



DREXEL UNIVERSITY

College of  
**Medicine**

*Department of Pharmacology and Physiology*

## **DRUG DISCOVERY AND DEVELOPMENT GRADUATE PROGRAM**

### ***Policies & Procedures***

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**POLICIES AND PROCEDURES FOR**  
**MASTER OF SCIENCE PROGRAM IN**  
**DRUG DISCOVERY AND DEVELOPMENT**

**I. MISSION STATEMENT**

**A. Statement of the Goals of the Program**

The overall goal of this Program is to provide students with an intensive, multifaceted training experience along with extensive professional skills development and diverse research opportunities to prepare graduates for a career in the field of Drug Discovery and Development. The Program covers all aspects involved in the discovery, development and commercialization of drugs. Depending on a student's preferences, there are multiple options and areas of concentration that can be pursued using elective courses in different departments, schools and colleges. The biomedical sciences are the foundation of this field so the initial emphasis of the curriculum is on the disciplines of Pharmacology and Physiology. The pharmaceutical and biotechnology industries are complex, highly specialized, and constantly evolving, and require a diversity of expertise. There are numerous technical specialties required and diverse organizational disciplines necessary to successfully advance a candidate compound to an approved drug. Consequently, the program has been designed to provide a solid foundation in the sciences as well as in depth exposure to the entire process of drug discovery and development. This is coupled with opportunities to do hands-on laboratory research or industry internships and further focus training on individual segments or disciplines within the field. In addition to several experienced faculty, we have successfully attracted individuals from all levels and sectors of the pharmaceutical industry to participate in the development and delivery of the Program. The Program also capitalizes on the rich and diverse resources available within the Drexel University academic community to draw on courses available in the LeBow College of Business, the Dornsife School of Public Health, the Close School of Entrepreneurship and other departments and schools at the University.

**B. Statement of the Career-oriented Outcomes of the Program**

By providing in depth exposure to the multiple elements associated with drug discovery and development, this program provides graduates with numerous rewarding career options. For recent undergraduates, it provides entrance into a competitive field with multiple opportunities for growth and advancement. For active professionals, it provides valuable training to advance in their discipline or make a smooth and successful transition to another discipline within the field. For students who continue their training in advanced or professional degree programs, it provides an added expertise that will help set them apart from their competition. Graduates of the program are prepared to assume positions in pharmaceutical and biotechnology companies, nonprofit foundations, government agencies and academic institutions.

## II. PLAN OF STUDY

### A. Required Courses

All students in the Drug Discovery and Development Program are required to take the following programmatic courses: Drug Discovery and Development I and II, which provide a comprehensive overview of the discovery and development process; Graduate Pharmacology which provides a solid foundation in this key interdisciplinary science; Drug Discovery and Development Research, which is intended to provide hands-on or practical experience; and Current Topics in Drug Discovery and Development which is a seminar/discussion course that provides valuable exposure to some of the more rapidly evolving elements of the pharmaceutical field as well as multiple opportunities to enhance presentation skills. All students in the Graduate School are required to take Responsible Conduct of Research and Biostatistics or Statistics for Neuro/Pharm Research.

Required Courses		Credits Hours
IDPT 500S	Responsible Conduct of Research <sup>1</sup>	2.0
IDPT 501S	Biostatistics I <sup>2,3</sup>	2.0
PHRM 512S	Graduate Pharmacology*	3.0
PHRM 525S	Drug Discovery and Development I*	3.0
PHRM 526S	Drug Discovery and Development II*	3.0
PHRM 605S	Research in Drug Discovery and Development <sup>4</sup>	4.0
PHRM 527S	Current Topics in Drug Discovery and Development	1.0
<b>Total</b>		<b>18.0</b>

<sup>1</sup>CR 612S\* may be substituted for IDPT 500S

<sup>2</sup>CR 520S\* may be substituted for IDPT 501S

<sup>3</sup>NEUR 500S may be substituted for IDPT 501S

<sup>4</sup>PHRM 610S\* may be substituted for PHRM 605S

\* course available online

All face-to-face (onsite) students must register and participate in the seminar/discussion course Current Topics in Pharmacology and Physiology. It is expected that each student will complete at least one research rotation in Drug Discovery and Development Research. The Program Director(s) will advise each student on the selection of the flexible aspects of the curriculum such as choice of electives.

### B. Elective Courses

In consultation with the student's advisor and according to the anticipated area of interest, the student is required to select elective courses totaling a minimum of 18-20 credits from a diverse range of topics that complement the core curriculum and which provide relevant, in-depth knowledge to enhance career options. Onsite students who are interested in discovery research are encouraged to take Graduate Physiology and Advanced Topics in Physiology. They are also encouraged to repeat Current Topics in Pharmacology and Physiology if their schedule permits. Courses outside of the Drug Discovery and Development program may be taken on the advice and with the permission of the Program Director and the course instructor.

A list of potential electives is provided below. It is recommended that you consult with the course director for each course to receive approval to register for the course and to determine if there are prerequisites or class limitations. For courses outside the College of Medicine, please consult the Graduate catalog at:

<http://catalog.drexel.edu/coursedescriptions/quarter/grad/>

### Approved Electives

MIIM 515S	Concepts in Biomedicine I*	3.0
MIIM 516S	Concepts in Biomedicine II*	3.0
MIIM 521S	Biotechniques I: Molecular and Genomic Methods*	2.0
MIIM 522S	Biotechniques II: Immunological Methods*	2.0
MIIM 524S	Vaccines and Vaccine Development*	3.0
MIIM 527S	Immunology, Immunopathology & Infectious Disease*	3.0
MLAS 536S	Animal Models for Biomedical Research	1.0
NEUR 508S	Graduate Neuroscience I	3.0
BIOC 510S	Cancer Biology	3.0
PHGY 503S	Graduate Physiology	4.0
PHRM 502S	Current Topics in Pharmacology & Physiology	1.0
PHRM 503S	Pharmacology & Physiology Lab Rotation	4.0
PHRM 507S	Principles of Neuropharmacology	3.0
PHRM 516S	Advanced Topics in Physiology	1.0
PHRM 517S	Advanced Topics in Pharmacology*	1.0
PHRM 518S	New Frontiers in Therapy	1.0
PHRM 519S	Methods in Biomedical Research	2.0
PHRM 520S	Internship in Drug Discovery	4.0
PHRM 521S	Intensive Internship in Drug Discovery and Development	9.0
PHRM 610S	Practicum in Drug Discovery and Development*	4.0
PHRM T580S	Special Topics in Pharmacology and Physiology	2.0
CR 500S	Epidemiology*	3.0
CR 501S	Emerging Trends in Medical Device History*	3.0
CR 505S	Ethical Issues in Research*	3.0
CR 508S	Medical Device Combination Product Regulation*	3.0
CR 510S	Sponsored Projects Finance*	3.0
CR 511S	The History of Misconduct in Biomedical Research*	3.0
CR 512S	Fundamentals of Academic Research Administration*	3.0
CR 513S	Pharmaceutical R&D: Business Process and Information Flow*	3.0
CR 514S	Worldwide Regulatory Submissions*	3.0
CR 515S	Introduction to Clinical Trials*	3.0
CR 518S	Clinical Trials Budgeting*	3.0
CR 520S	Applications of Clinical Research Biostatistics*	3.0
CR 523S	Current Issues in Review Boards*	3.0
CR 525S	Scientific Writing and Medical Literature*	3.0
CR 527S	Clinical Data Management*	3.0
CR 530S	Tech Transfer*	3.0

CR 535S	Current Regulatory Issues in Biomedical Research*	3.0
CR 541S	Patient Recruitment and Informed Consent*	3.0
CR 545S	Pharmaceutical Law*	3.0
CR 546S	Clinical Outsourcing*	3.0
CR 550S	Leadership Skills*	3.0
CR 551S	International Regulatory Affairs*	3.0
CR 555S	Compliance and Monitoring Issues*	3.0
CR 565S	Contemporary Issues in Human Research Protection*	3.0
CR 570S	Principles and Practice of Pharmacovigilance*	3.0
CR T580S	Special Topics in Clinical Research*	3.0
CR 600S	Designing the Clinical Trial*	3.0
CR 609S	Innovative Produce Development*	3.0
CR 612S	Fundamentals of Compliance*	3.0
CR 614S	Pharmacotherapy in New Drug R&D*	3.0
CR 616S	Intro to Therapeutic Products*	3.0
CR 617S	Informatics in Pharmaceutical Research & Development*	3.0
CR 620S	Biotech/Research*	3.0
CR 625S	Health Policy and Economics*	3.0
CR 630S	Translational Research*	3.0
CR 631S	Applications of Clinical Research Biostatistics II*	3.0
CR 633S	Quality Assurance Audits*	3.0

*\*Courses available online*

### **Approved Electives (quarter-based)**

BIO 631	Bioinformatics I	3.0
MGMT 685	Implementing Strategies Using Project Teams	3.0
MGMT 910	Readings in Strategic Management	3.0
PROJ 501	Introduction to Project Management	3.0
PROJ 535	International Project Management	3.0
PBHL 530	Principles of Epidemiology	4.0
BMES 604	Pharmacogenomics	3.0
MGMT 940	Seminar in Organizational Behavior	3.0
ORGB 625	Leadership and Professional Development	3.0

**Note:** *One quarter credit is equal to two-thirds of a semester credit for satisfying program credit requirements*

## C. Suggested Plans of Study

### Full-Time Plan of Study

#### Fall Semester I

	<b>Credit Hours</b>
• Graduate Physiology	4.0
• Advanced Topics in Physiology	1.0
• Drug Discovery & Development I	3.0
• Responsible Conduct of Research	2.0
• Current Topics in Pharmacology and Physiology	1.0

#### Spring Semester I

• Drug Discovery and Development II	3.0
• Graduate Pharmacology	3.0
• Advanced Topics in Pharmacology	1.0
• Biostatistics or Statistics for Neuro/Pharm Research	2.0
• Current Topics in Pharmacology and Physiology	1.0
• Elective 1	3.0

#### Fall Semester II

• Research in Drug Discovery and Development	4.0
• Current Topics in Drug Discovery & Development	1.0
• Current Topics in Pharmacology and Physiology	1.0
• Elective 2	3.0
• Elective 3	3.0

#### Spring Semester II

• Thesis Research	9.0
OR	
• Intensive Internship in Drug Discovery & Development	9.0
OR	
• Electives	9.0

## Online/Part-Time Plan of Study

Semester 1	Credit Hours
• Drug Discovery & Development I	3.0
• Elective 1	3.0
<b>Semester 2</b>	
• Drug Discovery and Development II	3.0
• Applications of Clinical and Research Biostatistics	3.0
<b>Semester 3</b>	
• Elective 2	3.0
• Fundamentals of Compliance	3.0
<b>Semester 4</b>	
• Graduate Pharmacology	3.0
• Current Topics in Drug Discovery & Development	1.0
• Elective 3	3.0
<b>Semester 5</b>	
• Elective 4	3.0
• Elective 5	3.0
<b>Semester 6</b>	
• Practicum in Drug Discovery & Development	4.0
• Elective 6	3.0

The Office of Biomedical Education has established criteria by which all students in all graduate programs will be uniformly evaluated. **A grade of B must be earned in each required course.** Programmatic courses must be repeated if the student earns a grade below a B in that particular course. Programmatic courses in which a student has earned a grade of B- can be remediated to a B. **Students must maintain a grade point average of at least 3.0.** If their average falls below 3.0, they will automatically be placed on academic probation.

### D. Research Internships

An internship is a highly desirable component of the training program in Drug Discovery and Development and provides a unique opportunity for the student to apply the didactic knowledge



gained in the laboratory in a professional setting. The internship experience can be utilized to obtain specialized training in a branch of the field that the student intends to pursue after graduation or it can provide valuable diversification to a student's background. Internships may be arranged with pharmaceutical companies, biotech companies, contract research organizations, foundations, government agencies or academic institutions. Several of these organizations have established formal internship or co-op programs that would be appropriate for this experience. Students may arrange an internship with the assistance of the Program faculty to take place after the Spring semester of their 1<sup>st</sup> year.

#### E. Journal Clubs and Seminars

Performance Criteria for Current Topics in Pharmacology & Physiology (face-to-face):  
Three unexcused absences are allowed per year for journal clubs. More than three absences will result in a grade of Unsatisfactory (U). The "U" must be remediated to the satisfaction of the course director. Students are expected to attend departmental seminars whenever possible.

### III. REQUIREMENTS FOR GRADUATION (PROGRAM SPECIFIC)

#### A. GPA Requirements – Required Courses

The program requirements for the program are the same as those established by the Office of Biomedical Education. **A grade of B must be earned in each required course.** Programmatic courses must be repeated if the student earns a grade below a B in that particular course. Programmatic courses in which a student has earned a grade of B- can be remediated to a B.

#### B. Overall GPA Requirements – Program

**Students must maintain a grade point average of at least 3.0.** If their average falls below 3.0, they will automatically be placed on academic probation.

#### C. Laboratory Rotation

For students who elect to do a laboratory rotation to fulfill the Research in Drug Discovery and Development course requirement, ***the rotation must be arranged in consultation with the Program Director*** and lab director. The research areas may be chosen to complement the student's long-term research interests. Research rotations should provide an opportunity to:

- Practice scientific logic and experimental design
- Acquire useful technical expertise
- Extend scientific and personal interactions within and between labs
- Explore the possibility for a future Thesis research topic
- Develop presentation skills

***At least 20 hours per week (minimum) for a three-month period are required for each rotation.*** Students must complete a rotation evaluation form with their mentor upon completion of their rotation which must be filed with the Program Director.

## IV. NON-THESIS TRACK

### A. Course Requirements

The Drug Discovery and Development Program offers a non-thesis MS degree in which students can earn the degree by taking graduate classes and writing a literature review paper as opposed to conducting original research. The requirements for a M.S. degree without thesis are essentially the same as those described above except that preparation of a scholarly review is required in lieu of a research-based thesis. The student is encouraged to choose a faculty or external mentor for the scholarly review. External mentors must be approved by the Program Director(s) who will help insure that the student is making adequate progress. The role of the mentor is to provide guidance in selecting the topic for the scholarly review, and in helping the student perform the literature search, and in writing the document. The selected topic must be approved by the Program Director(s).

### B. Scholarly Review

The scholarly review covers a topic in detail based on primary research literature. The body of the paper must be 35-50 double-spaced pages (12 pt font). This page number does not include citations but citations must be provided as well. The following format must be followed:

- Abstract (250 words)
- Body of Paper
  - Introduction – what is the purpose and scope of the review
  - Literature review – review and contrast findings in the field; identify unresolved issues and shortcomings of technical approaches
  - Summary – what are the key findings of the review
  - Conclusion- what gaps in our knowledge or unanswered questions emerge from the review; what are potential future directions for research in this area?

Formatting instructions can be found in the *Drexel Scholarly Review Guidelines* pamphlet. Successful completion of the literature review will be subject to the approval of the Program Director and the Scholarly Review Committee. The student is strongly encouraged to produce a document of sufficient quality to merit consideration for publication.

### C. Scholarly Review Committee

The committee consists of at least three members who must be Graduate School faculty. The student's mentor/advisor can be a voting member of the Committee. It is the responsibility of the Committee Chair to ensure that there is sufficient balance on the committee to enable a rigorous and unbiased critique of the student's work.

#### D. Review Proposal

1. Students will present or submit their Review Proposal to their Review Committee. For full-time students, the Proposal document will be submitted by the student after completion of their 3<sup>rd</sup> semester. Under special circumstances this can be extended (no more than 6 months but all proposals for extensions will be given due consideration). The Review Proposal must include an abstract and planned table of contents. Upon approval of the Proposal, the student will continue with his/her literature research, culminating with the submission of the Review. If the proposal is not approved, the student can re-submit a revised or new proposal in one month.

#### E. Review Evaluation

1. Copies of the scholarly review must be distributed to each member of the review committee for evaluation. The review can be submitted no less than 8 calendar weeks after satisfactory completion of the Proposal, and with the approval of his/her advisor or Program Director.
2. The Review Committee will review the document within two weeks of submission.
3. The Review Committee shall decide upon the merits of the Scholarly Review. To be recommended for a Master's degree, the candidate must receive unanimous approval of the Committee. By permission of the Committee a candidate who has failed the final evaluation may present a revised document for re-evaluation after one, but not more than six months.

### V. THESIS TRACK

#### A. Thesis Requirements

The thesis project need not be completely independent but rather should be at the suggestion and under the guidance of the major advisor. For full-time students, the project must be appropriate for completion and thesis defense no later than August of the second year. Laboratory work can begin as early as the second semester and continue through the second year.

#### B. Thesis Committee

**The student will propose members of the faculty to serve on the Thesis Committee subject to approval by the Program Director. For full time students, this should occur no later than the end of the third semester. For part-time students, this should occur at least nine months before the anticipated thesis defense.** Once formed, this committee will meet every three months to review the student's progress. The committee consists of at least three voting members who must be Graduate School faculty. The student's major advisor is a voting member of the Committee but cannot chair the Committee. The Chair of the Committee must not be a collaborator on the student's research project and

must not have any apparent conflicts of interest related to the publication or funding of the student's project. It is also the responsibility of the Chair to ensure that there is sufficient balance on the committee to ensure a rigorous and unbiased critique of the student's project and progress. Following the interim review by the Committee, a brief statement of the student's progress must be signed by each Committee member and submitted to the Program Director.

### C. Thesis Proposal

1. Master's degree students will present their thesis proposal to their Thesis Committee. A written Proposal will be submitted at least one week before the formal presentation to the Committee and, for full-time students, no later than the end of the 3<sup>rd</sup> semester. Under special circumstances this can be extended (no more than 6 months but all proposals for extensions will be given due consideration; approval must be obtained through written request to the Program Director). The Thesis Proposal must include an abstract and description of Specific Aims. Upon approval of the Thesis Proposal the student will continue with his/her thesis research, culminating with the public presentation of the M.S. thesis for defense.
2. At the time of the proposal the student will present a brief (15-20 minute) oral summary of his/her intended research project followed by a detailed question and answer session with the Thesis Committee.
3. The Thesis Committee will then reach a decision. If the decision is positive, the student may continue with his/her thesis research. If the decision is negative, the student can re-submit a revised or new proposal in one month. If the Thesis Proposal is rejected a second time, the student will be recommended for a non-thesis Master's degree.

### D. Thesis Defense

1. A written thesis is required with a public presentation and an oral defense before the Thesis Committee. A candidate may not present him/herself for the final thesis defense until he or she has the approval of his/her major advisor and the Thesis Committee.
2. At least two weeks prior to the date of the thesis defense, the student must notify the department office of the scheduled date of the thesis defense. At least one week prior to the date of the defense, typewritten or photocopies of the thesis must be distributed to each member of the advisory-examination committee.
3. The thesis defense will take place no less than one week and no more than four weeks after the thesis has been distributed to the members of the examination committee.
4. The thesis defense will be public. The candidate will be formally introduced by his/her advisor or the Chair of the Committee. The candidate will present a 30-45 minute seminar on his/her research, followed by questions from the general audience. After this initial question and answer period, the chair will dismiss the audience. The Thesis Committee will meet in private with the candidate to complete the examination process.
5. The Thesis Committee shall decide upon the merits of the candidate's performance on the thesis defense. To be recommended for a Master's degree, the candidate must receive unanimous approval of the Committee. By permission of the Committee, a candidate who has failed the final thesis defense may present him or herself for re-examination after one, but not

more than six months. This re-examination must be taken within a calendar year of failure to pass the first examination. A report on each final thesis defense whether passed, failed, or recommended for re-examination must be filed with the Program Director.

6. The Instructions for preparation and submission of the thesis document can be found in the *Drexel Thesis Guidelines* pamphlet.

## VI. UNSATISFACTORY PERFORMANCE

### A. Definition of Unsatisfactory Performance

Unsatisfactory performance is defined as not obtaining a final grade of “B” or better in all courses required for the completion of the Master of Science in Drug Discovery and Development degree. Unsatisfactory performance is also defined as not maintaining an overall cumulative GPA of 3.0 or better for all courses.

### B. Remediation Policy

Each course will have individual remediation policies in the case of unsatisfactory performance. Please consult the syllabi for each of the courses. Remediation may range from a requirement to repeat the course, undertake a special examination, or submit a defined written assignment in addition to all other forms of assessment.

## VII. ACADEMIC INTEGRITY

### A. Code of Behavior

#### **CODE OF BEHAVIOR**

The Graduate Program in Drug Discovery and Development subscribes to the **Code of Professionalism** that can be found at: <http://drexel.edu/medicine/academics/graduate-school/interdisciplinary-career-oriented/> (in: Student Handbook -Interdisciplinary and Career-Oriented programs) for all of its members. This policy states that professional behavior appropriate to faculty and students in an academic research setting is expected and required at all times. Admission to and continued participation in the Graduate Program is therefore contingent upon the student's understanding of this policy, and his/her agreement to adhere to its guidelines.

## B. Code of Ethics

### **CODE OF ETHICS**

The Graduate Program in Drug Discovery and Development subscribes to the **Code of Academic Integrity** (presented in its complete form in the Student Handbook at, <http://drexel.edu/medicine/academics/graduate-school/interdisciplinary-career-oriented/>) This policy states that cheating, plagiarism, forgery, or other forms of academic misconduct are not tolerated at our institution. Admission to and continued participation in the Graduate Program is therefore contingent upon the student's understanding of this policy, and his/her agreement to adhere to its guidelines.