

Below is a general schedule of the courses offered each semester by the International Biomedical Regulatory Sciences (IBRS) Department. *This list is subject to change at any time without notice.* IBRS students will be advised based on the availability of course outlined below. Course scheduling depends on an instructor's availability and is subject to the University's minimum registration requirement of five students.

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 the permission of 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.

Fall Semester – 15/16 weeks in length

Course	Course Title	Credit Hours
1. PHAR 4010E	Introduction to Drugs, Biologics, and Devices Regulated by the Food and Drug Administration	3
2. PHAR 6010E	Introduction to Pharmaceutical, Biotechnology, and Device Industries - Introduction to Regulatory	4
3. PHAR 6020E	Food and Drug Law	3
4. PHRM 7230E	Ethical Issues in Research	3
5. PHAR 6030E	Current Good Manufacturing Practices	4
6. PHAR 6120E	Process Control and Validation	3
7. PHAR 6140E	Overview of Drug Safety Throughout Medical Product Lifecycle	4
8. PHAR 6160E	Chemistry, Manufacturing, and Controls	4
9. PHAR 6310E	Good Clinical Practice	3
10. PHAR 6380E	Global Medical Device Regulatory Submission - the Marketing Application Process	3
11. PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	3

Spring Semester - 15/16 weeks in length

Course	Course Title	Credit Hours
1. PHAR 4010E	Introduction to Drugs, Biologics, and Devices Regulated by the Food and Drug Administration	3
2. PHAR 6010E	Introduction to Pharmaceutical, Biotechnology, and Device Industries - Introduction to Regulatory	4
3. PHAR 6020E	Food and Drug Law	3
4. PHRM 7230E	Ethical Issues in Research	3
5. PHAR 6030E	Current Good Manufacturing Practices	4
6. PHAR 6100E	Quality Assurance Quality Control	3
7. PHAR 6130E	U.S. Marketing Applications for New Drugs, Biologics, Medical Devices, and Animal Health Products	4
8. PHAR 6140E	Overview of Drug Safety Throughout Medical Product Lifecycle	4

9. PHAR 6180E	Animal Health Regulatory Course	4
10. PHAR 6200E	Clinical Trials Design and Management	4
11. PHAR 6340E	European Pharmaceutical and Biologics Regulatory Sciences	3
12. PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	3

Summer Semester – 11 weeks – **Extended Summer Semester Schedule**

Course	Course Title	Credit Hours
1. PHAR 6020E	Food and Drug Law	3
2. PHRM 7230E	Ethical Issues in Research	3
3. PHAR 6030E	Current Good Manufacturing Practices (<i>if needed</i>)	4
4. PHAR 6210E	Project Management for Clinical Trials Design and Management	3
5. PHAR 6310E	Good Clinical Practice	3
6. PHAR 6360E	Latin American Pharmaceutical and Biologics Regulatory Sciences	3