

1 **Table 1 - An illustrative model to link competency levels , accreditation and career paths**

Competency level, focus of learning efforts or role description	Accreditation / Certification requirements	Link to Career Path or job titles
<p>Foundation Level (Level I)</p> <p>Applies prior knowledge and skills while learning regulatory frameworks, requirements, legislation, and processes</p>	<p>Number of core modules; number of hours of subject matter experience gained “on-the-job” and work outputs documented in a portfolio;</p>	<p>Regulatory Officer</p>
<p>Intermediate Level (Level II)</p> <p>Learns all technical aspects of regulatory tasks connected with specified areas of regulation</p>	<p>Number of core modules; number of hours of subject matter experience gained “on-the-job” and work outputs documented in a portfolio; post-graduate certificate or diploma qualification</p>	<p>Senior Regulatory Officer</p>
<p>Advanced Level (Level III)</p> <p>Transitions into using technical knowledge into regulatory strategy.</p>	<p>Number of core and supplementary modules; number of hours of subject matter experience gained “on-the-job” and work outputs documented in a portfolio; research project with peer-reviewed publications; masters-level or doctoral qualification</p>	<p>Regulatory Expert</p>
<p>Expert Level (Level IV)</p> <p>Strategic regulatory leader who develops new approaches based on a sound understanding of regulatory requirements, opportunities, risks, and alternatives.</p>	<p>Number of additional core and supplementary modules, number of hours of subject matter experience gained “on-the-job” and work outputs documented in a portfolio; research in the regulatory sciences documented with peer-reviewed publications masters-level or doctoral qualification</p>	<p>Senior Regulatory Expert</p>
<p>The competency-driven programs follow a professional qualification approach and might be assessed for a specified area of regulation e.g. clinical trials regulation. The number of competency levels may be reduced or expanded depending on the size of agencies. The accreditation requirements might be aligned with internal agency job profiles and the qualifications (diploma, masters or doctorate) offered by local academic institutions . Suitable academic degrees or work experience documented in a portfolio may replace attendance of modules as recognition of prior learning. Competency assessments may be waived if modules are completed within an accredited network of course providers.</p>		