

DRUG SAFETY TRAININGS

by
DDREG



US FDA
EMA/MHRA
WHO
INDIA
GCC ARAB
ASEAN

Simplifying PV complexities!



PROVIDING YOUNG STUDENTS—THE FUEL TO EXCEL IN DRUG SAFETY MANAGEMENT

DDReg, an India based Drug Safety & Regulatory Services organization and ISO 9001:2015 certified by TUV-SUD, is involved in a wide variety of Drug Safety/PV consulting, advisory & operational assignments which span across global markets that include key markets like USA, UK & European Union, ASEAN and Africa. DDReg has gained rich experience of handling pharmacovigilance and Drug Safety assignments for submission to US FDA, UK MHRA and EU EMA. DDReg is extensively involved in supporting global organizations to manage their worldwide Safety Obligations by way of Case Management, Aggregate Reporting, Safety Compliances, Signal Detection and Risk Management.

Over the years DDReg has effectively utilized its rich experience of handling Drug safety/PV assignments for regulated and emerging markets, by way of Regulatory Trainings. Our outstanding reputation as one of the most trusted 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

Drug Safety Trainings

- Subjects of critical importance
- Interactive problem based learning
- Live Issue discussions
- Practical interpretation of Drug Safety /PV requirements worldwide
- Safety Crisis Management—Best Practices
- Domain expertise
- Post Training Support

Simplifying PV complexities!

Drug Safety/PV Training Portfolio

- Basics of Pharmacovigilance
- Adverse Event & Adverse Drug Reaction
- Sources of ADRs
- Literature search
- MedDRA Overview & Coding with MedDRA
- Safety databases - operational understanding
- Case Processing
- Medical Review
- Causality assessment
- Reporting of Individual case safety reports (ICSRs)
- ICH E2B guideline
- Aggregate reports
- Risk management systems
- Signal management
- Pharmacovigilance audits and inspections
- Pharmacovigilance Guidelines in Various Countries including WHO Programme

DDREG's TRAINING PORTFOLIO

DDReg's training portfolio includes a host of Drug Safety / Pharmacovigilance topics that the team has mastered over the year through its experience providing these 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. For young graduating students DDReg has customized Drug Safety/PV training portfolios that help them to get peach jobs in PV departments of leading pharma organizations.

For corporates, DDReg's Drug Safety /PV excellence trainings can be run for an organization on site or at another location of choice, which means that:

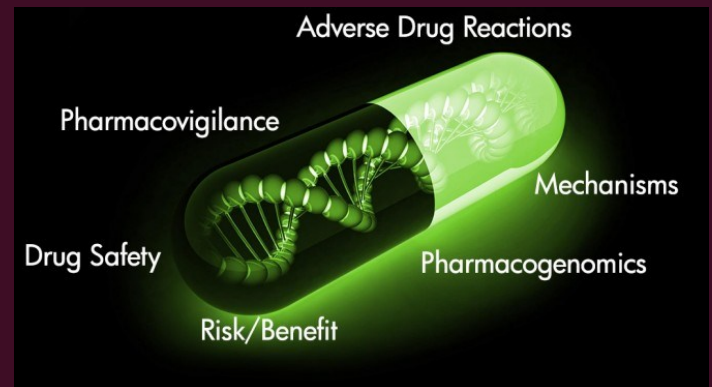
- A number of staff can be trained at the same time, and ensuring a consistent message
- There are no employee travel and accommodation costs
- Trainings can be tailored to cater to the level of content and degree of expertise required for particular needs,
- There can be the opportunity to continuously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

DDReg training team discusses the key learning topics and recent worldwide developments & trends in the area of Drug Safety & Risk Management and accordingly provide the most updated trainings to the trainees so that each trainee - once out of DDReg's Training

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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