

King Saud University College of Pharmacy

Drug Benefit-Risk Assessment Course Syllabus

General Information

Course Number	EDRA 543
Course Title	Drug Benefit-Risk Assessment
Lecture Hours/Week	2 (2+0)
Credit Hours/Semester	2
Admission Particulars	Pre-requisites: PHRM 226: Drug Information and Evidence Based Practice Co-requisites: None
Schedule & Locations	Lectures: Mondays, from 18:45 pm to 20:55 pm Male campus: Main Auditorium
Course Director	Yasser Albogami, BSc.Pharm, MPH, PhD Assistant Professor Office Location: Office No. 1B44 Email: yalbogami@ksu.edu.sa Office hours: TBA

Participating Faculty*

Faculty	Email
Prof. Hanan Alyousef, PhD	halyousef@ksu.edu.sa
Dr. Ahmed Alkhaldi, MSc	afkhaldi@sFDA.gov.sa

*to arrange for a meeting or ask for the office hours contact each faculty directly

Course Description and Objectives

1. Course Description

This course focuses on drug benefit-risk assessment, which is a key element in approving drugs for therapeutic uses. Benefit-risk assessment is used during drug development, preclinical and clinical research, regulatory review and post-market safety monitoring, and students will learn various perspectives on how to identify, assess, and incorporate it into the drug decision-making process. By the end of the course, students will be able to understand and use various methodologies pertaining to different benefit-risk processes applied by various stakeholders.

2. Course Main Objective

At the completion of the course series, the student should be able to:

1. Explain advanced knowledge of drug benefit-risk assessment.
2. Identify the appropriate tools for benefit-risk assessment throughout the drug lifecycle.
3. Evaluate various drug benefit-risk assessment methodologies applied by the stakeholders.
4. Understand the current regulations of the Saudi FDA and WHO guidelines concerning benefit-risk assessment of medicinal products.
5. Acquire the professional skill to describe and discuss the usefulness of benefit risk assessment to healthcare practice.

Course Learning Outcomes

Resources

Required Textbooks	<ul style="list-style-type: none"> • Benefit-Risk Assessment of Medicines The Development and Application of a Universal Framework for Decision-Making and Effective Communication by James Leong , Sam Salek , Stuart Walker, ISBN: 978-3-319-15805-1 (Available via the Saudi digital library (SDL): https://sdl.edu.sa/)
Essential References Materials	<ul style="list-style-type: none"> • The International Conference on Harmonization (ICH) guideline. • Benefit-Risk Assessment for New Drug and Biological Products Guidance for Industry (USFDA). • Materials provided on the LMS.

Required Instructional Materials

All supplemental materials will be available to students electronically through blackboard. Class handouts and patient cases (when applicable) will be posted on the KSU blackboard server (<https://lms.ksu.edu.sa/>) at least 24 hours prior to the scheduled session date. It is the student responsibility to check the blackboard site regularly for any updates.

Course Policies

Academic Dishonesty/Plagiarism

- Students are expected to attend all classes.
- Students are expected to demonstrate professionalism and honesty during this course. Academic dishonesty includes, but is not limited to, cheating, plagiarizing, fabricating of information or citations, facilitating acts of academic dishonesty by others, having unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, or tampering with the academic work of other students. Students found in violation of such policy are subjected to disciplinary actions as per University Policy.
- Please read the manual of study and tests for university students and operational rule (لائحة الدراسة والاختبارات للمرحلة الجامعية والقواعد التنفيذية المعتمدة) <http://dar.ksu.edu.sa/Regulations>
- Also, check the graduate studies rules and regulations
- <https://graduatestudies.ksu.edu.sa/ar/node/586>

Class Participation and Professionalism

- It is expected that all students come to class prepared by completing where applicable all assigned readings, online homework, and other assignments before class and ready to actively participate in classroom activities. Faculty will clarify and expand on the reading material.
- Use of phones is prohibited during class.
- Use of phones is prohibited during class. If you have emergency or need to make urgent

phone call, ask for permission and when granted, you can leave the class and get back again.

Guidelines for E-Mail Communication

Email Etiquette

- In general, basic rules of style or etiquette are expected when using E-mail to communicate with teaching staff. Also;
 1. All emails should be sent from your KSU account ONLY
 2. Mail should have a subject heading which reflects the content of the message.
 3. Your message should begin with an appropriate salutation, including the name of the person being addressed, and end with the full name of sender.
 4. Use mixed case and proper punctuation.
 5. Current e-mail addresses for all students must be maintained in the Blackboard system. Each student must edit this in the "Personal Information" section of "Tools". Faculty will not be able to contact you if your email address is not updated and you could miss important information about courses.
 6. **Check your e-mail daily.** Most information and communication from instructors will come via e-mail or will be posted on Blackboard under announcements.
 7. Direct your request to the appropriate person, as indicated below. Please note that discussion board posts are preferred whenever your questions do not involve personal matters to reduce the number of individual emails.
 8. If you have a general course question or if you are unsure of where to direct questions, please, contact the Course Director. DO NOT send message to "All Instructors". At once.

Attendance and Excused Absence

- In the case of illness or prolonged absence, it is the student's responsibility to notify the Course Director within 5 days from the first date of absence. Exceptions to the five-day notification period are rare and can only be approved by the Vice Dean of postgraduate education. Upon acceptable documentation from a student, an official memorandum will be issued notifying faculty of an excused absence. In the case of a legitimate excused absence, course instructors will make all reasonable attempts to assist the student to satisfy requirements of the course.
- Students missing 25% or more on attendance are forbidden from setting in the final exam per University Policy.
- If a student missed a midterm exam for an ELIGIBLE reason, Student must submit proper documentation within 2 weeks of scheduled exam time to the faculty member and the course coordinator.
- For any missed exams, student should fill a make-up exam form to obtain the necessary signatures and approvals from faculty member, the course director and head of the program.
- The faculty member has the right to determine the method for make-up exam, which can be any of the following:
 - i) Increasing the percentage of the remaining exams to cover the missed exam
 - ii) Assigning the final exam, a higher percentage to cover the missed exam for that student
 - iii) A make-up exam

Conflict Resolution:

Any issues related to this course teaching and grading should be resolved with the course instructor promptly to ensure healthy learning atmosphere. Unresolved matter should be

directed to the course coordinator. If matter is not yet resolved, please direct your complaint to the program head.

Grade Distribution

#	Assessment task*	Week Due	Percentage of Total Assessment Score
1	Midterm	8 th (15/5/2023)	30%
2	Assignment	Throughout the semester	15%
3	Group Discussion (Case studies)	Throughout the semester	15%
4	Final Exam	13 th (19/06/2023)	40%
5	Total		100%

*Details of each assignment and case studies via LMS

Grading Scale

Grades will be earned based on KSU grading policy using the following scale:

Letter Grade	Score Achieved	Letter Grade	Score Achieved
A+	> 95%	C+	75 - 79.99 %
A	90 - 94.99 %	C	70 - 74.99 %
B+	85 - 89.99 %	D+	65 - 69.99 %
B	80 - 84.99 %	D	60- 64.99 %
		F	< 60%

Course Schedule/ Lectures

W	Date	Topics	Instructor's name
1	13/03/2023	Introduction to Drug BRA	Dr. Yasser Albogami
2	20/03/2023	Pre-Approval Drug BRA 1	Dr. Ahmed Alkhalidi
3	27/03/2023 شهر رمضان	Pre-Approval Drug BRA 2	Dr. Ahmed Alkhalidi
4	03/04/2023 شهر رمضان	Pre-Approval Drug BRA 3	Dr. Ahmed Alkhalidi
5	10/04/2023 شهر رمضان	Post-Approval Drug BRA 1	Dr. Yasser Albogami
Eid al Fitr, 14/04/2023-----25/04/2023			
6	01/05/2023	Post-Approval Drug BRA 2	Guest speaker (Private sector)
7	08/05/2023	Methods of BRA in practice	Dr. Hanan M Alyousef
8	15/05/2023	Mid-term Exam	
9	16/05/2023	Drug BRA in Practice	Dr. Hanan M Alyousef
10	29/05/2023	Herbal BRA	Dr. Hanan M Alyousef
11	05/06/2023	Advanced Quantitative BRA	Dr. Yasser Albogami
13	19/06/2023	Final Exam (EDRA-543) 5:00 P.M.-7:00 P.M.	