

# PHARMACEUTICAL REGULATORY SCIENCES (PRS)

## Spring 2025 Schedule

*Note: Due to visa requirements, international students must attend courses on-campus, which includes taking online courses in the Ft Washington computer lab.*

### Scheduling notes:

All matriculated PRS students should take at least two required PRS courses before registering for electives. Most required courses are offered only once a year.

Students who have not been formally accepted into the PRS MS are required to start the program by taking 3 of the following courses and earn an overall 3.33 GPA: 8003, 8005, 5575, 5577 or 8006.

PRS courses are open to RAQA students with strong science backgrounds, including a degree in pharmacy, chemistry, biochemistry, biology, or chemical engineering. RAQA students must resume when registering.

### Required PRS Courses:

- **Preformulation- Small Molecules (8003)** –Fall 2024 (*previously Pharm Manufacturing I*)
- **Solid Dosage Forms – Small Molecules – Spring 2025** (*previously Pharm Manufacturing II*)
- **Pharmaceutical Biotechnology (8005)** – Spring 2025
- **Facilities, Utilities and Equipment (5468)** – Fall 2025
- **IND/NDA Submissions (5495)** – Spring 2025
- **Regulatory Sciences: Managing the Guidelines for Quality (5575)** –Spring 2025
- **Chemistry, Manufacturing and Controls (CMC) (5576 or 5577)** – 5577 offered Spring 2025
- **Physical Pharmacy I (8006)** – to be offered Spring 2026

PRS Electives – PRS students may take one RAQA elective from the following available this Spring 2025 (see RAQA website for entire list of RAQA electives in the PRS degree program).

- **Vaccines: RA and QA Issues (5572)** – Spring 2025
- **Global CMCs: Biopharmaceuticals and Other Biologics (5577)**

PRS Electives – One Pharmaceutical Science elective from the following

- **Applied Biopharmaceutics (8007)**

### SCHEDULE of REQUIRED COURSES – PRS

#### **5575. Regulatory Sciences: Managing the Guidelines for Quality (990) crn: 53069 (ONLINE)**

*This course uses Proctorio online proctoring.*

Prerequisite: strong science background required. Include resume with registration for approval.

5:30 pm – 8:30 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

#### **Proctored exam: Mar 4 (Proctorio)**

Faculty: T. Schultz

No required text.

*Not open to students who have completed RAQA 580.*

#### **8004. Solid Dosage Forms – Small Molecules (990) crn: 55324 (ONLINE)**

*This course uses Proctorio online proctoring.*

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

#### **Proctored exam: Mar 5 (Proctorio)**

Faculty: K. Zimm

No required text.

Not open to students who have completed Pharmaceutical Sciences

**8005. Pharmaceutical Biotechnology (990) crn: 51044 (ONLINE)**

6:00 pm – 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10, 17. Meets 12 times plus final exam. Make-up, if needed, Apr 24 and May 1.

**Proctored exams: Mar 6 and Apr 17 (proctored through Zoom)**

Faculty: T. Parry

Required text: *Pharmaceutical Biotechnology: Fundamentals and Applications*, Crommelin, Sindelar & Meibohm, editors, any of the 3rd through 6th editions should be ordered, Informa Healthcare 2007 (ISBN 10: 1420044370), ISBN 13 978 1420044379). Paperback recommended. Suggested: *Biopharmaceutical: Biochemistry and Biotechnology*, Walsh, G., 2nd edition, (ISBN 0 470 84327 6), available online. Students should have access to textbooks in biochemistry and/or molecular biology.

*Not open to students who have completed Pharmaceutics 475.*

**5495. IND/NDA Submissions (990) crn: 20675 (ONLINE)**

*This course uses Proctorio online proctoring.*

*Prerequisite: Drug Development (5459) or Food and Drug Law (5592).*

6:00 pm – 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

**Proctored exam: Mar 10 (Proctorio)**

Faculty: A. Smith

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th revised edition.

*Not open to students who have completed RAQA 495.*

**5495. IND/NDA Submissions (991) crn: 31567 (ONLINE)**

*This course uses Proctorio online proctoring.*

*Prerequisite: Drug Development (5459) or Food and Drug Law (5592).*

8:30 am – 2:00 pm Saturdays: Jan 18, Feb 1, 15, Mar 1, 15, 29, Apr 12. Meets 7 times plus final exam. Make-up, if needed, Apr 26.

**Proctored exam: Mar 1 (Proctorio)**

Faculty: P. Smith

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th revised edition.

*Not open to students who have completed RAQA 495.*

## **SCHEDULE of ELECTIVES - PRS**

### **PHARMACEUTICAL SCIENCE ELECTIVE**

**Tentative: 8007. Applied Biopharmaceutics (990) – to be announced.**

### **RAQA Electives (Students may choose one of the following electives offered this spring)**

**5572. Vaccines: RA and QA Issues (990) crn: 45613 (ONLINE)**

*This course uses Proctorio online proctoring.*

*This course has limited seats. If you wish to enroll, send in your registration form right away.*

*Prerequisite: Drug Development (5459). Students are also expected to have a college-level background in general biology and chemistry and some knowledge of general microbiology and/or immunology.*

6:00 pm - 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13 (recording), 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 (Passover) and 24.

**Proctored exam: Feb 27 (Proctorio)**

Faculty: K. Surowitz

Required texts: **Do not purchase texts** until AFTER hearing discussion in the first class.

(1) *Autism's False Prophets*, P Offit, 2008, Columbia U Press. Available in the Temple U Charles Library online.

(2) *Epidemiology and Prevention of Vaccine Preventable Diseases*, 13th edition, U.S. Centers for Disease Control (CDC). Students may download individual chapters for free or purchase the paperback from the CDC.

(3) *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and other Biologics*, John Geigert, 3rd edition, 2019, Springer. Available in the Temple U Charles Library online.

(4) *Plotkin's Vaccines*, 7th edition, 2018, Plotkin, Orenstein, Offit, Edwards, editors, Elsevier. Available in the Temple U Charles Library online.

*Not open to students who have completed RAQA 572.*

**5577. Global CMCs – Biopharmaceuticals and Other Biologics (990) crn: 55328 (ONLINE)**

*This course uses Proctorio online proctoring.*

6:00 pm - 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

**Proctored exam: Feb 25 (Proctorio)**

Faculty: J. Quinn

Required text: *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals*, J. Geigert, 2024

<https://link.springer.com/book/10.1007/978-3-031-31909-9>