



VIVEKANAND EDUCATION SOCIETY'S COLLEGE OF PHARMACY

Hashu Advani Memorial Complex, Behind Collector Colony, Chembur (E), Mumbai – 400 074

Sindhi Linguistic Minority, Approved by AICTE, DTE, Pharmacy Council of India & Govt. of Maharashtra, Affiliated to University of Mumbai

B.Pharm Programme is accredited by NBA, New Delhi from 2016-17 to 2021-22

1.2.2.

Number of Add on /Certificate programs offered during the last five years

Brochure: Containing Name of the program, duration of the Programme

Activity Report: Summary report of each program along with their outcome

VES COLLEGE OF PHARMACY

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Academic Year
2020-21

Transition from Graduates students to research Scholars

Vivekanand Education Society's
College of Pharmacy
organizes



NATIONAL LEVEL
INDUCTION PROGRAM FOR
M. PHARM STUDENTS

TRANSITION FROM A GRADUATE STUDENT TO A RESEARCH SCHOLAR

13th -21st August 2020 | Duration : 30 Hours



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ABOUT VESCOP

Vivekanand Education Society's College of Pharmacy was established in the year 2007. The Institute was established with a mission to work closely with industry and work on solving problems for industry. The Institute is headed by Principal, Prof. (Mrs.) Supriya Shidhaye, since July 2009. VESCOP works with the vision to create competent pharmacy professionals to positively impact healthcare of the Society. VESCOP is in the process of applying for NAAC and IQAC coordinator is Dr. Rajashree Hirlekar.

Courses Run:

- **B. Pharm.** Course with 100 intake
 - **M. Pharm.** Courses: Quality Assurance, Pharmaceutics and Pharmaceutical Chemistry with total 36 intake.
 - **Ph.D.** Programs: Pharmaceutics and Pharmaceutical Chemistry with total 18 intake
- All programs are affiliated to University of Mumbai. The Institute is approved by All India Council for Technical Education (AICTE), Pharmacy Council of India (PCI) & Government of Maharashtra.

KEY ACHIEVEMENTS

- **AICTE-CII survey:** Awarded as Best Industry Linked Pharmacy Institute in 2018 in AICTE-CII survey. VESCOP was one of the top 7 Pharmacy Institutes at National level to receive the platinum ranking in 2019.
- **NIRF Ranking:** Ranked 63rd and 67th among Pharmacy institutes across the nation at NIRF 2020 and 2019 respectively.
- **Avishkar Research Convention:** Won the overall runner-up championship at 52nd Avishkar- Interuniversity Research Convention held by University of Mumbai for year 2019. One of the projects is selected for presentation at National research convention - Anveshan.
- **NBA Accreditation:** NBA Accreditation for the B. Pharm. up to 2022 as per Outcome Based Education - OBE System.
- **Best Educational Quality Enhancement Team Award:** National Centre of Quality Management awarded the Institute with top ranks in two consecutive years, 2018 and 2019 in the contest of "Best Educational Quality Enhancement Team".
- **Institute Innovation Cell (IIC) Ranking:** The Institute has set up an Institute Innovation Cell (IIC) in the year 2018 as per the directives of MHRD, Government of India, and we are glad to share that our Institute has received 4- star rating.

ABOUT THE WEBINAR

This induction program is being organized with an intent to inculcate research aptitude in M. Pharm students who will be entering the research lab to carry out their project work. Additionally it will also help the students to understand and adopt multidisciplinary approaches in order to do translational research work which will lead to innovation and will be at par with industrial standards and requirements.

Key Highlights:

- Eminent speakers from academia and industry
- Virtual tours to laboratories
- Live demonstrations of software and equipment

Target Audience: M. Pharm Students, Session is open for Ph.D. Students and faculty

Patron

Shri. B. L. Boolani
President, Vivekanand Education Society

Mentor

Prof. (Mrs.) Supriya Shidhaye
Principal, VES College of Pharmacy

Organizing Committee

Dr. Ganga Srinivasan (Professor and HOD)	Dr. Mushtaqe Shaikh (Associate Professor)
Dr. Anita Ayre (Associate professor)	Mrs. Pradnya Korlekar (Assistant professor)



Dr. (Mrs.) Supriya S. Shidhaye
PRINCIPAL
Vivekanand Education Society's
College of Pharmacy
HAMC, Behind Collector Colony,

Registration details:

Click here to register or Copy paste the link

(<https://forms.gle/zUESQtkfEBwG7B4J9>)

Last date for registration: 12th August, 2020

This is a free add-on certificate course. E-certificates will be issued to participants who will complete all e-assessment forms within 3 days of completion of the course.

Online platform: Live YouTube streaming.

Link will be shared with registered participants.



Schedule for the course

Time: 2:00 pm to 6:00 pm

Topic	Speaker
Day 1: Thursday, 13th August 2020	
Inauguration and Address by the Chief Guest	Dr. Pravin Digambar Chaudhari President APTI (Central Committee), Professor & Principal, P.E.S. Modern College of Pharmacy.
Keynote speaker	Dr. Anilkumar Gandhi Consultant, Associate Professor and Research Advisor, VES College of Pharmacy
A virtual tour to sophisticated instruments for research	Mr. Anirish Dave Head of Director, analytical and Synthetic Chemistry, Anton Paar India Pvt. Ltd.
Day 2: Friday, 14th August 2020	
Module 1: Application of Synthetic chemistry in research	
A Guidance for Post-graduate Research in Synthetic Chemistry Laboratory.	Dr. Urmila Joshi Principal, Prin. KAM Kamdani College of Pharmacy
	Dr. Premalata Ambre Associate Professor, Bombay College of Pharmacy
Module 2: Computer Aided Approaches	
Computer Aided Methods in Pharmacy Research: Where to begin?	Dr. Mushtaqe Shaikh HOD and Associate Professor, Vivekanand Education Society's College of Pharmacy
Discovery Studio for multidisciplinary research: A Demonstration	Dr. Anand Chintabandi Assistant Professor, Vivekanand Education Society's College of Pharmacy
Day 3: Monday, 17th August 2020	
Module 3: Insights into Formulation Development	
Phospholipid based vesicular systems: Design and applications	Dr. (Mrs.) Mangal Nagarsenkar Research Advisor, VES College of Pharmacy
Operation of Tablet compression Machine and significance of machine tooling	Mr. Sudeep Kumar Director, Pacific Tools
An overview of Regulatory Affairs: In research	Mrs. Tejal Bedekar Senior Officer, Global Regulatory Affairs FinOrion Pharma India Pvt. Ltd

Schedule for the course

Time: 2:00 pm to 6:00 pm

Topic	Speaker
Day 4: Tuesday, 18th August 2020	
Module 3: Insights into Formulation Development	
Formulation Development for oral solid dosage form	Mrs. Nirali Shah Scientist (R&D), Evonik India Pvt Ltd
Selection of Excipients for Oral solid dosage forms	Mr. Siddesh Juvekar Scientist, Inem Nostrum
Preformulation Science	Mrs. Preeti Dali Founder/Director, Inventus Solutions
Day 5: Wednesday, 19th August 2020	
Module 4: Analytical method development and validation	
Practical aspects of method development by UV-Vis spectroscopy pertaining to assay and dissolution	Dr. Anita Ayre Associate Professor, VES College of Pharmacy
Standardization of herbal drugs	Ms. Sneha Singh Application Scientist, Anchrom Enterprises Pvt. Ltd.
Day 6: Thursday, 20th August 2020	
Module 4: Analytical method development and validation	
Practical aspects of method development by HPLC	Dr. Anita Ayre Associate Professor, VES College of Pharmacy
Module 5: Pharmacological Evaluation	
In vitro assays, Metabolism based studies	Prof. Krishna Iyer Bombay College of Pharmacy
Day 7: Friday, 21st August 2020	
Module 5: Pharmacological Evaluation	
Preclinical Protocol Writing as per the CPCSEA Guidelines	Dr. Mrunal Ghag Head Scientific officer, Department of Zoosoon, Haffkine Institute
Zebra Fish: Preclinical model for Pharmacological and toxicological screening	Dr. Kalidas Kohale Scientific Officer (3), Department of Biological Science, IITK
Validatory function and Address by the Chief Guest on "Guidance and insights into research endeavors of M.Pharm"	Dr. Anuradha Majumdar Dean, Faculty of Science and Technology, University of Mumbai



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Activity Report A.Y 2020-2021

POST GRADUATE DEPARTMENT

(Dept. of Pharm. Chemistry, Quality Assurance & Pharmaceutics)

IQAC ACTIVITY No: PG 01/2020-21

Details of activity:

Name of the Activity	National level webinar on "Induction Program for M. Pharm – Transition from a Graduate student to a Research Scholar"	Activity No.	01
Day, Date	13 th to 21 st August, 2020	Department/Committee/Faculty	PG Dept. of Pharm. Chemistry, Quality Assurance & Pharmaceutics
Venue	Online via You Tube	Time	2.00 p.m. to 5.00 p.m.
Nature of activity	Indoor/Outdoor (Tick mark appropriate)	Total no. of participants	103

Activity Information:

Objectives	The objective of the program was to inculcate research aptitude in M. Pharm students who will be entering the research lab to carry out their project work. Additionally, it will also help the students to understand and adopt multidisciplinary approaches in order to do translational research work which will lead to innovation and will be at par with industrial standards and requirements.
Methodology	The course was conducted through online mode via You Tube channel. At the end of each day, participants were assessed for the modules taught on that day by taking e-assessment. Course completion certificate was issued only to those students who scored more than 60% in assessment of all 7 days
Outcomes	The students gained knowledge on how to use modern tools for various pharmaceutical applications, planning experimentation for analytical and formulation method development. The students also gained knowledge on how to apply the theoretical concepts in research for various pharmaceutical, analytical and pre-clinical applications

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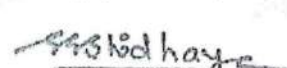
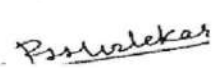
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PROOFS & DOCUMENTS ATTACHED (Tick mark the proofs attached):

	Notice and communication	✓	Feedback form
✓	Student list of participation	✓	Feedback analysis
✓	Photos		Media news details
✓	Certificate		Any other

Name & Signature of Coordinator	Name & Signature of Head/Committee In charge	Name & Signature of IQAC Coordinator
Anita Ayre 	Dr. Supriya Shidhaye 	Dr. Rajashree Hirlekar 





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“AI for Healthcare - In pursuit of innovations for Atma-Nirbhar-Bharat using the promising

Report: AI for Healthcare - In pursuit of innovations for Atma-Nirbhar-Bharat using the promising technologies

Brochure:

 **VIVEKANAND EDUCATION SOCIETY'S**

 **VES COLLEGE OF PHARMACY - IIC**
&
 **VES INSTITUTE OF TECHNOLOGY - IIC**
Jointly Organizes

A 30 HOURS CERTIFICATE COURSE ENTITLED

ARTIFICIAL INTELLIGENCE FOR HEALTHCARE

**IN PURSUIT OF INNOVATION FOR ATMA-NIRBHAR BHARAT USING
THE PROMISING TECHNOLOGIES**

24th June - 1st July 2021

PATRON
Shri. B. L. BOOLANI
PRESIDENT, VIVEKANAND EDUCATION SOCIETY

MENTORS
Prof. (Mrs.) SUPRIYA SHIDHAYE, PRINCIPAL, VES COLLEGE OF PHARMACY
Dr. J. M. NAIR, PRINCIPAL, VES INSTITUTE OF TECHNOLOGY

COURSE COORDINATORS
Dr. M. VIJAYALAKSHMI
VICE PRINCIPAL, VESIT

Dr. NEHA CHHABRA
ASSISTANT PROFESSOR, VESCOP
Email: neha.chhabra@ves.ac.in
Contact No. 9619516596


Mrs. PRADNYA KORLEKAR
ASSISTANT PROFESSOR, VESCOP
Email: pradnya.korlekar@ves.ac.in
Contact No. 8976974298

Registration Fees in Rupees:
• Students: 3000/- • Academicians: 3500/- • Industry professionals: 4000/-

Registration Link
*Desktop users click on the link for registration / Mobile users please copy the link and paste in the browser
<https://forms.gle/PFe6GvoQehXsBFV9>
Last date of registration 21st June 2021

Payment Details

Bank Account
VES College of Pharmacy - B Pharm
Bank Name: ICICI Bank
IFSC CODE: ICIC0001208
Branch: Chembur Naka
Account Number: 120801000114



"Arise, awake, and stop not till the goal is reached"
- SWAMI VIVEKANAND

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Supriya Shidhaye
Dr. (Mrs.) Supriya S. Shidhaye
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ABOUT THE COURSE

In the pursuit of our vision of - 'Creating competent pharmacy professionals to positively impact healthcare of the society', VESCOLP is coming up with another milestone activity for the pharmacy professionals. Artificial Intelligence (AI) is a new buzzword and has immense applications in the healthcare. In order to make the pharmacy professionals acquainted with it, VESCOLP in collaboration with VESIT is launching this online certificate course.

TARGET AUDIENCE

B. PHARM, M. PHARM, Ph.D. STUDENTS, FACULTY, INDUSTRY PROFESSIONALS

ARTIFICIAL INTELLIGENCE FOR HEALTHCARE

TOPICS

MACHINE LEARNING-BASIC ALGORITHM AND ADVANCED ALGORITHM

CASE STUDY AND FUTURE TREND IN AI HEALTH CARE APPLICATIONS

DESIGNING A HEALTHCARE MACHINE LEARNING WORKFLOW

IOT,HEALTH AND WARBLER IN HEALTHCARE

BASIC ARTIFICIAL INTELLIGENCE

NEURAL NETWORKS

CNN,RNN

INSTRUCTORS

DR. M. VIJAYLAKSHMI, DR. NADIR CHARNIYA

DR. SUJATA KHEDKAR, MRS. ASHA BHARAMBE

MRS. SANGEETA OSWAL

COURSE WILL RUN IN 3 SESSIONS PER DAY EACH SESSION

OF 1.5 HOURS TOTAL 30 HOURS, 24TH JUNE 2021 TO 1ST JULY 2021

✉ ai_healthcare@ves.ac.in

🌐 <https://ves.ac.in/pharmacy/>

📷 vescop_official https://instagram.com/vescop_official?utm_medium=copy_link

📘 VESCollegeOfPharmacy <https://www.facebook.com/VESCollegeOfPharmacy/>

🐦 Vescopefficial <https://twitter.com/vescopefficial?s=11>

🌐 VES College of Pharmacy <https://www.linkedin.com/in/ves-college-of-pharmacy-744492b7>

📺 Vivekanand Education Society's College of Pharmacy

<https://www.youtube.com/channel/UCNNw6HPLjYEamqHwwWdWoQ/videos>

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Shidhaye
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Activity Report A.Y 2020-2021

DEPARTMENT/ COMMITTEE/ FACULTY

IQAC ACTIVITY No: Add On course/20-21/02

Details of activity: AI for Healthcare - In pursuit of innovations for Atma-Nirbhar-Bharat using the promising technologies

Name of the Activity	AI for Healthcare - In pursuit of innovations for Atma-Nirbhar-Bharat using the promising technologies	Activity No.	02
Day, Date	Thursday, June 24 th to Thursday, July 1 st , 2021	Department/ Committee/Faculty	Dr. Neha Chhabra (Pharmaceutics), Mrs. Pradnya Korlekar (Pharmacology)
Venue	Online (Zoom)	Time	10 am to 4.30 PM daily.
Nature of activity	Online	Total no. of participants	26 (7 VES COP faculty, 15 VES COP students, 4 Outside VES COP students)

Activity Information:

Objectives	This program was launched under the aegis of IIC of VES College of Pharmacy in collaboration with IIC of VES Institute of technology with an objective to quench the quest for knowledge and application of Artificial intelligence particularly in healthcare research. We also aimed at igniting the spark for research in this field as one aspect of multidisciplinary approach in order to do translational research work, which will lead to innovation and will be at par with industrial standards and requirements to the Pharmacy professionals
Methodology	The sessions were conducted online via zoom. Theory sessions were followed by practice sessions and daily MCQ based tests. There were a total of 26 participants including academicians, B.Pharm and M.Pharm students and Ph.D. research fellows. They were enlightened by experienced and knowledgeable faculties of VESIT: Dr. Nadir Charniya, Dr. Sujata Khedkar, Mrs. Asha Bharambe, Mrs. Sangeeta Oswal, Dr. Anjali Yeole and Mrs. Sangeetha Prasanna Ram who took all possible efforts to inculcate health application entity to every theoretical session.
Outcomes	The session provided sufficient knowledge and skills of the topic in Pharmaceutical Sciences.

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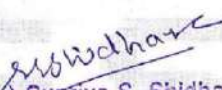
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PROOFS & DOCUMENTS ATTACHED (Tick mark the proofs attached):

✓	Brochure		Feedback form
✓	Student list of participation		Feedback analysis
✓	Photos	✓	Media news details
✓	Certificate	✓	Methodology, One course one tree initiative, website

Name & Signature of Coordinator	Name & Signature of Head/Committee In charge	Name & Signature of IQAC Coordinator
 Mrs. Pradnya Korlekar	 Dr. Mushtaque Shaikh	 Dr. Rajashree Hirlekar
 Dr. Neha Chhabra	President, IIC	


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**Academic Year
2019-20**

Advanced Pharmacovigilance and Medical Writing certificate Course

Online Participants - B.Pharm/ M.Pharm/ B.Sc/ M.Sc
Intake: Only 30 seats!
Registration Fees: Rs. 2500/- [Inclusive of GST]
Does not include food]
Registration procedure:
Submit your details at
<https://docs.google.com/forms/d/1h45uq31lg9WAoY1daz-CjvkHzzVw2aH1j1KhKifEc/edit>
and send a demand draft of the said amount in
favour of 'Vivekanand Education Society's College of
Pharmacy, Chembur'
Online payment details : A/c No 0170101138349
IFSC: CNRB0000170
Last date of Registration: 30 January 2020

Course Highlights

Basics techniques in Pharmacovigilance
Signal detection
Causality assessment of Adverse Drug
Reactions
Pharmacovigilance audits
Protocol writing
Research paper writing
Literature search and review writing
Medico Marketing writing and e content
development

Vivekanand Education Society's College of Pharmacy [VESCOP] Hashu Advani Memorial Complex, Chembur, Mumbai Advanced Pharmacovigilance and Medical Writing Certificate Course

[Organized by the Department of Pharmacology]

10 Feb 2020 to 15 Feb 2020

[Monday to Saturday]

Organizing Chairperson

Dr. Supriya Shidhaye
Principal, VESCOP

Patron

Shri. B.L. Boolani
Trustee Incharge

Organizing Secretaries

Pradnya Korlekar
Brinal Figer Pereira
Avinash Suryawanshi

Eminent speakers from
Industry and academia
will cover the topics

Hurry!
Seats fast
filling!!

Outcomes of the Course

Students will receive industry oriented training suited to improve their employability

For more information contact:

brinal.pereira@ves.ac.in [9637684674]

pradnya.korlekar@ves.ac.in [8976974298]

Dr. (Mrs.) Supriya S. Shidhaye

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Activity Report

Name of the Activity: Advanced Pharmacovigilance and Medical Writing certificate Course

Activity conducted under: Pharmacology Department

Activity Description:

This add on course conducted to bridge the gap between industry and academia. In this conducted a Thirty hours Advanced Pharmacovigilance and Medical Writing certificate Course (10th Feb to 15th Feb 2020), which had total 61 participants from TY and LY B. Pharm along with faculties from VES COP. In this 6 days, 17 eminent speakers from Industry and Academia enlightened the participants.

Day, Date, Year: 10th Feb to 15th Feb 2020

Activity details:

Event organized	Duration	Location for event	Name of the Members involved in organizing the event	Number of Participated population (In total)	Number of VES COP students participating in the event	Communication and Photos attached
Advanced Pharmacovigilance and Medical Writing certificate Course	10th Feb to 15th Feb 2020	VES COP seminar hall	Faculty: Mrs. Pradnya Korlekar, Mrs. Brinal Pereira and Mr. Avinash Suryawanshi Administrative support team: Mr. ¹	67	61	YES

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			Milind, Mrs. Gayatri Vazirani, Mrs. Aparna Srinivasan, Mr. Yogesh Borkar, Miss. Kajol, Mr. Raut, Mr. Nitin, Mr. Sunil, Mr. Mangesh Students: Vrushti, Ankita Rai, Hardik, Natasha, Shreya Ajithkumar, Sumeet, Suprita, Ambika, Shambhavi, Anjali, Shruti Patil, Ruturaj and Umang.			
--	--	--	--	--	--	--

Prepared by: Mr. Avinash S

Checked by: Mrs. Brinal F

Approved By: Mrs. Pradnya K

Submitted on: Date and sign of Committee incharge

18 Feb 2020

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Workshop on Novel Drug Delivery Systems



Zonal Center Program

In Association with Makeintern & Mood Indigo IIT Bombay Event

5 Days Workshop on Novel Drug Delivery Techniques From 3rd - 7th February, 2020
Organised by :

VES College of Pharmacy, Chembur, Mumbai

Our Presence



copyright@makeintern.com

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Sushidhaye
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Zonal Center Program

In Association with Makeintern & Mood Indigo IIT Bombay Event



Duration
5 Days
(6 Hours/Day)

Details

Topic : Novel Drug Delivery Techniques
Date : 3rd - 7th February, 2020
Faculty Coordinators :
Mr. Pratik V. Barve : 09619515815
pratik.barve@ves.ac.in
Ms. Bhagyashri Parab : 08828497649
bhagyashri.parab@ves.ac.in
Registration Fee : 2500/- INR

Benefits:

- ★ Winners will be awarded by prize money of 50,000 INR.
- ★ Best Platform for Students to showcase their skills in front of best minds
- ★ All the Participants will be Awarded with the Participation Certificate.
- ★ Merit certificate for Selected Students and Coordination Certificate for Coordinators.
- ★ Final Round will be in Mood Indigo IIT Bombay Event.

Venue:

1st Round:
5 Days Training Program
VES College of Pharmacy,
Chembur, Mumbai
Finale
@ Mood Indigo IIT Bombay

Student Coordinator

Sushidhaye
Dr. (Mrs.) **Supriya S. Shidhaye**
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Mr. Sachin P. Yadav : 09819151128



sachinyadav1st@gmail.com

12A

VES COLLEGE OF PHARMACY

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Activity Report

Name of the Activity: Workshop on Novel Drug Delivery Techniques

Activity conducted under: NA

Activity Description: Hands on training workshop on NDDS and its application in pharmacy

Day, Date, Year: 10th – 14th February 2020

Activity details:

Event organized	Duration	Location for event	Name of the Members involved in organizing the event	Number of Participated population (In total)	Number of VES COP students participating in the event	Communication and Photos attached
5 day Training Workshop on Novel Drug Delivery Techniques	5 days (10 th – 14 th February 2020)	VES College of Pharmacy, Chembur, Mumbai	Ms Bhagyashri Parab Mr Pratik Barve	44	43	https://drive.google.com/drive/folders/12dFrkAGpyngIPsvbuct-ZowdwTEk_UEP?usp=sharing

Prepared by: Ms Bhagyashri Parab & Mr Pratik Barve

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Since 1962

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Academic Year
2018-19

Add on course for Drug Regulatory Affairs in collaboration with Institute of Pharmaceutical Management

REGISTRATION FEE

Payment. Rs. 7,000/- for entire course
The course fee includes: Tuition fees, Course materials
Mode of payment: Cheque in favour of "VES College of Pharmacy"

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 Drug Regulatory Affairs in the pharmaceutical industry.

Course structure

Duration: 5 days [20,21,22,23,24 February 2019]
Contact hours: 32

Course Contents

- ICH and its quality guidelines: Introduction to ICH and Quality guidelines Q1 to Q14
- RA profession and regulatory agencies like US, Europe, Japan, India
- ICH CTD format and Module 1,2,3,4 and 5
- Innovator and generic drugs
- DMF, Dossier: structure and contents
- Drug registration procedure of US: administrative & technical requirements, submissions to approval
- Visiting websites of regulatory agencies

Who should attend

The certificate course will enable participants to understand:

- ✓ Key quality aspects
- ✓ Universal format (CTD) followed for dossier preparation
- ✓ Quality sections of Drug Master File /Dossier
- ✓ How drug products can be sold in the regulated markets

Lectures will be delivered by experts from pharmaceutical industry.

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

- ✓ Formulation development- Trainee /Officer/ Analyst
- ✓ Quality Control- Trainee /Officer/ Analyst
- ✓ Quality Assurance-Trainee/ Officer
- ✓ Quality Associate
- ✓ Regulatory Affairs- Trainee/ Associate/ Officer
- ✓ Documentation assistant/officer
- ✓ Marketing/Business development- Trainee /Officer

Course Coordinators

Mrs. Anagha Maharao
Founder & Managing director,
Institute of Pharmaceutical Management

Dr. Rajashree Hirlekar
Professor & HOD, Dept. of Quality Assurance
Contact No: 9769244623



Dr. Anita Ayre
Associate Professor, Dept. of Quality Assurance
Contact No: 9769174278

Mr. Keyur Shastri
Assistant Professor, Dept. of Quality Assurance
Contact No: 9322378504

**CERTIFICATE COURSE
IN
DRUG REGULATORY AFFAIRS**

Conducted by
**VIVEKANANDA EDUCATION
SOCIETY'S COLLEGE OF
PHARMACY**
Shri Hashu Advani Memorial Complex
Behind Collector Colony
Chembur
Mumbai-400074


in collaboration with
**INSTITUTE OF PHARMACEUTICAL
MANAGEMENT**

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

Shri. B. L. Boolani
Trustee in charge, VES COP

Dr. (Mrs.) Supriya S. Shidhaye
PRINCIPAL
Vivekanand Education Society's
College of Pharmacy
HAMC, Behind Collector Colony,
Chembur, Mumbai - 400 074.



Drug Regulatory Affairs
 Page 13

Name: Arundhati P. Tri...

Summary report
Certificate course on Drug Regulatory Affairs
Conducted by
VES College of Pharmacy
In collaboration with
Institute of Pharmaceutical management

Academic Year: 2018-19 Date: 20th to 24th February, 2019

Objective:

To provide students with the comprehensive knowledge and skills in the fields of Regulatory Affairs. The course also aimed to provide the participants a thorough understanding of various regulatory agencies such as the US FDA, EMA, CDSCO; ICH guidelines and technical documents needed for submission to various regulatory bodies.

Methodology:

The course was delivered by experts from both pharmaceutical and biopharmaceutical industries through classroom instructions and PPTs. After every module, assessment was conducted through set of questionnaire or case studies.

Outcome:

After completion of the course, the students were equipped with a basic understanding of the following:

- Key quality aspects
- Universal format for dossier preparation
- Quality section of Drug master File Dossier

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

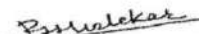
- Formulation Development – Trainee, Officer, Analyst
- Quality Assurance/Quality Control Executive
- Quality Assurance Technicians or Analysts
- Quality Assistant
 - Regulatory Affairs- Trainee
 - Regulatory Affairs – Officer
 - Documentation Associate Officer

Signature of activity co-ordinator

Anita Ayre


: 

Dr. Rajashree Hirlekar

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Workshop on Medical Devices



Makeintern.com



Workshop Partner with E-Cell IIT Kharagpur

+91-9910338092 (Mitra) +91-9211922743 (Vibha) 01149095855



AGENDA

About Medical Devices: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means

Day 1st:

- Introduction to Medical devices (History, development and needs)
- Innovative technologies in device development
- Hands on training – Emerging platforms for new devices (Design and Development of paper-based devices)

Day 2nd:

- Hands on training – (Detection and Development of basic biochemical assays (protein and glucose tests) and discussion on various detection approaches)
- Understanding the phases of medical device development (WHO and FDA guidelines)
- Real time strategic development of a Diagnostic device (any new technique)

Day 3rd:

- Strategic task for student groups ongoing Device development process - Conceptual task (to create ideas and visualizing the concepts from students)
- Barriers to Developing or adapting new technologies for global scale devices
- Key steps in product launch (validation and assessment) – protecting Intellectual Property Rights (Trademark)

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Day 4th:


- Multidisciplinary approach for successful device design and scale-up: Biology and engineering tangled (Intervened approaches), Overcoming the barriers of technology
- Building a successful diagnostic device start-up company by graduates and aiming to outperform the established ones.

- Synthesis of Gold nanoparticles for diagnostic platform (conventional and non-conventional methods) understanding the dynamics in detection (Plasmon, Scattering and Aggregation phenomenon)

Day 5th:

- Top 5 Medical technological innovations and their impact (Inspiring stories)
- Understanding and deciphering the FDA (Food and Drug Administration) rules and regulations (Device safety)
- Micro fluidic approach for reagent mixing using syringes and non-conventional way in lab and understanding of the device concepts and dynamics
- Developing and Delivering of a innovative solutions to the problems (Group tasks with a short project proposals to identify and how to address the issue)- Competition

Timings: 10AM-4 PM


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VES COLLEGE OF PHARMACY

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

Activity Report

Name of the Activity: Workshop on Medical Devices						
Activity conducted under: NA						
Activity Description: Hands on training workshop on medical devices and its application in pharmacy						
Day, Date, Year: 26 th – 30 th December 2018						
Activity details:						
Event organized	Duration	Location for event	Name of the Members involved in organizing the event	Number of Participated population (In total)	Number of VES COP students participating in the event	Communication and Photos attached
5 day Training Workshop on Medical Devices	5 days (26 th – 30 th December 2018)	VES College of Pharmacy, Chembur, Mumbai	Dr Rakesh R Somani Mr Pratik Barve	40	40	https://drive.google.com/drive/folders/1-WJmSsOjRv03Tz109FEdNr2cCvn8hWHv?usp=sharing

Prepared by: Mr Pratik Barve

Pratik Barve



SSS
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**Academic Year
2017-18**

QC, QA & RA aspects in pharma and clinical research industries

REGISTRATION FEE

Payment. Rs. 3,500/- for entire course
The course fee includes:
Lecture 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

RESOURCE PERSONS

Mr. Sunil Budhkar
GMP & GCP consultant, Mumbai

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

Mr. Sameer Shelar
Independent Quality Assurance Auditor, Mumbai

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

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

Mrs. Meena Shah
General manager- Regulatory Affairs, Gletec, Mumbai

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

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


Course coordinators

Dr. Rajashree Hirlekar
Professor & HOD,
Dept. of Quality Assurance, Vivekanand Education Society's College of Pharmacy, Chembur

Dr. Anita Ayre
Associate Professor

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



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, VESCOR

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
mail: vespharm@viveco.in
ves@gmail.com



<http://vespharm.com>


<http://www.viveco.in>

<http://www.vivekanand.edu.in>

<https://www.facebook.com/vespharm>

<https://www.instagram.com/vespharm>

<https://www.linkedin.com/company/vespharm>



ABOUT US

MILESTONES



2013: First Batch of M.Pharm (Pharmaceutics)

2013: First Batch of M.Pharm in Quality Assurance Branch of Ph.D Programme in pharmaceuticals

2014: MOU and joint research centres with Merck Pvt Ltd

2015: First Batch of M.Pharm in Pharmaceutical Chemistry

2016: NBA accreditation of B Pharm programme
NBA ranking in band of 88.75
AICTE survey placement ranking

Dr. (Mrs.) Supriya S. Shidhaye
Principal, Vivekanand Education Society's College of Pharmacy, Chembur, Mumbai - 400 074

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 mesher 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)	05 Each session will comprise of 4 lectures of one hour duration each
Total no. of hours (A*B)	30



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 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 & DCGL, 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

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Summary report

Add-on course on QC, QA & RA aspects in Pharma and Clinical industries

Academic Year: 2017-18

Date: 30th December, 2017 to 24th February, 2018

Objective:

To provide students with the comprehensive knowledge and skills in the fields of Pharmaceutical Analysis, Quality Assurance and Regulatory Affairs. The course also aimed to provide the participants a thorough understanding of various regulatory agencies such as the US FDA, EMA, CDSCO; investigational and new drug applications; regulatory strategies and various other concepts. Further, the course was also aimed to provide the students with strong technical and practical skills needed in a regulated work environment.

Methodology:

The course was be delivered by experts from both pharmaceutical and biopharmaceutical industries through classroom instructions and PPTs. After every module, assessment was conducted through set of questionnaire or case studies.

Outcome:

After completion of the course, the students were equipped with a basic understanding of the following:

- Overview of quality control and assurance
- Good Manufacturing Practice (GMP)
- Regulatory agencies
- Documentation

The course also enabled 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

Signature of activity co-ordinator

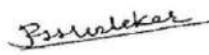
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Dr. Rajashree Hirlekar

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