



**TEMPLE UNIVERSITY
SCHOOL OF PHARMACY
REGULATORY AFFAIRS AND
QUALITY ASSURANCE
GRADUATE PROGRAM**

**CERTIFICATE IN
BIOLOGICS AND
BIOSIMILARS:
REGULATORY ASPECTS**

APPLICATION

1. Mail hard copy of this form to Temple U, RA and QA Graduate Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034.
2. Include photocopies of transcripts from all undergraduate and graduate colleges and universities attended.
3. Certificates are not automatically awarded. You must submit the Notice of Completion (available on the Certificate Link) to the RAQA Office by the stipulated deadline.



Name _____
 Address _____ Apt _____
 City _____ State _____ Zip _____
 TUID _____ email _____
 Daytime phone _____
 Undergraduate School attended _____
 Degree Received _____ Year _____
 Graduate School attended _____ Year _____
 Signature _____ Date _____

*Please write a brief statement of why are are interested in pursuing the Certificate in Biologics and Biosimilars:
Regulatory Aspects:*

To be completed by the RAQA Office:

Required:

Drug Development (5459) _____ Biologics/Biosimilars: A Regulatory Overview (5515) _____
 Global CMCs - Biologics (5577) _____

Then students choose one elective from:

Production of Sterile Products (5492) _____ Regulatory eSubmissions (5514) _____
 Vaccines: RA and QA Issues (5572) _____ Biologics/Biosimilars: A Regulatory Overview (5515) _____
 Pharmacovigilance (either Clinical Drug Safety and Pharmacovigilance - 5538 **or** Post Marketing Safety Surveillance - 5571)
 Current Issues in Clinical Trials (5560) _____
 Other elective (must be approved in advance with written authorization from RAQA Office) _____