# PHA5956 Pharmacists' Roles in Drug Development

Fall Semester 2020-2021

1 Credit Hour – [Pass/Fail Grading]

*This elective course teaches the key components of the drug development process through project-based activity. Students will apply critical thinking skills in a self-directed team based learning environment. The student will gain knowledge and exposure to career opportunities in the biotechnology industry.*

## Teaching Partnership Leader

Michael Ujhelyi, Pharm.D., FCCP
Associate Dean for Lake Nona Campus
Email: michael.ujhelyi@cop.ufl.edu
Office: (407) 313-7031
Office Hours: Please see Canvas course site for posted office hours.

William C Mobley, PhD
Clinical Associate Professor
Email: mobley@cop.ufl.edu
Office: (352) 273-6282
Office Hours: Please see Canvas course site for posted office hours.

## Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

EPA 6 Collaborate as a member of an interprofessional team.
EPA 8 Population Health Promoter Domain
EPA 11 Information Master Domain
EPA 15 Create a written plan for continuous professional development.

## Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Describe the drug development process and key inputs that affect decision making for product requirements, including evidence needs, FDA requirements and barriers, provider and stakeholder education and product awareness/marketing.
2. Describe unmet medical needs specific to drug products, including its dosage form, and explain how the product will address this need.

3. Design a high-level clinical development plan that supports a drug candidate through all phases of clinical trials, including the generation of sufficient safety and efficacy data to support approval from health authorities
4. Develop a medical plan that sets evidence requirements during clinical develop and post marketing strategies that optimizes the product safe and effective use. Incorporate strategies to overcome anticipated barriers to market adoption.
5. Develop plans to educate providers and stakeholders that states the product value and how it meets an unmet medical need, instructions for use in a safe and effective manner, cost and effectiveness relationship, patient benefits and satisfaction.
6. Develop a US-focused regulatory strategy that will maximize the probability of success in achieving approval, while also utilizing regulatory pathways that will accelerate drug development and differentiation.
7. Create a commercial strategy that will successfully differentiate your company's product in the marketplace, highlighting the brand's benefits and maximizing product uptake.
8. Describe the variety of roles and experiences that industry pharmacists bring to the drug development process.

## Course Prerequisites

Successful completion of Block 4 of the PharmD curriculum.

## Course Co-requisites

- None

## Course Outline

Please see Appendix A for course schedule. Routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/ times, deadlines, and room changes.

**Requirements and Assignments:**

Drug Development Project: Students will create a drug development plan for their assigned role (clinical research, medical affairs, regulatory affairs, and commercialization/marketing)

1. Workgroups Activities
    a. There are 4 workgroups consisting of 4-6 members per group
    b. Students will self-select their preferred workgroup. The choices are medical affairs, clinical development, regulatory affairs and commercial/marketing
    c. Each workgroup has assigned tasks and objectives (see Appendix B – VIP Competition Guide)
    d. Tasks and objectives are divided into three assignment blocks.
2. Assignment blocks (3)
    a. There are 3 three-week assignment blocks

b. Each workgroup must meet for a minimum of three hours per assignment block. Note that this is cumulative meeting time; the group may break up an assignment block over three weeks. For example, the group can meet for one hour per week for three weeks to complete the assignment block meeting time requirement. There is maximum flexibility scheduling days, times and meeting duration.
c. Assignment due dates for each block are provided in the course schedule (Appendix A)
d. The work group must submit a work plan for each assignment block. The work plan must align with the project work instructions listed in Appendix B. The plan must be submitted and approved by the instructor before the assignment block can begin.
e. Each group member must have an assignment stated in the submitted and approved work plan for each block (Appendix B).
f. There will be three one hour optional review sessions with the instructor (please see course outline). The instructor will provide general feedback on assignment tasks, block reports and hold Q&A.

3. Group Final Written Project: The final project is a written plan for the assigned functional area (e.g clinical development plan).
4. Individual Assignments:
    a. Written Report (4): Each student will complete one written report per assignment block on the Value of Industry Pharmacists (see Appendix B for objectives). The report for each block must be submitted on or before the due dates listed in the course outline. Written reports must comply with the structured report form.
    b. Oral Presentation (1): Each student will deliver a 15 minute PowerPoint presentation reporting out on their assigned tasks.
    c. Top Concepts Oral Presentation Brief (3): Each student must submit a brief for each presentation group (n=4). The presentation brief report must be hand-written and must be turned in the day of the presentations at the end of the session. Presentation-brief instructions are:
        i. For each presentation workgroup, the student will identify two important concepts within the presentation and write a one-sentence description for each concept.
        ii. For each presentation workgroup, write a 2-3 sentence description where the team provided a strong defense argument. What was the topic and why was the defense strong.
        iii. For each presentation workgroup, write a 2-3 sentence description where the team provided a defense argument that could use improvement. What was the topic and how would you have improved the defense statement.

## Required Textbooks/Readings

None

## Suggested Textbooks/Readings

1. Kosegarten DC, Pisano DJ. eds. Pharmacy & Federal Drug Law Review: A Patient Profile Approach New York, NY: McGraw-Hill; 2006.

2. "Chapter 21: Investigational Drugs" & "Chapter 22: Pharmaceutical Industry and Regulatory Affairs" in: Malone PM, Malone MJ, Park SK. eds. Drug Information: A Guide for Pharmacists, 6e New York, NY: McGraw-Hill

Both texts are available via Access Pharmacy, which is accessible through the UF Library.

- Use UF VPN to access UF Libraries Resources when off-campus.
- The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the HSC Library Website at this URL: http://www.library.health.ufl.edu/

Other Required Learning Resources

- Zoom
- Canvas
- IPhO co-requisite options Guest membership - Email/account created on IPhO website.

## Materials & Supplies Fees

NONE

## Student Evaluation & Grading

Pharmacist Role in Drug Development: Pass/Fail. Passing grade will be 70% or greater and all assignments. Attendance is mandatory for each block meeting and oral presentation.

| Assessment Item | Grade Percent |
|---|---|
| Individual Block Written Reports (n=3). Note: Students must log and document their attendance at block assignment meetings on a weekly basis to receive credit for written report. | 30% |
| Individual Oral Presentation (15 minutes with defense) | 30% |
| Individual Oral presentation "Top Concepts" Briefs (n=4) | 10% |
| Group Final Written Project | 30% |

## Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the Pharm.D. Course Policies carefully, at this URL: http://curriculum.pharmacy.ufl.edu/current-students/course-policies/

**Course Specific Policies:** Students are expected to attend all group meetings within the assignment blocks. Student attendance is optional for group meetings exceeding the required three hour meeting time for an assignment block. For each unexcused absence for a required assignment block meeting, students are required to meet with the course director within 1 week of the missed class for assessment and evaluation to determine if they are able to continue in the course and project team. It is the student's responsibility to contact the course director to schedule this meeting. Students must attend all individual presentations to receive credit.

Curricular credit is offered onetime. Note: A student can participate in the VIP competition and not be enrolled in this course.

Students enrolled in this course will not receive co-curricular credit for the activities completed in this course.

**Course Evaluation Process:** Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu/results/ 

Students are expected to evaluate their group throughout the course to ensure positive and effective teamwork.

Questions to Ask:
• Concerns about performance
• Guidance when there are performance problems (failing grades)
• General questions about content

## Instructional Designer:

TBA,
Email: TBA
Office: HPNP 4309

## Academic Coordinators:

TBA
Email: TBA
Phone: TBA
*Absence/Tardy Email:* absent1pd@cop.ufl.edu, absent2pd@cop.ufl.edu, absent3pd@cop.ufl.edu

## Educational Coordinators:

McKenzie Wallen
Email: mwallen@cop.ufl.edu
Office: Jacksonville Campus

Iverta Allen
Email: iallen1@cop.ufl.ed
Office: Orlando Campus

## Questions about dates, deadlines, meeting place

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)

## How to Request Learning Accommodations

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, www.dso.ufl.edu/drc/) by providing appropriate documentation. Once registered with the Disability Resource Center, students will receive an accommodation letter which must be presented to both the instructor and academic coordinator to utilize classroom accommodations. Students registered with the Disability Resource Center who are requesting clinical accommodations for rotations or clinical experiences should contact their Learning Specialist in the Disability Resource Center. Students with disabilities should follow this procedure as early as possible in the semester. Additionally, students at all College of Pharmacy campuses are expected to provide a copy of the accommodation letter of the Office of Student Affairs by email (carswell@cop.ufl.edu), fax (352-273-6219) or in person at G235 (Student Services Suite) of the Health Professions, Nursing and Pharmacy Building since some learning activities, exams, and assessments require additional assistance. The College of Pharmacy highly encourages that this procedure be completed before each course begins. Being proactive in this process will ensure that accommodations are in place for each student's learning activities, exams, and assessments because grades cannot be retroactively changed.

Computer and Other Technology Requirements Students are required to meet the following computer and technology requirements: http://pharmacy.ufl.edu/education/student-affairs/admissions/student-computer-requirements

# Appendix A. Course Schedule

| Date | Activity Title | Contact Hrs | Responsible |
|---|---|---|---|
| **Aug 31st** | **Lecture: Introduction to Product Development** | **1 hr** | **Ujhelyi** |
| **Aug** | **IPHO Team Registration Opens** | **0 hr** | Team Captains |
| **Sept (TBA)** | **IPHO Introductory Webinar** | **0 hr** | **Ujhelyi** |
| **Sept (TBA)** | **Assignment and Objectives Overview** | **1 hr** | **Ujhelyi** |
| **Oct 5th** | **Assignment Block 1 Review Session (optional)** | **0 hr** | **Ujhelyi** |
| **Oct 16th** | **Assignment Block 1 Due** | **1 hr** | **Ujhelyi** |
| **Oct 26th** | **Assignment Block 2 Review Session (optional)** | **0 hr** | **Ujhelyi** |
| **Nov 6th** | **Assignments Block 2 Due** | **1 hr** | **Ujhelyi** |
| **Nov 19th** | **Assignment Block 3 Review Session (optional)** | **0 hr** | **Ujhelyi** |
| **Nov 30th** | **Assignment Block Due** | **1 hr** | **Ujhelyi** |
| **Dec** | **Final Group Presentations: 15 min per individual; 50 minute group defense** | **12 hr** | **Ujhelyi** |

Students are required to log time spent in assignment block meetings to document attendance.

# Appendix B. VIP Objectives and Task Assignments

Clinical Development

Main objective: Design a high-level clinical development plan (CDP) that supports your drug candidate through all four phases of clinical trials. You will need to generate sufficient safety and efficacy data to support approval from health authorities.

1. Student #1
    a. What is the primary indication for which you are seeking US regulatory approval?
    b. Describe and defend the primary and secondary objectives/endpoints of your pivotal trial and how these support your primary indication
    c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

2. Student #2
    a. As a clinical scientist, describe the "proof of concept" trials (e.g. dose ranging) needed to design a pivotal trial
    b. Describe the pivotal trial design to prove your safety and efficacy endpoints
    c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

3. Student #3
    a. What are the objectives, and patient population for proof of concept clinical trials? Provide the necessary justification
    b. What are the objectives and patient population for the pivotal clinical trial? Provide the necessary justification
    c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

4. Student#4
    a. What difficulties do you foresee for the proof of concept development process and what steps can you take to avoid them?
    b. What difficulties do you foresee for the pivotal trial development process and what steps can you take to avoid them?
    c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

5. Student #5
    a. How will you engage and collaborate with the regulatory and medical affairs teams in creating the proof of concept clinical plan?
    b. How will you engage and collaborate with the regulatory and medical affairs teams in creating the pivotal trial clinical plan?

c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

6. Student #6
    a. Create the clinical development timeline with justification. Provide ideas that could help accelerate the timeline along with drawbacks.
    b. What are other potential indications that can be investigated after approval?
    c. How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

<u>Regulatory Affairs</u>

Main objective: Develop a US-focused regulatory strategy that will maximize your probability of success in achieving approval, while also utilizing regulatory pathways that will accelerate drug development and differentiation. Note: Strategy should focus on product novelty (i.e. new therapeutic class, next generation for established class etc), strength of efficacy (survival vs disease management vs quality of life etc), severity of adverse reactions and complexity of using the therapy (both patient and provider)

1. Student #1
    a. Develop a pre IND filing strategy for your internal filing timelines to enable "First-Patient-In (FPI)". Note: This should focus on first in human safety.
    b. What is your regulatory strategy for filing IND submission to NDA submission?
    c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

2. Student #2
    a. For IND filling; describe specific safety concerns that will be address with the CDP proof of concept studies.
    b. Describe the clinical efficacy and safety claims (e.g decrease mortality) targeted for the package insert label.
    c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

3. Student #3
    a. Describe comparator drugs and filing status that supports your regulatory strategy
    b. Create summary document outlining IND submission to IND clearance?
    c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

4. Student #4
    a. What is your filing strategy for a US-focused NDA? (i.e. align pivotal and supportive trials used to support approval, etc...)

b. Align NDA filling timelines with CDP
c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

5. Student #5
    a. What are the key messages of your IND package?
    b. What are the key messages for your NDA package?
    c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

6. Student #6
    a. How and when will health authority (FDA) interactions be utilized?
    b. Will you try to utilize any expedited programs? If so, which ones?
    c. What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

<u>Medical Affairs</u>

Main objective: Develop evidence-based information regarding your company's drug, both pre and post-launch, to optimize product utilization. Establish and maintain relationships with prominent experts in the field.

1. Student #1
    a. Who is on your Medical Affairs team? (What other professionals do you work with and why?)
    b. Describe how the MA role can support the CDP
    c. What is the value of a pharmacist in Medical Affairs?

2. Student #2
    a. What resources or training will you provide to internal stakeholders?
    b. How will you use clinical data for internal and external education
    c. What is the value of a pharmacist in Medical Affairs?

3. Student #3
    a. When will your company start disseminating medical information to external stakeholders?
    b. Differentiate and describe how you will provide external education on disease state awareness and medical need versus product specific education
    c. What is the value of a pharmacist in Medical Affairs?

4. Student #4
    a. Who can receive off-label information about our new molecular entity?
    b. Create a medical information and communication plan
    c. What is the value of a pharmacist in Medical Affairs?

5. Student #5
    a. Who are your key opinion leaders (KOLs), and how would you go about approaching them?
    b. Create a strategy for mapping KOLs and potential impact on product advocacy
    c. What is the value of a pharmacist in Medical Affairs?

6. Student #6
    a. At what points during the drug development process will the company need to consult Medical Affairs for review?
    b. Describe potential barriers for product adoption and a few solutions
    c. What is the value of a pharmacist in Medical Affairs?

<u>Marketing Research & Marketing/Commercial</u>
Main objective: Create a commercial strategy that will successfully differentiate your company's product in the marketplace, highlighting the brand's benefits and maximizing
Product uptake.

1. Student #1
    a. What is the competitive landscape? Should you conduct market research to fill in the gaps?
    b. Develop a brand strategy: Who is your target audience (i.e. customer segments)?
    c. How do industry pharmacists add value and fit into a role on a marketing team?

2. Student #2
    a. Develop a brand strategy: What customer insight would you use to drive your strategy
    b. Develop a brand strategy: What is the product positioning statement
    c. How do industry pharmacists add value and fit into a role on a marketing team?

3. Student #3
    a. Develop a brand strategy: What are the core messages?
    b. Develop a brand strategy: Create a comparison between your product and competitors as it relates to patient population, efficacy, safety, patient satisfaction, cost and ease of use
    c. How do industry pharmacists add value and fit into a role on a marketing team?

4. Student #4
    a. Develop a brand strategy: How will you market/advertise your brand utilizing media, printed materials, sales force, etc.?
    b. Create a policy for good promotional practices for your product
    c. How do industry pharmacists add value and fit into a role on a marketing team?

5. Student #5
    a. Develop a brand strategy: What materials will you give your sales team to communicate these messages?
    b. Develop a brand strategy:  How will you use these messages in your marketing materials?
    c. How do industry pharmacists add value and fit into a role on a marketing team?

6. Student #6
    a. Develop a brand strategy: From a strategy perspective, how will you utilize landscape-based medical education? What will be your avenues/tactics for promotional marketing?
    b. Develop a brand strategy: What will be your avenues/tactics for promotional marketing?
    c. How do industry pharmacists add value and fit into a role on a marketing team?

<u>Value of Industry Pharmacists</u>

Main objective: Showcase the variety of roles and experiences that industry pharmacists bring to the drug development process.  This is a group assignment integrated in the final group report.

- Clinical Development group
    - ➢ What did you learn about the roles that pharmacists play?
    - ➢ Role and value of the industry pharmacist in clinical development.
- Medical Affairs group
    - ➢ How do you think pharmacists could play a bigger role in drug development and commercialization?
    - ➢ Role and value of the industry pharmacist in clinical development.
- Regulatory Affairs group
    - ➢ What aspects of a pharmacist's education and training help position them to be valued members within pharmaceutical industry?
    - ➢ Role and value of the industry pharmacist in clinical development.
- Marketing/Commercialization group
    - ➢ How can pharmacists better contribute to determining the value of a new medication?
    - ➢ Role and value of the industry pharmacist in clinical development.

# Appendix C: Rubric for Assessing Block Written Reports and Final Written Assignments

| ***Proficiency Level*** | **Deficits Exist** | **Meets Expectations** | **Accomplished** |
|---|---|---|---|
| **Subject Knowledge** | Student demonstrates an inadequate understanding of more than one presented concept **(0)** | Student demonstrates an inadequate understanding of one presented concept **(3)** | Student demonstrates an accurate understanding of all presented concepts **(6)** |
| **Completeness** | Two or more objectives were not adequately addressed.**(0)** | One objective was not adequately addressed. **(3)** | All objectives were adequately addressed **(6)** |
| **Organization** | Information is disorganized **(0)** | Information is logically organized and most sentences/paragraphs are well organized **(2)** | Information is very well organized with well-organized complete sentences and paragraph form **(3)** |
| **Mechanics** | Three or more grammatical, spelling or punctual errors **(0)** | Average sentence structure, some grammatical, spelling or punctual errors **(2)** | Well written using good sentence structure, minimal grammatical, spelling or punctual errors **(3)** |
| **Referencing** | No references **(0)** | References were given, but were inadequate **(1)** | References were adequate **(2)** |
| | | | Total Points (20 max) |

# Appendix D. Rubric for Presentation

## Presentation Specific

| *Proficiency Level* | **Deficits Exist** | **Meets Expectations** | **Accomplished** |
|---|---|---|---|
| **Subject Knowledge** | Student demonstrates an inadequate understanding of more than one presented concept **(0)** | Student demonstrates an inadequate understanding of one presented concept **(2)** | Student demonstrates an accurate understanding of all presented concepts **(4)** |
| **Organization** | Illogical sequencing makes it difficult to follow **(0)** | Logical sequencing, but without an identifiable introduction, body, or summary. **(1)** | Logical sequencing with an introduction, body, and summary **(2)**. |
| **Completeness** | Two or more objectives were not adequately addressed.**(0)** | One objective was not adequately addressed. **(2)** | All objectives were adequately addressed **(5)** |
| **Grammar & Spelling** | Presentation has 3 or more misspellings and/or grammatical errors. **(0)** | Presentation has no more than 2 misspellings and/or grammatical errors. **(1)** | Presentation has no misspellings or grammatical errors. **(3)** |
| **Graphics Quality (Including images, graphs, and tables)** | More than one slide contained a graphic that was not legible or was overloaded with information; and the need for their inclusion "as-is" was not adequately justified. **(0)** | One slide contained a graphic that was not legible or was overloaded with information; and the need for its inclusion "as-is" was not adequately justified. **(1)** | All slides with graphics were legible and not overloaded with information; or the need for its inclusion "as-is" was adequately justified. **(3)** |
| **Typed Information (e.g., bullet points)** | More than one slide with typed information had more than or 6 lines per slide and/or 6 words per line, without adequate justification. **(0)** | One slide with typed information had more than 6 lines per slide and/or 6 words per line, without adequate justification. (**1)** | All slides with typed information had less than or equal to 6 lines per slide and/ or 6 words per line **(3)** |
| **Pacing & Timing** | Pace too fast or slow and could not finish on time.**(0)** | Pace too fast or slow, but finished on time **(1)** | Proper pace and finished on time **(3)** |
| **Elocution** | Significant problems with voice clarity, volume, or pronunciation **((0)** | Minor problems with voice clarity, volume, or pronunciation **(1)** | Clear voice, good volume, and correct pronunciation.**(2)** |
| **Eye Contact / Slide Reading** | Little or no eye contact with the audience or excessive reading of slides **(0)** | Moderate eye contact with the audience or significant reading of the slides **(1)** | Good eye contact with audience with limited reading from the slides **(3)** |
| **Referencing** | No references (0) | References were given, but were inadequate (1) | References were adequate (2) |

| | |
|---|---|
| | Total Points (30 max) |

## Topic Specific

| Points | 2 | 4 | 6 | 8 | 10 | 12 |
|---|---|---|---|---|---|---|
| Clinical Development | Inaccurate and incomplete. Clinical development plan did not provide enough efficacy or safety information to support approval by the FDA. | Several major flaws. It is unlikely that this clinical development plan would provide sufficient safety and/ or efficacy data to support approval by the FDA. | Minimum requirements were met. Clinical development plan was not well laid out and possibly missed some details. Provides enough safety and efficacy data and would likely be approved by the FDA. | Some detail provided on the clinical development plan. Not especially robust but would likely provide sufficient safety and efficacy data to support approval by the FDA. | Only minor flaws in execution. Submitted a robust development plan that would provide sufficient safety and efficacy data to support approval by the FDA. | Provided a very robust clinical development plan. Explanation went into depth on key details. Clinical studies would provide sufficient safety and efficacy data to support approval by the FDA. |
| Regulatory Affairs | Inaccurate and incomplete. Regulatory plan would not support approval by the FDA. | Several major flaws. It is unlikely that this regulatory plan would be sufficient to support approval by the FDA. | Minimum requirement was met. The regulatory plan was not well laid out and possibly missed some details. Plan would likely be approved by the FDA. | Some detail provided on the US-focused regulatory strategy. Not especially robust but would likely be sufficient to support approval by the FDA. | Only minor flaws in execution. Provided a robust US-focused regulatory strategy that would sufficiently support approval by the FDA. | Provided a very robust US-focused regulatory strategy. Explanation went into depth on key details. Strategy would support approval by the FDA. |

| | | | | | | |
|---|---|---|---|---|---|---|
| Medical Affairs | Inaccurate and incomplete. Plan would not to provide evidence-based information on the company's drug. No relationship with experts developed. | Several major flaws. Plan would be unlikely to provide evidence-based information on the company's drug. Unclear relationship with experts. | Minimal detail provided on the development of evidence-based information on the company's drug. No plan to establish and maintain relationships with prominent experts provided. | Some detail provided on the development of evidence-based information on the company's drug. Plan to establish and maintain relationships with prominent experts may have been outlined. | Only minor flaws in execution. Developed robust evidence-based information on the company's drug. Plan to establish and maintain relationships with prominent experts was outlined. | Developed very robust evidence-based information on the company's drug. Plan to establish and maintain relationships with prominent experts was outlined. Explanation went into depth on key details. |
| Marketing/ Commercial | Inaccurate and incomplete. Commercial strategy would not be able to differentiate the drug in the marketplace. No benefits mentioned. | Several major flaws. Commercial strategy would be unlikely to differentiate itself in the marketplace. Benefits unclear or communicated inappropriately. | Minimal detail provided on commercial strategy. Benefits of this drug may be unclear or communicated inappropriately. | Some detail provided. Developed commercial strategy to differentiate company's product. Benefits highlighted to maximize uptake. | Only minor flaws in execution. Developed robust commercial strategy to successfully differentiate company's product. Benefits highlighted to maximize uptake | Developed very robust commercial strategy to successfully differentiate company's product. Benefits clearly highlighted to maximize uptake. Explanation went into depth on key details. |

| | | | | | | |
|---|---|---|---|---|---|---|
| Demonstrating Value of Industry Pharmacists | Inaccurate and incomplete. Details provided are unclear or don't accurately capture the roles and experiences that industry pharmacists bring to the drug development process. | Several major flaws. Details provided may be unclear or don't accurately capture the roles and experiences that industry pharmacists bring to the drug development process. | Minimal detail provided, with occasional or minor flaws present, on the of roles and experiences that industry pharmacists bring to the drug development process. | Some detail provided on the roles and experiences that industry pharmacists bring to the drug development process. | Provided a very robust showcase on the variety of roles and experiences that industry pharmacists bring to the drug development process. | Provided a very robust showcase on the variety of roles and experiences that industry pharmacists bring to the drug development process. Explanation went into depth on key details. |