

# Schedule of Classes for IBRS

## Schedule of Classes for The International Biomedical Regulatory Sciences Masters and Certificate Programs

The purpose of this document is to provide a general guide for student planning. *Deviations may be necessary.* Therefore, this schedule is subject to change without notice. Course availability is dependent upon a number of factors, including instructor availability, course need, and the University's minimum registration requirement of five students. Students should always check with the IBRS Program for the current course schedule.

IBRS students will be advised based on the availability of courses outlined below. All courses in the IBRS Program are set up as Permission of Department, or POD. You will not be able to register for any of these courses without permission from the department.

If you are a student outside the IBRS Program and require an IBRS course for your program of study, it is incumbent upon you to adjust your schedule or to ensure that the course is offered when needed.

IBRS Courses start on the Saturday BEFORE University classes start for the semester.

This schedule does not include independent study courses like PHAR 6800, PHAR 6900E, PHRM 7000, and PHRM 7300. These courses are independent studies and are created for individual IBRS students on an as-needed basis.

This schedule does not include undergraduate Double Dawg courses or PHRM 8250. For those courses, contact Dr. Gurvinder Singh.

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**Fall Semester: Undergraduate Class**

15/16 weeks in length

<b>Course ID #</b>	<b>Course Title</b>	<b>Course Common Name</b>	<b>Course Instructor</b>	<b>Credit hours</b>
PHAR 4010E	Introduction to Drugs, Biologics, and Devices Regulated by the Food and Drug Administration	Undergrad Intro Class	Grace Gowda	3

**Fall Semester: Graduate Classes**

15/16 weeks in length

<b>Course ID #</b>	<b>Course Title</b>	<b>Course Common Name</b>	<b>Course Instructor</b>	<b>Credit hours</b>
PHAR 6010E	Pharmaceutical, Biotechnology, and Device Industries - Introduction to Regulatory	Intro Class	Samuel Silva	4
PHAR 6030E	Current Good Manufacturing Practices	GMP Class	Alexander Jacks	4
PHAR 6120E	Process Control and Validation	PC PV Class	Seppe De Gelas	3
PHAR 6140E	Overview of Drug Safety Throughout Medical Product Lifecycle	Drug Safety class	Kristen Mandello	4

PHAR 6160E	Chemistry, Manufacturing, and Controls	CMC class	Monica Escobar	4
PHAR 6310E	Good Clinical Practice	GCP Class	John Brennan	3
PHAR 6380E	Global Medical Device Regulatory Submission - the Marketing Application Process	Medical Device Class	Al Jacks, Evangeline Loh	3
PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	Biostats class	Steve Rathbun	3
PHRM 7230E	Ethical Issues in Research	Ethics Class	Robert Geiger	3

### Spring Semester: Undergraduate Class

15/16 weeks in length

Course ID #	Course Title	Course Common Name	Course Instructor	Credit hours
PHAR 4010E	Introduction to Drugs, Biologics, and Devices Regulated by the Food and Drug Administration	Undergrad Intro Class	Sepe DeGelas, Grace Gowda	3

**Spring Semester: Graduate Classes**

15/16 weeks in length

<b>Course ID #</b>	<b>Course Title</b>	<b>Course Common Name</b>	<b>Course Instructor</b>	<b>Credit Hours</b>
PHAR 6010E	Pharmaceutical, Biotechnology, and Device Industries - Introduction to Regulatory	Intro Class	Sam Silva	4
PHAR 6020E	Food and Drug Law	Law Class	Alexander Jacks	3
PHAR 6030E	Current Good Manufacturing Practices	GMP Class	Monica Escobar	4
PHRM 7230E	Ethical Issues in Research	Ethics Class	Robert Geiger	3
PHAR 6100E	Quality Control and Quality Assurance	QC QA Class	Robert Geiger	3
PHAR 6130E	U.S. Marketing Applications for New Drugs, Biologics, Medical Devices, and Animal Health Products	Submissions Class	Robert Geiger	3
PHAR 6180E	Animal Health Regulatory	Animal Health	Kristen Mandello	4

PHAR 6200E	Clinical Trials Design and Management	Clinical Trials Class	John Brennan	4
PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	Biostats Class	Steve Rathbun	3

### Summer Semester: Graduate Classes

11 weeks in length

Course ID #	Course Title	Common Name	Course Instructor	Credit Hours
PHAR 6020E	Food and Drug Law	Law Class	Alexander Jacks	3
PHAR 6030E	Current Good Manufacturing Practices <i>(if needed)</i>	GMP Class	Monica Escobar	4
PHAR 6210E	Project Management in Clinical Trials	Clinical Trials Project Mngt Class	Kristen Mandello	3
PHAR 6340E	European Pharmaceutical and Biologics Regulatory Sciences	EU Class	Seppe De Gelas	3
PHAR 6360E	Latin American Pharmaceutical and Biologics Regulatory Sciences	Latin America Class	Samuel Silva	3

PHRM 7230E	Ethical Issues in Research	Ethics Class	Robert Geiger	3
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