

Vivekanand Education Society's College of Pharmacy

Hashu Advani Complex, Near Collector's Colony, Chembur (E) Mumbai 400074

<u>Criteria 1- Curricular Aspects</u> Key Indicator 1.2: Academic Flexibility

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

DVV Query

Kindly provide 1)Name of the program, duration, list of students enrolled (with signature of students), curriculum, assessment procedures year-wise 2)Summary report of each program year- wise along with their outcome.

DVV Response

The required documents are attached below.

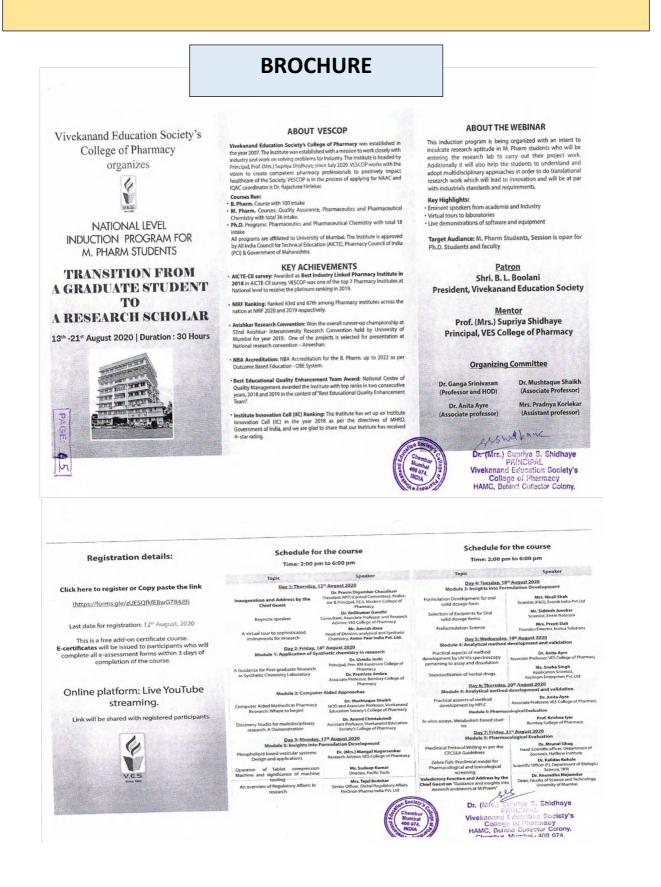
Index

Sr. No.	Contents	Page No.
1.	Details of Add on courses conducted in A.Y. 20-21	3-20
1.1	Transition from Graduates students to research Scholars	4-11
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	
1.2	Add on Course on "AI for Healthcare - In pursuit of innovations for	12-20
	Atma-Nirbhar-Bharat using the promising technologies"	
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	
2.	Details of Add on course conducted in A.Y. 19-20	21-46
2.1	Advanced Pharmacovigilance and Medical Writing certificate Course	22-39
	Brochure 1	

	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report Evaluation Process	
2.2	Workshop on Novel Drug Delivery Systems	40-46
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	
3.	Details of Add on course conducted in A.Y. 18-19	47-60
3.1	Add on course for Drug Regulatory Affairs in collaboration with	48-54
	Institute of Pharmaceutical Management	
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	
3.2	Workshop on Medical Devices	55-60
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	
4.	Details of Add on course conducted in A.Y. 17-18	61-75
4.1	QC, QA & RA aspects in pharma and clinical research industries	62-75
	Brochure	
	Curriculum	
	List of students enrolled	
	Assessment Procedure	
	Summary Report	

Academic Year 2020-21

Transition from Graduates students to research Scholar



CURRICULUM



Vivekanand Education Society's College of Pharmacy, Chembur, Maharashtra 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

	y 3: Monday, 17th August 2020 Insights into Formulation Development	
Phospholipid based vesicular systems: Design and applications	Prof. (Mrs) Mangal Nagarsekar Advisor, VES College of Pharmacy	2:00 pm
Operation of Tablet compression Machine and significance of machine tooling	Mr. Sudeep Kumar Director, Pacific Tools	3:00 pm
В	reak for 10 Minutes at 4:00 pm	
An overview of Regulatory Affairs: In research	Mrs. Tejal Bedekar Senior Officer, GlobalRegulatory Affairs, FinOrion Pharma India Pvt. Ltd	4:10 pm
Da Module 3:	y 4: Tuesday, 18th August 2020 Insights into Formulation Development	
Formulation Development for oral solid dosage form	Mrs. Nirali Shah Scientist (F&D), Evonik India Pvt Ltd	2:00 pm
Selection of Excipients for Oral solid dosage forms	Mr. Siddesh Juvekar Scientist, Enem Nostrum	3:00 pm
В	reak for 10 Minutes at 4:00 pm	
Preformulation Science	Mrs. Preeti Dali Founder/Director, Insitus Solutions	4:10 pm
Day Module 4: Ans	5: Wednesday, 19th August 2020 lytical method development and validation	
Practical aspects of method development & validation by UV-Vis spectroscopy	Dr. Anita Ayre Associate Professor, Vivekanand Education Society's College of Pharmacy	2:00 pm
В	reak for 10 Minutes at 3:30 pm	
Standardization of herbal drugs	Ms. Sneha Singh Application Scientis, Anchrom Enterprises Pvt. Ltd.	3:40 pm

showdha-Dr. (Mrs.) Supriva S. Shidhaye PRINCIPAL Vivekanand Education Society's

Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

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Page 2 of 3



Vivekanand Education Society's College of Pharmacy, Chembur, Maharashtra

organizes

NATIONAL LEVEL INDUCTION PROGRAM FOR M. PHARM STUDENTS

TRANSITION FROM A GRADUATE STUDENT TO

A RESEARCH SCHOLAR

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

	6: Thursday, 20th August 2020 lytical method development and validation	
Practical aspects of method development & validation by HPLC	Dr. Anita Ayre Vivekanand Education Society's College of Pharmacy	2:00 pm
Bi	reak for 10 Minutes at 4:00 pm	
Modu	le 5: Pharmacological Evaluation	
In vitro assays, Metabolism based studies	Prof. Krishna Iyer Bombay College of Pharmacy	4:10 pm
	ay 7: Friday, 21st August 2020 le 5: Pharmacological Evaluation	
Preclinical Protocol Writing as per the CPCSEA Guidelines	Dr. Mrunal Ghag, Head Scientific officer, Department of Zoonosis, Haffkine Institute	2:00 pm
В	reak for 15 Minutes at 3:00 pm	
Zebra Fish: Preclinical model for Pharmacological and toxicological screening	Dr. Kalidas Kohale, Scientific Officer (F), Department of Biological Science, TIFR	3:15 pm
Valedictory function and Address by the Chief Guest on "Guidance and insights into research endeavors at M.Pharm"	Dr. Anuradha Majumdar Dean, Faculty of Science and Technology, University of Mumbai	4:15 pm

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



Page 3 of 3

LIST OF ENROLLED STUDENTS

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

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ASSESMENT PROCEDURE

VES COLLEGE OF PHARMACY Hoshu Advant Mentorial Complex, Behind Collector Colony, Chembur (E), Mumbul - 400 074

ASSESSMENT PROCEDURE

For

National level weblinar on "Induction Program for M. Pharm – Transition from a Graduate student to a Research Scholar'

Date: 13th to 21th August; 2020

- The course was divided into five modules as follows:
 - 1. Computer-alded approaches
 - 2. Application of synthetic chemistry in research
 - 3. Insight into formulation development.
 - 4. Analytical method development and validation
 - 5. Pharmacological Evaluation
- After completion of each module, feedback cum e-assessment form was shared to all students. The e-assessment form contained a list of questions devised by the resource person based on the contents taught in the module
- The score obtained by each student for each e-assessment form was evaluated.
- Course completion certificate was issued only to those students who had submitted the eassessment forms for all modules with a minimum score of at least 50% in each of the assessments.

1 Ano

Dr. Anita Ayre Activity coordinator

Finilela

Dr. Rajashree Hirlekar IQAC Activity coordinator

ges wed har Dr. (Mrs.) Supriya S. Shidhaye PRINCIPAL

 PRINCIPAL
 Vivekanand Education Society's College of Pharmacy
 HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.



SUMMARY REPORT OF ADD ON COURSE

VES COLLEGE OF PHARMACY

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

Activity Report A.Y 2020-2021

POST GRADUATE DEPARTMENT

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

IQAC ACTIVITY No: PG 01/2020-21

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/Fac ulty	PG Dept. of Pharm. Chemistry, Quality Assurance & Pharmaceutics
17	Online via You Tube	Time	2.00 p.m. to 5.00 p.m.
Venue	Indoor/Outdoor	Total no. of	103
Nature of activity	(Tick mark appropriate)	participants	

Details of activity:

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 industrials 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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VES COLLEGE OF PHARMACY

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

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

	Notice and communication	1	Feedback form	
1	Student list of participation	1	Feedback analysis	
1	Photos		Media news details	
1	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
whith	-Stokid hay-e	Postenlekar

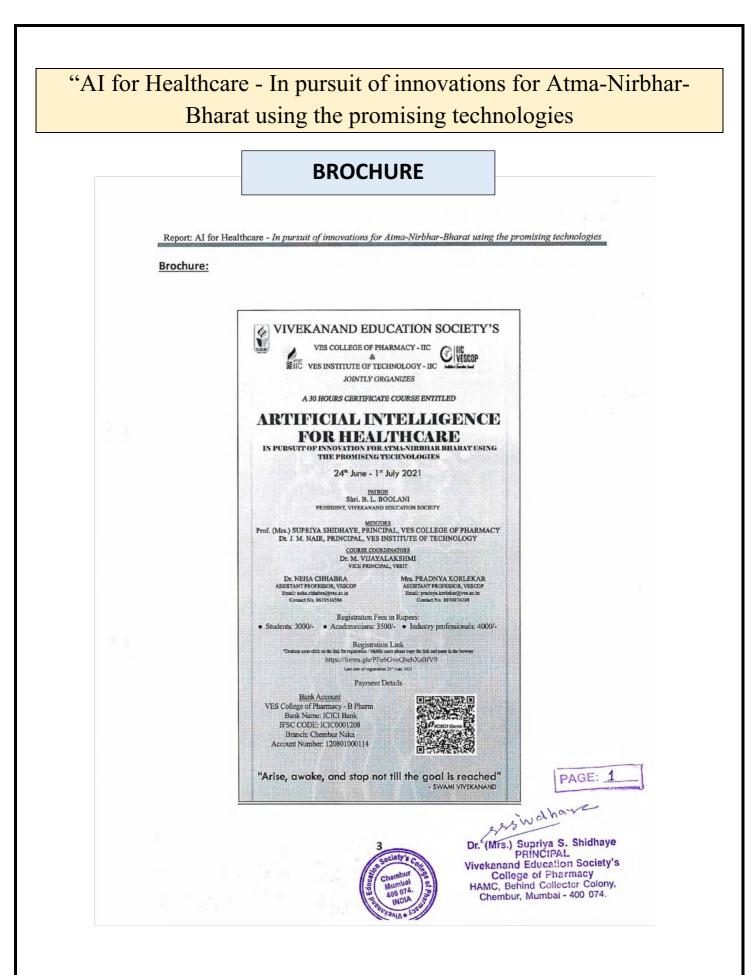


Dr. (Mrs.) Sopriva S. Shidhaye PhinGPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

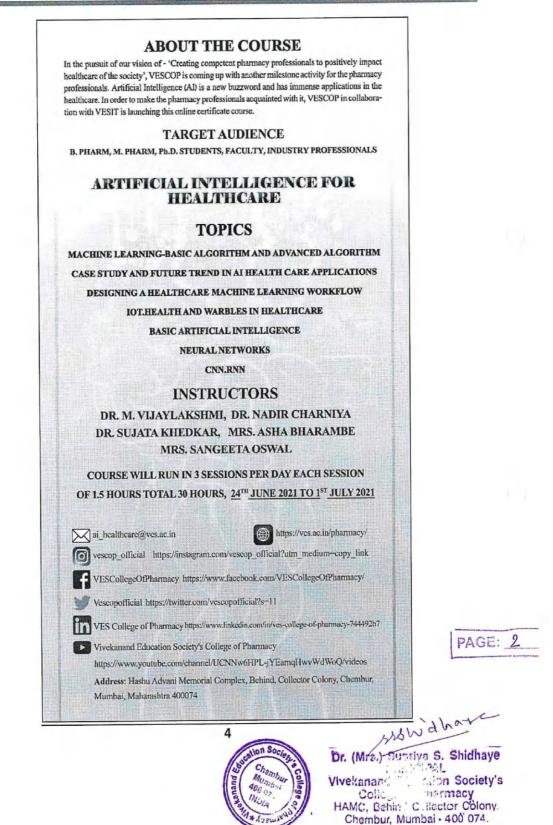
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8

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



CURRICULUM

<u>Artificial Intelligence for HealthCare</u> in pursuit for innovation of Atma Nirbhar Bharat using promising technologies

Proposed Course Content - Each Session of 1 ½ hours Total 30 hours

Sr. No	Date	Timing	Торіс	Faculty In charge	Content
	24 th June 2021	10.00 AM – 11.30 AM	Introduction and Overview of the Course	Dr. M. Vijayalakshmi	 Basics of AI (Artificial Intelligence) and ML (Machine learning) Introduction to AI ML Why is it important to Healthcare?
		11.30 AM - 11.45 AM	and the state of the	TEA	BREAK
		11.45 AM - 01.15 PM	Basic Artificial Intelligence	Dr. M. Vijayalakshmi	Problem solving search.Knowledge representation
		01.15 PM - 2.30 PM		LUNC	H BREAK
		2.30 PM – 04.00 PM	Basic Artificial Intelligence	Dr. M. Vijayalakshmi	 Rule based systems and Planning. Probability and reasoning
	潮	的人们在这个主	na se		Nu d' Marking Lamming?
2	25 th June 2021	10.00 AM – 11.30 AM	Machine Learning - Basic Algorithms	Dr. Sujata Khedkar	 What is Machine Learning? Types of Learning Classification -Decision Tree, Bayesian Classifier, Regression
		11.30 AM - 11.45 AM		TEA	BREAK
		11.45 AM - 01.15 PM	Machine Learning - Basic Algorithms	Dr. Sujata Khedkar	Clustering – Kmeans, K-Medians, Hierarchical Clustering
		01.15 PM -		LUI	NCH BREAK
		2.30 PM 2.30 PM – 04.00 PM	Machine Learning - Basic Algorithms	Dr. Sujata Khedkar	Frequent Pattern Mining
		· All A local line		Dr. Sujata	Support Vector Machines
3	26 th June 2021	10.00 AM – 11.30 AM	Machine Learning - Advanced Algorithms	Khedkar	Introduction to Reinforcement learning
	2021	11.30 AM - 11.45 AM		Т	EA BREAK
		11.45 AM - 01.15 PM	Machine Learning - Advanced Algorithms	Dr. M. Vijayalakshmi	 DBSCAN Mixture Models for Clustering Anomaly Detection
		01.15 PM -		L	UNCH BREAK
		2.30 PM 2.30 PM – 04.00 PM	Introduction to Neural Networks and Deep Learning	Dr. Nadir Charniya	Neural Networks – learning Models. Deep Neural Network
Parts at					upriva S. Shidhaye
				Vivekanand E College HAMC, Behir	Chembur Education Society's of Pharmacy nd Collector Colony, Mumbai - 400 074.

4	28 th June 2021	10.00 AM – 11.30 AM	Deep Learning Algorithms and Applications	Mrs Asha Bharambe	 Convolution Neural Networks Recurrent Neural Networks and Natural Language Processing
		11.30 AM - 11.45 AM			TEA BREAK
		11.45 AM - 01.15 PM	Deep Learning Algorithms and Applications	Mrs Sangeeta Oswal	 Commonly Used and Advanced Neural Network Architectures Computer Vision
		01.15 PM - 2.30 PM		LU	JNCH BREAK
		2.30 PM – 04.00 PM	Internet of Things (IoT), Remote Patient Monitoring	Dr. Nadir Charniya	 Introduction to IoT, Process flow and Tools in IoT, Connected world Used cases, Remote Patient Monitoring
5	29 th	10.00 AM –	Internet of Things,	Dr. Nadir	• IoT data series streaming and
	June 2021	11.30 AM	ThingSpeak demo and Hands-on	Charniya	 Ior data series streaming and visualization on Cloud, Demonstration and hands-on using ThingSpeak and Google Colab platform.
		11.30 AM - 11.45 AM		TE	A BREAK
		11.45 AM - 01.15 PM	Designing a Healthcare Machine Learning Workflow	Dr. Sujata Khedkar	 Common Sources of Healthcare Data Data available from Healthcare systems Data Pre-processing
		01.15 PM - 2.30 PM		LUN	ICH BREAK
		2.30 PM – 04.00 PM	Designing a Healthcare Machine Learning Workflow	Dr. Sujata Khedkar	 Handling unstructured healthcare data Creating analysis ready datasets- Electronic Health Records and AI Electronic phenotyping
	30 th				
6	June 2021	10.00 AM – 11.30 AM	AI Software and platforms for Health care applications	Mrs Asha Bharambe	 Overview of Data analytics tools like Python R. Statistical and Visualization tools
		11.30 AM - 11.45 AM		TE	A BREAK
		11.45 AM - 01.15 PM	AI Software and platforms for Health care applications	Mrs Sangeeta Oswal	Open source healthcare.ai Framework
	-	01.15 PM - 2.30 PM		LUN	ICH BREAK
		2.30 PM – 04.00 PM	AI Software and platforms for Health care applications	Mrs Sangeeta Oswal	Healthcare datasets

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



7	1 st July 2021	10.00 AM – 11.30 AM	Case studies and Future trends in AI Healthcare	Dr. M. Vijayalakshmi Mrs. Asha Bharambe	Several Actual AI applications can be introduced, and students can see the whole lifecycle of an AI in healthcare scenario
		11.30AM - 11.45 AM		TE	CA BREAK
		11.45 AM - 01.45 PM	Case studies and Future trends in AI Healthcare	other faculty	Several Actual AI applications can be introduced, and students can see the whole lifecycle of an AI in healthcare scenario

Speaker Contact:

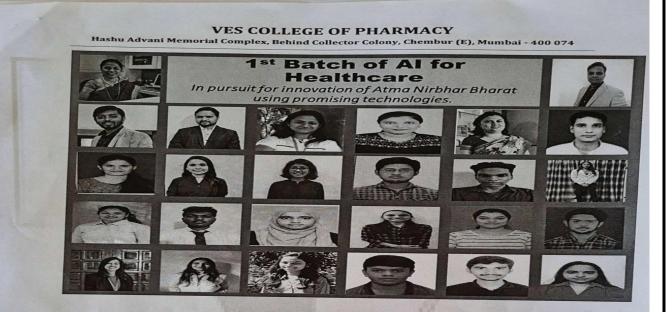
Dr. M. Vijayalakshmi: <u>m.vijayalakshmi@ves.ac.in</u> Dr. Nadir Charniya: <u>nadir.charniya@ves.ac.in</u> Dr. Sujata Khedkar: <u>sujata.khedkar@ves.ac.in</u> Mrs Asha Bharambe: <u>asha.bharambe@ves.ac.in</u> Mrs Sangeeta Oswal: <u>sangeeta.oswal@ves.ac.in</u>

RUS W d han

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



LIST OF ENROLLED STUDENTS



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

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List of the stu

Name	Designation	Name	Designation
fanvi Ajit Dalvi	UG Student	Ria Rajput	UG Student
Nishant Behar	PhD Scholar	Avinash Aniruddha Punvatkar	UG Student
Akshada Manik ndalkar	UG Student	MAMTA VENNA	Faculty Member
Abhishek bhagwan sahu	UG Student	Jayesh Rajesh Lakhpatiani	UG Student
Sakshi Prajapati	UG Student	Rakshit Poojari	UG Student
Nasihah.M	UG Student	Tejasvi Hanumant Sul	PG Student
Dishank Arondekar	UG Student	Vinita Anand Wadhwani	UG Student
Shreya Ajithkumar	UG Student	Dr. Rajashree Hirlekar	Faculty Member
Shruti Ashok Shinde	UG Student	Pratik Barve	Faculty Member
oash Monterio	UG Student	Sakshi Patil	UG Student
Dr. Shweta Gupta	Faculty Member	Dr Mushtaque Shaikh	Faculty Member
Manasi Sawant	UG Student	Mr.Avinash Suryawanshi	Faculty Member
Khushboo Malbari	Faculty Member	Nidhee Bhanushali	UG Student

10

PAGE:

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

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ASSESMENT PROCEDURE

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

Assessment:

Assessment Scheme:

Each participant must attempt all the daily assessments from Day 1 to 6.

Certification criteria is minimum 60% in assessment and 80% in attendance.

Daily assessment (for 6 days) was carried out via google forms in the form of MCQs.

r. No	Name	Score Day 1	Score Day 2	Score Day 3	Score Day 4	Score Day 5	Score Day 6	Total out of 60	Percentage
1	Abhishek bhagwan sahu	8	8	10	9.1	8	9	53.1	88.5
2	Akshada Manik Indalkar	5	8	7	6.4	7	7	40.4	67.3
3	Avinash Punyatkar	8	9	10	9.1	9	10	55.1	91.8
4	Dishank Arondekar	8	8	9	8.2	7	10	50.2	83.6
5	Dr. Shweta Gupta	6	10	6	8.2	9	7	49.2	82.0
6	Jayesh Lakhpatiani	8	9	10	9.1	10	8	54.1	90.2
7	Joash Monterio	3	8	9	8.2	8	ô	40.2	67.0
8	Khushboo Malbari	7	10	8	7.3	9	8	49.3	82.1
9	MAMTA VENNA	5	7	10	9.1	8	10	50.1	83.5
10	Manasi Jagdish Sawant	8	10	10	9.1	8	10	55.1	91.8
11	NASIHAH.M	6	9	10	9.1	8	8	48.1	80.2
12	Nidhee Bhanushali	8	10	10	9.1	8	8	53.1	88.5
13	nishant behar	5	10	5	5.5	7	8	41.5	69.1
14	Pratik Barve	10	9	8	7.3	8	7	49.3	82.1
15	Rajashree Hirlekar	9	4	10	9.1	9	10	51.1	85.2
16	Rakshit Poojari	8	8	8	7.3	10	9	50.3	83.8
17	Ria Rajput	8	10	10	9.1	8	9	54.1	90.2
18	Sakshi Patil	8	10	10	9.1	8	10	55.1	91.8
19	Sakshi Prajapati	6	5	7	8.4	õ	6	36.4	60.6
20	Shreya Ajithkumar	7	5	9	8.2	10	9	51.2	85.3
21	Shruti Ashok shinde	6	9	9	8.2	9	9	50.2	83.6
22	Tanvi Ajit Dalvi	5	7	5	4.5	9	9	39.5	65.9
23	Tejasvi Hanumant Sul	3	5	8	7.3	10	8	41.3	68.8
24	Vinita Anand Wadhwani	8	9	10	9.1	8	9	53.1	88.5
25	Avinash Suryavanshi	7	9	8	6.4	8	7	45.4	75.7
26	Mushtaque Shailkh				-			0.0	0.0

Seminar Coordinator:-Mrs. Pradnya Kortetor Bhowel Dr. Neha Chhabra

Marshellhare

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



SUMMARY REPORT OF ADD ON COURSE

VES COLLEGE OF PHARMACY

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

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-Name of th

Activity	AI for Healthcare - In pursuit of innovations for Atma-Nirbhar-Bharat using the provi	Activity No.	02
Day, Date	the promising technologies Thursday, June 24 th to		
	Thursday, July 1 st , 2021	Department/ Committee/Fac ulty	Dr. Neha Chhabra (Pharmaceutics), Mrs
Venue	Online (Zoom)		Pradnya Korlekar (Pharmacology)
Nature of activity		Time	10 am to 4.30 PM
	Smille	Total no. of	daily. 26 (7 VESCOP
		participants	faculty, 15 VESCOP
Activity Informatio	on:		students, 4 Outside VESCOP students)
	This program was launched un Pharmacy in collaboration with with an objective to quench the Artificial intelligence particular aimed at igniting the spark for r multidisciplinary approach in or which will lead to innovation an standards and requirements to th	quest for knowled ly in healthcare res esearch in this field der to do translatio	ge and application of search. We also d as one aspect of mal research work
f a N	The sessions were conducted onl followed by practice sessions and total of 26 participants including A.Pharm students and Ph.D. resea y experienced and knowledgable harniya, Dr. Sujata Khedkar, Mc	ine via zoom. Theo daily MCQ based g academicians, B.	pry sessions were tests. There were Pharm and

arniya, 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

The session provided sufficient knowledge and skills of the topic in Pharmaceutical Sciences, Wark

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

Outcomes

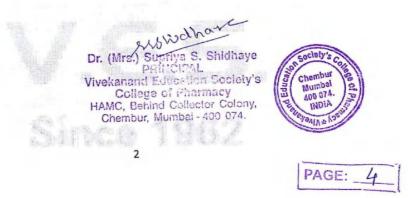
VES COLLEGE OF PHARMACY

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

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

1	Brochure		Feedback form
1	Student list of participation	151	Feedback analysis
1	Photos	1	Media news details
1	Certificate	1	Methodology, One course one tree initiative, website

hit in	Bundele
Dr. Mushtaque Shaikh	Dr. Rajashree Hirlekar
	Dr. Mushtaque Shaikh President, IIC



Academic Year 2019-20

Advanced Pharmacovigilance and Medical Writing certificate Course

BROCHURE



CURRICULUM

Add on Course in Advanced Pharmacovigilance and Medical Writing

Topic	ture search and academic medical w Speaker	Time
Registration and Tea	openier	9:30 am
Course Inauguration	Dr Supriya Shidhaye	10:00 am
Doing Literature Search: Where do we begin?	Vasumathi Sriganesh Founder and Honorary CEO QMed Knowledge Foundation	10:30 to 12:30 pm
Lun	ch break	12.30 to 1 pm
Protocol Writing for Animals Ethics committee approval	Mrunal Ghag Sawant Head/Scientific Officer Department of Zoonosis Haffkine Institute, Parel	1 to 2 pm
Protocol writing for a Clinical Study	Shruti Bhide Associate Professor Department of Pharmacology Seth GS Medical College and KEM Hospital	2 to 3 Pm
	Day 2 : 11 February 2020	
	nent of Regulatory Documents	
Reporting and Tea		9:00 am
How to develop regulatory documents: Investigator's brochure, protocol, clinical study report	Jyoti Adnani Deputy General Manager Siro Clin Pharm Pvt.Ltd Thane,Maharashtra	9:30 to 11:30
Essentials of Medical writing	Bhagyashree Naik Gunjikar Sr.Executive Medico Marketing Rusan Healthcare Pvt.Ltd Mumbai	11:30 to 12:30
Lun	ch break	12.30 to 1 pm
Writing for Medico Marketing	Bhagyashree Naik Gunjikar Sr.Executive Medico Marketing Rusan Healthcare Pvt.Ltd Mumbai	1 to 2 pm
Developing content for package inserts	Tushar Deshpande Domain Consultant and Head Wedico Marketing Services Tata Consultancy Services	2 to 3 Pm
Dr. (N Viveka HAMO	Mrs.) Supriya S. Shidhaye PRINCIPAL anand Education Society's College of Pharmacy C, Behind Collector Colony, embur, Mumbai - 400 074.	Page 1 of

Schedule for the course

	Day 3: 12 February 2020 pt writing and <i>e</i> content writing	
Reporting and tea	-	9:00 am
Writing e content for websites	Tushar Deshpande	9:30 to 10:30
	Domain Consultant and Head	am
	Medico Marketing Services	
	Tata Consultancy Services	
Case Study based exercise on e	Tushar Deshpande	10:30 to 11:30
content development	Domain Consultant and Head	pm
	Medico Marketing Services	
	Tata Consultancy Services	
Malpractices in writing research	Jeffrey Pradeep Raj	11:30 to 12:3
papers	Third Year DM Resident	pm
	Department of Clinical Pharmacology	
	Seth GS Medical College and KEM	
	Hospital	
	ch break	12.30 to 1 pm
Writing a research manuscript	Elvis Martis	1 to 3 pm
	Assistant Professor	
	Department of Pharmaceutical	
	Chemistry	
	Bombay College of Pharmacy	
	Kalina,Santacruz,Mumbai	
	Day 4: 13 February 2020	l
Reporting and tea	eview and Pharmaceutical Market reso	9:00 am
a construction of the second se		
Writing abstracts for research	Priyanka Bose Bhattacharya	9:30 to 10:30
paper	Associate Director-Clinical Operations	
	Roche Products (India)Pvt.Ltd	
How to write narrative reviews	Bandra Kurla Complex,Mumbai Rajesh Pandey	10:30 to 12:30
now to write narrative reviews	Lead and Domain Consultant-Medical	
		pm
	Writing Tata Consultancy Services	
Lun	ich break	12.30 to 1 pm
Writing Lay Summaries	Rajesh Pandey	1-2 pm
	Lead and Domain Consultant-Medical	1-2 pm
	Writing	
	Tata Consultancy Services	
Pharmaceutical Market	Vivek Singh	2-3 pm
Research	Market Analyst	
	Competitive Intelligence	
This topic is off track but added	Novartis Healthcare	
as per student's demand]		
	N	
	wy wid harr	

Dr. (Mrs.) Stipriya S. Shidhaye PRINCIPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074. 24 Chembur Mumbal M

	Day 5: 14 February 2020 ntials of Pharmacovigilance	
Reporting and tea	-	9:00 a m
Principles of Pharmacovigilance	Indu Nambiar	9:30 to
	Head-Pharmacovigilance	10:30am
System and Organ Classes in	Boehringer Ingelheim	10:30 to 11:30
Pharmacovigilance	Mumbai	am
Global Pharmacovigilance safety	Abhay Chimankar	11:30 to
standards and regulations in	Founder and director	12:30pm
Pharmacovigilance	Rhyme Lifesciences, Mumbai	
Lun	ich break	12.30 to 1 pm
Global Pharmacovigilance safety	Abhay Chimankar	1 to 2 Pm
standards and regulations in	Founder and director	
Pharmacovigilance	Rhyme Lifesciences, Mumbai	
Role of Hospitals in	Nayan Chaudhari	2 to 3 Pm
Pharmacovigilance	Assistant Professor	
	Department of Clinical Pharmacology	
	Seth GS Medical College and KEM	
	Hospital	
	Day 6: 15 February 2020 ovigilance and insights into peer review	
Reporting and tea	-	9:00 am
Signal detection in Pharmacovigilance and	Saket Thaker	9:30 to 10:30
algorithms in signal detection	Senior Medical Advisor and Safety Lead, Clinical Study Unit	am
algorithms in signal detection	India South East Asia Cluster	
	Sanofi	
Audits in Pharmacovigilance	Rameez Don	10:30 to 11:3
0	Pharmacovigilance and Quality	am
	assurance Lead	
	PVCON Consulting	
Safety Report Generation case	Indu Nambiar	11:30 am to
studies	Head-Pharmacovigilance	12:30 pm
	Boehringer Ingelheim	
	Mumbai	
	ich break	12.30 to 1 pm
Safety Report Generation case	Indu Nambiar	1 to 2 Pm
studies	Head-Pharmacovigilance	
	Boehringer Ingelheim	
Deers	Mumbai	
Peer review process : an insight into the minds of a reviewer	Sandeep Bavdekar	2-3pm
into the minus of a reviewer	Former Professor and Head	
	Department of Paediatrics	
	BYL Nair Charitable Hospital and TN	
	Medical College	
	Mumbai Central Mumbai	

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

Page $\mathbf{3}$ of $\mathbf{3}$

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LIST OF ENROLLED STUDENTS

the spinsterior.	Monday	Advanced Pharmacovigilance and	and the second s	A surface second second
PELS PORT	includy	Medical Writing Course	10-Feb-20	
Sr.No	Class	Attendance Sheet	The contraction	and the second s
and the second se	LY	Name of the Participants	Morning Sign	Evening Sign
and the second s	LY	Muskan Tardeja	Karaya	Massey
Barba Barbara Barbara	LY	Shubham Jain	de-	AT I
and the second s	LY	Pooja Harisingh Rathod	trathod -	Traned
	LY	Chetan Suhas Mhaprolkar	Charagueter.	al transition
and it is that the second s	and the state of the second	Barkha Makhija	Bart	WAR AND A
And Mark and Andrews	LY	Kavneel sayal	Charles	Rayal-
Charles and the second second	LY	Kishan Choudhary	Croudady	chardent_
the second s	LY	Vanashree H. Chaudhari	(Change)	Chang-
State Providence and the	LY	Rohini Avinash Salunkhe	Platinette	Nh
10	LY	Kirti Sawant	Bawant	Osalunicus
11	. LY	Reema gupta	lacens	Bautant
12	LY	Mukesh Choudhary	Rutezer.	livento
13	LY	Kinjal Kishor Gawde		Bikesh
14	LY	Kartik Dattatray Sonawane	Vande	Rand
15	5 LY	Salonee Prabhakar Tawde	L'antile	Variat
16	5 LY	Suyog Tangade	Pawde	Paude
17	7 LY	Natasha Coutinho	Stade	Sigle
18	3 LY	Prajwal Vasant Raut	Natal	Nater
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Annual of a local state of the	5 LY	Gauri Shete	GMStele	GM Hek
Contraction of the Association o	5 LY	Ashish Dubey	Jambery -	Jauber
	7 TY	Shreya Ajitkumar	Hunge	Augu
	3 TY	Santhanalaxmi Kumaresan	Santhallalans	Saithanten
		Prajkta Deole	PED	Pike
	A CONTRACTOR OF A CONTRACTOR O	Sharma Nisha Sushil	aman	ashame
and the second se	YTY	Rishabh Chaube	Charles	Chause
Contraction of the local states of the local s	LTY	Sweety Chheda	In elt	Sur ,
and the second s	2 TY	Sonali Gudalkar	Sonah'	Sonat
	3 TY	Reetu Bhakta	Chight	Conaktor
The second second	t TY	Hitesh Lodh	alods	plade
	5 TY	Vishal Thale	pint	Vishow
the second second	TY	Umang Ashar	talshare.	16Ashow.
(37	TY	Gurpreet Kaur Mattar		
38	3 TY	Subrat Panigrahi	Anne	lar
39	TY	Vinita Wadhwani	Div	Man 2
40	TY	Ashok Ramlal Choudhary	ARIAS	non 1-
41	TY	Saurabh Yadav	Saurakh	MXha-
42	TY	Bhairavee chimane	Raiceye	Sabella -
43	TY	Ankita Prakash Kanade	Bhall	dv als
	TV	Divya Dhavan	Chappe (see)	At Shidhay
		PAGE:	F Vivekanand	RINCIPAL Education Society e of Pharmacy

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	Tuesday	Medical Writing Course	11-Feb-20	and the state
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	3 TY	Reetu Bhakta	Produkta	(E)shakta
	4 TY	Hitesh Lodh	allode	alat
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			Chembur	SI. (IVI

Dr. (Mrs.) Supriya S. Shidhaye PRINCIPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai 200, 271

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46	TY	Jagdish Kumavat	Johngran C	I funail	
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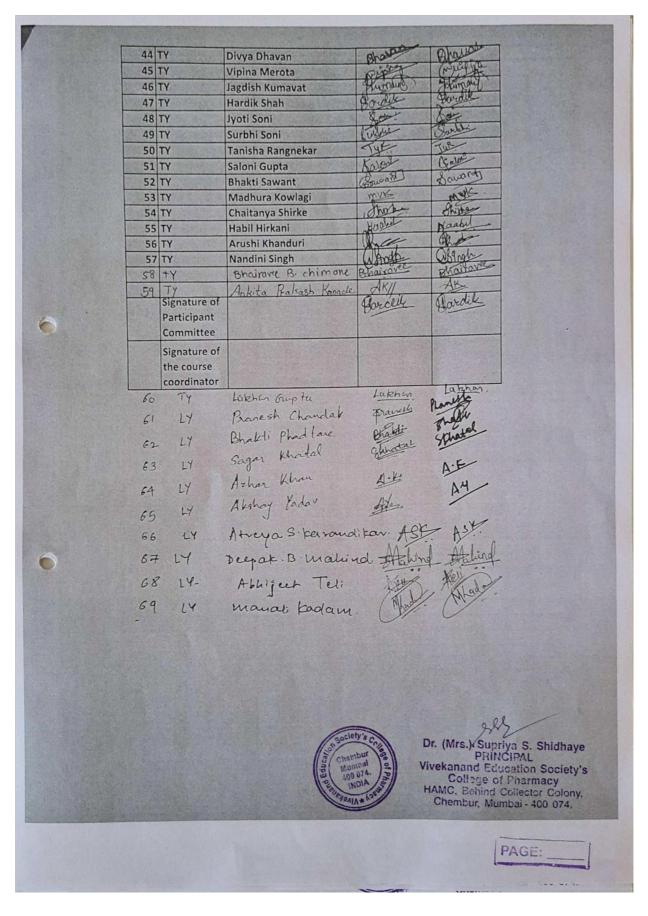
Dr. (Mrs.) Supriya S. Shidhaye PPINCIPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

PAGE:

	Wednesday	Advanced Pharmacovigilance and Medical Writing Course	12-Feb-20	12-02-20
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1000 C 20	TY	Saurabh Yadav	Saucia.	Sayan
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Stoward 44 TY Divya Dhavan Bhaucin muip 45 TY There Vipina Merota Humay 46 TY Hugany Jagdish Kumavat MARIal HASlah 47 TY Hardik Shah Ban 48 TY Jyoti Soni Som Swelles Sixbia 49 TY Surbhi Soni TUB TYM 50 TY Tanisha Rangnekar Aalon palone 51 TY Saloni Gupta \$ awants Sawants 52 TY Bhakti Sawant MUK MUK 53 TY Madhura Kowlagi ahite chinge 54 TY Chaitanya Shirke Habit Habe Habil Hirkani 55 TY all the Arushi Khanduri 56 TY Nandini Singh 57 TY 58 L.Y Abhileel Tell Mady Signature of Manali Kadam 59 Realit Provelile Participant the Committee Signature of the course coordinator Lakhan Lutana TY Lakhar Gupta Sthated 58 Schatal Sagar know al 59 LY A.Y A. Y. Aleshay yadau CO LY GI LY Pranesh chandale 62 LY Bhakki phaeltore thethe: 62 LY Bhakk phanton A.F. 63 LY Azhar khan A.F. 64. LY Atruya, karandikar Ask 63- LY Deepak maling -Bretond Dr. (Mrs.) Supriya S. Shidhaye Vivekanand Education Society's Collage of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074. PAGE:

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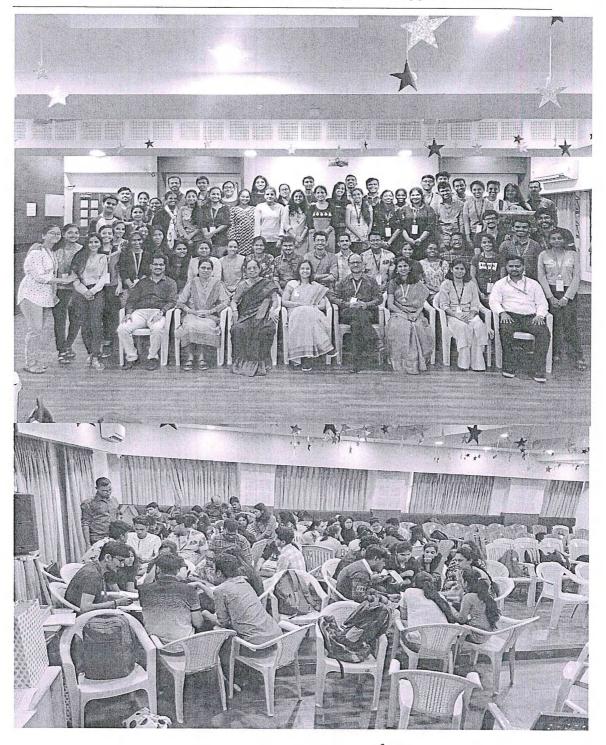


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	8 LY	Vanashree H. Chaudhari	Psolumero	Recuelto	
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	42 TY	Ankita Prakash Kanade	ATA -	Dr. (Mrs.) Super	
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VES COLLEGE OF PHARMACY

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



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



ASSESMENT PROCEDURE

Vivekanand Education Society's College of Pharmacy [VESCOP]

Advanced Pharmacovigilance and Medical Writing Certificate Course Detailed instructions for the participants

- **1.** The course schedule will be shared with all and **all are requested to refer to it**
- 2. The program will be strictly as per the schedule and all **participants must report** on time
- 3. On the first day of the course, all participants have to report by 9:30 am
- 4. Each participant has to go to the registration counter, sign the registration reporting section and take his/her kit. A badge will be issued which the participant must wear during the course
- 5. If kit is misplaced no new kit will be issued. All participants must take care of their kit and badge
- 6. Tea will be made available to all participants twice, in the morning and evening
- 7. No lunch will be provided. Participants have to arrange their own tiffin
- 8. Participants have to sign the attendance sheet twice during the day
- 9. The attendance sheet will be circulated in the morning and in the afternoon
- 10. Each day session will begin at 9:30 am and continue till 3:00 Pm
- 11. All the participants have to fill in an online quiz after completion of each day of the course
- 12. The link to the quiz will be sent on each participant's email id
- 13. Those who do not complete the quiz will not be issued the certificates
- 14. At the end of each day, participants will received the instructions for the next day on whatsapp and email and they must keep checking their inbox regularly
- 15.No Refund of fees will be provided in case a participant leaves the course midway
- 16.Participants are encouraged to carry their laptops and pendrives for some hands on training sessions

Advanced Pharmacovigilance and Medical Writing Certificate Course



Dr. (Mrs.) Supriya S. Shidhaye PRINCIPAL Page 1 of 1 Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

SUMMARY REPORT OF ADD ON COURSE

VES COLLEGE OF PHARMACY

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

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 VESCOP. 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 VESCOP students participating in the event	Communication and Photos attached
Advanced Pharmacovigilance and Medical Writing certificate Course	10th Feb to 15th Feb 2020	VESCOP seminar hall	Faculty: Mrs. Pradnya Korlekar, Mrs. Brinal Pereira and Mr. Avinash Suryawanshi	67	61	YES
			Administrative support team: Mr. ¹			PAGE: 10



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

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.	

VES COLLEGE OF PHARMACY

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

Prepared by: Mr. Avinash S

Checked by: Mrs. Brinal F

Approved By: Mrs. Pradnya K

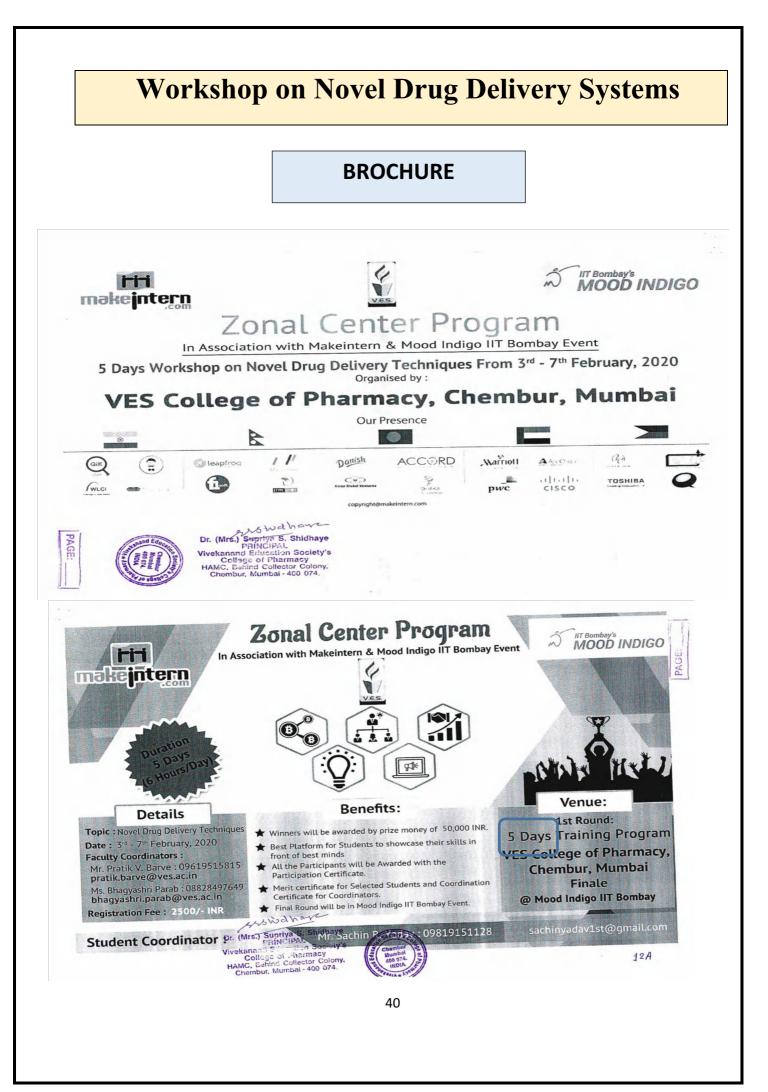
Submitted on: Date and sign of Committee incharge

S 18 Feb 2020

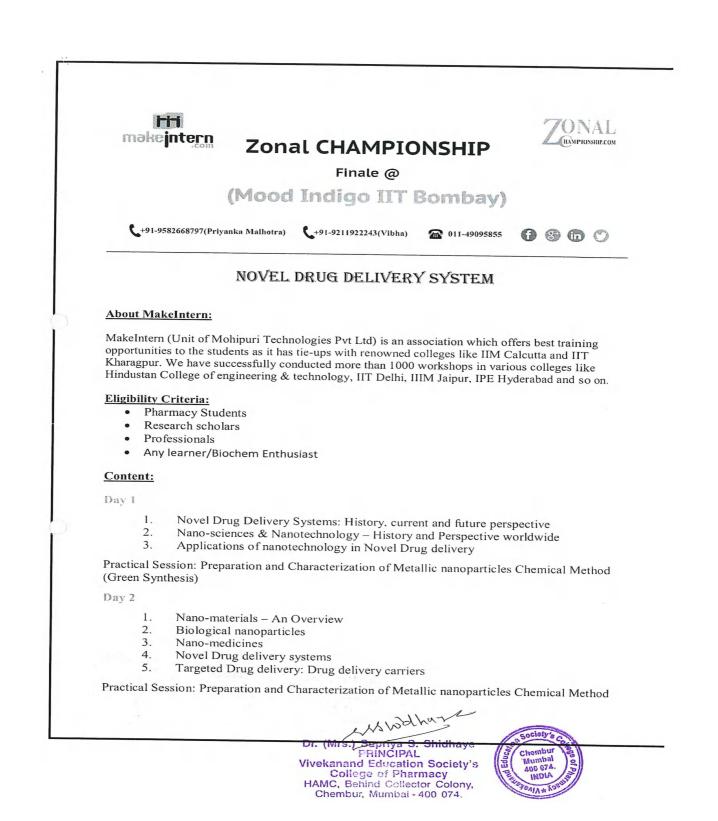
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22 Dr. (Mrs.) Supriva S. Shidhaye Pith/CiPAL Vivekanand Education Society's College of charmacy HAMC, Behind Collector Colony, Chembur, Mumbal - 400 074.



CURRICULUM



(Chemical Synthesis)

Day 3

- Nano-devices, Nano-capsules, Nano-pills 1.
- Polymers in novel drug delivery system: Bio-polymers, Protein-Polymers, 2.
- Polymernanocomposites

Practical Session: Preparation of Biopolymer Nanoparticles Green Synthesis

Day 4

- Lipid based nanoparticles, Ceramic nanoparticles 1.
- **Bio-MEMS** 2.

Exam and Evaluation

Practical Session: Drug Release evaluation assay

Dav 5

- Current Scenario of Nano Drug Delivery 1.
- Future Scope of Nano Drug Market and research 2.

Presentation and final selection

Chemicals Required:

1. Silver nitrate (AgNO3)

2. Acetic acid

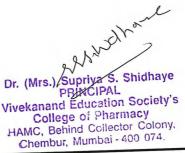
- 3. Chloroauric acid (HAuCl4)
- 4. Chitosan (deacetylated grade 85%)
- 5. Starch, Glucose, Sucrose or fructose
- 6. Sodium Hydroxide (NaOH)
- 7. Dialysis tubing (MW3500)

Instruments Required:

1. Water Bath

- 2. Magnetic Stirrer with Temperature controller
- 3. Magnetic beads
- 4. Autoclave
- 5. UV-Vis Spectroscopy Instrument

6. Glass Beaker, Glass bottles



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LIST OF ENROLLED STUDENTS

VES COLLEGE OF PHARMACY

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

Workshop on Novel Drug Delivery Techniques

(In Association with Makeintern and MOOD INDIGO IIT BOMBAY Event)

List of Participants

Sr.no	Name	Email id	Institute/ Industry name	Contact no	
		nidheebhanushali0908@gma			
1	Nidhee Bhanushali	i I.com	VES College of Pharmacy	8788023028	
2	Anushka Bhoir	anushkabhoir9@gmail.com	VES College of Pharmacy	8108773181	
3	Sakshi Patil	psakshi832@gmail.com	VES College of Pharmacy	9004380555	
4	Manasi Sawant	mjsawant30@gmail.com	VES College of Pharmacy	9594258664	
5	Ria Rajput	riarajput10@gmail.com	VES College of Pharmacy	9653305773	
6	Mekhala Naik	naikmekhala2908@gmail.com	VES College of Pharmacy	9833343997	
7	Aditi Ombale	aditiomble09@gmail.com	VES College of Pharmacy	9326437812	
8	Maya Mhatre	mayamhatre87@gmail.com	VES College of Pharmacy	9819576878	
9	Sarita sonar	saritasonar3459@gmail.com	VES College of Pharmacy	7506850130	
10	Archit Kadu	architk1349@gmail.com	VES College of Pharmacy	9029467546	
11	Shaina Rebello	shainarebello@gmail.com	VES College of Pharmacy	9619883395	
12	Pradnya Shetty	pradnyashetty600@gmail.co m	VES College of Pharmacy	7045426110	
13	Karan Desai	kd9920@gmail.com	VES College of Pharmacy	9967553928	
14	Hrishitaa Kandpal	kandpalhrishitaa30@gmail.co m	VES College of Pharmacy	9930916732	
15	Piyush Nitin Patil	rpiyush65@gmail.com	VES College of Pharmacy	8983135795	
16	SAMARTH	rangnekarsamarth@gmail.co m	VES College of Pharmacy	9619635264	
17	Aishvi Dharmendra Bajpai	aishvib123@gmail.com	VES College of Pharmacy	9284818522	
18	Sanika Sharad Kuveskar	sanikakuveskar@gmail.com	VES College of Pharmacy	9757110650	
19	Mangalesh Rawle	rawlemangalesh@icloud.com	VES College of Pharmacy	9167760497	
20	Sonali Dattatraya Dangat	sonalidangat1997@gmail.co m	VES College of Pharmacy	9892140864	
1	Palak karia	palakkaria75@gmail.com	VES College of Pharmacy	9967601835	
2	Manasi Sudhakar Sutar	manasisutar.sutar@gmail.co m	VES College of Pharmacy	9082156489	
1000	Jueeli Mahesh Shiriskar	jueeli.shiriskar@gmail.com	VES College of Pharmacy	9967690136	
1000	Choudhary Payal Tararam	payalchoudhary496@gmail.c om	VES College of Pharmacy	9967766996	
5	Tanvi Ajit Dalvi	ashwinidalvi.1973@gmail.co	VES College of Pharmacy	9702113662	

PAGE:

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

26	Suyash Ramesh Inamdar	suyash05042000@gmail.com	VES College of Pharmacy	7506273770
27	SHELKE SHIVANI ASHOK	shivanishelke315@gmail.com	VES College of Pharmacy	9172338833
28	Aswathi Thankam Peter	aswathipeter97@gmail.com	VES College of Pharmacy	9699977506
29	Miloni Tarun Lalka	lalkamiloni16@gmail.com	VES College of Pharmacy	9687559998
30	Kirandeep Parihar	kirandeepparihar16@gmail.c	VES College of Pharmacy	7977108130
31	Hreesheeka Mungekar	hreesheekamungekar@gmail. com	VES College of Pharmacy	9082872011
32	Sonali G Padekar	padekarsonali452@gmail.com	VES College of Pharmacy	7400506414
33	Simone Mendonca	simendonca55@gmail.com	st John Institute of Pharmacy and Research	7498441033
34	Bhavisha murli wadhwani	wadhwanibhavisha@gmail.co m	VES College of Pharmacy	7744824609
35	Vantika yogendra vadav	vyy2473@gmail.com	VES College of Pharmacy	8007956023
36	Shukla Sundaram Anil	sundaramshukla2002@gmail. com	VES College of Pharmacy	9137943490
37	Karishma Gunwant Patil	karishmapatil1310@gmail.co m	VES College of Pharmacy	9922398494
38	Sanskruti	sanskrutisharma12@gmail.co m	VES College of Pharmacy	9137760325
39	Tanvi Shivnekar	shivnekar.tanvi@gmail.com	VES College of Pharmacy	8850271870
10	Fernandes Gerard Edwin Mary Jasmine	gerryferns20@gmail.com	VES College of Pharmacy	7045650190
1	Sakshi Shiraskar	sakshishiraskar9@gmail.com	VES College of Pharmacy	9545323153
2	Samiksha Pujare	pujaresamiksha@gmail.com	VES College of Pharmacy	8879465967
3	Bhairavi Patankar	patankarbhairavi@gmail.com	VES College of Pharmacy	8080642575
4	Poorvi Joshi	poorvi2224@gmail.com	VES College of Pharmacy	8169439102



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

PAGE:

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Assessment:	The students were given hands-on training on formualtion and development of novel drug delivery systems. The training for all the participants was conducted in the laboratories on the 5th & 6th floor of the college. All the participants performed series of experiments and the formulations were evaluated by the resource person (Mr. Shriram Joglekar)					
Sr.no	Name	Assessment test score				
1	Nidhee Bhanushali	17				
2	Anushka Bhoir	20				
3	Sakshi Patil	18				
4	Manasi Sawant	18				
5	Ria Rajput	16				
6	Mekhala Naik	17				
7	Aditi Ombale	22				
8	Maya Mhatre	16				
9	Sarita sonar	12				
10	Archit Kadu	18				
11	Shaina Rebello	22				
12	Pradnya Shetty	21				
13	Karan Desai	22				
14	Hrishitaa Kandpal	15				
15	Piyush Nitin Patil	20				
16	SAMARTH	22				
17	Aishvi Dharmendra Bajpai	15				
18	Sanika Sharad Kuveskar	20				
19	Mangalesh Rawle	18				
20	Sonali Dattatraya Dangat	16				
21	Palak karia	19				
22	Manasi Sudhakar Sutar	24				
23	Jueeli Mahesh Shiriskar	17				
24	Choudhary Payal Tararam	15				
25	Tanvi Ajit Dalvi	16				
26	Suyash Ramesh Inamdar	16				
27	SHELKE SHIVANI ASHOK	18				
28	Aswathi Thankam Peter	8				
29	Miloni Tarun Lalka	15				
30	Kirandeep Parihar	19				



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Dr. (Mrs.) Supriya S. Shidhaye
PRINCIPAL Wivekenand Education Conjectule

Hand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

31	Hreesheeka Mungekar	21
32	Sonali G Padekar	16
33	Simone Mendonca	21
34	Bhavisha murli wadhwani	20
35	Vantika yogendra yadav	15
36	Shukla Sundaram Anil	11
37	Karishma Gunwant Patil	18
38	Sanskruti	20
39	Tanvi Shivnekar	13
40	Fernandes Gerard Edwin Mary Jasi	14
41	Sakshi Shiraskar	17
42	Samiksha Pujare	11
43	Bhairavi Patankar	16
44	Poorvi Joshi	<u>23</u>

Seminar Coordinator :-

Par

Bhagyashree Parab

erswidthar

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



SUMMARY REPORT OF ADD ON COURSE

VES COLLEGE OF PHARMACY

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

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 VESCOP students participati ng in the event	Communicati on and Photos attached
5 day Training Workshop on Novel Drug Delivery Technique s	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/c rive/folders/1 2dFrkAGpyng IPSvbuct-Zow dwTEk_UEP? usp=sharing

Prepared by: Ms Bhagyashri Parab & Mr Pratik Barve

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



PAGE: 12B

Since 1962

Academic Year 2018-19

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

BROCHURE

REGISTRATION FEE	Vho should allenu	
	Who should attend he certificate course will enable participants to understand:	DRUG REGULATORY AFFAIR
. 7,000/- for entire course ee includes: Tuition fees, Course materials ment: Cheque in favour of	Key quality aspects Universal format (CTD) followed for dossier preparation Quality sections of Drug Master File /Dossier Quality sections of Drug master sold in the regulated markets	Conducted by VIVEKANANDA EDUCATION SOCIETY'S COLLEGE OF
	Lectures will be delivered by experts from plantimeters	PHARMACY Shri Hashu Advani Memorial Complex Behind Collector Colony
designed for Final Year B.	industry. The course will enable the participants to be prepared for various positions in the Pharma industry at the fresher level,	Chembur Mumbai-400074
where the students/PhD scholars/ faculty "harm research students/PhD scholars/ faculty and individuals who want to expand their on various aspects of Drug Regulatory Affairs naccutical industry.	some of which are: ✓ Formulation development- Trainee /Officer/ Analyst ✓ Quality Control- Trainee /Officer/ Analyst ✓ Quality Assurance-Trainee/ Officer	in collaboration with INSTITUTE OF PHARMACEUTICA MANAGEMENT
ructure	 Regulatory Affairs- Traince/Associate/Onicer 	
i days [20,21,22,23,24 February 2019] urs: 32	Documentation assistant officer Marketing/Business development- Trainee /Officer	Ce an
ontents	Course Coordinators	
d its quality guidelines: Introduction to ICH and	Foundar & Managing director,	V.E.S. Since 1962
fession and regulatory agencies like US, Europe,	Institute of Pharmaceutical Management	Course Mentors
ndia	Professor & HOD, Dept. of Quanty Assurance	Dr. Supriya Shidhaye
D format and Module 1,2,5,4 and 5		College of Pharmacy, Mumbai
Descier structure and contents	Contact No: 9769174278	Shri. B. L. Boolani
registration procedure of US: administrative &	Mr. Keyur Shastri Assistant Professor, Dept. of Quality Assurance	Trustee in charge, VESCOP
g websites of regulatory agencies		A CALLER AND
TD format and Module 1,2,3,4 and 5 tor and generic drugs Dossier: structure and contents registration procedure of US: administrative & al requirements, submissions to approval	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	Course Me Dr. Supriya S Principal, Vivekanand Ec College of Pharm Shri, B. L.

CURRICULUM

Vivekanand Education Society's College of Pharmacy Hestu Advani Memorial Complex, Behind Collector Colony, Chembur (Biss), Munibur-400 074 S

SCHEDULE OF REGULATORY AFFAIRS ADD ON COURSE (2018-2019)

	SR.NO.	DATE	TIMINGS	NAME OF THE SPEAKER	And being and an and
	1.	20 February [Wednesday]	10:00am to 12:30pm	Anagha Mahamo	guidelines Q1 to Q6
			1:30pm to 3:00pm	~	 Introduction to ICH and Quality guidelines Q7 to Q14 Visiting website Question-answers
(C)	2.	21 February [Thursday]	10:00am to 12:30pm	Anagha Maharao	 RA profession and regulatory agencies like Europe, Japan, India
			1:30pm to 3:00pm	and C.P.Bapat	 ICH M4 Q CTD format & and Module 1,2,3,4 and 5 Innovator and generic drugs Visiting websiles
	3.	22 February (Friday)	10:00am to 12:30pm	Anagha Maharao	DMF: structure and contents, Quality Module 3
			1:30pm to 3:00pm		Quality Module 3 (contd)
G	4.	23 February [Saturday]	10:00am to 12:30pm	Simpoo Singh	Dossier: structure and contents, Quality Module 3
	- Sec.P	F	1:30pm to 3:00pm		Quality Module 3 (contd)
	5,	24 February (Sunday)	10:00nm to 12:30pm	Amol Yelgaonkar	 Concept of Bio-equivalence studies Drug registration procedure of US: Introduction to FDA Types of applications
			1;30pm to 3:00pm		 > Administrativo & technical requirements > Submissions to approval • Visiting website
	Antonio and a summer of				od han society's car
			Dr. (M	Mrs.) Supriva 8. PRINCIPAL	Shidhaye
			Viveka	PHINCIPAL anand Education College of Pharr C, Behind Collecto	NDIA Society's

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LIST OF ENROLLED STUDENTS

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William faille	

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Vivelcanand Education Society's College of Pharmacy Inshu Advani Memorial Complex, Behind Collector Colony, Chembur (Bast), Mumbai-400 074 DRUG REGULATORY AFFAIRS ADD ON COURSE (2018-2019)

Sr. No.	NAMES	20/02/2019	21/02/2019	22/02/2019	23/02/2019	24/02/2019
1	Shivangi Sawant	Coulous	Gaugand	Gasando	Gounants	Gausaro
2	Yushica Shah	Gelala.	(ishali	alister	(thinks -	the starting
3	Dhanashree Kanite	thands	plante	Hours	Frank	Thomas
4	Dhanashri Agre	sharashini	Marashui	Diarcolin	Spanastin	Shoolershine
5	Shubham Ukoy	Brunt.	alunt.	Calum	Boging.	Danne
6	Kanchan Dodani	Prolaw .	Podani.	Dodawi.	Codaus.	Ebdam:
7	Swaroop Pansare	BURNER :	FIELDER	thurse.	twower.	tion of
8	Sushmita Nichal	Aber	And	Anal	And	Anor
9	Kshitija Phatak	(Pelantation	Reverence	Butthe	Butak	Ret
10	Yash Gada	Hibada	THGreeda	YH Gudia	YKGada	YHGoula.
11	Sapana Patil	(DE E	Patri	Prt-	Obtin_	BRATS
12	Laxmi Yadav	Landes.	Auren	Logiani	Linge	Jones
.13	Sumit Gupta	Anning .	And.	and	P	Chip !!
14	Vinayak Kashid	Ame	(Drant-	- Angt	Ompre-	(Alingue_

ATTENDANCE SHEET - FIRST YEAR M.PHARM



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

		ATTENDA		y Affair et – fina			
	Sr. No.	NAMES	20/02/2019	21/02/2019	22/02/2019	23/02/2019	24/02/2019
		Krupoli shah	Kourtster	Kunste	Kanster	Know	A low Shipt
	2	Anushka Rajesh	Anuthing	I must have	Anustries	Anuinte	Amushika
	3	Aishwarya Yeitdhe	Asyendar	asympton	anyreller	anenal	Beyman
	4	Vinita Ajwani	Vivita	1 IIANU	10 at a 1	11 WWW	1 Sporte
	5	Sinnan Motwaii	timber	Nimistry	Linvian	SAWWOW)	ARNHAUS
		Ummesplama	Allie	17	h.e.	N.	na.
0	6	Rampuryla	1	51.	Pres	Y	X
	7	Rakshita Raut	ARBOULE.	REAL	PRROUDE 12	RROUT	Repair
	8	Prajakta Mali	PLALI	(PP) LIELU	Capital _ 1	pp nati-	Phasali_
	9	Jagniti Yadav	Consula	Dugading .	augurt (Dyachare !!	Augar !!
	10	Bikas Yadav	Gener	(interior	Biten (Bullion	(Tauro)
	11	Arundhati Jog	ARIOS !!	APIES	Apjes 1	Rjog	ARIOS
		Tejáswini		0	0/	Q:	Q.
	12	Dewasthule	N.	N	- 1	V	-
	13	Prachi Kaduskar	Pharting	Brachast	P.Kaulikt .	Phoneticity	Piacink
	14	Purvashree Gawde	Tely and the	the parties of	24000000	all and a	Religence
،C	15	Jasleen kaur Chuos	Jubien	CILL IN	Adres	Con 9	Courses-
	16	Abhisbek Ashturkar	a state	All and All	Aller No	ALDEL T	7043
	17	Rutuja Shingate	the second		1449- 0	titles in	4649-
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	20	(Sanjay Mourya)	2	1 In -	the shire the	Tala	stati
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	24	Flanshada Ogale	Hoefer	Dollar. 1.			<u> </u>

ASSESMENT PROCEDURE



Institute of Pharmaceutical Management

A / 2 - 409, Kasturi Plaza, Manpada Road, Dombivil (E) - 421 201. Tel.: 0251 - 2860207 Cell No.: 9320049805 / 9619301401 email: Infopharmainstitute@gmail.com

28/02/2019

To,

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

Subject: Evaluation sheet

During the execution of the 'Certificate course in Drug Regulatory Affairs' conducted from 20 to 24th February 2019 at Vivekanand Education's Society's College of Pharmacy, the enrolled students were evaluated based on the presentations they delivered. The evaluation sheet is attached with this letter.

Thanking you.

Yours sincerely,

28/02/25 Anagha Maharao,

Managing director



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11

Dr. (Mest) riya S. Shidhaye PRINCIPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074, Pg1of2

Sr No	Name of the student	Grade	
1	l Mis. Krupali Shah	B 1	
2:	Ma, Anushka, Rajesh	· B++	
3	Ms. Aishwarya Yendhe	Bt	_
<u>२</u> भ	Ms. Vinita Ajwani		_
5	Ms, Simma Motward	B÷	-
6	Mis. Ummesalahia Rampurawala	B+·	_
7	dels, Rukshita Raut	Bab	-
8	i Mis. Prajakta Mali	B+	-
9	Ms. Jagrafi Yaday	B+	
10	Mr. Bikas Yaday	. 124;	-
11	Ms. Anundhati Jag	B++	
12	Ms. Tejastvini Dewastbale	TS I	
EI	Ms. Prachi Kaduskar	₽÷	
14	Ms. Pürvesluree Gawde	B+	
15	Ms, Jasleon Kour Clinas	B+-	
16	Mr. Abhishek Ashturkee	13-1	
1.7	Ms. Rutuja Shingute	B+	
18	Mt: Adiiya More	B≉	
19	Ms. Nonirata-Jadhay	B,+	
20	Mr. Sanjaykumar:Maurya	B [.] ⊢	_
21	Ms, Sneha Jostil	·B+	
22	Ms. Reklin Chaudliary	<u>D</u> +	
23	Ms. Varsha Daund		
24	Ms. Harshada Ogale	B+	
25	Ms. Shivangi Sovant	B+	
26	Ms: Vashica Shah	8+	
27	Ms. Dhanashree Kainte		
28	Ms. Dhanashiji Agre	B+	_
29	Ms. Sljuliham Ukey	; <u>1</u> 3+	
30.	Ms, Kanehan Dodani	B+	_
31	(Mr. Swaroop Pinsare	Bil	_
32	Ms. Sushinita Nichal	D+	
	Ms, Kshitiju Phatak	₿t	
33	Mr. Yash Guda	B4	
34	Ms. Sapana-Patil	Bit	
35	No. Sapanar on	D4	
36	Mr. Lexni Yaɗay	·B+	
37	Mr. Sumit Gupta Mr. Vinayak-Kashid	B+	

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

SUMMARY REPORT OF ADD ON COURSE

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

9 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 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:

- 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

white

Dr. Rajashree Hirlekar

Fortustekar : PAGE: 14

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

Workshop on Medical Devices

BROCHURE and CURRICULUM



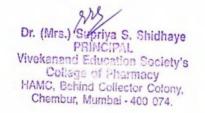
Day 4th:

- 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 luidic approach for
- Micro luidic approach for reagent mixing using syringes and nonconventional 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





LIST OF ENROLLED STUDENTS

VIVEKANAND EDUCATION SOCIETY'S COLLEGE OF PHARMACY A Workshop on Medical Devices organised in association with Makeintern and E-cell IIT Kharagpur. Dr. (Mrs.) Suprive S. Shidhaye Vivekanand Education Society's ATTENDANCE RECORD College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074. 26.12.18 Sr. No Name of the student with Year 27.12.18 30.12.18 28.12.18 29,12,18 1 Anchit Kadu - F.Y 2 Aitsh Lad - F.Y 3 Shruti G. Kulkarni-FY 4 Saloni Maindan - F.Y Ina PKoli 5 Dicoli DKeli Dhanashree N. Koli FY RKoh shant Tebaok 451-24 Alshank 6 Distank Anondekor FY Raj & Patura F.Y Rature Aug 7 Ummesalama. R - LY 8 Awasthate alwasthale Aucesta Dewasthal Dewasthale Tejaswini Dewasthale-LY 9 Mskathare Mikathore Mkather Milath Matha Maitrey, Kathare 1.4 10 Fushing Feshi 11 SUSHIL YADAN LY. Panjana Ranjama Pangana SANJANA PARAMESWARAN 12 Allishuk Datta att ALLAS ADIta ADito M 13 D. Ota Shreya threeye Horeya 14 Shreeya Jadhar (LY) tomito smith Asmita cheithraman ton 15 Kroudas Khattaa Houday Khathad (Hardoo 16 Kishan Chardborry TY W Shybham . R. UKey (F.Y.M) Caum Pat 17 18 Sachin R. Yaday (F.Y. Mt) Earban (FYM RH aulo 19 Chivangi P. Sawan Plants thanks ree P. Kamte Dhan 20 (FYN. pharm) godam. Kanchan M. Dodani (F.Y.MPharm) Godan Godam 21

	Chembur Mumbel 400 074.	edical Devi intern and	ces organ E-cell IIT I	ised in ass Kharagpur. Dr. (Mrs Vivekana Co DRD HAMC, I	ociation a.) Suprive PhinCiP/ and Educati	S. Shidh on Socie armacy ector Cold
Sr. No	Name of the student with Year	26.12.18	27.12.18	28.12.18	29.12.18	30.12.1
1	Anchit Kadu - F.Y	AK	Ale	XK	XK	-11
2	Hitesh Lad - F.Y	Reland	Helend	Holand	Perland	Pulace
3	Shruti G. Kulkarni-F.Y.	Sykulker	89 Kulkami	Sykulker	84Kulkeen	Jak 14
4	Saloni Maindan - F.Y	Snaid	browd	Snaind	Drained	8.
5	Dhanashree N-Koli FY	Dikali	Dicoli	DKoli	RKali	• •
6	Dishank Anondekor FY	Atthank	aspant	Debank	Dishank.	1)istran
7	Ray & Patura F.Y	Rature	Platura	Platura.	Ratur	Plan
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10	Maitreyi Kathare 1.4	Mikathore	Mikather	Mskathare	Mikather	Mikatha
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ASSESMENT PROCEDURE

Name of the Activity: Workshop on Medical Devices

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

Day, Date, Year: 26th - 30th December 2018

Activity assessment:

The students were given hands-on training on making medical devices. The training for all 40 participants was conducted in the seminar hall on the 2nd floor of the college. The evaluation of the participants was done and the five best candidates were selected for further rounds at IIT Hyderabad

The winners were chosen by the joint committee comprising of Workshop coordinator (Dr Rakesh R Somani) and the Module coordinator (Mr Gopi). All the participants were inquisitive and had some brilliant device ideas.

The five best candidates are the following:

- 1. Sachin Rajmani Yadav (FYMPharm)
- 2. Karen Prakash (Final Year BPharm)
- 3. Sanjana Nair (Final Year BPharm)
- 4. Asmita Choithramani (Final Year BPharm)
- 5. Archit Kadu (First Year BPharm)

Seminar Coordinator:. Mr. Pratik Barve Protik Barve



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

SUMMARY REPORT OF ADD ON COURSE

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: 26th - 30th 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 VESCOP students participati ng in the event	Communicati on and Photos attached
5 day Training Worksho p on Medical Devices	5 days (26 th – 30 th Decembe r 2018)	VES College of Pharmacy, Chembur, Mumbai	Dr Rakesh R Somani Mr Pratik Barve	40	40	https://drive. google.com/d rive/folders/1 - WJmSsOjRv0 3TzI09FEdNr2 cCvn8hWHv? usp=sharing

Prepared by: Mr Pratik Barve

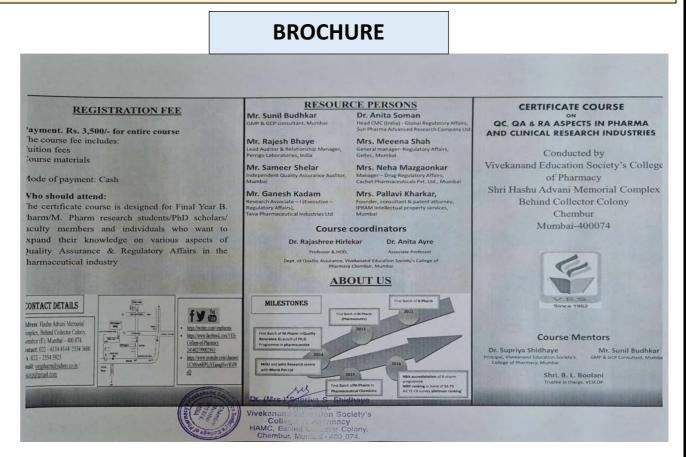
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Dr. (Mrs.) Supriya S. Shidhaye PRINCIPAL Vivekanand Education Society's College of Pharmacy HAMC, Behind Collector Colony, Chembur, Mumbai - 400 074.

PAGE: 17

Academic Year 2017-18

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



ABOUT	THE COURSE		COURSE STRUCTURE
bout the course:		MARKING STOR	QC/QA aspects in Pharma and clinical research industries
	e will enable participants to		
equire:	1.1	Module 1	Introduction to GXPs & Quality
& RA	wledge in the fields of QC, QA	Module 2	Quality Assessment – Quality audits; Handling non- conformances; Handling market complaints; Management of CAPA; Annual product review
such as the U	nding of regulatory agencies (S FDA, EMA, CDSCO; new drug applications and	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
regulatory strategies	lls needed in a regulated work	Module 4	Elements of quality- Functions of QA; Role of QA in imparting training to employees; Calibration, qualification and validation; Clinical trials
environment	delivered by experts from	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
narmaceutical industries ne course will enable the participants to be prepared r various positions in the Pharma industry at the		Module 6	Quality documentation – Documentation system; SOPs; Document storage and archival
		THE REAL PROPERTY OF	RA aspects in Pharma and clinical research industries
or various positions in resher level, some of		Module 7	Introduction to global regulatory authorities for Pharma and healthcare industries
	e/Quality Control Executive	Module 8	Drug development process, clinical trials and related norms and regulations
	e Technicians or Analysts	Module 9	Healthcare Industry IPR, patents, copyrights and trademarks
Quality Assistant Quality Assistant Regulatory Affair		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
Regulatory Affair	s – Omcer	Module 11 Module 12	Food, Drug and Cosmetic Acts & Rules – (India) Documentation of drug elinical trials and regulatory filings in US, Europe, UK, India, Japan, Canad Australia, South Africa, etc. (CTD document) and dossier preparation in CTD format, e-CTD
Duration of course	Two months		Australia, South Africa, etc. (CTD document) and dossier preparation in CTD format, e-CTD
No. of sessions (A)	06	Module 13	Quality assurance and Drug regulations, ICH and WHO guidelines
Contact hours per	05	Module 14	Pharmaceuticals and healthcare products- Marketing, Import and Export regulations
session (B)	Each session will comprise of 4		Regulatory compliance & FDA's approach to GMP inspections of pharmaceutical companies
Total no. of hours (A*B		Module 15 Module 16	L hater marifa area studios
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CURRICULUM

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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, Mumb	
	12.00 pm. To 12.30 p.m.	Welcome	address by Dr. Rajashree Hirlekar & Addres		
	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	Genec, wombar	
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	L	
	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	Mrs. Sonali Gujar General Manager – Product Quality Management, Johnson & Johnson	
	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	Mr. Sunil Budhkar, GMP & GCP Consultant, Mumba	
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, Mumba	

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



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LIST OF ENROLLED STUDENTS

	QA-RA COURSE	
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ASSESMENT PROCEDURE

VES COLLEGE OF PHARMACY

Hashu Adyani Memorial Complex, Behind Collector Colony, Chembur (E), Munibai - 400 074

ASSESSMENT PROCEDURE

For

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

- The course was divided into total 16 modules; 6 modules on QC & QA and 10 modules on RA
- After completion of each module, assignments were given to the students based on specific questions from the module
- The assignments submitted by the students were evaluated, students whose assignments were not up to the mark were tutored and told to re-submit the assignments covering all points
- Course completion certificate was issued only to those students who had submitted the assignments for all modules

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Dr. Anita Ayre Activity coordinator

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Dr. Rajashree Hirlekar Activity coordinator

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



SUMMARY REPORT OF ADD ON COURSE

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

Anita Ayre

Dr. Rajashree Hirlekar



Protecter

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PAGE: