

Pharmaceutical Regulatory Affairs 2012: Importance of personnel training and education in regulatory affairs - Lipient Software (India) Private Limited, India

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Abstract

The role of Regulatory Affairs (RA) personnel is crucial in the pharmaceutical industry. Their involvement is essential throughout any product lifecycle. RA personnel provide strategic support and direction for working within regulatory framework to expedite the development and delivery of safe and effective pharmaceutical products. Constant changes in the regulatory environment give RA personnel the scope to grow and achieve their career goals. RA professionals must continually sharpen their knowledge and skills to be effective and advance in their profession. Adequate awareness of the importance of Regulations in the healthcare industry must be engendered right from the basics. These requirements need to be incorporated at the bachelor's level. This awareness will go a long way in influencing the way the documents are viewed and the way in which data is handled by the RA personnel.

- Training the new joinee with a strong foundation – good understanding, better performance, knowledge of the skill sets involved.
- Coordination between departments involved – R&D to Packaging.
- A good understanding of the drug-development process workflow, which would also involve a thorough knowledge of the documentation process.
- Continuous training – keeping abreast of the latest trends and changes in regulations, thereby enhancing their professional growth.
- Attending a host of conferences that are scheduled all-round the year at various levels of entries, workshops, discussion forums, Webinars, and e-journals.
- Employers actively encouraging their RA personnel to participate in various conferences/workshops, conducting interdepartmental discussions, and software application demos.
- Motivation and appreciation go a long way in enhancing the performance of the RA personnel.

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 Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work, are comfortable with multi-tasking and are eager to expand their knowledge in the wide realms of the Pharmaceutical world. Regulatory Affairs is a rewarding, intellectually stimulating and highly regarded profession within pharmaceutical companies.