

GMP, GCP & QUALITY CONTROL

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PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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Regulatory affairs

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Scope of Regulatory Affairs: The regulation of medical products has been expanding since early 20th century. Regulatory agencies are being established in an ever increasing number of countries across the globe. Regulatory Affairs within the biomedical and health products sector is a relatively young, multidimensional profession that is international in scope. RA professionals come from a variety of disciplines such as law, academics, industrial research and medicine. It is a promising field for scientists searching for alternative careers because it offers a multitude of jobs and opportunities for development. The modern view of RA as a dynamic, business oriented unit, focused on getting products to the market with a commercially viable label as quickly as possible is a visionary and competitive paradigm.

Importance of Regulatory Affairs: Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way and also is to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities.

Regulatory Procedure Manual: The Regulatory Procedures Manual is a reference manual for FDA personnel. It provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The primary purpose of the Regulatory Procedures Manual (RPM) is to provide FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. While the RPM is intended mainly to provide guidance to FDA inspectors, investigators, and compliance officers, the document is useful to all of FDA.

Career Development in Regulatory Affairs: The work of a regulatory professional is diversified and dynamic. The profession offers a unique perspective of various aspects of the development and commercialization of healthcare products (i.e., medicines, medical devices, cosmetics, and nutritionals). For example, in a typical week a regulatory professional working in industry might interact with colleagues from sales, marketing, research and development, and production. The regulatory professional will sit on a cross functional team that reviews carcinogenicity results, clinical protocols, manufacturing batch records, and promotional material. The team's activities will make an impact on patients, public health, and the company's bottom line. One other area for discussion that may be confusing for people both within and external to the world of regulatory involves the job titles that are used. Although there are basically only five terms used, they may vary widely on the skills that are needed for each. Regulatory Associate/Coordinator – This is an entry-level position where staff will develop the basic knowledge needed to participate in the processes and procedures for regulated products. Regulatory Specialist – This is the next level in the progression of experience for a RA professional and may be when the employee begins to specialize. These positions often focus on specific technical skills and project management techniques. Regulatory (Project) Manager – Often this position does not involve the management of staff only projects (RPM), but when it does it is usually in a small team setting. Regulatory managers will typically have responsibility for time-sensitive activities and provide input for strategy decisions. Associate/Director RA – This leadership position is more strategic than the technical and tactical manager positions and will require experience and expertise that is either directly related to product development and lifecycle or specific activities within a company, such as advertising/promotion or pharmacovigilance reporting. Vice President/Head of RA – This represents the most senior and strategic level that RA professionals will attain within this discipline.

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