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Importance of personnel training and education in regulatory affairs

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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 inter-departmental discussions, and software application demos.
- Motivation and appreciation go a long way in enhancing the performance of the RA personnel.

Biography

Sapna L Kanth has completed M.Sc. in Applied Genetics from Bangalore University. She has been associated with Liquent, earlier called Datafarm, for 6 yrs as a Regulatory Associate. Currently she is with Liquent as Team Lead. Preethi GiriRaju has completed Bachelor of Pharmacy from Rajiv Gandhi University of Health Sciences and MBA in Operating Systems and Marketing from SMU, Manipal. She has been working in Pharmaceutical Industry for over 4 yrs in Regulatory and Quality Compliance department. Currently, she is with Liquent's Regulatory and Clinical Services team.

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