

See the future of RA & QA...  
Now.



Study Regulatory Affairs and Quality Assurance Online  
Temple University School of Pharmacy



## Certificates You Can Complete Online

### Certificate Name

### Availability

#### Drug Development

Yes. Can be completed online.

#### Medical Devices

Yes. Can be completed online. All courses available EXCEPT Pharmaceutical Packaging: Technology & Regulation.

#### Clinical Trial Management

Yes. Can be completed online. All courses available EXCEPT Statistics for Clinical Trials.

#### Basic Pharmaceutical Development

Yes. Can be completed online.

#### Biosimilars/Generic Drugs

Yes. Can be completed online. All courses available EXCEPT Good Distribution Practices.

#### Global Pharmacovigilance

Yes. Can be completed online.

#### GMPs for the 21st Century

No.

#### Labeling, Advertising and Promotions

Yes. Can be completed online. All courses available EXCEPT Regulation of Non-Prescription Healthcare Products.

#### Food RA and QA

Yes. Can be completed online.

#### Biopharmaceutical Manufacturing

Yes. Can be completed online.

#### Sterile Product Manufacturing

No.

#### Post-Master's Certificates in Advanced QA and RA

Yes. Refer to other side for the list of available courses.

See **Expectations of Online Students** for student policies, technical requirements, proctored exams, and other information.



Temple University School of Pharmacy | RA and QA Graduate Program  
425 Commerce Drive, Suite 175 | Fort Washington, PA 19034

Phone: 267.468.8560 | Fax: 267.468.8565  
Email: [qara@temple.edu](mailto:qara@temple.edu) | [www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)



# RAQA Online Courses



*The following courses are offered online by the RA and QA graduate program of Temple University's School of Pharmacy\**

## REQUIRED COURSES

*Note: Four courses are required for the MS: Drug Development, Food & Drug Law, one GxP course and either Quality Audit or IND/NDA Submissions. All are available online.*

Drug Development (5459)  
Food and Drug Law (5592)  
Quality Audit (5494)  
IND/NDA Submissions (5495)

Good Laboratory Practices (5476)  
Good Manufacturing Practices (5477)  
Good Clinical Practices (5536)  
Advanced GMPs – defining “c” (5479)

## ELECTIVE COURSES

Pharmacology & Pharmacokinetics (5401)  
Pharmacoeconomics (5408)  
The Global Biopharmaceutical Industry (5458)  
Biotechnology: Bioprocess Basics (5471)  
Pharmaceutical Marketing (5472)  
Generic Drug Regulation: ANDAs (5473)  
Process Validation (5474)  
High Purity Water Systems (5478)  
Pre-Approval Inspections (5491)  
Regulation of Medical Devices: Compliance (5496)  
Computer Validation (5498)  
Regulation of Medical Devices: Submissions (5502)  
Medical Device Change Controls (5503)  
Global Regulation of Medical Devices (5505)  
Good Pharmacovigilance Operations (5508)  
Active Pharmaceutical Ingredients (APIs) (5513)  
Regulatory eSubmissions (5514)  
Biologics/Biosimilars: A Regulatory Overview (5515)  
Cleaning Validation (5516)  
Global Labeling Regulation (5532)  
Product Labeling and Advertising (5533)  
Biomedical/Technical Communications (5534)  
Advanced Topics in Labeling Development (5535)  
Clinical Trial Management (5537)  
Clinical Drug Safety and Pharmacovigilance (5538)  
Global Clinical Drug Development (5539)  
Post Approval Changes (5545)

Global Pharmaceutical Excipient Regulation (5546)  
Project Management for Clinical Trials (5547)  
Risk Management of Pharmaceutical and Medical Devices (5548)  
Post-Marketing Safety Surveillance (5571)  
Pharmacoepidemiology (5573)  
Regulatory Sciences (5575)  
Global CMCs and Regulatory Dossiers (5576)  
Global CMCs for Biopharmaceuticals (5577)  
Risk Management and Safety Signaling of Healthcare Products (5578)  
Regulatory & Legal Basis of Pharmacovigilance (5579)  
Global Regulatory Affairs (5591)  
Dietary Supplements, Botanicals, and Nutraceuticals (5594)  
Food Law (5595)  
Food Labeling and Regulatory Affairs (5596)  
Food GMPs (5597)  
Clinical Aspects of Pharmaceutical Medicine I (5599)  
Industry Interactions with FDA/Health Authorities (5601)  
Advanced Topics in Food and Drug Law (5605)  
Regulation of Advertising and Promotions (5611)  
Bioethics for Pharmaceutical Professionals (5612)  
Project Management (5615)  
Current Global Regulatory Issues (5650)  
FDA Medical Device Regulation (5650)  
Analytical Chemistry in Pharmaceutical Laboratories (5655)  
Pharmaceutical Manufacturing II: Solid Dosage Forms (8004)  
Pharmaceutical Biotechnology (8005)

*Not every course is offered each semester. Required courses are usually offered each semester. Electives are rotated every year or two years. Adobe Connect is used for online course delivery.*



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