



 **pshp** ANNUAL ASSEMBLY

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Development of an Investigational Drug Services Rotation for Students and Residents

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***Adapted from presentation given at 2022 McCreadie Research Summit with Erica Gray, PharmD, BCPS**

Disclosure Statement

- I have no conflict of interest with respect to the material presented.

Objectives

- Describe IDS activities that students and residents can complete while on rotation
- Outline objectives to use for APPE rotations and objectives for PGY-1 and PGY-2 residencies according to ASHP residency standards
- Discuss lessons learned to improve IDS rotation experiences



POLL

1. What student / resident option(s) does your IDS currently offer? (select all that apply)

- A. APPE Rotation
- B. PGY1 Rotation
- C. PGY1 Residency
- D. PGY2 Rotation
- E. PGY2 Residency
- F. None

Advanced Pharmacy Practice Experience (APPE) Rotation

APPE Rotation – Student Background

Considerations:

Previous rotation
experience

Pharmacy experience

- Retail, hospital, etc.

Work experience

- Size, number of colleagues, interdepartmental work, independent vs group setting

Motivation for selecting
rotation

Prior research
experience

Documents provided to APPE Students

Rotation Manual

- Site Description
- Site Goals
- Learning Objectives
- Assignments/Activities
- Rotation Projects
- Reading Assignments
- Preceptor Information

Rotation Calendar

Rotation Checklist

Rotation Student Questions

- Why did you select this rotation?
- What rotations and research experiences have you had thus far?
- What are your career interests?
- What specific disease states interest you the most?

Advanced Pharmacy Practice Experience (APPE) Rotation

5 weeks (time divided between 2 hospitals)



Topic Discussion

- Based on student's interests
 - Should be a disease state covered by IDS



Journal Club

- Typically, the same disease state as topic discussion
- Recent journal
- Attempt to focus on investigational drug seen by IDS



Drug Builds and Pharmacy Procedures

- 1 Procedure
- Up to 2 Drug Builds

Advanced Pharmacy Practice Experience (APPE) Rotation

5 weeks (time divided between 2 hospitals)

Quality Improvement Project (“Big Project”)



• **Pharmacist Education**

- Management of Immunotherapy-Related Toxicities
- Recent Drug Approvals
- Expanded Access and Emergency Use Authorization
- USP 795
- USP 800



• **Improving IDS Service Line**

- Technician Role in IDS
- Fee Structure Overview and Analysis

Advanced Pharmacy Practice Experience (APPE) Rotation

5 weeks (time divided between 2 hospitals)



Cost-Effectiveness Assignment

- Review 2-3 articles on the economic impact of IDS
- Find one article on the cost-savings associated with research pharmacy program



Day-to-Day Activities

- Budgets
- Site Initiation Visits/Close Out Visits/Monitoring Visits*
- Dispensing assistance
- Drug shipment receipt
- Drug information questions
- Satellite shipments
- Drug inventory audits
- Patient cases and lab review
- Mini topic discussions

Advanced Pharmacy Practice Experience (APPE) Rotation

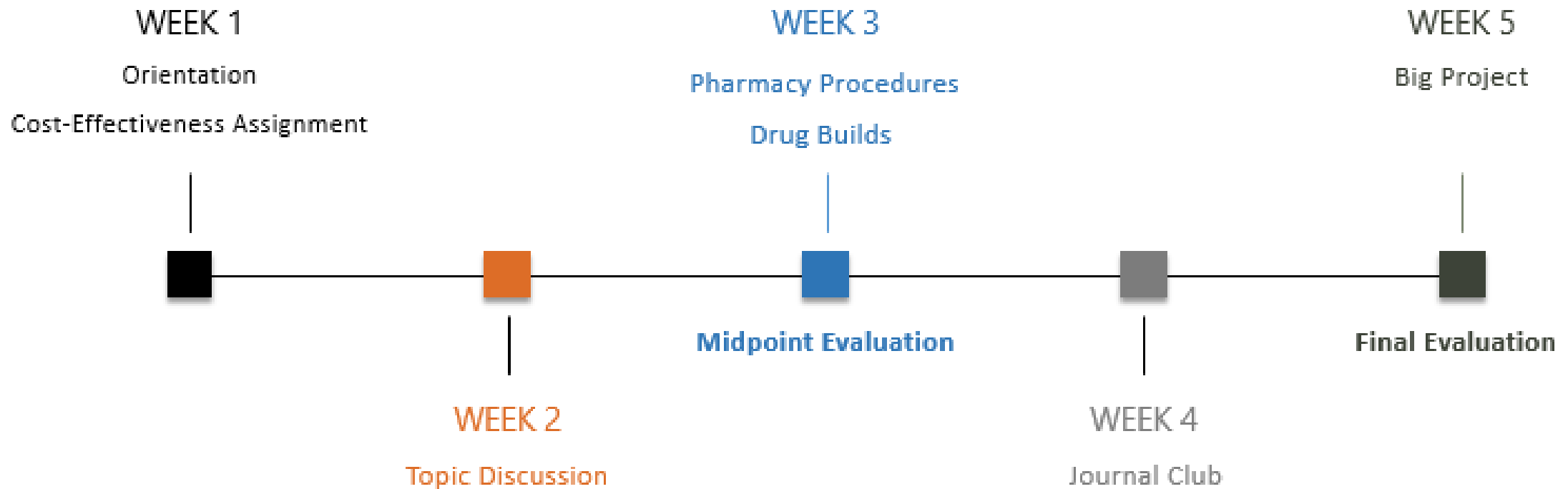
5 weeks (time divided between 2 hospitals)



Reading Requirements

- HOPA IDS Best Practice Guidelines
- ASHP Guidelines for the Management of Investigational Drug Products
- National Comprehensive Cancer Network investigational drug service consensus recommendations
- ISMP – Investigational Drugs (Part I and II)
- Belmont Report
- Economic Impact of IDS Pharmacy Articles
- CFR - Code of Federal Regulations Title 21

APPE Rotation Timeline



Additional opportunities – APPE Rotation

Shadow

- Operations Pharmacist in Cancer Center
- Coordinator

Attend

- **Interdepartmental Meetings**
 - Policy Review
 - Nursing Management
 - Hospital Research
 - Medication Safety
- **Research/Regulatory Meetings**
 - IRB
 - Office of Sponsored Research (OSR)
 - Internal Data Safety and Monitoring Committee

Examples of Objectives – APPE Rotation

- **Create** pharmacy procedures and drug information documents for clinical studies
- **Attend** and **prepare documents** for site initiation visits, monitoring visits, audits or other inspections
- **Discuss** the drug development process including; investigational new drug application, pre-clinical studies, clinical studies, new drug application or biologics license application, regulatory approval, and post-marketing studies.

Examples of Objectives – APPE Rotation

- **Assist** in the development of an IDS pharmacy budget
- **Demonstrate** proper investigational drug dispensing and inventory management
- **Summarize** standard operating procedures within IDS and practice standards for IDS (e.g., HOPA, ASHP)

Post-Graduate Year 1 – Pharmacy Residency

IDS Rotation

PGY-1 Pharmacy Resident Background

Setting	Staffing	Rotations	IDS Experience
• Pharmacist-led ambulatory care clinic within a hospital • Minimal IV room experience	• Pharmacist-led ambulatory care clinic • Outpatient pharmacy	• Majority are outpatient • At least 1 inpatient	• Typically limited • Some Research Compliance Training

Documents provided to PGY-1 Residents

Rotation Manual

- Site Description
- Site Goals
- Learning Objectives
- Assignments/Activities
- Rotation Projects
- Reading Assignments
- Preceptor Information

Rotation Calendar

Rotation Checklist

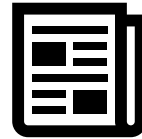
PGY-1 Pharmacy Residency Rotation

4 weeks (Mon - Thurs)



Topic Discussion

- Based on resident's interests
 - Should be a disease state covered by IDS



Journal Club

- Typically, the same disease state as topic discussion
- Recent journal
- Attempt to focus on investigational drug seen by IDS

PGY-1 Pharmacy Residency Rotation

4 weeks (Mon - Thurs)



Drug Builds and Pharmacy Procedures

- 1 Procedure
- Up to 2 Drug Builds



Mini Topic Discussion

- Disease state covered by IDS
- Disease states outside of IDS may be selected

PGY-1 Pharmacy Residency Rotation

4 weeks (Mon - Thurs)



Day-to-Day Activities

- Budgets
- Site Initiation Visits/Close Out Visits/Monitoring Visits*
- Dispensing assistance
- Drug shipment receipt
- Drug information questions
- Satellite shipments
- Drug inventory audits
- Patient cases and lab review
- Patient counseling

PGY-1 Pharmacy Residency Rotation

4 weeks (Mon - Thurs)



Reading Requirements

- HOPA IDS Best Practice Guidelines
- ASHP Guidelines for the Management of Investigational Drug Products
- National Comprehensive Cancer Network investigational drug service consensus recommendations
- ISMP – Investigational Drugs (Part I and II)
- Belmont Report
- Economic Impact of IDS Pharmacy Articles
- CFR - Code of Federal Regulations Title 21

PGY-1 Pharmacy Residency Rotation

4 weeks (Mon - Thurs)

Quality Improvement Project



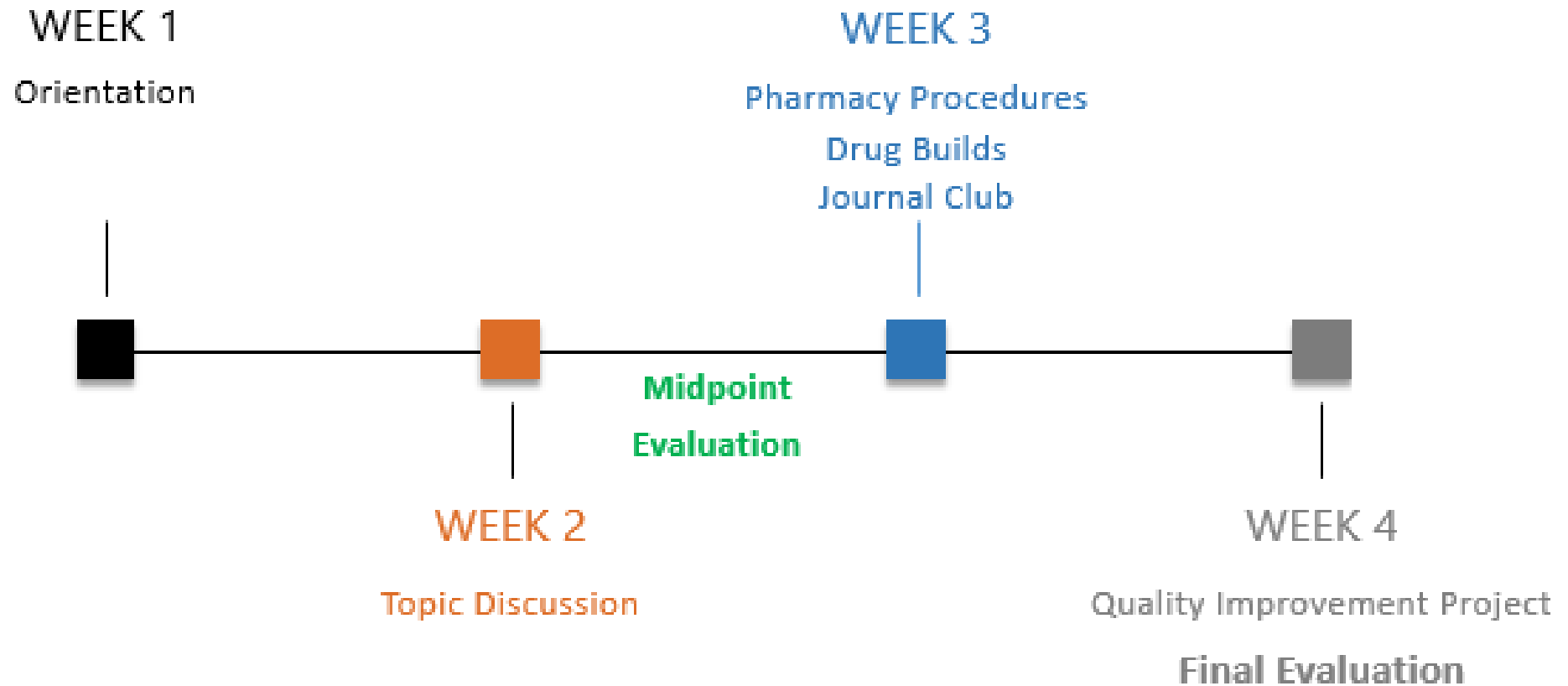
- **Pharmacist Education**



- **Project focused on improving the IDS service line**

- Examples:
 - Metrics
 - Complexity tool used to evaluate studies

PGY-1 Pharmacy Residency Rotation



Examples of Objectives – PGY-1 Rotation

- Ensure objectives satisfy required ASHP residency objectives

Objective R1.1.1: (Applying) Interact effectively with healthcare teams to manage patients' medication therapy

Objective R1.1.2 (Applying) Interact effectively with patients, family members, and caregivers.

- Patient counseling

Objective R1.1.3: (Analyzing) Collect information on which to base safe and effective medication therapy.

Reference: ASHP Required Competency Areas, Goals, and Objectives for PostGraduate Year One (PGY1) Pharmacy Residencies.

Examples of Objectives – PGY-1 Rotation

- Ensure objectives satisfy required ASHP residency objectives

Objective R1.1.8: (Applying) Demonstrate responsibility to patients.

Objective R1.3.1: (Applying) Prepare and dispense medications following best practices and the organization's policies and procedures.

Objective R3.2.3: (Applying) Contribute to departmental management.

- Pharmacy Budgets
- Time spent with IDS Manager

Reference: ASHP Required Competency Areas, Goals, and Objectives for PostGraduate Year One (PGY1) Pharmacy Residencies.

Examples of Objectives – PGY-1 Rotation

- Ensure objectives satisfy required ASHP residency objectives

Objective R3.2.4: (Applying) Manage one's own practice effectively.

Objective R4.1.3: (Applying) Use effective written communication to disseminate knowledge.

- Pharmacy Procedures
- Drug Information
- Pharmacy and Nursing Education

Objective R4.1.2: (Applying) Use effective presentation and teaching skills to deliver education.

- Topic Discussion
- Journal Club
- Quality Improvement

Reference: ASHP Required Competency Areas, Goals, and Objectives for PostGraduate Year One (PGY1) Pharmacy Residencies.

Examples of Objectives – PGY-1 Rotation

- Objectives can also have elective options

Objective E2.1.5 (Applying) Manage the use of investigational drug products (medications, devices, and biologicals).

Reference: ASHP Required Competency Areas, Goals, and Objectives for PostGraduate Year One (PGY1) Pharmacy Residencies.

Post-Graduate Year 2 – Pharmacy Residency

IDS Rotation

PGY-2 Pharmacy Resident Background

Setting	Staffing	Rotations	IDS Experience
• Outpatient and Inpatient • Clinical focus on hematologic and oncologic disease states	• Cancer Center operations pharmacy • Inpatient pharmacy	• Majority are outpatient cancer center clinics • At least 2 inpatient (BMT and Med Onc)	• Exposure while staffing • Investigational oncology treatment plans • Some Research Compliance Training

PGY-2 Oncology Pharmacy Residency - IDS Rotation

2 weeks (Mon - Fri)



Treatment Plan Creation and/or Validation

- Patient Specific
- Template



Drug Builds and Pharmacy Procedures

- Up to 4 Drug Builds
- Up to 2 Procedures

PGY-2 Oncology Pharmacy Residency - IDS Rotation

2 weeks (Mon - Fri)



Day-to-Day Activities

- Budgets
- Site Initiation Visits/Close Out Visits/Monitoring Visits*
- Dispensing assistance
- Drug shipment receipt
- Drug information questions
- Satellite shipments
- Drug inventory audits
- Patient cases and lab review
- Patient counseling

PGY-2 Oncology Pharmacy Residency - IDS Rotation

2 weeks (Mon - Fri)



Reading Requirements

- HOPA IDS Best Practice Guidelines
- ASHP Guidelines for the Management of Investigational Drug Products
- National Comprehensive Cancer Network investigational drug service consensus recommendations
- ISMP – Investigational Drugs (Part I and II)
- Belmont Report
- Economic Impact of IDS Pharmacy Articles
- CFR - Code of Federal Regulations Title 21

Examples of Objectives – PGY-2 Rotation

- Ensure objectives satisfy required ASHP residency objectives

Objective R5.1.1: (Evaluating) Accurately assess and/or actively participate in an institutional cancer-specific clinical trial.

Objective R5.1.2: (Creating) Prepare and implement investigational medication sheets or documents and order templates for an assigned clinical research study.

Objective R5.1.3: (Applying) Facilitate the proper preparation and dissemination of investigational medications.

Reference: ASHP Required Competency Areas, Goals, and Objectives for PostGraduate Year One (PGY1) Pharmacy Residencies.

Comparison of rotations

Task	APPE Rotation	PGY-1 Rotation	PGY-2 Rotation
Drug Build and Pharmacy Procedure Creation	✓	✓	✓ & Validation
Independent Patient Counseling	✗	✓	✓
Cost Effectiveness Assignment	✓	✗	✗
Topic Discussions	✓	✓	✓
Journal Club	✓	✓	✗
Budgets	✓	✓	✓
Quality Improvement Project	✓	✓	✗
Sponsor Visits	✓ Attendance	✓ Preparation	✓ Preparation



Lessons Learned

Lessons Learned

Residents provide a list of external rotation activities ~1-2 weeks prior to start of rotation

Discuss timelines and capabilities

Include activities in the Resident's Calendar

Daily Check-ins

Plans for the day

Nearing deadlines

Limit Residents/Students in the beginning

Assess how many residents/students you are capable of managing

"Start low and increase slow"

Give yourself breaks

Lessons Learned

Make small changes to the rotation requirements

Change the number of assignments

Technology Issues...

Certain computers have access to different things

No USB use

Electronic medical record access

Lessons Learned

Feedback

Student/Resident feedback given by preceptor

Rotation feedback from resident/student

Continuous, Midpoint, Final

Student feedback of themselves

Utilize the pharmacy school's Experiential Education Office if needed

Don't be afraid to reach out

Preceptor development

ASHP Objectives – Tips and Tricks

Be specific with quantities

Avoid the word "Review"

Questions

References

- Amin S, et al. National Comprehensive Cancer Network investigational drug service consensus recommendations. Am J Health-Syst Pharm. 2022;79:486-491.
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