



# 2019 Skill Development Programme

## Pharmacopoeial Standards for Pharmaceuticals (PSP) & Pharmacovigilance for Medical Products (PvM)



Organized By  
**Indian Pharmacopoeia Commission**

Ministry of Health & Family Welfare, Govt. of India,  
Sector-23, Raj Nagar, Ghaziabad - 201002

# Training Calendar 2019

Duration of the training Programme is 5 days and the training is available round the year as per training calendar

## Training Details

07

### July 2019

Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

8<sup>th</sup> - 12<sup>th</sup>  
July, 19

**PSP**

**Last Date of Application**  
June 30, 2019

15<sup>th</sup> - 19<sup>th</sup>  
July, 19

**PvM**

**Last Date of Application**  
July 3, 2019

09

### September 2019

Mon	Tue	Wed	Thu	Fri	Sat	Sun
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

16<sup>th</sup> - 20<sup>th</sup>  
Sept, 19

**PSP**

**Last Date of Application**  
September 10, 2019

23<sup>rd</sup> - 27<sup>th</sup>  
Sept, 19

**PvM**

**Last Date of Application**  
September 13, 2019

12

### December 2019

Mon	Tue	Wed	Thu	Fri	Sat	Sun
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

2<sup>nd</sup> - 6<sup>th</sup>  
Dec, 19

**PSP**

**Last Date of Application**  
November 25, 2019

9<sup>th</sup> - 13<sup>th</sup>  
Dec, 19

**PvM**

**Last Date of Application**  
November 29, 2019

# Skill Development Programme on Pharmacopoeial Standards for Pharmaceuticals (PSP)

## OBJECTIVE

- ◆ To develop or enhance skills/ technical knowledge of participants in new Pharmacopoeial standards to prepare them to strengthen the quality medicine for betterment of health of Indian and global population.
- ◆ To broaden experience of an area of work of participants with an opportunity to learn analytical and Pharmacopoeial concepts.
- ◆ To create the awareness about the present scenario of development of drug standards and to better understand the regulatory aspects.

## TARGET GROUP

- ◆ Graduate/ Post Graduate, Research Students of Pharmacy, Science, Applied Sciences, technology and engineering.
- ◆ QC/QA/ Regulatory personnel from pharmaceutical industry
- ◆ Technical persons from drug regulatory authority
- ◆ Academicians

## PROGRAMME FEATURES

- ◆ Employment opportunities in analytical laboratories in Government & Private sector.
- ◆ Career opportunities in regulatory system and CROs
- ◆ Acquiring basic knowledge in Pharmacopoeial education

## EXPECTED OUTCOMES

- ◆ Able to strengthen the skills on various modern sophisticated methodology in Pharmacopoeia.
- ◆ Able to understand the basic requirement of Good Pharmacopoeial Practices.
- ◆ Able to correctly compile and interpret the analytical data and data integration.
- ◆ Be aware in the field of drug standard development with regard to regulatory aspects in present scenario.

## COURSE CONTENT

- ◆ The training programme is designed in a systematic way such that the classroom presentations were followed by the hands on training on Pharmacopoeial Monograph development and harmonization.
- ◆ Topics included in the curriculum will cover all the facts of professional and personal challenges for the analyst.
- ◆ Training will include presentation from various experts in different disciplines from all over the country.
- ◆ Pre assessment and post assessment of participants is done to evaluate the effectiveness of training programme.

# Skill Development Programme on Pharmacovigilance for Medical Products (PvM)

## OBJECTIVE

The objective of this skill development programme is to enhance Pharmacovigilance Knowledge and skills of the health care professionals, which in turn promote patient safety.

## TARGET GROUP

- ◆ Young Pharmacy/Medical/Paramedical professionals seeking care Pharmacovigilance
- ◆ Existing professionals in Pharmacovigilance

## CAREER PROSPECTUS

- ◆ Employment opportunities in Pharmacovigilance in Government & Private sector.
- ◆ Career opportunities in regulatory system/CROs and public health programmes.
- ◆ Abilities to deliver Good Pharmacovigilance Practice at par with international requirement.
- ◆ Providing a platform for being an entrepreneur in PV.

## EXPECTED OUTCOMES

- ◆ Acquiring basic knowledge in Pharmacovigilance.
- ◆ Creating a workforce at National/International level to meet challenges in PV.
- ◆ Enable and mobilize a large number of health care professionals to take up training and acquire requisite skills for employment.
- ◆ Capacity building and strengthening of QPPv (Qualified Person for Pharmacovigilance) as per the requirement of the schedule Y of D&C Act.

## COURSE CONTENT

- ◆ Pharmacovigilance: Basics, Objectives & Methods.
- ◆ ADRs: Understanding, Prevention & Reporting.
- ◆ Understanding of Individual Case Safety Reports (ICSR).
- ◆ Hands on training on ICSR processing.
- ◆ Pharmacovigilance Programme of India.
- ◆ Materiovigilance Programme of India.
- ◆ Causality Assessment & Quality review.
- ◆ Role in Public Health Programmes.
- ◆ Signal Detection & Assessment.
- ◆ PV based Regulatory Action - Application of IT tools.
- ◆ Adverse Events Following Immunization(AEFI).
- ◆ Periodic Safety Reports: PSURs/PBRERs.

## How to Apply!

Interested candidates may send their application form in the prescribed format available on [www.ipc.gov.in](http://www.ipc.gov.in). The duly filled application along with resume & bonafide certificate from their institution to be submitted to [sdp.nccpvpi@gmail.com](mailto:sdp.nccpvpi@gmail.com)

Application shall be processed on  
**"First-come-first-serve"**  
basis

## Faculties

### For PSP & PvM

#### Renowned experts from:

- ◆ Government Teaching & Corporate Hospitals
- ◆ Regulatory Authority
- ◆ Pharmaceutical Industries
- ◆ Academic & Research Institutions
- ◆ Drugs Testing Laboratories

## Training Fees

### SDP on Pharmacopoeial Standards for Pharmaceuticals (PSP) : Rs. 5,000/-

(Rs. 4235/- +18% GST)

### SDP on Pharmacovigilance for Medical Products (PvM) : Rs. 5,000/-

(Rs. 4235/- +18% GST)

### For both PSP & PvM

10% concession : **Rs. 8995/-**

(Rs. 7623/- +18% GST)

## Fees include

- ◆ Resource Material (Electronic/Printed)
- ◆ Field visits
- ◆ Lunch & Refreshments during training sessions

## Note

Aspirants have to make their own arrangements for travelling & Accommodation



**Venue :**

## **Indian Pharmacopoeia Commission**

Ministry of Health & Family Welfare, Govt. of India  
Sector-23, Raj Nagar, Ghaziabad-201002  
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