REGISTRATION FEE

Payment. Rs. 3,500/- for entire course
The course fee includes:
Tuition fees
Course materials

Mode of payment: Cash

Who should attend:
The certificate course is designed for Final Year B. Pharm/M. Pharm research students/PhD scholars/ faculty members and individuals who want to expand their knowledge on various aspects of Quality Assurance & Regulatory Affairs in the pharmaceutical industry

CONTACT DETAILS

Address: Hashu Advani Memorial Complex, Behind Collector Colony, Chembur (E), Mumbai – 400 074
Contact: 022 – 6114 4144/ 2554 3600
Fax: 022 – 2554 3925
Email: vespharm@yahoo.co.in / vescop@gmail.com

- https://twitter.com/vespharma
- https://www.facebook.com/VES-College-of-Pharmacy-245402799002943/
- https://www.youtube.com/channel/UCNNw6HPLjYEamgHwvWdWg0

RESOURCE PERSONS

Mr. Sunil Budhkar
GMP & GCP consultant, Mumbai

Dr. Anita Soman
Head CMC (India) - Global Regulatory Affairs, Sun Pharma Advanced Research Company Ltd.

Mr. Rajesh Bhaye
Lead Auditor & Relationship Manager, Perrigo Laboratories, India

Mrs. Meeena Shah
General manager- Regulatory Affairs, Geltec, Mumbai

Mr. Sameer Shelar
Independent Quality Assurance Auditor, Mumbai

Mrs. Neha Mazgaonkar
Manager – Drug Regulatory Affairs, Cachet Pharmaceuticals Pvt. Ltd., Mumbai

Mr. Ganesh Kadam
Research Associate – I (Executive – Regulatory Affairs), Teva Pharmaceutical Industries Ltd.

Mrs. Pallavi Kharkar,
Founder, consultant & patent attorney, IPRAM Intellectual property services, Mumbai

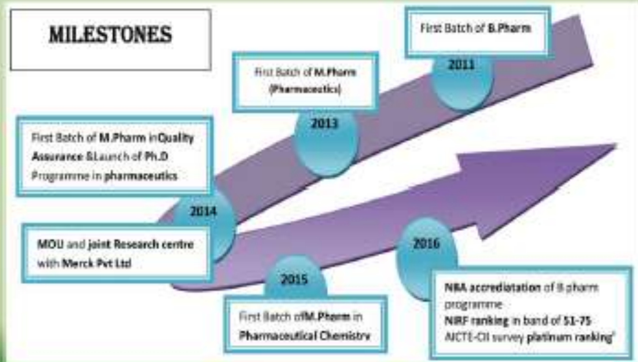
Course coordinators

Dr. Rajashree Hirlekar
Professor & HOD,

Dr. Anita Ayre
Associate Professor

Dept. of Quality Assurance, Vivekanand Education Society's College of Pharmacy Chembur, Mumbai

ABOUT US



CERTIFICATE COURSE
ON
QC, QA & RA ASPECTS IN PHARMA AND CLINICAL RESEARCH INDUSTRIES

Conducted by
Vivekanand Education Society's
College of Pharmacy
Shri Hashu Advani Memorial Complex
Behind Collector Colony
Chembur
Mumbai-400074

V.E.S.
Since 1962

Course Mentors

Dr. Supriya Shidhaye
Principal, Vivekanand Education Society's College of Pharmacy, Mumbai

Mr. Sunil Budhkar
GMP & GCP Consultant, Mumbai

Shri. B. L. Boolani
Trustee in charge, VESCOP

ABOUT THE COURSE

About the course:

The certificate course will enable participants to acquire:

- ✓ Comprehensive knowledge in the fields of QC, QA & RA
- ✓ Thorough understanding of regulatory agencies such as the US FDA, EMA, CDSCO; investigational and new drug applications and regulatory strategies
- ✓ Strong technical skills needed in a regulated work environment

The course will be delivered by experts from pharmaceutical industries

The course will enable the participants to be prepared for various positions in the Pharma industry at the fresher level, some of which are:

- Quality Assurance/Quality Control Executive
- Quality Assurance Technicians or Analysts
- Quality Assistant
- Regulatory Affairs- Trainee
- Regulatory Affairs – Officer

Course structure

Duration of course	Two months
No. of sessions (A)	06
Contact hours per session (B)	04 Each session will comprise of 4 lectures of one hour duration each
Total no. of hours (A*B)	24

COURSE STRUCTURE

QC/QA aspects in Pharma and clinical research industries	
Module 1	Introduction to GXPs & Quality
Module 2	Quality Assessment – Quality audits; Handling non- conformances; Handling market complaints; Management of CAPA; Annual product review
Module 3	Quality Control aspects- Functions of QC laboratory; Quality evaluation of raw materials, intermediates and finished products; Qualification and validation of instruments, equipments and computer devices; Microbiological aspects
Module 4	Elements of quality- Functions of QA; Role of QA in imparting training to employees; Calibration, qualification and validation; Clinical trials
Module 5	Stability studies of pharmaceutical products as per ICH Guidelines; Handling misconduct and fraud in clinical trials- QA role; Handling regulatory inspections and sponsor audits
Module 6	Quality documentation – Documentation system; SOPs; Document storage and archival
RA aspects in Pharma and clinical research industries	
Module 7	Introduction to global regulatory authorities for Pharma and healthcare industries
Module 8	Drug development process, clinical trials and related norms and regulations
Module 9	Healthcare Industry IPR, patents, copyrights and trademarks
Module 10	Compliance guidelines, Regulatory Inspections (USFDA, MHRA, PMDA, TGA, ANSM-France, MCC-South Africa, ANVISA-Brazil, COFEPRIS-Mexico, Latin America, WHO-Geneva & DCGI, CDSCO-India) and Inspection reports
Module 11	Food, Drug and Cosmetic Acts & Rules – (India)
Module 12	Documentation of drug clinical trials and regulatory filings in US, Europe, UK, India, Japan, Canada, Australia, South Africa, etc.(CTD document) and dossier preparation in CTD format, e-CTD submissions.
Module 13	Quality assurance and Drug regulations, ICH and WHO guidelines
Module 14	Pharmaceuticals and healthcare products- Marketing, Import and Export regulations
Module 15	Regulatory compliance & FDA's approach to GMP inspections of pharmaceutical companies
Module 16	Industry specific case studies

Vivekanand Education Society's College of Pharmacy

Hashu Advani Memorial Complex, Behind Collector Colony, Chembur (East), Mumbai-400 074

CERTIFICATE COURSE
ON
'QC, QA & RA ASPECTS IN PHARMA AND CLINICAL RESEARCH INDUSTRIES'

COURSE SCHEDULE

Date	Time	Module type and No. (QC/QA/RA)	Topic	Resource person
30/12/17	10.00 a.m. to 12.00 p.m.	QC/QA; Module 1	Introduction to GXPs & Quality	**Mr. Sunil Budhkar,** GMP & GCP Consultant, Mumbai
	12.00 pm. To 12.30 p.m.	Welcome address by Dr. Rajashree Hirlekar & Address by Shri. B. L. Boolani		
	12.30 p.m. to 1.00 p.m.	Lunch break		
	1.00 p.m. to 2.00 p.m.	RA; Module 7	Introduction to Global Regulatory Authorities for Pharma and healthcare industries	**Mrs. Meeena Shah,** General manager-Regulatory Affairs, Geltec, Mumbai
	2.00 p.m. to 3.00 p.m.	RA; Module 8	Drug Development Process, Clinical Trials and related norms and regulations	
06/01/18	10.30 a.m. to 12.30 p.m.	QC/QA Module 2	Quality Assessment – Quality audits, handling non-conformances, handling market complaints, management of CAPA, annual product review	**Mr. Rajesh Bhaye,** Lead Auditor & Relationship Manager, Perrigo Laboratories, India
	12.30 p.m. to 1.00 p.m.	Lunch break		
	1.00 p.m. to 3.00 p.m.	QC/QA Module 3	Quality Control aspects-Functions of QC laboratory, quality evaluation of raw materials, intermediates and finished products, qualification and validation of instruments, equipments and computer devices, microbiological aspects	**Mr. Rajesh Bhaye,** Lead Auditor & Relationship Manager, Perrigo Laboratories, India

13/01/17	10.30 a.m. to 12.30 p.m.	QC/QA; Module 4	Elements of quality- Functions of QA, Role of QA in imparting training to employees, calibration, qualification and validation, clinical trials	**Mr. Sameer Shelar,** Independent Quality Assurance Auditor, Mumbai
	12.30 p.m. to 1.00 p.m.	Lunch break		
	1.00 p.m. to 3.00 p.m.	RA; Module 9	Pharmaceuticals and Healthcare products- Marketing, Import and Export regulations	**Mrs. Neha Mazgaonkar,** Manager- Drug Regulatory Affairs, Cachet Pharmaceuticals Pvt. Ltd., Mumbai
03/02/18	10.30 a.m. to 12.30 p.m.	QC/QA Module 5	Quality documentation – Documentation system, SOPs, document storage and archival	**Mr. Sunil Budhkar,** GMP & GCP Consultant, Mumbai
	12.30 p.m. to 1.00 p.m.	Lunch break		
	1.00 p.m. to 2.00 p.m.	RA; Module 10	Compliance guidelines, Regulatory Inspections (USFDA, MHRA, PMDA, TGA, ANSM-France, MCC-South Africa, ANVISA-Brazil, COFEPRIS-Mexico, Latin America, WHO-Geneva & DCGI, CDSCO-India) and Inspection reports	**Mr. Sunil Budhkar,** GMP & GCP Consultant, Mumbai
	2.00 p.m. to 3.00 p.m.	RA, Module 11	Food, Drug and Cosmetic Acts & Rules – (India)	
10/02/18	10.30 a.m. to 12.30 p.m.	RA; Module 12	Documentation of drug Clinical trials and regulatory filings in US, Europe, UK, India, Japan, Canada, Australia, South Africa, etc.(CTD document) and Dossier preparation in CTD format, e-CTD submissions.	**Dr. Anita Soman** Head CMC (India) - Global Regulatory Affairs at Sun Pharma Advanced Research Company Ltd.
	12.30 p.m. to 1.00 p.m.	Lunch break		

	1.00 p.m. to 2.00 p.m.	RA; Module 13	Quality Assurance and Drug Regulations, ICH and WHO guidelines	**Dr. Anita Soman** Head CMC (India) - Global Regulatory Affairs at Sun Pharma Advanced Research Company Ltd.
	2.00 p.m. to 3.30 p.m.	QC/QA Module 6	• Stability studies of pharmaceutical products as per ICH Guidelines • Handling Misconduct and fraud in Clinical Trials- QA role • Handling Regulatory inspections and Sponsor Audits	**Mr. Ganesh Kadam,** Research Associate – I (Executive – Regulatory Affairs), Teva Pharmaceutical Industries Ltd., Mumbai
24/02/18	10.00 a.m. to 11.30 a.m.	RA; Module 14	Healthcare Industry IPR, Patents, copyrights and Trademarks	**Mrs. Pallavi Kharkar,** Founder, consultant and patent attorney, IPRAM Intellectual property Services, Mumbai
	11.30 a.m. to 12.30 p.m.	RA; Module 15	Regulatory Compliance & FDA's Approach to GMP Inspections of Pharmaceutical Companies	**Mr. Sunil Budhkar,** GMP & GCP Consultant, Mumbai
	12.30 p.m. to 1.00 p.m.	Lunch break		
	1.00 p.m. to 2.00 p.m.	RA; Module 16	Industry specific case studies	**Mr. Sunil Budhkar,** GMP & GCP Consultant, Mumbai
	2.00 p.m. to 3.00 p.m.	Valedictory function & Certificate distribution		