

# GLOBAL CLINICAL & PHARMACOVIGILANCE REGULATIONS (GCPR) Spring 2025 Schedule

## Requirements for the MS in GCPR: 30 credits

### Eight Required Courses

- **Drug Development (RAQA 5459 OR P381) – Spring 2025**
- **Good Clinical Practices (RAQA 5536 OR P383) – Spring 2025**
- **Clinical Trial Management (RAQA 5537 or P388) – Spring 2025**
- **Pharmacoepidemiology (RAQA 5573) – Spring 2025**
- **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) - Spring 2025**
- Clinical Drug Safety & Pharmacovigilance (5538) – Fall 2024
- Post Marketing Safety Surveillance (5578) – Spring 2024

### Two Electives from:

- Global Clinical Drug Development (RAQA 5539) -
- Bioethics for Pharmaceutical Professionals (RAQA 5612) – Spring 2025
- 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.*

### **5459. Drug Development (990) crn: 42713 (ONLINE)**

*This course uses Proctorio online proctoring.*

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

#### **Proctored exam: Mar 6 (Proctorio)**

Faculty: C. Ciliberto

Suggested 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 TUSP PharmD students who have taken P381.*

### **5459. Drug Development (991) crn: 28687 (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: J. Hayes

Required text: *Drugs, From Discovery to Approval*, 3rd 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. *Ten Drugs*, Hager, ISBN: 13-97: 1419735226
2. *For Blood and Money: Billionaires, Biotech, and the Quest for a Blockbuster Drug*; Vardi; ISBN-13: 978-0393540956,
3. *Making Medicine: Surprising Stories from the History of Drug Discovery*, hardcover – July 15, 2022; K. Veronese; ISBN-13: 978-1633887534

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

## WEEKEND COURSE

### **5459. Drug Development (992) crn: 51026 (ONLINE)**

*This course uses Proctorio online proctoring.*

10:00 am – 1:00 pm Saturdays: Jan 18, 25, Feb 1, 8, 15, 22, Mar 1, 8, 15, 22, 29, Apr 5. Meets 12 times plus final exam. Make-ups, if needed, Apr 12 and 19 (Passover).

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

Faculty: D. Walsh

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 Great Influenza*, John M. Barry, Penguin 2004-5, (ISBN 0-14-303649-1)

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

### **5508. Good Pharmacovigilance Operations (990) crn: 53066 (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, 16 (Passover), 23. Meets 12 times plus final exam. No class April 9. Make-up, if needed, Apr 30 and May 7.

**Proctored exam: Apr 23 (Proctorio)**

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.

## AFTERNOON ON-CAMPUS COURSE at Fort Washington

### **5536. Good Clinical Practices (101) crn: 55326 (ON-CAMPUS COURSE)**

2:00 pm – 5:30 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25. Meets 10 times plus final exam. Makeup, if needed, Apr 1 and 8.

**In-class, proctored exam: Feb 18.**

Faculty: P. Sax

No required text. Students may purchase the CFR/ICH GCP Reference Guide from

[www.barnettinternational.com](http://www.barnettinternational.com), but the regulations may also be downloaded for free through Internet sources.

*Not open to students who completed RAQA 536.*

### **5536. Good Clinical Practices (990) crn: 51052 (ONLINE)**

*This course uses Proctorio online proctoring.*

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: J. Hayes

No required text.

Optional texts (Do not purchase until after the first class meeting):

1. *The Autumn Ghost: How the Battle Against a Polio Epidemic Revolutionized Modern Medical Care*; H. Wunsch; ISBN-13: 978-1771649452
2. *The Breakthrough: Immunotherapy and the Race to Cure Cancer*; C. Graeber; ISBN-13: 978-1455568505
3. *Frances Oldham Kelsey, the FDA, and the Battle against Thalidomide*; C.K. Warsh; ISBN-13: 978-0197632543

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

### **5537. Clinical Trial Management (990) crn: 20667 (ONLINE)**

*This course uses Proctorio online proctoring.*

*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: Jan 22, 98, 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: J. Scavone

No required text.

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

**5573. Pharmacoepidemiology (990) crn: 51062 (ONLINE)**

*This course uses Proctorio online proctoring.*

6:00 pm - 9:30 pm Mondays: Jan 27, Feb 3, 10, 17 Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7. Meets 10 times plus final exam. Make-ups, if needed, Apr 14 (Passover) and 21.

**Proctored exam: Apr 7 (Proctorio)**

Faculty: N. Cossrow

No required text.

**5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 53070 (ONLINE)**

*This course uses Proctorio online proctoring.*

*Prerequisite: either RAQA 5538 or RAQA 5571.*

**7:00 pm - 10:00 pm** Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10, 17 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 24 and May 1.

**Proctored exam: Apr 17 (Proctorio)**

Faculty: J. Robinson

No required text.

## **ELECTIVE COURSES in GCPR**

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

**5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (ONLINE)**

*This course uses Proctorio online proctoring.*

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

**Proctored exam: Mar 6 (Proctorio)**

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.*