



## The Four RAC Credentials

### An Overview

	RAC (US)	RAC (EU)	RAC (CAN)	RAC (General Scope)
<b>Knowledge required and regulatory basis</b>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceutical, and biologics</li> <li>▪ FDA regulations</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, medicinal products (e.g., pharmaceuticals, biologics)</li> <li>▪ European regulations and guidances from the European Commission, EMEA, competent authorities</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics</li> <li>▪ Health Canada regulations</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics</li> <li>▪ ICH, GHTF, WHO and ISO guidelines and standards</li> <li>▪ Critical thinking and analytical skills</li> </ul>
<b>Best suited for</b>	Regulatory professionals submitting to, or involved with, regulatory authorities in the US	Regulatory professionals submitting to, or involved with, regulatory authorities in the European Union	Regulatory professionals submitting to, or involved with, regulatory authorities in Canada	Regulatory professionals without an RAC credential, not currently involved with regulatory authorities in the US, EU or Canada
<b>Eligibility</b>	Baccalaureate degree (or equivalent) or 3–5 years regulatory experience			
<b>The exams</b>	Two hours to complete; 100 multiple-choice questions; administered at locations worldwide			
<b>Application fee</b> (In US\$)	<b>RAPS members:</b> \$325; late registration: \$425 <b>Nonmembers*:</b> \$510; late registration: \$610 <i>* Includes one year RAPS membership</i>			
<b>Credential maintenance</b>	RAC-credentialed professionals must accumulate 36 recertification credits every three years after initial certification to maintain RAC status.			