UNMC COLLEGE OF PHARMACY  
ADVANCED PHARMACY PRACTICE EXPERIENCE SYLLABUS  
(Revised November 2014)  

COURSE TITLE: Clinical Research at Celerion Advanced Pharmacy Practice Experience (APPE)  

COURSE NUMBER: PHPR 788-01  

CREDIT HOURS: 4 semester hours  

CLOCK HOURS/WEEK: 40  
NO. OF WEEKS: 4  

REQUIRED/ELECTIVE: This APPE may serve as an Elective  

PREREQUISITES: P-4 standing and registration as an intern with the Nebraska Department of Health & Human Services.  

DESCRIPTION: Drug development process focusing on phase 1 clinical research in human subjects  

INSTRUCTORS: Jennifer Moorehead  

COURSE OBJECTIVES:  

Upon completion of this course, students will be expected to:  

1) Understand the different type of Phase 1 and 2 studies (first in human, radiolabeled, bioequivalence, drug-drug interactions, pharmacodynamics, food effect)  
2) Understand drug development processes (full cycle from the clinic – bio analysis – PK – stats – report writing)  
3) Understand federal regulations (FDA), protocols, participant safety, informed consents, and IRB practices  
4) Understand unique areas of pharmacy including clean room preparations (USP797), nuclear pharmacy and extemporaneous compounding  

PROGRAMMATIC OUTCOMES:  

See PHPR 788-01 Clinical Research at Celerion APPE Core Competencies document, attached as Appendix A.  

INSTRUCTIONAL METHODS:  

Instructional methods include review of early drug development and clinical pharmacology services, self-study, observation, problem solving, and participation in discussions with preceptor, and other health care professionals.  

ASSESSMENT MEASURES:  

Student competencies will be evaluated based on drug information skills, communication skills, and presentational skills. Subjective evaluation by the preceptor will be based on quality and completeness of projects and communication skills (written and verbal) with preceptor and others.  

Student's performance will be assessed in each category applicable to the rotation based upon the skills and knowledge demonstrated during the rotation; expectations may vary depending on the timing of the rotation during the rotation year (e.g., higher expectations during later rotations). The student will be evaluated at mid-rotation and at the end of the rotation using UNMC COP General APPE Mid-rotation and Final Evaluation forms (see Appendix B).
Mid-rotation evaluation: The preceptor will complete an evaluation of the student at mid-rotation, and the student is required to complete a self-assessment. The preceptor and student will meet to discuss these performance assessments.

The preceptor will notify the Director of Experiential Programs in cases where students are not progressing to satisfactory levels and are unlikely to successfully complete rotation outcomes to discuss student standing.

Final evaluation: At the conclusion of the rotation, the preceptor will complete the final evaluation, and the student is required to complete a self-assessment. The preceptor will interact with the student in an exit interview to discuss final grade.

GRADING METHODS:

Grading for this APPE is Pass/Fail/Honors:

Pass = Student meets or exceeds expectations
Fail = Student does not meet expectations
Pass with Honors is a grade assigned by a review committee within the Office of Experiential Programs (OEP) to not more than 20% of students completing Non-Direct Patient Care APPE rotations in a given semester. The OEP review utilizes the preceptor assessment forms and written justification of the honors recommendation. Pass with honors recommendations by preceptors should not be discussed with students at the time of the final rotation grading meeting; the student should only be instructed that they have passed.

INSTRUCTIONAL OBJECTIVES:

- Compare and contrast early stages of drug development (Phase 0, I and IIa)
- Describe the role of a Bioanalytical Services Department in the early stages of drug development including selection/determination of; assay (LC-MS/MS, immunoanalytical, etc.), biological medium (blood, urine, tissue, etc.), and entity (active drug, metabolite, biomarker).
- Describe the role of Clinical Pharmacology Sciences (modeling and simulation, study design and protocol development, data management, biostatistics, PK/PD, medical writing and reporting) in drug development.
- Explain program and project management, regulatory services, and drug development support necessary for early drug development.

COURSE OUTLINE:

Recurring activities:

- Protocol review and work-ups
- Sponsor visits
- Review of standard operating procedures & procedure guides
- Internal company meetings
- Investigational Drug preparation
- Investigational Drug packaging
- Various projects (i.e.: researching questions)

Department Overviews:

- Protocol Development Overview
- Project Management Overview
- Data Management Overview
- Study Manager Overview
- Admissions/Screening and Informed Consent Forms
- PK/PD Analysis Overview
- Biostatistics Overview
- Bioanalytical Overview
- Institutional Review Board (IRB) Overview
Appendix A

PHPR 788-01 Clinical Research at Celerion APPE Core Competencies

(January 2013, Approved February 2013)

Outcomes and competencies from the *University of Nebraska College of Pharmacy Doctor of Pharmacy (PharmD) Program Learning Outcomes and Competencies* that will be addressed in this course.

I. PHARMACEUTICAL CARE. Provide pharmaceutical care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound physical, chemical, biological, and therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving biomedical, sociobehavioral, and clinical sciences that may impact therapeutic outcomes.

A. Provide patient-centered care

2. Applied competencies

a. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to patients, their families, and other involved health care providers

1) Maintain awareness of evidence-based information resources, and use principles of evidence based medicine to assess information needs, formulate focused queries, acquire the best available evidence, evaluate the evidence and communicate it to the appropriate individuals

b. Design, implement, monitor, evaluate, and adjust pharmaceutical plans that are patient-specific and evidence based which ensure effective, safe, and economical care

1) Maintain awareness of evidence-based information resources and use principles of evidence based medicine to assess information needs, formulate focused queries, acquire the best available evidence, evaluate the evidence, and apply clinical expertise in using the evidence in providing patient-centered care

5) Carry out proper handling, compounding, and storage of common dosage forms, including those for newer drugs that are being approved at a rapid pace, such as proteins, peptides, and poorly water-soluble drugs requiring drug solubilization

6) Ensure that participants their agents understand the importance, nature and scope of the therapeutic plans being implemented, are informed about the benefits and risks of such plans, agree to participate in the implementation of the plans, and understand the appropriate use of medication included in the plans

e. Demonstrate the ability to practice within a selected clinical research setting within state and federal pharmacy regulations

1) Label and package a selected dosage form according to state and federal laws

B. Provide population-based care

2. Applied competencies

a. Retrieve, evaluate, and manage professional information and literature

b. Prepare and deliver educational programs to health professionals, patients, and other stakeholders in health care systems regarding drug therapy, accessing drug therapies via health insurance including prescription insurance, and navigating the health care system

f. Communicate and collaborate with pharmacy colleagues, prescribers, population members, caregivers, and other involved health care providers to engender a team approach to patient
g. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to other health care providers and to the public
h. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines

II. SYSTEMS MANAGEMENT. Manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health, provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution, and to improve therapeutic outcomes of medication use

A. Manage human, physical, medical, informational, and technological resources

2. Applied competencies

d. Specify, acquire, maintain, and update facilities, equipment, and information technology required to fulfill the practice mission
e. Continually review the operational functioning of the pharmacy and recommend strategic changes in relation to the established mission, fiscal resources, and customer needs
f. Resolve ethical dilemmas that develop in management of the pharmacy practice setting

B. Manage medication use systems

2. Applied competencies

a. Manage the drug distribution system

3) Manage systems for storage, preparation, and dispensing of medicines

b. Assure the quality of drug products

3) Ensure that drug products are stored under appropriate conditions
5) Ensure that products are delivered to patients in a timely, safe, efficient, and ethical manner
6) Ensure the security of the drug product inventory
EVALUATION FORM: ELECTIVE APPE
PRECEPTOR'S MID-ROTATION EVALUATION OF THE STUDENT
P-4 ADVANCED PHARMACY PRACTICE EXPERIENCE

Student Name: 

Preceptor Name: 

Rotation Site: 

Start Date: 

Mid-rotation Evaluation Date: 

Instructions:
* In order to provide a consistent evaluation process and valuable feedback to students regarding their professional development, please assess the student's performance in each category (when applicable to this rotation) based upon the skills and knowledge demonstrated throughout the rotation, as well as the student's previous experience. Please use the evaluation chart below to assess the students' performance in each category. Clearly indicate your assessment by checking the corresponding points for each category.

* The student is required to complete a self-assessment at mid-rotation and at the end of the rotation.

* The preceptor must complete an evaluation of the student at mid-rotation and interact with the student in discussion as it relates to performance. To submit the mid-rotation evaluation, please choose - "Mid-rotation Evaluation - Submit now." If you wish to save the evaluation and submit later, please choose - "Mid-rotation Evaluation - Work in Progress."

* The final evaluation portion of the form must be completed at the conclusion of the rotation using the final evaluation form.

* While some students may initially require substantial redirection and supervision, improvement should become evident through practice with minimal supervision. In cases where students are not progressing to Satisfactory levels and are unlikely to successfully complete rotation outcomes, please contact Mr. John Ridgway, Director of Experiential Programs at (402) 559-5774 or Jridgway@unmc.edu to discuss student standing.

* The evaluation of student performance will be utilized by future preceptors and the Office of Experiential Programs for student development during remaining clerkships.

Evaluation Guidelines: Choose the category that is most representative of the student's performance

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<td>* High level of proficiency</td>
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<tr>
<td>* Numerous mistakes; inability to problem-solve</td>
<td>* Numerous mistakes; has ability to problem-solve but does not make corrections</td>
<td>* Occasionally mistakes; ability to self correct</td>
<td>* Occasional mistakes; ability to problem-solve and utilizes resources consistently</td>
<td>* Mistakes are minimal; ability to problem solve and utilizes resources consistently</td>
<td>* Mistakes are minimal; ability to problem solve and utilizes resources consistently</td>
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<tr>
<td>* Constant redirection and supervision is required</td>
<td>* Somewhat confident in abilities</td>
<td>* Minimal redirection and supervision is required</td>
<td>* Consistent performance</td>
<td>* Minimal supervision is required</td>
<td>* Minimal supervision is required</td>
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<tr>
<td>* Lacks confidence in abilities</td>
<td>* Student has some awareness of mistakes made</td>
<td>* Student is confident in abilities</td>
<td>* Student can identify and solve problems/issues</td>
<td>* Student can identify and solve problems/issues</td>
<td>* Minimal supervision is required</td>
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## I. PHARMACY PRACTICE

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### 1. Pharmacy Profession: demonstrates the activities of the pharmacist appropriate to the practice site. Integrates the role of other pharmacy support personnel in the delivery of pharmacy services and patient care. Identifies and implements necessary changes in pharmacy practice and health care delivery to advance the profession.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 2. Integrative Competence/Critical Thinking and Decision-Making Abilities: examines issues rationally and logically. Evaluates, analyzes and synthesizes information and knowledge based upon sound physical, chemical, biological, and therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving biomedical, sociobehavioral, and clinical sciences that may impact therapeutic outcomes.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 3. Informatics and Evidence-Based Pharmacootherapy: evaluates, analyzes, and synthesizes information. Manages knowledge to mitigate error(s) and support decision-making using appropriate information and technology.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 4. Oral Communication: listens, assesses health literacy, and uses effective oral communication skills to clearly communicate relevant, concise, comprehensive and timely information about safe and appropriate medication use to patients, health care professionals, and members of the community using appropriate terminology and vocabulary for the intended audience.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 5. Written Communication: listens, assesses health literacy, and uses effective written communication skills to clearly communicate relevant, concise, comprehensive and timely information about safe and appropriate medication use to patients, health care professionals, and members of the community using appropriate terminology and vocabulary for the intended audience.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 6. Interactions with Health Professionals: interacts actively and effectively with other health professionals. Respects other health professionals’ contribution to patient care.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 7. Self-Directed Learning Abilities: assesses his/her own knowledge, sets appropriate learning goals and takes appropriate action to accomplish these goals.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 8. Social Awareness and Responsibility: takes responsibility for adapting and providing quality patient care to culturally, economically, and socially diverse populations. Promotes public health and minimizes health care disparities. Applies population-specific data, informatics, and research processes to identify and solve public health problems and help develop health policy as appropriate to the practice site.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E

### 9. Health Promotion: counsels individuals and/or groups on health lifestyles for disease prevention, wellness, health promotion and public health issues.

MID-ROTATION: [ ] N/O [ ] U [ ] SN [ ] S [ ] G [ ] E
### II. PATIENT CENTERED PHARMACY PRACTICE

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#### 10. Disease State Knowledge: explains pathophysiology and clinical presentation of disease state(s).

MID-ROTATION: N/O U SN S G E


MID-ROTATION: N/O U SN S G E

#### 12. Patient Information: obtains all necessary and pertinent information from patient/family/caregiver interviews, patient medical records, medication profiles, patient labs, physical assessment findings, diagnostic tests, and/or other health care providers.

MID-ROTATION: N/O U SN S G E

#### 13. Patient Pharmacotherapy Assessment: assesses the appropriateness of the patient’s drug therapy, determines therapeutic endpoints and explains drug therapy including assessment of all medications, evidence-based literature and standards of treatment

MID-ROTATION: N/O U SN S G E

#### 14. Pharmacy Care Plan: formulates and recommends appropriate pharmacy care plans, uses information about patient’s medical and socio-behavioral needs, preferences and economic status to encourage medication adherence and optimize patient’s health outcomes. Determines the goals of therapy, states appropriate efficacy and toxicity monitoring parameters, and identifies and completes appropriate follow-up. Recommendations are reasonable and consider potential consequences of recommendations.

MID-ROTATION: N/O U SN S G E

#### 15. Patient/Caregiver Communication: able to choose, apply and integrate the effective mode(s) of communication (verbal, nonverbal, and/or written) to provide education and counseling on prescription and OTC medication in a caring manner. Verifies understanding and follows HIPAA guidelines.

MID-ROTATION: N/O U SN S G E

### III. MEDICATION DISTRIBUTION AND CONTROL SYSTEMS

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#### 16. Prescription Verification: accurately interprets and transcribes verbal and written prescription orders and assures the appropriateness of the prescription order. Assists patient in problems related to prescription medication coverage.

MID-ROTATION: N/O U SN S G E

#### 17. Dispensing: safely dispenses medications while applying professional standards and legal guidelines. Administers medications when appropriate and upon adequate training.

MID-ROTATION: N/O U SN S G E

#### 18. Acquisition: uses and evaluates drug acquisition, inventory control and time-sensitive medication distribution systems and related technology, while documenting and maintaining quality.

MID-ROTATION: N/O U SN S G E
19. **Management**: describes principles of personnel, financial and marketing management to medication distribution and control systems in pharmacy practice.

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20. **Pharmaceutical Product Knowledge**: discusses aspects of the pharmaceutical sciences that relate to the properties and formulation of drugs and drug products, and medically-related tests and devices. Prepares compounded prescriptions accurately.

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IV. **PROFESSIONALISM, ETHICS & RESPONSIBILITY**

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<th>U = UNSATISFACTORY</th>
<th>SN = SATISFACTORY NEEDS IMPROVEMENT</th>
<th>S = Satisfactory</th>
<th>G = Good</th>
<th>E = Excellent</th>
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22. Demonstrate motivation, initiative, and active participation in the rotation (actively participates in answering drug information questions and offering to assist with problem-solving patient issues)

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23. Maintain a consistent, positive attitude and behavior even in stressful situations. Appropriate interactions. Accept constructive criticism and feedback to improve skills.

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24. Demonstrate accountability and responsibility

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25. Demonstrate punctuality

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26. Display honesty, integrity and trustworthiness

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27. Evaluate ethical dilemmas

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28. Maintain confidentiality of all patient & health organization related information

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29. Demonstrate effective time management skills

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30. Appearance, attire, and personal hygiene are professional

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OVERALL PERFORMANCE COMMENTS FOR MID-ROTATION

Describe the student’s strengths:


Describe areas that need improvement:


  Confidential Concerns (Optional): Please use ONLY for issues and concerns you don’t want the student to see. Please leave box blank if you have no confidential concerns to report. The Office of Experiential Programs will be immediately notified of your concerns.


GRADING METHODS:

Mid-rotation grading for this APPE is Passing or Failing:

Passing = Student is meeting or exceeding expectations       Failing = Student is not meeting expectations

MID-ROTATION EVALUATION

Recommend Grade:  ○ Unsatisfactory = Failing       ○ Satisfactory = Passing

○ Mid-rotation Evaluation: Work in Progress       ○ Mid-rotation Evaluation: Submit Now
EVALUATION FORM: ELECTIVE APPE
PRECEPTOR'S FINAL EVALUATION OF THE STUDENT
P-4 ADVANCED PHARMACY PRACTICE EXPERIENCE

Student Name: 

Preceptor Name: 

Rotation Site: 

Start Date: 

Final Evaluation Date: 

Instructions:
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<td><strong>1. Pharmacy Profession</strong></td>
<td>Demonstrates the activities of the pharmacist appropriate to the practice site. Integrates the role of other pharmacy support personnel in the delivery of pharmacy services and patient care. Identifies and implements necessary changes in pharmacy practice and health care delivery to advance the profession.</td>
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<td><strong>2. Integrative Competence/Critical Thinking and Decision-Making Abilities</strong></td>
<td>Examines issues rationally and logically. Evaluates, analyzes, and synthesizes information and knowledge based upon sound physical, chemical, biological, and therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving biomedical, sociobehavioral, and clinical sciences that may impact therapeutic outcomes.</td>
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<td><strong>3. Informatics and Evidence-Based Pharmacotherapy</strong></td>
<td>Evaluates, analyzes, and synthesizes information. Manages knowledge to mitigate error(s) and support decision-making using appropriate information and technology.</td>
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<td><strong>4. Oral Communication</strong></td>
<td>Listens, assesses health literacy, and uses effective oral communication skills to clearly communicate relevant, concise, comprehensive and timely information about safe and appropriate medication use to patients, health care professionals, and members of the community using appropriate terminology and vocabulary for the intended audience.</td>
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<td><strong>5. Written Communication</strong></td>
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<td><strong>6. Interactions with Health Professionals</strong></td>
<td>Interacts actively and effectively with other health professionals. Respects other health professionals’ contribution to patient care.</td>
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<td><strong>7. Self-Directed Learning Abilities</strong></td>
<td>Assesses his/her own knowledge, sets appropriate learning goals and takes appropriate action to accomplish these goals.</td>
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<td><strong>8. Social Awareness and Responsibility</strong></td>
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<td><strong>9. Health Promotion</strong></td>
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II. PATIENT CENTERED PHARMACY PRACTICE

10. Disease State Knowledge: explains pathophysiology and clinical presentation of disease state(s).

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12. Patient Information: obtains all necessary and pertinent information from patient/family/caregiver interviews, patient medical records, medication profiles, patient labs, physical assessment findings, diagnostic tests, and/or other health care providers.

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14. Pharmacy Care Plan: formulates and recommends appropriate pharmacy care plans, uses information about patient’s medical and socio-behavioral needs, preferences and economic status to encourage medication adherence and optimize patient’s health outcomes. Determines the goals of therapy, states appropriate efficacy and toxicity monitoring parameters, and identifies and completes appropriate follow-up. Recommendations are reasonable and consider potential consequences of recommendations.

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15. Patient/Caregiver Communication: able to choose, apply and integrate the effective mode(s) of communication (verbal, nonverbal, and/or written) to provide education and counseling on prescription and OTC medication in a caring manner. Verifies understanding and follows HIPAA guidelines.

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III. MEDICATION DISTRIBUTION AND CONTROL SYSTEMS

16. Prescription Verification: accurately interprets and transcribes verbal and written prescription orders and assures the appropriateness of the prescription order. Assists patient in problems related to prescription medication coverage.

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17. Dispensing: safely dispenses medications while applying professional standards and legal guidelines. Administers medications when appropriate and upon adequate training.

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18. Acquisition: uses and evaluates drug acquisition, inventory control and time-sensitive medication distribution systems and related technology, while documenting and maintaining quality.

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IV. PROFESSIONALISM, ETHICS & RESPONSIBILITY

20. Pharmaceutical Product Knowledge: discusses aspects of the pharmaceutical sciences that relate to the properties and formulation of drugs and drug products, and medically-related tests and devices. Prepares compounded prescriptions accurately.

21. Appropriate Medication Use: performs activities that improve the safety and quality of the medication use process by preventing, reporting, and managing medication errors and adverse events. Understands and adheres to safety design principles in the health care system.

IV. PROFESSIONALISM, ETHICS & RESPONSIBILITY

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<td>22. Demonstrate motivation, initiative, and active participation in the rotation (actively participates in answering drug information questions and offering to assist with problem-solving patient issues)</td>
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<td>23. Maintain a consistent, positive attitude and behavior even in stressful situations. Appropriate interactions. Accept constructive criticism and feedback to improve skills.</td>
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<td>24. Demonstrate accountability and responsibility</td>
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<td>25. Demonstrate punctuality</td>
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<td>26. Display honesty, integrity and trustworthiness</td>
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<td>27. Evaluate ethical dilemmas</td>
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<td>28. Maintain confidentiality of all patient &amp; health organization related information</td>
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<td>29. Demonstrate effective time management skills</td>
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<td>30. Appearance, attire, and personal hygiene are professional</td>
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Describe the student's strengths:

Describe areas that need improvement:

Confidential Concerns (Optional): Please use ONLY for issues and concerns you don’t want the student to see. Please leave box blank if you have no confidential concerns to report. The Office of Experiential Programs will be immediately notified of your concerns.

GRADING METHODS: Grading for this APPE is Pass/Fail/Honors:

Pass = Student meets or exceeds expectations  
Fail = Student does not meet expectations

Pass with Honors is a grade assigned by a review committee within the Office of Experiential Programs (OEP) to not more than 20% of students completing an APPE rotation of a respective category in a given semester. The OEP review utilizes the preceptor assessment forms and written justification of the honors recommendation. Pass with honors recommendations by preceptors should not be discussed with students at the time of the final rotation grading meeting; the student should only be instructed that they have passed or failed the rotation.

FINAL EVALUATION

Recommend Grade:  
○ Unsatisfactory = Fail  
○ Satisfactory = Pass  
○ Pass with Honors (must justify below)

If you recommend a grade of fail, explain the reason for this grade:

Honors Justification:

1. How did this student exceed your expectations: (required)

2. Please give one or more examples of exceptional work performed by this student: (required)

Confidential Concerns (Optional): Please use ONLY for issues and concerns you don’t want the student to see. Please leave box blank if you have no confidential concerns to report. The Office of Experiential Programs will be immediately notified of your concerns.

Submissions of this evaluation affirm that the student has completed the required minimum of 160 hours of APPE for a 4-week rotation.