REGULATORY EXCELLENCE TRAININGS
by
DDREG

US FDA
EMA/MHRA
WHO PQ
ROW

Simplifying RA complexities!

Regulatory Excellence Trainings

- Subjects of critical importance
- Interactive problem based learning
- Live Issue discussions
- Practical interpretation of pharmaceutical regulations
- Regulatory Crisis Management—Best Practices
- Domain expertise
- Post Training Support

PROVIDING YOUR RA TEAM THE FUEL TO EXCEL

DDReg, an India based Regulatory Services organization and ISO 9001:2015 certified by TUV-SUD, is involved in a wide variety of regulatory consulting, advisory & operational assignments which span across global markets that include key markets like USA, UK & European Union, ASEAN and Africa. DDReg has, rich experience of handling ANDA and ANADA filings to US FDA as well as DCP/MRP procedures in EU. The teams at DDReg have carried out extensive due diligence activities of technical documents, gap analyzed the documentation, developed and authored the CTD Modules for submission to FDA, EMA & UK MHRA and published eCTD modules

Over the years DDReg has effectively utilized its rich experience of handling regulatory assignments for regulated and emerging markets, by way of Regulatory Trainings. Our outstanding reputation as one of the most trusted regulatory services providers, gives the confidence to our clients, of the highest standards of the trainings that we offer. DDReg mentors are all industry specialists, bringing current and future thinking to the knowledge content. The emphasis on interactive problem based learning methods imparts a pragmatic understanding of the subject by the participants which helps them to gain the confidence to put it into practice in the workplace.

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Regulatory Excellence Training Portfolio

- Generic Drug Product Development—Global RA Perspective for OSDs
- Generic Drug Product Development—Global RA Perspective for Injectables
- Analytical Method Validation—ICH Q2 (R1)
- Process Validation
- ANADA Submissions—CVM Perspective
- Post Approval Life Cycle management
- Module Writing—ICH M4Q Compliance
- API /DMF Assessments—Current RA Scenario

DDREG's TRAINING PORTFOLIO

DDReg's training portfolio includes a host of regulatory topics that the team has mastered over the year through its experience providing regulatory services. Please refer to left panel for some of the examples where DDReg has mastered the subject matter and has provided customized trainings on these.

In addition to above topics, DDReg can develop customized trainings for its clients on any of the regulatory pertaining to generic pharmaceuticals - be it related to regulatory strategies, operations or compliances.

DDReg's regulatory excellence trainings can be run for an orgnization on site or at another location of choice, which means that:

- A number of staff can be trained at the same time, and ensuring a consistent message
- There are no employee travel and accommodation costs
- Trainings can be tailored to cater to the level of content and degree of expertise required for particular needs,
- There can be the opportunity to continuously relate regulatory issues to organization situation

DDReg training team discusses the learning outcomes that a client organization wants to achieve, and then tailor the course to meet them, using your client's own examples in exercises.

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QUALITY DRIVEN BY PASSION @DDREG

We stand committed to high QUALITY of services for global markets in cost efficient manner. By QUALITY we mean more than just services meeting our own specifications. It means meeting customers' requirements and ensuring QUALITY at all levels of dealing with our customers.

When we think of QUALITY, our aim is therefore to continuously meet and exceed the quality levels expected by our customers in everything we do!

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