



REGULATORY AFFAIRS CERTIFICATE PROGRAM

RAPS Member ID#: _____ Mr Ms Dr First Name _____ MI _____ Last Name _____
 Company Name _____
 Address _____ City State/Province _____
 Mail Stop _____ Postal Code _____ Country _____
 Phone (with area/country code) _____ Business Email Address (required for confirmation) _____

CERTIFICATE IN MEDICAL DEVICES OR PHARMACEUTICALS

Member – \$1700
 Nonmember* – \$1925

MEDICAL DEVICE CERTIFICATE

Core Courses (all required)

- Ethics – OL104C
- Global Regulatory Strategy for Medical Devices – OL109C
- Medical Devices: Definition & Lifecycle – OL106C
- Role of the Regulatory Professional – OL105C

Elective Courses (select 5)

- Effective Communication and Negotiation – OL117C
- Good Clinical Practice – OL102C
- Good Laboratory Practice – OL101AC
- Intermediate Medical Writing: Medical Devices – OL151C
- Introduction to Global Healthcare Product Regulations – OL135C
- Introductory Medical Writing – OL122C
- Medical Devices: Canada Regulations – OL108C
- Medical Devices: Compliance & Audits – OL141C
- Medical Devices: Corrections, Removals and Directed Recalls – OL150C
- Medical Devices: EU Regulations – OL110C
- Medical Devices: Postmarket Surveillance – OL139C
- Medical Devices: Risk Management – OL143C
- Medical Devices: US Regulations – OL114C
- Project Management – OL115C
- Quality System Regulations – OL138C
- Regulation of Combination Products – OL107C
- Regulation of IVDs – OL111C
- Supplier Management – OL147C
- Understanding & Managing the US Clinical Trial Process – OL118C

PHARMACEUTICALS CERTIFICATE

Core Courses (all required)

- Ethics – OL104C
- Global Regulatory Strategy for Pharmaceuticals – OL121C
- Pharmaceuticals: Definition & Lifecycle – OL119C
- Role of the Regulatory Professional – OL105C

Elective Courses (select 5)

- Chemistry, Manufacturing and Controls – OL146C
- Effective Communication and Negotiation – OL117C
- Good Clinical Practice – OL102C
- Good Laboratory Practice – OL101AC
- Good Manufacturing Practices – OL103C
- Intermediate Medical Writing: Biologics and Pharmaceuticals – OL152C
- Introductory Medical Writing – OL122C
- Introduction to Global Healthcare Product Regulations – OL135C
- Pharmaceuticals: Canada Regulations – OL126C
- Pharmaceuticals: Compliance & Audits – OL142C
- Pharmaceuticals: EU Regulations – OL125C
- Pharmaceuticals: US Regulations – OL124C
- Pharmacovigilance – OL140C
- Project Management – OL115C
- Regulation of Combination Products – OL107C
- Regulation of Dietary Supplements and NHPs – OL148C
- Regulation of US and EU Biologics – OL120C
- REMS and RMPs – OL144C
- Supplier Management – OL147C
- Understanding & Managing the US Clinical Trial Process – OL118C

CERTIFICATE IN MEDICAL DEVICES AND PHARMACEUTICALS (DUAL)

Member – \$2645
 Nonmember* – \$2870

Core Courses (all required)

- Ethics – OL104C
- Global Regulatory Strategy for Medical Devices – OL109D
- Global Regulatory Strategy for Pharmaceuticals – OL121D
- Medical Devices: Definition & Lifecycle – OL106D
- Pharmaceuticals: Definition & Lifecycle – OL119D
- Role of the Regulatory Professional – OL105D

Elective Courses (select 8)

- Chemistry, Manufacturing and Controls – OL146D
- Effective Communication and Negotiation – OL117D
- Good Clinical Practice – OL102D
- Good Laboratory Practice – OL101AD
- Good Manufacturing Practice – OL103D
- Intermediate Medical Writing: Biologics and Pharmaceuticals – OL152D
- Intermediate Medical Writing: Medical Devices – OL151D
- Introduction to Global Healthcare Product Regulations – OL135D
- Introductory Medical Writing – OL122D
- Medical Devices: Canada Regulations – OL108D
- Medical Devices: Compliance & Audits – OL141D
- Medical Devices: Corrections, Removals and Directed Recalls – OL150D
- Medical Devices: EU Regulations – OL110D
- Medical Devices: Postmarket Surveillance – OL139D
- Medical Devices: Risk Management – OL143D
- Medical Devices: US Regulations – OL114D
- Pharmaceuticals: Compliance & Audits – OL142D
- Pharmaceuticals: EU Regulations – OL125D
- Pharmaceuticals: US Regulations – OL124D
- Pharmacovigilance – OL140D
- Project Management – OL115D
- Quality System Regulations – OL138C
- Regulation of Combination Products – OL107D
- Regulation of Dietary Supplements and NHPs – OL148D
- Regulation of IVDs – OL111D
- Regulation of US and EU Biologics – OL120D
- REMS and RMPs – OL144D
- Supplier Management – OL147D
- Understanding & Managing the US Clinical Trial Process – OL118D

UPGRADE TO CERTIFICATE IN MEDICAL DEVICES AND PHARMACEUTICALS (DUAL) OPTION**

Member – \$945
 Nonmember – \$1045

MEDICAL DEVICES CERTIFICATE

Additional Core (all required)

- Global Regulatory Strategy for Medical Devices – OL109C
- Medical Devices: Definition & Lifecycle – OL106C

Additional Electives (select 3***)

- Effective Communication and Negotiation – OL117C
- Good Clinical Practice – OL102C
- Good Laboratory Practice – OL101AC
- Intermediate Medical Writing: Medical Devices – OL151C
- Introduction to Global Healthcare Product Regulations – OL135C
- Introductory Medical Writing – OL122C
- Medical Devices: Canada Regulations – OL108C
- Medical Devices: Compliance & Audits – OL141C
- Medical Devices: Corrections, Removals and Directed Recalls – OL150C
- Medical Devices: EU Regulations – OL110C
- Medical Devices: Postmarket Surveillance – OL139C
- Medical Devices: Risk Management – OL143C
- Medical Devices: US Regulations – OL114C
- Project Management – OL115C
- Quality System Regulations – OL138C
- Regulation of Combination Products – OL107C
- Regulation of IVDs – OL111C
- Supplier Management – OL147C
- Understanding & Managing the US Clinical Trial Process – OL118C

PHARMACEUTICALS CERTIFICATE

Additional Core (all required)

- Global Regulatory Strategy for Pharmaceuticals – OL121C
- Pharmaceuticals: Definition & Lifecycle – OL119C

Additional Electives (select 3***)

- Chemistry, Manufacturing and Controls – OL146C
- Effective Communication and Negotiation – OL117C
- Good Clinical Practice – OL102C
- Good Laboratory Practice – OL101AC
- Good Manufacturing Practice – OL103C
- Intermediate Medical Writing: Biologics and Pharmaceuticals – OL152C
- Introductory Medical Writing – OL122C
- Introduction to Global Healthcare Product Regulations – OL135C
- Pharmaceuticals: Canada Regulations – OL126C
- Pharmaceuticals: Compliance & Audits – OL142C
- Pharmaceuticals: EU Regulations – OL125C
- Pharmaceuticals: US Regulations – OL124C
- Pharmacovigilance – OL140C
- Project Management – OL115C
- Regulation of Combination Products – OL107C
- Regulation of Dietary Supplements and NHPs – OL148C
- Regulation of US and EU Biologics – OL120C
- REMS and RMPs – OL144C
- Supplier Management – OL147C
- Understanding & Managing the US Clinical Trial Process – OL118C

PAYMENT INFORMATION

Check # _____ American Express MasterCard Visa

Account # _____ Exp. Date _____ Billing Postal Code: _____

Name as it appears on the card _____ Signature _____

*The nonmember fee includes RAPS membership for 12 months for qualified applicants
 I have reviewed and understand RAPS membership qualifications and accept membership with RAPS
 I waive the RAPS membership

** Only available to individuals who have completed or are in the process of completing the Medical Devices or Pharmaceuticals Certificate.

*** Courses cannot have been previously completed as part of the Medical Devices or Pharmaceuticals Certificate

HOW TO REGISTER

- ONLINE:** RAPS.org/onlineu
 - BY FAX:** +1 301 770 2924
 - BY MAIL:** RAPS c/o SunTrust, Lockbox Dept, PO. Box 79546, Baltimore, MD, 21279-0546
- Full payment must accompany this form.**