Ph.D. in Pharmaceutical Sciences

Last modified March25, 2024

The current Ph.D. in Pharmaceutical Sciences graduate program is offered by the Department of Pharmaceutics. The departmental faculty has decided to use the 'track' method for accommodating its multi- and inter-disciplinary diversity of the Department.

The Department of Pharmaceutics houses the Center for Pharmacometrics and Systems Pharmacology. The department's focus differs sufficiently from that of other departments in the College. The uniqueness of the department is evident in the ongoing research activities which encompass basic, applied and clinical investigations in the areas of Biopharmaceutics and Pharmacokinetics-Pharmacodynamics, Pharmacometrics and Systems Pharmacology, Pharmaceutical Biotechnology, Pharmaceutical Analysis, Drug Delivery, and Drug Discovery. Specifically, Biopharmaceutics and Pharmacokinetics-Pharmacodynamics encompasses the absorption, distribution, metabolism and excretion of drugs in animals and humans, and the relationship between drug concentration and effect. Pharmaceutical Biotechnology includes molecular biology, immunology, immunotherapy and aspects of the delivery of nucleic acid, peptide and protein drugs. Pharmaceutical Analysis involves the application of a broad array of analytical methods to drug determination. Drug Delivery includes physical, biological and chemical approaches to drug delivery, and the formulation and evaluation of dosage forms. Pharmacometrics focuses on dose optimization using pharmacokinetic-pharmacodynamic correlations to improve the therapeutic index for active pharmaceutical ingredients.

- Objectives of the Ph.D. Program
- Faculty
- Governance
- Recruitment of Students
- Admission Procedures
- Financial Assistance
- Selection of Discipline for Degree and Major Professor
- Supervisory Committee
- Curriculum
- Qualifying Examination
- Final Examination
- Specific Requirements for the Master of Science in Pharmacy Degree

The objectives of the Ph.D. program in the Department of Pharmaceutics are:

- To provide a foundation in the pharmaceutical sciences in general, as well as in the specific tracks identified, with emphasis on pharmacokinetics, pharmacometrics and systems pharmacology, biopharmaceutics, pharmaceutical analysis, pharmaceutical technology/drug delivery, pharmacodynamics, pharmaceutical biotechnology, and drug design and discovery.
- To educate individuals to be capable of conducting independent research and to be able to apply in-depth specialized knowledge in one of the above areas and to provide a solid educational, technical and experiential foundation for students in the industrial, academic, governmental or other arenas.
- To provide an environment that nurtures and stimulates the research interests and the intellectual advancement of students and faculty, including a forum for scientific and professional discussion.
- To prepare students to meet the expectations of different professional endeavors, including careers in the pharmaceutical industry (big pharma and CROs), academia, regulatory agencies such as the US Food and Drug Administration.

Faculty

Thomas D. Schmittgen, Ph.D. — **Profile CV Email**
Professor and Chair

Rodrigo Cristofoletti, Ph.D. — **Profile CV Email**
Assistant Professor

Natalia V. de Moraes, Ph.D. — **Profile CV Email**
Assistant Professor

Mei He, Ph.D. — **Profile CV Email**
Associate Professor
Graduate Coordinator

Guenther Hochhaus, Ph.D. — **Profile CV Email**
Professor

Sarah Kim, Ph.D. — **Profile CV Email**
Assistant Professor

William Cary Mobley, Ph.D. — **Profile CV Email**

Clinical Associate Professor

Stephan Schmidt, Ph.D., F.C.P. **Profile CV Email**
Professor, Director CPSP, Certara Professor

Abhisheak Sharma, Ph.D. **Profile CV Email**
Assistant Professor

Sihong Song, Ph.D. **Profile CV Email**
Professor

Fan Zhang, Ph.D. **Profile CV Email**
Assistant Professor

Francine J Azeredo B.Pharm, Ph.D. **Profile CV Email**
Assistant Professor

Brian Cicali Ph.D., M.S. **Profile CV Email**
Assistant Professor

Governance

Decisions concerning curricular revision and student admissions are made after the department faculty has met to discuss such matters and each faculty member has voted on that particular issue.

Selection of Discipline for Degree and Major Professor

Students must select a major advisor by the end of their second semester of graduate school but are encouraged to do so as early as possible.

If a student desires to change the major advisor, he/she must discuss the change with the current advisor. If both parties agree to such change, the student may select a new advisor. If the parties cannot come to an agreement concerning the proposed change, then the student and the faculty member must each write a letter to the department chairperson explaining the situation. The student must specify the reason(s) for deciding to change. The advisor's letter must specify the reason(s) for the disagreement and contain an overall evaluation and appraisal of the situation. The department chairperson will evaluate the letters, discuss the situation with both individuals, and a decision will be made. If the student is permitted to change advisors, he/she will not be allowed to continue the same research project with another faculty member, except if both faculty members agree in writing to the department chairperson that the student should continue the same project under the new advisor.

The department graduate coordinator will advise the student in general policies as set forth in this document. The graduate coordinator is also responsible for general oversight of the graduate program for quality assurance of the program, assignment of teaching duties, and recruitment of graduate students.

Supervisory Committee

The supervisory committee is proposed by the student's major advisor in consultation with the student, nominated by the department chairperson, approved by the Dean of the College of Pharmacy, and appointed by the Dean of the Graduate School. Each committee member must hold Graduate Faculty status with the Graduate School. The Dean of the Graduate School is an ex-officio member of all supervisory committees. By no later than the end of the first year of graduate study, students should have a committee of at least 3 members formed to serve as their supervisory committee. Students are strongly encouraged to complete this step by the end of the fourth semester.

Committee meetings should occur no less than once per academic year, with a strong recommendation to meet twice per year, to review student progress and their IDP and career progress, and provide guidance.

The supervisory committee shall consist of at least four (4) members of the Graduate Faculty. At least two (2) members must be from the Department of Pharmaceutics, and at least one (1) member other than the chairperson must be tenured faculty; at least one (1) member must be from a different educational discipline outside the College of Pharmacy. The chairperson need not be tenured, but must hold a full-time tenure track position in the Department of Pharmaceutics.

In unusual cases, the doctoral research may require the guidance of a specialist in an area of study other than that of the supervisory committee chairperson. In such cases, the department chairperson may recommend the appointment of a co-chairperson who should be on the graduate faculty.

Duties of the Supervisory Committee

- To provide optimal support and guidance to the student to help the student meet his/her academic goals.
- Inform the student of all regulations governing the Ph.D. degree. This does not absolve the student from the responsibility of becoming informed of these regulations.
- To meet soon after appointment with the student to consider the student's individual goals and proposed program, and evaluate the student's progress to date.
- To conduct the student's **written** qualifying examination after the student has completed all required course work. The supervisory committee should also assist in the departmental oral qualifying exam. After successful completion of the written and oral exam the committee will discuss and approve the student's dissertation topic, and, if the student has passed the examination to the committee's satisfaction,

recommend the student's admission to candidacy.

- The supervisory committee should monitor and evaluate the student's progress and give clear directions as to the final work plan leading to graduation. It is recommended that the committee meet once a year before the student advances to candidacy and every six months thereafter to review the student's research and to make suggestions for completion of research, and approve that the student is ready to write up the dissertation as soon as the major advisor and student are convinced that the research is nearing completion.
- To conduct the final oral examination in defense of the dissertation.

Courses

Each student, together with his/her committee, will construct a course program of study specifically designed to meet the student's interest including the following core courses:

Course	Course Title	Semester offered
Statistics	STA 6166 (3) Statistical methods in Research 1	
	Or PHC 6050 Statistical Methods Health Science	
	Or PHC 6052 Intro to Biostats Methods	
Drug Metabolism	PHA 6427 (2) Pharmacogenetics of Drug Metabolism	Fall (Odd Years)
	Or PHA 6935 (2) Biotransformation Considerations in Drug Design	Fall (Even years)
Ethics	VME 6767(1) Issue Responsible Research	Spring
	Or GMS 7877 Responsible Conduct of Biomedical	Spring
College-wide	PHA 6185 Life Cycle of a Drug (Dr. McCurdy)	Summer
	PHA 6894 Intro to Graduate Studies (Dr. Keller-Wood)	Summer
Grant Writing	PHA 6936 Grant Writing (Dr. Schmittgen)*	Summer (Yearly)
Pharmaceutics	PHA 6416 (3) Pharmaceutical Analysis (Dr. He)	Spring (Even Years)
	PHA 6125 (3) Introduction to Quantitative Pharmacology (Drs. Vozmediano and Cristofoletti)	Fall (Yearly)
	PHA 6938 (1) Seminar (Max 3)	Spring and Fall
Research	PHA 7979 Advanced Research (prior to candidacy)	
	PHA 7980 Doctoral Research (for PhD candidates)	

*The department will cover the tuition cost for PHA6936 in the summer if needed.

The students may also select any of the following non-required courses related to their research projects.

Course	Course Title	Semester offered
PHA 6131	Physiologically-Based Modeling (Drs. Schmidt and Cristofoletti)	Spring (Odd Years)
PHA 6133	Translational Clinical Pharmacology (Dr. Bulitta)	Spring (Odd Years)

PHA 6183	Pharmaceutical Gene Delivery (Dr. Song)	Spring (Odd Years)
PHA 6418	Model Informed Drug Development (Dr. Schmittgen)	Fall (Yearly)
PHA 6935*	Population Pharmacokinetics and Pharmacodynamics (Dr. Kim)	Spring (Yearly)
PHA 6935*	Nanomedicine-based Immunotherapy (Dr. Zhang)	Fall (Odd Year)
PHA 7900	Journal Club (Dr. Zhang)	Summer, Fall and Spring (Yearly)

* PHA 6935 is a temporary course number for these courses

Students with adequate training in any of the above courses may apply for exemption from such courses, but they must have credit for a minimum of thirty (30) semester hours of approved didactic courses. The remaining course requirements can be fulfilled by completion of electives from the provided list or the graduate catalog selected in consultation with the students advisory committee. It is also essential that the student ensure that they have a basic understanding of Pharmaceutics either by taking the appropriate classes or from previous education. They should be proficient in the basic sciences at a minimum to the same degree as students in the professional program. Questions will be asked during the oral qualifying exam.

ALL GRADUATE STUDENTS should register at least once for Research Seminar **(PHA 6938**; 1 credit; S/U option), up to 3 times (**maximum 3 credits**) in any Spring or Fall semester.

Qualifying Examination

Satisfactorily passing the qualifying examination is a requirement for admission to candidacy, i.e., when the student actually becomes a candidate for the Ph.D. degree. In order to take the qualifying examination, the student must (i) have a minimum 3.00 GPA; (ii) have completed letter- grade course work; (iii) have completed all core courses; and (iv) be registered at the time the examination is taken. Exceptions (e.g., if a core course is not offered, but the student has fulfilled all other requirements and has formulated a research program) may be granted by the supervisory committee. It is expected that the qualifying exam will focus on the student's own prepared NIH (R21 or F31 like) grant proposal but in addition; background information from course work and general questions of pharmaceutics may be asked of the student.

General Guidelines

- The format for the comprehensive examination will be a combined written/oral examination.
- The comprehensive examination should be completed between the time when all course work is completed and no later than eight months prior to scheduling of the

dissertation defense. It is expected that the oral comprehensive examination will be taken by the end of the third year in the graduate program.

- The written part of the comprehensive examination committee for each student will be chaired by a faculty member in the Department of Pharmaceutics who is a member of the graduate faculty. The student's academic advisor will be a member of the committee but may not be the committee chair. Composition of the committee will be consistent with University guidelines for dissertation committees. All committee members must be graduate faculty. It is anticipated that the examination committee will subsequently serve as the dissertation committee.
- The comprehensive examination committee will have a meeting prior to the comprehensive examination to discuss lines of questioning and to address core competencies (relative to each focus area). The chair of the examination committee will communicate the proceedings of this meeting to the Graduate Coordinator. The oral part of the exam is open to the entire department.

Guidelines for Proposal Preparation

1. The topic of the research proposal must be an **original research project**. The topic may be the student's proposed dissertation research. A written abstract of the research proposal, maximum of one page in length, should be examined and approved by the academic advisor and the oral comprehensive examination committee prior to preparation of the complete proposal.
2. The written proposal, maximum of 10 pages of text plus references, prepared in the format of a granting agency (e.g., NIH F31) should be distributed along with "key" references to the committee at least 14 days prior to the oral comprehensive examination.
3. The graduate student will give an oral presentation that should be succinct, yet complete (approximately 20-30 minutes), and be supported by visual aids.
4. The committee will identify questions relevant to each research focus area, which may include but not be limited to:
    - Literature evaluation skills
    - Writing skills
    - Scientific background
    - Study design
    - Utility of animal models of disease or conditions relative to the human situation
    - Analytical methods
    - Clinical measurement methods
    - Data and statistical analysis skills
    - Differentiation of clinical and statistical significance
    - Basic Sciences covered in the Professional Program (Physical Pharmacy, Biochemistry, Pharmacokinetics, Biochemistry, Pharmacology, Medicinal Chemistry and Statistics)

5. The final evaluation by the dissertation committee should be communicated to the student and the Office of Graduate Programs utilizing the following scale:
   a. Pass - With written feedback on strengths and weaknesses
   b. Remedial work needed:
      - Specific needs for additional learning experiences (e.g., scientific area, statistics, writing, etc.) may be identified.
      - Remedial work may include a minor rewrite of the proposal or a major rewrite and re- defense of the proposal.
      - Remedial work must be completed within six months from the time of examination.
   c. Fail - If a student fails the qualifying examination, the Graduate School should be notified. A re-examination may be requested, but it must be recommended by the supervisory committee. At least one term of additional preparation is needed before re-examination.

Oral Comprehensive Examination Guidelines for Proposal Preparation Procedures

Oral comprehensive exam proposals are to be submitted on NIH grant application form PHS 398 continuation pages and prepared according to the directions in the application packet, with the exceptions noted below. Forms and instructions are available on the NIH website.

Research Plan

Do not exceed a total of ten pages for the following parts (a-d): Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Experimental Design and Methods. Tables and figures are included in the ten-page limitation. Applications that exceed the page limitation or PHS requirements for type size and margins (Refer to PHS 398 application for details) will be returned for revision. The ten-page limitation does not include parts e through i. (Human Subjects, Vertebrate Animals, or Literature Cited).

(a)- *Specific Aims* – (1 page). List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology.

(b) - *Background and Significance* – (2-3 pages). Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Concisely state the importance and healthcare relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.

(c)- *Preliminary Studies/Progress Report* – (2-3 pages). Use this section to provide an account of the students'/academic advisors' preliminary studies pertinent to the application information that will also help to establish the feasibility of the proposed project.

(d) - *Research Design and Methods* – (4-5 pages). Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will

be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project.
For complete instructions regarding sections (e) and (f), visit the NIH website.
(e) – *Human Subjects Research*
(f) – *Vertebrate Animals*
(g) – *Literature Cited.* (No page limit). List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and select only those literature references pertinent to the proposed research.

The student should inform the Office of Graduate Programs at least two weeks in advance of the Oral Qualifying Exam, including their time/date/location of the exam and their research topic title. The department admin should send out the announcement for the Oral Qualifying exam at least one week prior to the exam to the department faculty, staff, and students.

Final Examination-defense

After submission of the original copy of the dissertation to the Graduate School (see below) and completion of all other work for the degree, and the appropriate dates and time intervals will follow the guidelines set forth by the University of Florida Graduate School, as detailed in the Graduate Catalog.
The student should inform the Office of Graduate Programs at least three weeks in advance of the Final Dissertation Defense Exam, including their time/date/location of the exam and their research title. The Office of Graduate Programs will send out the announcement for the Final Dissertation Defense Exam at least two weeks prior to the exam to the College.
At least four (4) faculty members, including all members of the supervisory committee, must be present at the final oral portion of the final examination. The four (4) faculty members must be Graduate Faculty members. Only the official members of the supervisory committee sign the dissertation signature pages.
Assuming the candidate is successful, the Final Examination Report shall be signed by all faculty members attending the examination. Confirmation of passing the Final Examination by submitting the appropriate paperwork to the Graduate School is handled by the COP Office of Graduate Programs.
Every candidate for a doctoral degree is required to prepare and present a dissertation that shows independent investigation, and is acceptable in form and content to the supervisory committee and to the Graduate School. Since all doctoral dissertations will be published it is necessary that the work be of publishable quality and that it be in a form for publication. A draft copy of the dissertation must be given to the supervisory committee

members at least one month prior to the defense. This allows time for any major changes to be made. A final copy of the dissertation should be circulated to the committee at least one week before the final defense.
Students must submit their approved final dissertation defense document to the Graduate School digitally in GIMS before the final deadline, as stated on the Graduate School Calendar.

Specific Requirements for the Master of Science in Pharmacy Degree

A student admitted to the doctoral program may be allowed to graduate with a Masters in Pharmacy subject to approval by the student's supervisory committee. The M.S. in Pharmaceutical Sciences is described in the graduate catalog and requires the completion of a thesis or dissertation.

Graduate Student Classification:

Students pursuing the Master of Science in Pharmacy degree are classified 7PH.

Degree Requirements:

Unless otherwise specified, for a master' degree, the student must complete a minimum of 30 credits including no fewer than 24 hours of regular course work and up to 6 credits in thesis research as a graduate student at the University of Florida. No more than six semester hours of course work earned with a grade A, B+ or B may be transferred from institutions approved by the Dean of the Graduate School.

Major:

All course work for a master's degree must be in courses open only for graduate credit (5000 and above).

Credits and Grades:

The 24 credits of minimum regular course work recommended by the supervisory committee and the supervisory chair, must be taken by letter grade. The student must have a minimum 3.00 GPA for all course work attempted for the degree, and a minimum 3.00 GPA for course work in the major. The course program will be determined by the thesis committee.

Thesis:

The candidate is required to prepare and present a thesis acceptable to his/her supervisory committee and the Graduate School. He/she should consult the Graduate School Editorial Office for formatting requirements and deadlines.

Supervisory Committee for the Master of Science in Pharmacy:

At least three members selected from the Graduate Faculty must be on the supervisory committee. These members are recommended by the student's supervisory chair. The Dean

of the Graduate School is an ex-officio member of all supervisory committees. If a minor is designated, it should be represented by one member of the committee who is on the Graduate Faculty. The committee should be appointed as soon as possible, and no later than the end of the second semester or 24 credits, whichever comes first.

Only members of the Graduate Faculty may be members of the supervisory committee. Names of courtesy faculty, regular faculty, and others not on the Graduate Faculty should not appear on the student's official supervisory committee.

At least three faculty members must be present at the student's final examination. Only members of the official supervisory committee are required to sign the thesis and the report of the final examination.

Residency Requirement:

There is no residency requirement for the master's degree.

Admission to Candidacy:

Admission to candidacy is no longer required for students pursuing master's degrees.

Final Examination:

The student should inform the Office of Graduate Programs at least three weeks in advance of the Final Thesis Defense Exam, including their time/date/location of the exam and their research title. The Office of Graduate Programs will send out the announcement for the Final Thesis Defense Exam at least two weeks prior to the exam to the College. When the student's course work is completed, or practically so, and the thesis is in final form, the student's supervisory committee is required to examine him/her in writing or orally on his/her thesis and the subject matter of the courses taken for the degree. The form Report on Thesis/Dissertation and Final Examination should be completed and signed by the official members of the committee.

Confirmation of passing the Final Thesis Defense examination by submitting the appropriate paperwork to the Graduate School is handled by the COP Office of Graduate Programs. The Final Examination Record should be submitted to the Graduate School with the thesis by the date specified in the University Calendar. The final examination may not be held any earlier than six months before the degree is to be conferred.

Time Limitation for Completion of the Master of Science in Pharmacy:

All work counted toward the M.S.P. degree must be completed during the seven years immediately preceding the date on which the degree is to be awarded.

Correspondence and Extension Work:

No courses may be taken for graduate credit by correspondence. No extension courses may be used for graduate credit.