

Spring 2010 Schedule
Quality Assurance/Regulatory Affairs (March 15, 2010)

Live Classes at Fort Washington

5459. Drug Development (101) crn: 077-328 Room 3

5:30 pm – 8:30 pm Wednesdays: Jan 20, 27, Feb 3, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7, 14. Make-up, if needed, Apr 21. Meets 12 times plus final exam. No class Feb 10 due to snow.

Faculty: Chris Wittrock

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th ed, (ISBN: 1-882615-85-9).
Formerly Pharmaceutics 459. Not open to students who have taken Pharmaceutics 459.

5459. Drug Development (102) crn: 077-332 Room 1

5:00 pm – 8:30 pm Thursdays: Jan 21, 28, Feb 4, 18, Mar 4, 11, 18, 25, Apr 1, 8, 15. Class meets 10 times plus final exam. No class Feb 11 or Feb 25 due to snow. Make-up, if needed, Apr 22.

Faculty: Peter Smith

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th ed, (ISBN: 1-882615-85-9).
Formerly Pharmaceutics 459. Not open to students who have taken Pharmaceutics 459.

5459. Drug Development (103) crn: 077-349 Room 13

8:30 am – 3:00 pm Sundays (1/2 hour lunch): Jan 17, 31, Feb 14, 28, Mar 14, 28. Make-up, if needed, April 18. Meets 6 times.

Faculty: Jim Krupa

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th ed, (ISBN: 1-882615-85-9).

Recommended Texts: 1) *The \$800 Million Pill: The Truth Behind the Cost of New Drugs*, Goozner, (ISBN: 0-520-23945-8),
and 2) *Drugs: From Discovery to Approval*, Ng, (ISBN: 0-471-60150-0).
Formerly Pharmaceutics 459. Not open to students who have taken Pharmaceutics 459.

5477. Good Manufacturing Practices (101) crn: 077-355 Room 19

8:30 am – 3:00 pm (1/2 hour lunch) Sundays: Jan 17, 31, Feb 14, 28, Mar 14, 28 (Palm Sunday). Make-up, if needed, Apr 18. Class meets 6 times.

Faculty: Beverly Zaber

Optional text: *Good Manufacturing Practices for Pharmaceuticals*, 6th ed, Nally (ISBN: 0-8493-3972-3).
Formerly Pharmaceutics 487. Not open to students who have taken Pharmaceutics 487.

5491. Pre-Approval Inspections (101) crn: 077-140 Room 4

5:30 pm – 8:30 pm Wednesdays: Jan 20, 27, Feb 3, 17, 24, Mar 3, 10, 17, 24, 31 Apr 7, 21. Meets 12 times plus final exam. No class Feb 10 due to snow. No class Apr 14.

Faculty: Karyn Campbell and Deb Pagano

No required text.

Formerly Pharmaceutics 491. Not open to students who have taken Pharmaceutics 491.

5494. Quality Audit (101) crn: 102-770 Room 3

Prerequisite: successful completion of any GXP course (GMPs – Pharmaceutics 5477, or GCPs – Pharmaceutics 5536, or GLPs – Pharmaceutics 5476, or Advanced GMPs – Defining “c” – Pharmaceutics 5479.)

8:30 am – 3:00 pm Saturdays (1/2 hour lunch): Jan 16, 30, Feb 13, 27, Mar 13, 27. Make-up, if needed, Apr 17. Class meets 6 times. Midterm: Feb 27.

Faculty: Teresa Preziosi

Required text: *The ASQ Auditing Handbook*, 3rd ed, J.P. Russell. Order from: www.asq.org, (ISBN: 9780873896665, ASQ item #1263).

Formerly Pharmaceutics 494. Not open to students who have taken Pharmaceutics 494.

5495. IND/NDA Submissions (101) crn: 080-842 Room 19

Prerequisites: Drug Development (Pharmaceutics 5459) or Food and Drug Law I (Pharmaceutics 5592).

5:00 pm – 8:30 pm Wednesdays: Jan 20, 27, Feb 3, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7. Make-up, if needed, Apr 14. Meets 10 times plus final exam. No class Feb 10 due to snow.

Faculty: Peter Smith

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th ed, (ISBN: 1-882615-85-9).

Formerly Pharmaceutics 495. Not open to students who have taken Pharmaceutics 495.

5508. Good Pharmacovigilance Operations (101) crn: 080-412 Room 13

6:00 pm – 9:00 pm Wednesdays: Jan 27, Feb 3, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7, 14, 21. Make-up, if needed, Apr 28. Meets 12 times plus final exam. No class Feb 10 due to snow.

Faculty: Jacqueline Grissinger

Required text: *Current Challenges in Pharmacovigilance: Pragmatic Approaches* (Report of CIOMS Working Group V) 2001, (ISBN 92 9036 074 7). Order from: http://www.cioms.ch/frame_publications.htm

Other on-line readings assigned.

5533. Requirements for Product Labeling and Advertising (101) crn: 103-616 Room 13

8:30 am – 3:00 pm (1/2 hr lunch) Saturdays: Jan 23, Feb 20, Mar 6, 20, Apr 10, **17**. Class meets 6 times. **Feb 6 class cancelled due to snow. New make-up date is April 17th.**

Faculty: Gerrit-Jan Nijveldt and Brian Bollwage

Required Text: To be announced.

Formerly Pharmaceutics 533. Not open to students who have taken Pharmaceutics 533.

5538. Clinical Drug Safety and Pharmacovigilance (101) crn: 102-557 Room 13

8:00 am – 4:00 pm (1/2 hr lunch) Saturdays: **Jan 16, 30, Mar 13, 27**. Make-up, if needed, **Apr 17**. Meets **4 times at Fort Washington**. **February lectures will be posted on the web for students to view. No “live” classes in February.**

Faculty: Janis Little

Required text: *Manual of Drug Safety and Pharmacovigilance*, Barton, Cobert, Novartis Consumer Health, Inc.

Formerly Pharmaceutics 538. Not open to students who have taken Pharmaceutics 538.

5543. Good Distribution Practices (101) 106-455 Room 4

6:00 pm – 9:30 pm Mondays: Jan 25, Feb 1, 8, 15 (President’s Day), 22, Mar 1, 8, 15, 22, 29 (Passover). Make-ups, if needed, Apr 5 (Easter Monday) or 12. Meets 10 times plus final exam.

Faculty: Thomas McGurk

Required text: *Supply Chain Management, Chopra and Meindl*, 4th ed, Pearson – Prentis Hall, (ISBN-10: 0136080405, ISBN-13: 9780136080404).

Fax registration form to QA/RA Office for this course. Space is limited. Priority will be given to students pursuing the Certificate in Biopharmaceuticals and Generic Drugs.

5571. Post Marketing Safety Surveillance (101) crn: 102-566 Room 3

6:00 pm – 9:00 pm Thursdays: Jan 21, 28, Feb 4, 18, Mar 4, 11, 18, 25, Apr 1, 8, 15. Final exam Apr 22.
No class Feb 11 or 25 due to snow.

Faculty: John Clark and Stephen Klincewicz

Required text: *Current Challenges in Pharmacovigilance: Pragmatic Approaches, Report of CIOMS Working Group*. Order from:

<http://www.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=84&codcch=24>

Formerly Pharmaceutics 571. Not open to students who have taken Pharmaceutics 571.

5591. Global Regulatory Affairs (101) crn: 080-815 Room 19

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

5:30 pm - 8:30 pm Thursdays: Jan 21, 28, Feb 4, 18, Mar 4, 11, 18, 25, Apr 1, 8, 15, 22. Make-up, if needed, Apr 29. Meets 12 times plus final exam. No class Feb 11 or 25 due to snow.

Faculty: Daniel Larkins

No required text.

Formerly Pharmaceutics 591. Not open to students who have taken Pharmaceutics 591.

5592. Food and Drug Law I (101) crn: 037-102 Room 19

8:30 am – 3:00 pm Saturdays (1/2 hour lunch): Jan 23, Feb 20, Mar 6, 20, Apr 10, 24. Meets 6 times.
Feb 6 class cancelled due to snow.

Faculty: Barry Berger

Required texts: 1) *Food and Drug Law: Cases and Materials*, 3rd ed, Hutt, et al, Foundation Press, 2007, (ISBN: 978-1-58778-068-4). (Be sure to order the 2007 edition and not an earlier version.) and 2) *FDLI Statutory Supplement*, (ISBN: 978-1-935065-01-2). Order Supplement from www.fdpi.org. FDLI will give QA/RA students a special student discount, only if you order the Supplement by phone from FDLI's Customer Service Department (1-800-956-6293) or fax (202-371-0649). You must include a copy of your Temple QA/RA schedule. Do not complete your transaction on-line or you will be charged the prices listed for non-members.

Formerly Pharmaceutics 592. Not open to students who have taken Pharmaceutics 592.

5592. Food and Drug Law 1 (102) crn: 037-117 Room 19

6:00 pm – 9:30 pm Mondays: Jan 25, Feb 1, 8, 15 (President's Day), 22, Mar 1, 8, 15, 22, 29 (Passover).
Make-ups, if needed, Apr 5 (Easter Monday) or 12. Meets 10 times plus final exam.

Faculty: Brian Bollwage

Required text: *Food and Drug Law: Cases and Materials*, 3rd ed, Hutt, et al, Foundation Press, 2007, (ISBN: 978-1-58778-068-4). (Be sure to order the 2007 edition and not an earlier version.)

Formerly Pharmaceutics 592. Not open to students who have taken Pharmaceutics 592.

Frazer, PA

5592. Food and Drug Law I (110) crn: 081-276

Meets at the Sheraton Great Valley, 707 E. Lancaster Ave, Frazer, PA 19355. Phone: 610.524.5500.

6:00 pm – 9:30 pm Wednesdays: Jan 27, Feb 3, 17, 24, Mar 3, 17, 24, 31, Apr 21, 28. No class Mar 10, Apr 7, or 14. Meets 10 times plus final exam. No class Feb 10 due to snow.

Faculty: Barry Berger

Required texts: 1) *Food and Drug Law: Cases and Materials*, 3rd ed, Hutt, et al, Foundation Press, 2007, (ISBN: 978-1-58778-068-4). (Be sure to order the 2007 edition and not an earlier version.) and 2) *FDLI Statutory Supplement*, (ISBN: 978-1-935065-01-2). Order Supplement from www.fdpi.org. FDLI will give QA/RA students a special student discount, only if you order the Supplement by phone from FDLI's Customer Service Department (1-800-956-6293) or fax (202-371-0649). You must include a copy of your Temple QA/RA schedule. Do not complete your transaction on-line or you will be charged the prices listed for non-members.

Formerly Pharmaceutics 592. Not open to students who have taken Pharmaceutics 592.

Tarrytown

5592. Food and Drug Law 1 (318) crn: 037-313

This class meets at the West Chester Marriott in Tarrytown, NY.

8:30 am – 5:00 pm Saturdays (1 hour lunch): Jan 30, Feb 13, Mar 13, 27, Apr 10. Feb 27 class cancelled due to snow. Meets 5 times. March 27 class at the Marriott Courtyard; April 10 class at the West Chester Marriott.

Faculty: Craig Hammes

Required texts: 1) *Food and Drug Law: Cases and Materials*, 3rd ed, Hutt, et al, Foundation Press, 2007, (ISBN: 978-1-58778-068-4). (Be sure to order the 2007 edition and not an earlier version.) and 2) *FDLI Statutory Supplement*, (ISBN: 978-1-935065-01-2). Order Supplement from www.fdpi.org. FDLI will give QA/RA students a special student discount, only if you order the Supplement by phone from FDLI's Customer Service Department (1-800-956-6293) or fax (202-371-0649). You must include a copy of your Temple QA/RA schedule. Do not complete your transaction on-line or you will be charged the prices listed for non-members.

Formerly Pharmaceutics 592. Not open to students who have taken Pharmaceutics 592.

5594. Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (101) crn: 102-598 Rm 3

5:30 pm – 9:00 pm Tuesdays: Jan 19, 26, Feb 2, 16, 23, Mar 2, 9, 16, 23, 30 (Passover). Make-up, if needed, Apr 6. Meets 10 times plus final exam. No class Feb 9 due to snow.

Faculty: Alexa Smith

Required text: *Regulation of Functional Foods and Nutraceuticals: A Global Perspective*, Hasler, 2nd ed, 2005.

Formerly Pharmaceutics 594. Not open to students who have taken Pharmaceutics 594.

5602. Clinical Aspects of Pharmaceutical Medicine II (101) crn: 102-610 Room 4

No prerequisite. Students may take Pharmaceutics 5599 and 5602 in any sequence.

8:30 am – 5:00 pm Sundays (1 hr lunch): Jan 17, 31, Feb 14, 28, Mar 14. Make-ups, if needed, Mar 28 or Apr 18. Meets 5 times.

Faculty: Andrew Fletcher

Required texts: (1) *The Merck Manual of Diagnosis & Therapy*, 18th ed on-line (free) at www.merckmanuals.com, or optionally the hard-copy edition, *The Merck Manual of Diagnosis & Therapy* (18th ed), 2006, (ISBN: 10:0-911-91018-2), eds. Beers, Porter, Jones, Kaplan, and Berkwitz. You may also refer to the Home Edition (same web-site), if you are having difficulty with the professional edition, and 2) *Smart Mice, Not So Smart People: An Interesting and Amusing Guide to Bioethics*, Arthur L. Caplan, paperback (2008): ISBN-10: 074254172X; ISBN-13: 978-0742541726 or hard-back (2006): ISBN-10: 0742541711; ISBN-13: 978-0742541719).

Formerly Pharmaceutics 602. Not open to students who have taken Pharmaceutics 602.

5612. Bioethics for Pharmaceutical Professionals (101) crn: 078-052 Room 19

8:30 am – 3:00 pm (1/2 hour lunch) Saturdays: Jan 16, 30, Feb 13, 27, Mar 13, 27. Make-up, if needed, Apr 17. Class meets 6 times.

Faculty: Sean Develin

Required text: *The Singularity is Near*, Kurzweil, Penguin Books, (ISBN: 0-14-303788-9).

Formerly Pharmaceutics 610. Not open to students who have taken Pharmaceutics 610.

5622. Unit Operations (101) crn: 102-632 Room 1

Prerequisite: Strong science background, including a BS in Pharmacy, Chemistry, Biology, or Engineering and familiarity with chemistry, biology, and physics. Students should also have a basic understanding of pharmaceutical manufacturing processes.

Live classes: 8:30 am – 3:30 pm Saturdays: Jan 23, Feb 6, 20, Mar 6, 20, Apr 10. Make-up date, if needed, Apr 24. Class meets 6 times.

Note: two classes will meet at Emerson Resources, 600 Markley St #1, Norristown, PA 19401, where students will practice milling, mixing, tableting and coating. Other lectures will be posted on the Internet weekly, which students may view at their convenience.

Faculty: David Lebo, et al

Required text: *Pharmaceutical Process Engineering*, Anthony J. Hickey and David Ganderton.

5629. Process Monitoring (101) crn: 106-122 Room 3

8:30 am – 5:00 pm Sundays (1 hour lunch): Jan 24, Feb 7, 21, Mar 21, Apr 11. Make-up, if needed, Apr 25. Class meets 5 times. No class March 7.

Faculty: Ronald Snee

Required text: *Statistical Process Control*, John Oakland, 6th ed., John Wiley and Sons.

NON-THESIS SECTIONS (01235)

Electives from the non-thesis MS in Pharmaceutics are open to QA/RA students who have strong science backgrounds. This consists of a minimum of 2 years of general chemistry, including organic and one analytical chemistry course. Students must fax their resume to 267.468.8565 for written permission to register.

8005. Pharmaceutical Biotechnology (101) crn: 080-923 Room 4

8:30 am – 3:00 pm Saturdays (1/2 hour lunch): Jan 23, Feb 20, March 6, 20, Apr 10, 24. Meets 6 times. Feb 6 class cancelled due to snow.

Faculty: Tom Parry

Required text: *Pharmaceutical Biotechnology: Fundamentals and Applications*, 3rd ed, Crommelin, Sindelar, Meibohm. Paperback: ISBN-13: 978-1420044379.

Highly recommended: students should have access to a recent molecular biology text (such as *Molecular Biology of the Cell*, Alberts, et al), or a biochemistry textbook (*Principles of Biochemistry*, Lehninger).

Formerly Pharmaceutics 475. Not open to students who have taken Pharmaceutics 475.

8006. Physical Pharmacy (101) crn: 102-649 Room 1

5:30 pm – 8:30 pm Tuesdays: Jan 19, 26, Feb 2, 9, 16, 23, Mar 2, 9, 16, 23, 30, Apr 6. Make-ups, if needed, Apr 13 or 20. Final exam: April 20. Meets 12 times plus final exam.

Faculty: David Lebo

Required text: *Martin's Physical Pharmacy and Pharmaceutical Sciences*, J. Sinko, Lippincott Williams & Wilkins, 5th ed, (ISBN: 9780781850271).

Formerly Pharmaceutics 485. Not open to students who have taken Pharmaceutics 485.

8007. Applied Biopharmaceutics (101) crn: 102-655 Room 1

5:30 pm – 8:30 pm Wednesdays: Jan 27, Feb 3, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7, 14, 21. Final exam: April 28. Make-up, if needed, May 5. Meets 12 times plus final exam. No class Feb 10 due to snow.

Faculty: Reza Fassihi

No required text.

Formerly Pharmaceutics 410. Not open to students who have taken Pharmaceutics 410.

On-line Classes for Fort Washington Students!

For a list of courses, click here:

www.temple.edu/pharmacy_QARA/FWconnect.htm

Priority is given to students formally enrolled in the QA/RA program, particularly graduating seniors (students who have completed nine or more classes). In addition, students must follow the SOPs for Adobe Connect (or their registration will automatically be cancelled).