

## PHARMACEUTICAL REGULATORY SCIENCES (PRS) Fall 2024 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 marked with two asterisks and earning an overall 3.33 GPA:

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)** – Fall 2024
- **Facilities, Utilities and Equipment (5468)** – to be offered Spring 2025
- **IND/NDA Submissions (5495)** – Fall 2024, Spring 2025, Summer 2025
- **Regulatory Sciences: Managing the Guidelines for Quality (5575)** –Spring 2025
- **Chemistry, Manufacturing and Controls (CMC) (5576 or 5577)** – 5577 offered Fall 2024
- **Physical Pharmacy I (8006)** – to be offered Spring 2026 (every 2 years of even years)

PRS Electives – One RAQA Elective from the following available this fall (see RAQA website for entire list of RAQA electives in the PRS degree program.

- **Process Validation (5474)** – Fall 2024
- **Computerized Systems Validation (5498)** – Fall 2024
- **Biologics/Biosimilars: A Regulatory Overview – Fall 2024**
- **Vaccines: RA and QA Issues (5572)** – Fall 2024
- See the link on the RAQA homepage for PRS for the complete list of RAQA electives

PRS Electives – One Pharmaceutical Science elective from the following

- **Pharmaceutical Analysis (8007)** – offered Fall 2024 (only offered in Fall semesters)

## SCHEDULE of REQUIRED COURSES – PRS

### REQUIRED PHARMACEUTICAL SCIENCE COURSES

#### **8003. Preformulation - Small Molecules (990) crn: 54371 (ONLINE)**

(Formerly Pharmaceutical Manufacturing I: Preformulation/Formulation)

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

5:30 pm - 8:30 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26. Meets 12 times plus final exam. Make-ups, if needed, Dec 3 and 10.

#### **Proctored exam: Oct 22 (RPNOW)**

Faculty: T. Schultz

Required text: *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*, Taylor & Aulton, 4<sup>th</sup> edition, 2013, Churchill Livingstone, (ISBN: 9780702042904 or 9780702053931).

*Not open to students who completed Pharmaceutics 406.*

#### **8005. Pharmaceutical Biotechnology (990) crn: 54372 (ONLINE)**

6:00 pm – 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17 (proctored midterm), 24, 31, Nov 7, 14, 21, Dec 5, 12 (final). No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. Make-up, if needed, Dec 19.

**Proctored exams: Oct 17 and Dec 12 (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.*

**RAQA REQUIRED COURSES**

**5495. IND/NDA Submissions (990) crn: 46250 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

6:00 pm – 9:00 pm Thursdays: Sept 12, 19, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5, 12. Meets 12 times plus final exam. No class on Sept 26 and Nov 28 (Thanksgiving). Make-up date, if needed, Dec 19.

**Proctored exam: Oct 24 (RPNOW)**

Faculty: A. Smith

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

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

**5577. Global CMCs – Biopharmaceuticals and Other Biologics (990) crn: 28578 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26. Meets 12 times plus final exam. Make-ups, if needed, Dec 3 and 10.

**Proctored exam: Oct 15 (RPNOW)**

Faculty: J. Quinn

Required text: *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics*, John Geigert, 3rd edition, 2019, Science & Media, NY, ISBN-13: 978-3030137533).

**SCHEDULE of ELECTIVES - PRS**

**PHARMACEUTICAL SCIENCE ELECTIVE**

**8002. Pharmaceutical Analysis (990) crn: 46377 (ONLINE)**

5:30 pm - 8:30 pm Mondays: Sept 9, 16, 23, 30, Oct 7, 14 (Columbus Day), 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2, 9. Meets 12 times plus final exam. No class Nov 25. Make-up, if needed, Dec 16.

**Proctored exams: Oct 21 and Dec 9 (via Zoom)**

Faculty: D. Canney, A. Fermier, S. Mehrman

No required text.

*Not open to students who have completed Pharmaceutics 411*

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

**5474. Process Validation (990) crn: 54364 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam-*

*Prerequisite: Students should have a basic understanding of pharmaceutical manufacturing processes.*

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. Make-ups, if needed, Dec 12 and 19.

**Proctored exam: Oct 17 (RPNOW)**

Faculty: K. Barnthouse

Required texts: 1) *Process Validation in Manufacturing of Biopharmaceuticals*, 3<sup>rd</sup> edition, Anurag S. Rathore and Gail Softer, editors, CRC Press 2012, AND 2) *How to Validate a Pharmaceutical Process*, 1<sup>st</sup> edition, Steven Ostrove, Elsevier, 2016.

*Not open to students who completed RAQA 484 or Pharmaceutics 8484.*

**DAYTIME ONLINE COURSE with recordings**

**5498. Computerized Systems Validation (990) crn: 54367 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

Noon - 1:00 pm Tuesdays and Thursdays (Eastern time), plus one hour recording each week, which students must watch before the next scheduled class:

Sept 10, 12 - watch recording before Sept 17

Sept 17, 19 - watch recording before Sept 24

Sept 24, 26 - watch recording before Oct 1

Oct 1, 3 (Rosh Hashanah) - watch recording before Oct 8

Oct 8, 10 - watch recording before Oct 15

Oct 15, 17 - watch recording before Oct 22

Oct 22, 24 - watch recording before Oct 29

Oct 29, 31 - watch recording before Nov 5

Nov 5, 7 - watch recording before Nov 12

Nov 12, 14 - watch recording before Nov 19

Nov 19 and 21 - watch recording before Dec 3

No class Nov 26 and 28 (Thanksgiving holiday)

Dec 3 and 5 (last live class)

Make-ups, if needed, Dec 10 and 12.

**Proctored exam: Oct 17 (RPNOW)**

Faculty: T. Preziosi

No required text.

*Not open to students who completed RAQA 498.*

**5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

*Prerequisites: Drug Development (5459) or IND/NDA (5495).*

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2, 9, 16, 23, 30 (recording), Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. Make-ups, if needed, Dec 11 and 18.

**Proctored exam: Oct 23 (RPNOW)**

Faculty: F. Diana

No required text.

**5572. Vaccines: RA and QA Issues (990) crn: 39783 (ONLINE)**

*This course uses RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to RPNOW via credit card at the start of the proctored exam.*

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

*Prerequisite: Drug Development (5459) or IND/NDA (5495).*

6:00 pm - 9:00 pm Mondays: Sept 9, 16, 23, 30, Oct 7, 14 (Columbus Day), 21, 28, Nov 4, 11 (recording), 18, 25. Meets 12 times plus final exam. Make-ups, if needed, Dec 2 and 9.

**Proctored exam: Oct 14 (RPNOW)**

Faculty: K. Surowitz

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

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

(2) *Epidemiology and Prevention of Vaccine Preventable Diseases*, 13<sup>th</sup> 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, 3<sup>rd</sup> edition, 2019, Springer. Available in the Temple U Charles Library online.

(4) *Plotkin's Vaccines*, 7<sup>th</sup> 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.*