

Do You  
Want To

- ☑ Become a Professional in Pharmacovigilance
- ☑ Make Career in Pharmacovigilance



Join Our  
Certificate  
Course in



# Essentials of Pharmacovigilance

**Objectives:** To train the B. Pharm., M. Pharm. and Life Science Graduates in the field of Pharmacovigilance.  
To train Industry Professionals to excel in their Job Function.

**Eligibility:** Pharmacy Graduates | Science/ Life science Graduates | Industry Professionals

**Duration:** Six weeks course (4 hr/day i.e. 8 hours per week). Course commences last week of July, 2018/ 1<sup>st</sup> week of August, 2018.

**Fees (INR):** BNCP students: 8,000.00 | External students: 10,000.00 + 18% GST =11800.00 | Industry professionals: 12,000.00+ 18% GST =14160.00

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Shri Vile Parle Kelavani Mandal's  
**Dr. Bhanuben Nanavati College of Pharmacy**  
In Association with  
**Indian Society for Clinical Research**



## Who Should Attend?

Students of Final Year B. Pharm., M. Pharm students, Medicine, Life sciences, and Industry professionals. The participants should have a background of Health care, Natural Science, Biological sciences, or related disciplines with basic information about Pharmaceutical operations.

### Course Convener

Dr. Munira Momin  
Principal and Professor

SVKM's Dr. Bhanuben Nanavati College  
of Pharmacy, Mumbai

Dr. Chirag Trivedi  
President, ISCR

Director, Clinical Study Unit  
Sanofi Ltd., Mumbai

### Course Coordinators

Dr. Sujata Sawarkar

Associate Professor & Head,  
Department of Pharmaceutics,  
SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mumbai

Dr. Babita Kirodian

Global Safety Manager, Amgen Ltd.

Ms. Indu Nambiar

Co-Chair PV Council, ISCR  
Senior Manager – Local Pharmacovigilance / LPVM  
Boehringer Ingelheim India Pvt. Ltd.

Dr. Sujata Sawarkar

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Vile Parle (W), Mumbai- 400056

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Certificate Course in

Essentials of

**Pharmacovigilance**

Academic Year 2018-19

## About BNCP

SVKM's Dr. Bhanuben Nanavati College of Pharmacy is one of the top most Pharmacy Institutes in the State of Maharashtra situated at Vile Parle (W), Mumbai. The college conducts B. Pharm, M. Pharm (with specializations in Pharmaceutics, Quality Assurance and Pharmacology) and Ph. D. Courses in Pharmaceutical Chemistry and Pharmaceutics.

The B. Pharm. Programme of the college is accredited by NBA for 5 years (2017-2022). The college is ranked 32nd in All India Pharmacy Colleges by NIRF Ranking, 2018. We have received the AICTE-CII award for Best Industry-linked Pharmacy institute for the year 2015 and 2017, and Platinum Category as per 2016 Survey. The institute has won the Best College trophy Six times in a row at the Rx Festival, an intercollegiate competition (technical and nontechnical events) organized by IPA-MSB. Since its genesis in 2004, the college has grown and achieved success in academic and extra-academic activities.

The college has strategically planned curriculum and activities that match with its vision of being recognised as a top institute of pharmaceutical sciences in the Country which develops professionally competent and socially sensitive individuals who cater to the needs of higher pharmacy education, research and industry. BNCP has identified gaps in the curriculum and has taken the initiative of offering short-term courses to its students that contribute to skill enhancement and increases their employability.

## About ISCR

The Indian Society for Clinical Research (ISCR) is an association of Indian clinical research professionals registered under the Societies Registration Act (1860). The Society brings together all those who are engaged in clinical research activities in India and provides a forum for exchange of information and learning. ISCR aims to build awareness of clinical research as a specialty in India and to facilitate its growth in the country while helping to evolve the highest standards of quality and ethics. The vision of ISCR is to promote a compelling scientific disposition and widespread awareness of clinical research for the advancement of healthcare. The objective of ISCR is to generate awareness of clinical research as a specialty, and of its scope, intricacies, and potential in India and establish a forum for exchange of learning and for imparting training to new entrants to the field.

The society is actively involved in facilitating the growth of clinical research in India by monitoring clinical research activity, providing review and peer consultation facilities for research projects, and making representation to government and other agencies on behalf of the clinical research community. Some the major Pharmaceutical companies involved in clinical research are accredited members of ISCR.



## About the Course

In association with Indian Society for Clinical Research we, at BNCP implement several measures to train pharma students/professionals for industry as JOB READY/INDUSTRY READY, in the field of Pharmacovigilance and Clinical research.

### Objectives

To train the B. Pharm. and M. Pharm. life science graduate students to take up job responsibility directly on joining the organization and train the industry professional so that they can function more efficiently.

### Course outcome

Students will be able to apply knowledge of different Clinical and Drug safety requirements in different countries while working in Pharmacovigilance Department.

### Course content

- ☒ General overview of Pharmacovigilance and key terminologies
- ☒ Regulatory Guidelines and Laws in Pharmacovigilance
- ☒ Introduction to Adverse Drug Reaction
- ☒ Drug Dictionaries and coding in PV
- ☒ Drug Safety in Clinical Trials
- ☒ ICSR - case management
- ☒ Labelling and Risk Management
- ☒ Signal Management
- ☒ Pharmacovigilance System Master File
- ☒ Post authorisation safety studies
- ☒ Audits and inspections

**Duration of the course :** Six weeks course (4 hr/day i.e. 8 hours per week)  
Course commences from last week of July, 2018/ 1st week of August, 2018.

### Fee Structure

BNCP students	: INR 8,000.00
External students	: INR 10,000.00 + 18% GST = 11800.00
Industry professionals	: INR 12,000.00 + 18% GST = 14160.00



**Indian Society for Clinical Research (ISCR)  
and**

**Shri Vile Parle Kelavani Mandal's  
Dr. Bhanuben Nanavati College of Pharmacy**

Gate No. 1, SVKM Campus, First Floor, V.M. Road, Vile Parle (W), Mumbai- 400 056  
Tel. 022-42332052/26134557, Fax. 022-26132905, E-mail: dr.bncp@gmail.com, Web:  
www.bncp.ac.in



**APPLICATION FORM FOR ADMISSION TO  
ISCR CERTIFIED SHORT TERM CERTIFICATE COURSE IN  
ESSENTIALS OF PHARMACOVIGILANCE**

Academic Year 2018-2019

Passport  
Size Recent  
Photograph

1. Full Name of the Candidate: Mr./Ms. \_\_\_\_\_  
(In Block Letters) (Surname) (First Name) (Fathers Name)

2. Sex: Male/Female Date of Birth: \_\_\_\_\_  
DD MM YYYY

3. Address of Correspondence: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ PIN \_\_\_\_\_

Telephone No.: \_\_\_\_\_

Mobile No.: \_\_\_\_\_

Email ID: \_\_\_\_\_

4. Name of the Institute / Organization : \_\_\_\_\_

(In-house student candidates fees: Rs.8,000 External Students candidates fees: Rs. 10,000 + GST 18% =Rs11, 800  
Industry Professionals: Rs.12,000 + GST 18% : Rs. 14,160)

D.D. /Cheque to be drawn in favour of Dr. Bhanuben Nanavati College of Pharmacy, External candidates are required to attach photocopy of their college/industry Identity card duly signed by the head of the institute along with form)

**CLASSES WILL BE ON WEEKENDS (SATURDAYS & SUNDAYS)**

Details of D.D. /Cheque : Rs. \_\_\_\_\_ Drawee Bank : \_\_\_\_\_

DD / Cheque No. and Date: \_\_\_\_\_

Signature of the candidate: \_\_\_\_\_

\_\_\_\_\_  
Verified by Course Co-ordinator

\_\_\_\_\_  
Signature of Principal