risk factors • Signs and symptoms 	
3	Drug Therapy <ul style="list-style-type: none"> • Explain indications and rationale for patient's drug therapy • Relate problem list with drug therapy– evaluate the appropriateness of current regimen and identify alternative treatment regimens where required • Discuss mechanisms of action of drugs • Evaluate the dosing regimen including pharmacokinetic considerations • Identify drug induced effects if present and outline its management • Identify potential common or serious adverse drug reactions and recommend appropriate prevention strategies when indicated • Identify potential drug interactions 	
4	Monitoring <ul style="list-style-type: none"> • Identify appropriate parameters for monitoring of therapeutic effects (including the desirable endpoint and frequency of monitoring) • Identify appropriate parameters for assessment of adverse effects (including frequency of monitoring) 	
5	Patient Information & Counseling <ul style="list-style-type: none"> • Explain purpose(s) of drug therapy • Important instructions for use • Side effects and precautions • Self-monitoring parameters 	
6	Presentation Style <ul style="list-style-type: none"> • Organization • Voice projection, correct pronunciation • Ability to answer questions– can support with evidence from the literature • Ability to present without “reading” notes • Distracting mannerisms 	
7	Audiovisual <ul style="list-style-type: none"> • If handouts are used –they are organized and appropriately referenced • If overheads or slides are used –they are clear 	
Total		/100

APPENDIX B-2: JOURNAL CLUB EVALUATION CRITERIA

#	Criteria	Points Earned
1	Described the study design <ul style="list-style-type: none"> • Study title • Type of study • Study group allocations, drug doses, regimens, duration (if applicable) • Follow-up tests, laboratory and otherwise (if applicable) • Assessment of compliance (if applicable) 	
2	Described the purpose of the study and the study's hypothesis: The student should discuss the question that the investigators are asking and what the study is trying to show	
3	Briefly placed the study in context by giving an overview of the current state of knowledge regarding the study's hypothesis: The student should discuss the existing standard of care about the topic generating the study.	
4	Described the characteristics of the study population <ul style="list-style-type: none"> • Inclusion/exclusion criteria • Date study conducted, country (ies), center (s) • Demographics, drugs being taken, co-morbidities of the research subjects • Disease states and conditions that preclude participation in the study 	
5	Described the statistical tests used and their interpretation	
6	Identified potential sources of bias (confounding) <ul style="list-style-type: none"> • Described the sources and methods used for controlling or adjusting for bias. • Explained how investigators would overcome/control for bias in the study 	
7	Described the study's end point (s) and if they are, clinically meaningful to patients.	
8	Described the magnitude of the differences (effect size) between treatments or interventions and whether or not they were clinically meaningful <ul style="list-style-type: none"> • Explained how the practice might change based on the study's results 	
9	Discussed the dropout rate (loss to follow-up or response rate) in the study and its effect on the study results <ul style="list-style-type: none"> • Adverse effects • Accountability of the number of patients initiating and completing the study 	
10	Discussed whether or not the student agrees or disagrees with the investigators Conclusions and why <ul style="list-style-type: none"> • Whether the study has ethical consideration or not • Limitations and strengths of the study 	
11	Delivery: Voice: volume, speed, enunciation, pronunciation Language: Accuracy of terminology used. Makes a clear attempt to answer questions accurately. Accepts questions and comments in non-defensive manner	
Total		/100

APPENDIX B-3: SAMPLE P&T COMMITTEE MONOGRAPH

[Instructions: This is a generic template for P&T Monographs. Delete this and other bracketed instruction paragraphs when you are finished. Replace text in square brackets [] with your text. The brackets [] should be replaced too. Parentheses () should be left in the text. Just replace the text inside them.]

[HOSPITAL NAME]

FORMULARY MONOGRAPH

Generic Name (Brand) [Manufacturer]

Therapeutic Use: [Disease State(s) or Clinical Use(s)]

Similar Drugs: [List all applicable]

Issues for Consideration by the Formulary Committee:

- ☐ Should [generic name] be added to the formulary?
- ☐ Is there a specific therapeutic niche and/or subpopulation of patients to which its use should be restricted? If so, how are they to be defined/identified?
- ☐ Should [generic name] be declared to be therapeutically equivalent to [similar drug(s)]?

INDICATIONS

[Per FDA approved manufacturer's labeling. If appropriate, may include off-label indications, identifying them as such.]

CLINICAL PHARMACOLOGY

[Keep very brief. Focus on pharmacology which is clinically relevant to the drug's formulary status.]

PHARMACOKINETICS [Keep brief, bulleted. List only clinically relevant parameters.]

Route of Admin:

Peak Levels:

Time to Peak:

Elimination:

Half Life:

ADVERSE EFFECTS

Summary:

Monitoring:

Reported Adverse Effects:

Table 1:

Adverse Effect	Reported Incidence in Trials (%)	
	Drug Therapy	Placebo

ALLERGIES AND INTERACTIONS

AVAILABILITY AND DOSING

AVAILABLE PRODUCTS

THERAPEUTIC EFFICACY:

1. Text summary of the evidence from the clinical trials listed in the following evidence table.
2. Any background info needed to interpret the results, e.g., explanation of clinical scores used as trial endpoints, should be provided.

NOTE: Although this section appears before the table, you should prepare the table first, then write this summary afterwards, as this follows the logical flow from massive amounts of detailed input to more condensed, summarized output table II.

Summary of Published Evidence

[Note: This is a generic table format. You can change column headings, subdivisions, etc. as necessary to fit the data you are reporting. A general overview of these data including the key “take home” points for P&T members should be given in the section just above this table. Detailed comments about a particular study, such as weaknesses in data or study design, can be put in the right hand column of this table.]

Table 2:

Ref.	Drug Regimens	n	Duration	Demographics	Design*	End Points	Results/Comments				NNT
1.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		<ul style="list-style-type: none">• [text]• [text]	[Arm 1]	[Arm 2]	[Arm3]	[Arm 4]	
							x	x	x	x	
							x	x	x	x	
2.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		<ul style="list-style-type: none">• [text]• [text]	[Arm 1]	[Arm 2]	[Arm 3]	[Arm 4]	
							x	x	x	x	
							x	x	x	x	
3.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		<ul style="list-style-type: none">• [text]• [text]	[Arm 1]	[Arm 2]	[Arm 3]	[Arm 4]	
							x	x	x	x	
							x	x	x	x	
4.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		<ul style="list-style-type: none">• [text]• [text]	[Arm 1]	[Arm 2]	[Arm 3]	[Arm 4]	
							x	x	x	x	
							x	x	x	x	
5.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		<ul style="list-style-type: none">• [text]• [text]	[Arm 1]	[Arm 2]	[Arm 3]	[Arm 4]	
							x	x	x	x	
							x	x	x	x	

*Study design abbreviations: DB = double-blind, RCT = randomized trial, PC = placebo-controlled, PG = parallel -group, XO = crossover.

Economic Evaluations

[Note: This is similar in format to Table 2. Since pharmacoeconomic studies vary considerably more in format than clinical trials, you should feel free to change this around. Delete the columns that don't apply. A general overview of these data including the key “take home” points for P&T members should be given in the section just above this table. Detailed comments about a particular study, such as weaknesses in data or study design, can be put in the right hand column of this table.]

Table 3:

Ref.	Drug/Treatment Arms	n	Time Horizon	Method*	Outcome Measures	Cost Measures	Results/Comments			
1.	1. [TEXT] 2. [TEXT] 3. [TEXT] 4. [TEXT]			[TEXT] • [text] • [text]		• [text] • [text]	[Arm 1] [Arm 2] [Arm 3] [Arm 4] x x x x x x x x			

*Method abbreviations: CEA=cost- effective analysis, CUA=cost-utility analysis, CBA=cost- benefit analysis,

CCA=cost-consequence analysis. Evidence grades: Grade 1 = randomized controlled trials, Grade 2 = nonrandomized concurrent studies, Grade 3 = historical cohort & case-control studies, Grade 4 = case series, Grade 5 = expert opinion. (move evidence grades to the clinical table)

SUMMARY OF PHARMACOECONOMIC STUDIES

[Summarize the key “take home” points from Table 3.]

BUDGET IMPACT/COST-EFFECTIVENESS MODELLING:

1. Describe type of model (Budget Impact, Markov, Decision Analysis, Simulation, etc...) [Show illustration of model, if applicable]
2. List key assumptions and elements of the model [What drives the model and its results?]

3. Describe sensitivity analyses and scenarios
4. List model results and conclusions
5. Discuss the projected impact of Formulary addition on the plan's drug budget.

SUMMARY AND RECOMMENDATION:

[Final summary of findings: a further condensation of the therapeutic efficacy and pharmacoeconomic summaries into one or more sentences.]

MONOGRAPH PREPARED BY:

[Author's name and title.]

REFERENCES: [List of references]

APPENDIX B-4: PATIENT ENCOUNTER DATA COLLECTION FORM

PATIENT'S DEMOGRAPHICS (Name, DOB, Age, Marital status, Education, Occupation, patient MRN)

CHIEF COMPLIANT (CC): Describe briefly your present symptoms?

DIAGNOSIS (Dx)

HISTORY OF PRESENTING ILLNESS (HPI)

Past Medical History (*ask about the presence of other illnesses, surgeries*)

Diagnosis	Date (Approximate)	Management

Previous surgeries

FAMILY HISTORY – *Are there any illnesses in the family – 1st degree?*

If living		
Relationship	Condition	Age of onset

MEDICATION HISTORY

Allergy:

Drug	Type of reaction

Recent vaccinations:

Present Prescribed Medications/ discontinued medications (include reason for stopping)/ OTC medications

Name	Dose (Strength, frequency, timing, route)	Start/End date	Indication	Helped? (a lot, some, no)	Recent changes (increase/decrease dose? Reason?)

Herbals/ vitamins and supplements:

Name	Dose	Reason for taking

Questions to ask to assess the adherence (adopted from: Morisky Medication Adherence questionnaire):

- ☐ Do you sometimes forget to take your medicine?
- ☐ People sometimes miss taking their medications for reason other than forgetting. Thinking about the past 2 weeks, were there any days you did not take your medicine?
- ☐ Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?
- ☐ When you travel/leave home, do you sometimes forget to bring along your medications?
- ☐ Did you take all your medications yesterday?
- ☐ When you feel like your symptoms under control, do you sometimes stop your medications? Do you ever feel hassled about sticking to your treatment plan?
- ☐ How often do you have difficult remembering to take all your medications?

Social History**Occupation****Mobility****Exercise****Smoking****Alcohol****Living situation****Activities of daily living****For women only:** *Pregnant? Planning to be pregnant? Breast feeding?***Objective data:**

- ✓ Vital signs
- ✓ Relevant and abnormal labs
- ✓ Relevant and abnormal physical examination notes

Drug Information Resources:

- ✓ Lexi-Comp Online
- ✓ Micromedex

Medical Databases:

- ✓ UpToDate
- ✓ BMJ best practice
- ✓ PubMed
- ✓ Cochrane Database of Systematic Reviews

Useful resources:

- ✓ [ClinicalTrials.gov](https://clinicaltrials.gov) a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world.
- ✓ [Drugs @ FDA](https://www.accessdata.fda.gov/drugsatfda/index.cfm) allows you to search for official information about FDA approved brand name and generic drugs and therapeutic biological products.
- ✓ [Drugs.com](https://www.drugs.com/pro/) Professional Resource Centre
- ✓ [FDA - For the Health Professional - Drugs](https://www.fda.gov/for-the-health-professional/drugs)
- ✓ [FDA - Paediatrics](https://www.fda.gov/for-the-health-professional/paediatrics)
- ✓ [LactMed - Drugs and Lactation Database](https://www.fda.gov/for-the-health-professional/lactation)
- ✓ [Medscape](https://www.medscape.com/)



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