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Instructors **Dr. Sachin Potawale**

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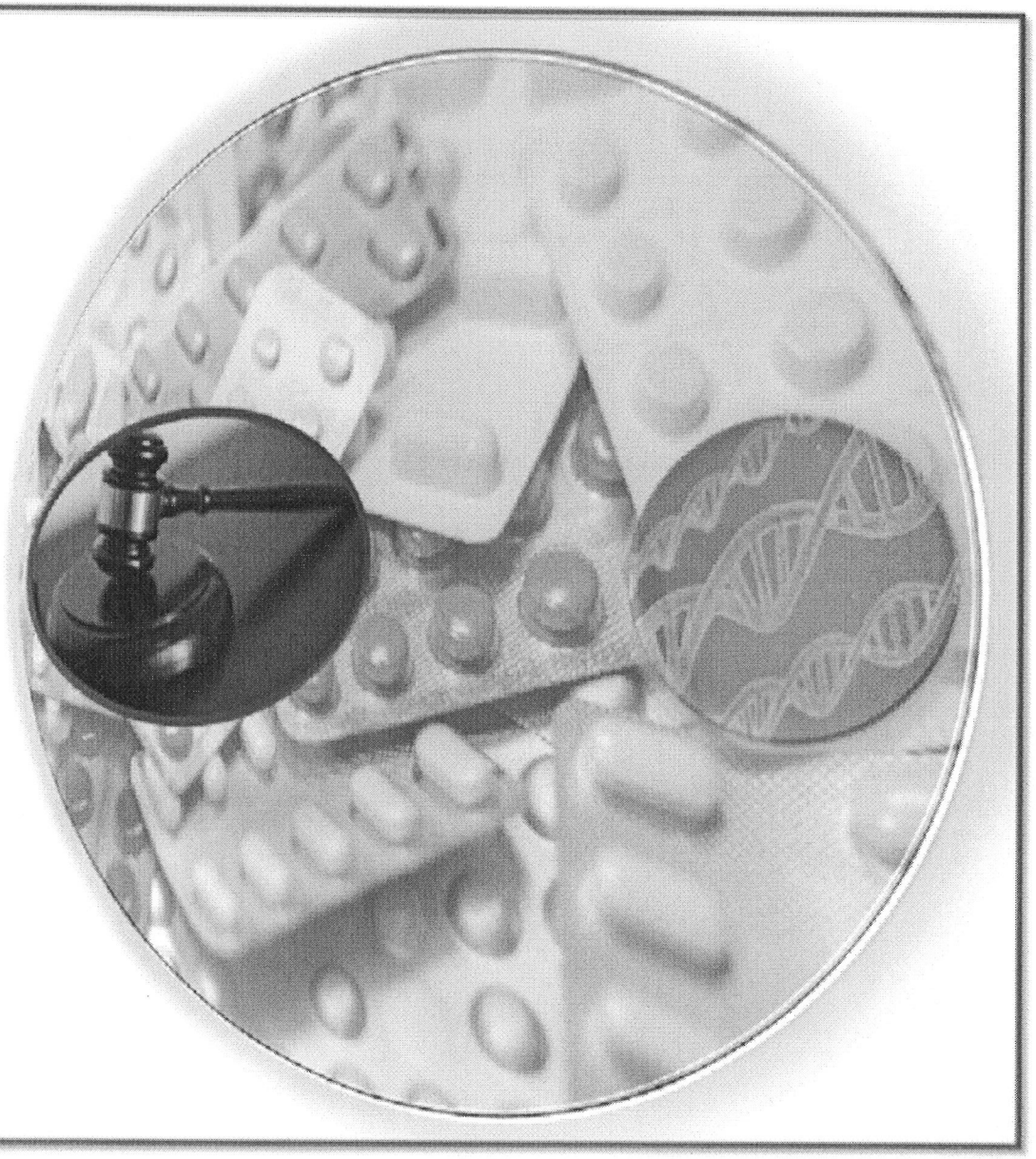

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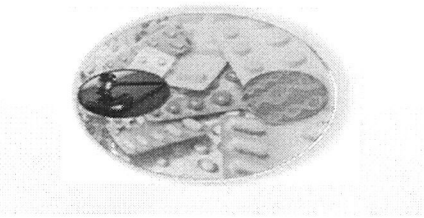

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- Basic Understanding and Terminologies related to DRA,
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- DRA objectives,
- The USFDA regulatory requirements and Drug Approval Procedure,
- History of US Drug Law and Regulations,
- Agencies for drug regulations in The United States of America,
- Investigational New Drug Application (INDA),
- New Drug Application (NDA),
- Abbreviated New Drug Application (ANDA),
- Supplemental New Drug Application (SNDA),
- Orange Book,
- Drug Master File (DMF),
- Common Technical Document (CTD),
- Electronic Common Technical Document (eCTD),
- Good Manufacturing Practices (GMP) and Current Good Manufacturing Practices (cGMP),
- Clinical Research,
- Biologics License Application (BLA) and Purple Book,
- Important Literature Search Websites for DRA Professional,
- Many more...

There will be several downloadable documents so that you can follow along with them whenever you need them. This course contains Commonly Asked Questions that will help you while preparing for DRA interviews. Last but not least, this course also contains a bonus course entitled "Meeting etiquettes" which will help you to shape your career in which the points that must be taken into consideration while attending/conducting meetings are covered. In this course, more than 30 informative videos are included and are designed in an easily digestible format and going to take you through step by step approach to understand Drug Regulatory Affairs and relevant activities. This course will help you to develop the ability to conduct regulatory intelligence and develop a regulatory strategic plan.

I believe "Quality improvement is a continuous and lifetime process". Upon completing this course, you will be a whole different professional with improved DRA skills and knowledge, which will help you to garner more respect from your team members, managers, clients, or anyone with whom ou are communicating/interacting.