

Temple University QA/RA Graduate Program
Summer 2009 Schedule of Classes (July 2, 2009)

All summer classes are in session. We are creating the fall schedule now and hope to have it posted by July 15th. Thank you for your patience.

5408. Pharmacoeconomics (111) 023-786

6:00 pm – 9:30 pm Wednesdays: May 27, June 3, 10, 17, 24, July 1, 8, 15, 22, 29. Meets 10 times plus final exam. Make-up if needed, Aug 5 or 12.

Faculty: Ahmad Naim

Required text: *Principles of Pharmacoeconomics*, J. L. Bootman, R.J. Townsend, W.F. McGhan. 3rd ed. Formerly *Pharmaceutics 480*. Not open to students who have taken *Pharmaceutics 480*.

5459. Drug Development (111) 023-745

8:30 am – 3:00 pm Sundays (1/2 hour lunch): May 3, 17, June 7, 21, July 12, 26. Meets 6 times. Make-up, if needed, Aug 9.

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*.

5459. Drug Development (112) 016-707

6:00 pm – 9:30 pm Wednesdays: May 13, 20, 27, June 3, 10, 17, 24, July 8, 15, 22. Class meets 10 times plus final exam. Make-ups, if needed, July 29 or Aug 5. No class July 1.

Faculty: Dan Walsh

Required text: *New Drug Development: A Regulatory Overview*. Mathieu, 8th ed, (ISBN: 1-882615-85-9).
Suggested texts: *Drugs: From Discovery to Approval, 2nd Edition*, Ng, December 2008, Wiley-Blackwell, (ISBN: 978-0-470-19510-9), AND *The Great Influenza: The Epic Story of the Deadliest Plague in History*, John M. Barry, Penguin Group Oct 2005, ISBN: 13- 9780143036494.
Formerly *Pharmaceutics 459*. Not open to students who have taken *Pharmaceutics 459*.

5471. Biotechnology: Bioprocess Basics (111) 023-759

6:00 pm – 9:30 pm Tuesdays: May 12, 19, 26, June 2, 9, 16, 23, 30, July 7, 14. Meets 10 times plus final exam. Make-up, if needed, July 21 or 28.

Faculty: Ray Bakhtiar

Required text: *Pharmaceutical Biotechnology: Concepts & Applications*, Gary Walsh, Wiley, 2007, ISBN: 978-0-470-01244-4.

Formerly *Pharmaceutics 481*. Not open to students who have taken *Pharmaceutics 481*

5476. Good Laboratory Practices (111) 023-762

6:00 pm – 9:30 pm Thursdays: Apr 30, May 7, 14, 21, 28, June 11, 25, July 2, 9, 16. Meets 10 times. Make-up, if needed, July 23 or 30. No class June 4, 18.

Faculty: Jane Goeke

No required text.

Formerly *Pharmaceutics 486*. Not open to students who have taken *Pharmaceutics 486*.

5473. Generic Drug Regulation: ANDAs (111) 023-790

Special note: this course will be part of a new certificate in Generic Drug Regulation.

Suggested prerequisite: Drug Development (Pharmaceutics 5459).

8:30 am – 3:00 pm Saturdays (1/2 hour lunch): May 2, 16, June 6, 20, July 11, 25. Meets 6 times. Make-up, if needed, Aug 8.

Faculty: Cynthia Ciliberto

Suggested texts: *The Generic Challenge*, Martin A. Voet (ISBN # 159942444-4), AND *The Legislative History of the Drug Price Competition and Patent Restoration Act of 1984*, Fox and Bennett, FDLI. FDLI will give QA/RA students a special student discount, only if you order 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 483. Not open to students who have taken Pharmaceutics 483.

5477. Good Manufacturing Practices (111) 016-205

8:30 am – 3:00 pm Saturdays: May 2, 16, June 6, 20, and July 11, 25. Make-up, if needed, Aug 8.

Faculty: Frank Stevenson

Recommended 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.

5494. Quality Audit (111) 016-220

Prerequisite: a good practices course (Pharmaceutics 5476, 5477, 5479, or 5536).

6:00 pm – 9:30 pm Mondays: Starts May 4, 11, 18, June 1, 8, 15, 22, 29, July 13, 20. Meets 10 times plus final exam. Make up if needed July 27 or Aug 3. No class May 25 (Memorial Day) or July 6.

Faculty: Teresa Preziosi

Required text: *The ASQ Auditing Handbook*, 3rd ed, J.P. Russell. Available from ASQ Quality Audit Division; www.asq.org (ISBN # 9780873896665, ASQ Item # 1263).

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

5495. IND/NDA Submissions (112) 023-963

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

5:00 pm – 8:30 pm Thursdays: Starts May 7, 14, 21, 28, June 4, 11, 18, 25, July 2, 9. Meets 10 times plus final exam. Make-ups, if needed, July 16, 23, or 30.

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.

5495. IND/NDA Submissions (111) 017-075

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

8:30 am - 3:00 pm (1/2 hr lunch) Sundays: May 10, 31, June 14, 28, July 19, Aug 2. Meets 6 times.

Make-up date if needed, Aug 16.

Faculty: Roger Kates

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.

5536. Good Clinical Practices (111) 016-263

8:00 am – 4:30 pm Saturdays: May 9, 30, June 13, July 18, Aug 1. Meets 5 times. Make-up, if needed, Aug 15. No class June 27.

Faculty: Nancy Smith

Required text: *2008 CFR/ICH GCP Reference Guide*, Order from www.barnettinternational.com. Students may use the 2005/06 version.

Formerly Pharmaceutics 536. Not open to students who have taken Pharmaceutics 536.

5502. Regulation of Medical Devices: Submissions (111) 023-806

8:30 am – 4:30 pm Sundays (1/2 hour lunch): May 3, 17, June 7, 21, July 12. Make-ups, if needed, July 26 or Aug 9. Meets 5 times.

Faculty: Marcia Arentz

No required text.

Formerly Pharmaceutics 500. Not open to students who have taken Pharmaceutics 500.

5538. Clinical Drug Safety and Pharmacovigilance (111) 023-835

Prerequisites: Drug Development (Pharmaceutics 5459) and GCPs (Pharmaceutics 5536).

Note: this class may be substituted in place of Clinical Data Management in the CTM Certificate

8:00 am – 4:00 pm Saturdays (1/2 hour lunch): May 9, 30, June 13, 27, July 18. Meets 5 times. Make-up, if needed, Aug 1.

Faculty: Janis Little

Required text: *Manual of Drug Safety and Pharmacovigilance*, Barton Cobert, Novartis Consumer Health, Inc. (ISBN 13:9780763738891 or ISBN 10:0763738891).

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

5575. Regulatory Sciences: Managing the Guidelines for Quality (111) 015-409

Prerequisite: strong science background and permission of QA/RA Office. Fax resume to 267.468.8565 for permission to register.

5:30 pm – 8:30 pm Thursdays: May 14, 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30. Make-ups, if needed, Aug 6 or 13.

Faculty: Thomas Schultz

No required text.

Formerly Pharmaceutics 580. Not open to students who have taken Pharmaceutics 580.

5591. Global Regulatory Affairs (111) 015-387

5:30 pm - 8:30 pm Tuesdays: Starts May 5, 12, 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21. Meets 12 times. Make-ups, if needed, July 28 or Aug 4.

Faculty: Daniel Larkins

No required text.

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

5592. Food and Drug Law I (111) 001-943

8:30 am – 3:00 pm (1/2 hour lunch) Saturdays: May 9, 30, June 13, 27, July 18, Aug 1. Meets 6 times. Make-up, if needed, Aug 15.

Faculty: Barry Berger

Required texts: Food and Drug Law: Cases and Materials, 3rd ed, Hutt, et al, Foundation Press, (ISBN: 978-1-58778-068-4). This is a new edition (2007) of this text. Please do not purchase earlier versions AND FDLI Statutory Supplement (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 (112) 015-618

6:00 pm – 9:30 pm Mondays: Starts May 4, 11, 18, June 1, 8, 15, 22, 29, July 6, 13. Meets 10 times plus final exam. Make-ups, if needed July 20 or 27. No class May 25 (Memorial Day).

Faculty: Brian Bollwage

Required text: *Food and Drug Law: Cases and Materials, 3rd ed, Hutt, et al, Foundation Press, (ISBN # 978-1-58778-068-4). This is a new edition (2007) of this text. Please do not purchase earlier versions.*

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

5592. Food and Drug Law I (113) 009-598

6:00 pm – 9:30 pm Tuesdays: May 12, 19, 26, June 2, 9, 16, 23, 30, July 7, 14. Class meets 10 times plus final exam. Make-ups, if needed, July 21 or 28.

Faculty: Craig Hammes

Required text: *Food and Drug Law: Cases and Materials, 3rd ed, Hutt, et al, Foundation Press, (ISBN: 978-1-58778-068-4). This is a new edition (2007) of this text. Please do not purchase earlier versions AND FDLI Statutory Supplement (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.

SECOND SUMMER SESSION

5594. Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (990) 011-104

This class is being offered on-line in a platform known as Adobe Connect. The course is open to Fort Washington students who have completed at least two courses in the program (including Drug Development). Students must agree in writing to “Expectations of Adobe Connect Students” before being allowed to register: http://www.temple.edu/pharmacy_qara/pdf/Connect_Expectations09.pdf Registration is by fax only.

6:00 pm – 9:00 pm Mondays and Wednesdays as follows:

June 1 (M), June 3 (W), June 10 (W),

June 15 (M), June 17 (W), June 24 (W),

June 29 (M), July 1 (W), July 8 (W),

July 13 (M), July 15 (W), July 22 (W).

Makeups, if needed, July 27 (M) and July 29 (W). Meets 12 times plus final exam.

Faculty: Alexa Smith

Required text: *Regulation of Functional Foods and Nutraceuticals: A Global Perspective*, Hasler (ed), first ed, 2005 (ISBN: 0-8138-1177-5).

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

5612. Bioethics for Pharmaceutical Professionals (111) 023-870

8:30 am - 3:00 pm (1/2 hr lunch) Sundays: May 17, June 7, 21, July 12, 26, Aug 9. Meets 6 times. Make-up, if needed, Aug 16.

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.

5627. Statistical Design of Experiments (111) 023-888

5:45 pm – 9:15 pm Mondays: May 18, June 8, 15, 22, 29, July 6, 13, 20, 27, Aug 3. Meets 10 times plus final exam. No class May 25 (Memorial Day) or June 1.

Faculty: Denita Winstead

Required text: *Pharmaceutical Experimental Design*, Lewis, Mathieu, Phan-Tan-Luu, Informa Healthcare, Volume 92, ISBN 0-8247-9860-0.

This course is part of the certificate in GMPs for the 21st Century. Students need familiarity with basic math to take the course. They will use a statistical programming package (Minitab), which is available in one of the Temple U Fort Washington computer labs for student use.

5650. Special Topics in QA/RA: Contemporary Issues in the Pharmaceutical and Device Industries (111) 015-912

Note: this seminar-style course will focus on very current issues in the pharmaceutical and device industries.

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

6:00 pm – 9:30 pm Wednesdays: Starts May 6, 13, 20, 27, June 3, 10, 17, 24, July 1, 8. Meets 10 times plus final exam. Make-up dates if needed, July 15, 22, or 29.

Faculty: Barry Berger

Required text: *Law, Medicine and Medical Technology-Cases & Materials*, Lars and Noah, Foundation Press, 2nd ed, 2007 (ISBN: 9781599410913).

Formerly Pharmaceutics 650. Not open to students who have taken Pharmaceutics 650.

8004. Pharmaceutical Manufacturing II 023-936

Prerequisite: science and basic math background. There will be no review of basic science concepts; it will be assumed that students are familiar with them. Completion of Pharmaceutical Manufacturing I is helpful but not required.

6:00 pm - 9:00 pm Thursdays: May 14, 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30. Meets 12 times plus final exam. Make-ups, if needed, Aug 6 or 13.

Faculty: Karen Zimm

Recommended text: *Aulton's Pharmaceutics: The Design & Manufacture of Medicines*, 2007, Aulton, ed, (ISBN 044-31-01086). Students must also download the FMC Problem

Solver from www.fmcbiopolymer.com (Pharmaceuticals, ToolKit).

Special note: This course will be offered in a “real time” on-line format, Adobe Connect. Students will be required to sign the “Expectations of Adobe Connect students” before their registration will be processed.

Go to: http://www.temple.edu/pharmacy_qara/pdf/Connect_Expectations.pdf

Students must FAX their registration form to the QA/RA office (this course will not be open on OWLnet.)

You must complete the self-test of Adobe Connect at yellowstone.temple.edu/qaraAdobeTest

Make sure you include the password on your registration form, or your registration will not be processed.

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 one organic and one analytical chemistry course. Students must fax their resume to 267.468.8565 for written permission to register.

Non-Thesis Students: for a complete list of QA/RA electives that you may take towards the Non-Thesis MS program, please go to: www.temple.edu/pharmacy_qara/pharmaceutics.htm

5575. Regulatory Sciences: Managing the Guidelines for Quality (111) 015-414

Prerequisite: strong science background and permission of QA/RA Office. Fax resume to 267 468 8565 for permission to register.

5:30 pm – 8:30 pm Thursdays: May 14, 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30. Make-ups, if needed, Aug 6 or 13.

Faculty: Thomas Schultz

No required text.

Formerly *Pharmaceutics 580*. Not open to students who have taken *Pharmaceutics 580*.

5627. Statistical Design of Experiments (111) 023-888

This course is part of the certificate in GMPs for the 21st Century. Students need familiarity with basic math to take the course. They will use a statistical programming package (Minitab), which is available in one of the Temple U Fort Washington computer labs for student use.

5:45 pm – 9:15 pm Mondays: May 18, June 8, 15, 22, 29, July 6, 13, 20m 27, Aug 3. Meets 10 times plus final exam. No class May 25 (Memorial Day) or June 1.

Faculty: Denita Winstead

Required text: *Pharmaceutical Experimental Design*, Lewis, Mathieu, Phan-Tan-Luu, Informa Healthcare, Volume 92, ISBN 0-8247-9860-0.

8004. Pharmaceutical Manufacturing II (990) 023-947

Prerequisite: science and basic math background. There will be no review of basic science concepts; it will be assumed that students are familiar with them. Completion of *Pharmaceutical Manufacturing I* is helpful but not required.

6:00 pm - 9:00 pm Thursdays: May 14, 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30. Meets 12 times plus final exam. Make-up dates if needed Aug 6 or 13.

Faculty: Karen Zimm

Recommended text: *Aulton's Pharmaceutics: The Design & Manufacture of Medicines*, 2007, Aulton, ed, (ISBN 044-31-01086). Students must also download the FMC Problem

Solver from www.fmcbiopolymer.com (Pharmaceuticals, ToolKit).

Special note: This course will be offered in a “real time” on-line format, Adobe Connect. Students will be required to sign the “Expectations of Adobe Connect students” before their registration will be processed.

Go to: http://www.temple.edu/pharmacy_qara/pdf/Connect_Expectations.pdf

Students must FAX their registration form to the QA/RA office (this course will not be open on OWLnet.)

You must complete the self-test of Adobe Connect at yellowstone.temple.edu/qaraAdobeTest

Make sure you include the password on your registration form, or your registration will not be processed.