

## GLOBAL CLINICAL & PHARMACOVIGILANCE REGULATIONS (GCPR) Fall 2024 Schedule

### Requirements for the MS in GCPR: 30 credits

#### Eight Required Courses

- Drug Development (RAQA 5459 OR P381) – Fall 2024
- Good Clinical Practices (RAQA 5536 OR P383) – Fall 2024
- Clinical Trial Management (RAQA 5537 or P388) – Fall 2024
- Pharmacoepidemiology (RAQA 5573) – Spring 2024
- Risk Management/Safety Signaling in Healthcare Products (RAQA 5578) – Spring 2025
- Regulatory and Legal Aspects of Pharmacovigilance (RAQA 5579) – Fall 2024
- Good Pharmacovigilance Operations (RAQA 5508) - Fall 2024
- Clinical Drug Safety & Pharmacovigilance (5538) – Fall 2024
- Post Marketing Safety Surveillance (5578) – Spring 2024

#### Two Electives from:

- Global Clinical Drug Development (RAQA 5539) - Spring 2024
- Bioethics for Pharmaceutical Professionals (RAQA 5612) – Fall 2024
- Clinical Trial Project Management (RAQA 5547) – offered Summer 2024
- Statistics for Clinical Trials (RAQA 5497) – offered Fall 2024
- TUSP PharmD students may transfer credits from Adverse Drug Reactions, Clinical Pharmacokinetics and Biostatistics

## REQUIRED COURSES – GCPR

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

### AFTERNOON ON-CAMPUS COURSE at Fort Washington

#### 5459. Drug Development (101) crn: 49409 (ON-CAMPUS COURSE)

2:00 pm – 5:30 pm Wednesdays: Sept 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20. Meets 10 times plus final exam. Makeup, if needed, Dec 4 and 11.

#### In-class, proctored exam: Oct 16.

Faculty: P. Sax

Required texts: 1). Drugs: From Discovery to Approval, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272), and 2) The Drug Hunters: the Improbable Quest to Discover New Medicines, Kirsch, 2017.

*Not open to students who completed RAQA 459 or P381.*

#### 5459. Drug Development (990) crn: 17910 (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, 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 24 (RPNOW)

Faculty: C. Ciliberto

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

*Not open to students who have completed RAQA 459 or P381.*

#### 5459. Drug Development (991) crn: 7407 (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 Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, 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: J. Hayes

Required text: *Drugs, From Discovery to Approval*, third edition, Rick, Ng, ISBN-13:978-1118907276 or ISBN-10: 1118907272.

In addition, students will be required to choose **one** of the following texts and write a book review:

1) *The Poison Squad: One Chemist's Single-Minded Crusade for Food Safety at the Turn of the Twentieth Century*, Paperback – Illustrated, Sep 2019, Deborah Blum OR

2) *The Jungle*, Paperback, 2019, Upton Sinclair

3) *The Great Influenza: The Story of the Deadliest Pandemic in History*, Paperback – Oct 2005, John M. Barry

4) *The Antidote: Inside the World of New Pharma*, Barry Werth.

*Not open to students who have completed RAQA 45 or P381.*

## WEEKEND COURSE

### **5459. Drug Development (992) crn: 28608 (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.*

8:30 am – 2:00 pm Saturdays: Sept 14, 28, Oct 12 (Columbus Day weekend), 26, Nov 9, 23, Dec 7. Meets 7 times plus final exam. Make-up, if needed, Dec 14.

**Proctored exam: Oct 26 (RPNOW)**

Faculty: P. Smith

Required text: *Drugs: From Discovery to Approval*, third edition, Rick, Ng, , ISBN-13:978-1118907276 or ISBN-10: 1118907272

*Not open to students who have completed RAQA 459 or P381.*

### **5536. Good Clinical Practices (990) crn: 9358 (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, Dec 3. Meets 12 times plus final exam. No class Nov 26. Make-ups, if needed, Dec 10 and 17.

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

Faculty: J. Scavone

No required text.

*Not open to students who have completed RAQA 536 or P383.*

### **5508. Good Pharmacovigilance Operations (990) crn: 51972 (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: Clinical Drug Safety and Pharmacovigilance (5538) OR Post Marketing Safety Surveillance (5571).*

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

**Proctored exam: Dec 2 (RPNOW)**

Faculty: L. Thomas

Required text: *Colbert's Manual of Drug Safety and Pharmacovigilance*, Colbert, Gregory & Thomas, 3<sup>rd</sup> edition, World Scientific, ISBN: 9813278846 or 9789813278833.

## WEEKEND COURSE

### **5536. Good Clinical Practices (991) crn: 56678 (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.*

10:00 am – 1:00 pm Saturdays: Sept 7, 14, 21, 28, Oct 5, 12 (Yom Kippur), 19, 26, Nov 2, 9, 16, 23. Meets 12 times plus final exam. Make-ups, if needed, Dec 7 and 14.

**Proctored exam: Oct 19 (RPNOW)**

Faculty: D. Walsh

Required texts: All references and readings are available online.

*Not open to students who have completed RAQA 536 or P383.*

### **5537. Clinical Trial Management (990) crn: 49401 (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: Good Clinical Practices (5536). Students with clinical experience may ask to take the course but must include their resume with registration.*

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

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

Faculty: J. Scavone

No required text.

*Not open to students who have completed RAQA 537 or P388.*

### **5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 56672 (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: Good Clinical Practices (5536 or P383) or appropriate experience in industry GCPs (send resume with registration form).*

*Note: GCPR students may take 5538 or 5571 but not both.*

**7:00 pm** – 10:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 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 exam: Dec 12 (RPNOW)**

Faculty: J. Robinson

No required text.

### **5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 56674 (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: Clinical Drug Safety and Pharmacovigilance (5538) or Post Marketing Safety Surveillance (5571) or permission of RAQA Office (forward resume).*

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

**Proctored exam: Dec 11 (RPNOW)**

Faculty: K. Ward

Required text: *Colbert's Manual of Drug Safety and Pharmacovigilance*, Colbert, Gregory & Thomas, 3<sup>rd</sup> edition, World Scientific, ISBN: 9813278846 or 9789813278833.

## **ELECTIVE COURSES in GCPR**

**Special note: Elective courses are not open to TUSP PharmD students pursuing the GCPR MS.**

### **5497. Statistics for Clinical Trials (990) crn: 54366 (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-up, if needed, Dec 3 and 10.

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

Faculty: K. Weiss

No required text.

*Not open to students who have completed RAQA 497 or to TUSP PharmD students pursuing the MS in GCPR.*

### **5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (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, 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 24 (RPNOW)**

Faculty: D. Walsh

Required text: *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, Emanuel, Crouch, Arras, Moreno and Grady, Johns Hopkins University Press, 2003.

*Not open to students who completed RAQA 512 or TUSP students pursuing the GCPR MS.*