

**ADVANCED BIOTHERAPEUTICS:
MANUFACTURING AND REGULATORY AFFAIRS (ABMRA)
Fall 2024 Schedule**

Requirements for the MS in ABMRA from Temple U: 36 credits. 21 credits from RAQA and 15 credits from Thomas Jefferson's JIB program.

Four Required RAQA Courses

- Drug Development (RAQA 5459 OR P381) – Fall 2024
- Biologics/Biosimilars: A Regulatory Overview (5515) - Fall 2024
- Vaccines: Regulatory Affairs and Quality Assurance Issues (5572) – Fall 2024
- Global CMC Regulatory Compliance for Biopharmaceuticals & Biologics (5577) – Fall 2024

Two Electives from:

- Development of Sterile Products (5501)
- **Pharmaceutical Biotechnology (PS 8005) - Fall 2024**
- Statistical Quality Control (5451)
- Validation of FUE (5468)
- Biotechnology: Bioprocess Basics (5471)
- **Process Validation (5474) – Fall 2024**
- Advanced GMPs (5479)
- **Production of Sterile Parenterals (5492) – Fall 2024**
- Sterilization Processes (5493)
- Microbiological Concepts in Pharmaceutical Manufacturing (5512)
- Regulatory eSubmissions (5514)
- Cleaning Validation (5516)
- **Clinical Drug Safety & Pharmacovigilance (5538) OR Post Marketing Safety Surveillance (5571) (one or the other but not both) 5538 is offered Fall 2024**
- Regulatory Intelligence (5544)
- **Pharmaceutical Quality Management Systems (5574) – Fall 2024**
- Regulatory Sciences: Managing the Guidelines for Quality (5575)
- Process Analytical Technology (PAT) (5625)
- Statistical Design of Experiments (DOE)
- Process Monitoring (5629)

REQUIRED RAQA COURSES

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, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-101: 1118907272), and 2) The Drug Hunters: the Improbable Quest to Discover New Medicines, Kirsch, 2017.

Not open to students who completed RAQA 459.

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, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

Not open to students who have completed RAQA 459.

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 459.

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.

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).

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).

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*, 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: 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).

RAQA ELECTIVE COURSES: in the ABMRA DEGREE PROGRAM

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.

5492. Production of Sterile Products (990) crn: 56673 (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, 12. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. Make-up, if needed, Dec 19.

Proctored exam: Dec 12 (RPNOW)

Faculty: D. Casaburi

Required text: *Aseptic and Sterile Processing Compliance and Future Trends*, Sandle and Tidswell, Parenteral Drug Association, 2017, ISBN 9781942911128. Available in hardcover or digital.

Not open to students who have completed RAQA 492.

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-

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*, 3rd edition, Anurag S. Rathore and Gail Softer, editors, CRC Press 2012, AND 2) *How to Validate a Pharmaceutical Process*, 1st edition, Steven Ostrove, Elsevier, 2016.

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

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.

ABMRA Students may take 5538 or 5571 as an RAQA elective but not both.

Prerequisite: Good Clinical Practices (5536 or P383) or appropriate experience in industry GCPs (send resume with registration form).

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.

5574. Quality Management Systems (990) crn: 46256 (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)

6:00 pm - 9:30 pm Mondays: Sept 16, 23, 30, Oct 7, 14 (Columbus Day), 21, 28 (recording), Nov 4, 11 (Veterans' Day), 18. Meets 10 times plus final exam. Make-ups, if needed, Nov 25 and Dec 2.

Proctored exam: Oct 21 (RPNOW).

Faculty: M. LaBruto

No required text.