PvPI Training Calendar 2018

सत्यमेव जयते

IPC

Indian Pharmacopoeia Commission

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

Dr. G. N. Singh
Secretary-cum-Scientific Director

VISION

To safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use

MISSION

To improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines

About IPC, NCC-PvPI

Indian Pharmacopoeia Commission (IPC), Ghaziabad is an autonomous institution under the aegis of Ministry of Health & Family Welfare (MoHFW), Government of India. The IPC is functioning as National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) since the year 2011.

This programme is an important initiative of MoHFW for improving safety and welfare of Indian population by monitoring drug safety and minimizing the risk associated with the use of medicines. It also aims to bolster the regulatory mechanisms in India by utilising the drug safety database for identifying signals and providing support for appropriate regulatory interventions. The programme seeks support from all stakeholders including the physicians, pharmacists, patients, hospitals, pharmaceutical industry and the consumers.

Recently IPC, has been recognised as WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services.

WHOCC - WHO Collaborating Centres

World Health Organization

WHO Collaborating Centres
Global database

Ref.No. [Initiator]
IND-145 [Headquarters]

Status
Active

Title of the centre:
WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Director / Head:
Dr GN Singh
Dr Vivekanandan Kalaiselvan
dci@nic.in
vivekarts@rediffmail.com

Institution:
Pharmacovigilance Division, Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare

Address:
Sector 23, Raj Nagar
201 002
Uttar Pradesh

Town: Ghaziabad
Country: INDIA
Region: SEARO
Phone: +91 120 6582849
Fax:
Web Site: http://www.ipc.gov.in/PvPI/pv_home.html

Date of Designation: 18/Jul/2017
Last Redesignation: 18/Jul/2017
Expiry: 18/Jul/2021

Terms of Reference:
1. Support WHO to develop relevant tools and guidelines for enhancing Pharmacovigilance (PV) practice in low and middle income countries (LMIC) in Asia and beyond.
2. Contribute to capacity building of WHO member states to establish high quality pharmacovigilance systems for medical products.
3. Scientific support to countries for pharmacovigilance in public health programmes (e.g. Tuberculosis, Neglected Tropical Diseases, Vector Borne Diseases, HIV-AIDS; Immunization Programme) and regulatory issues.
4. Work-sharing and joint activities in regulatory pharmacovigilance

Subjects:
1. Pharmaceuticals (including essential drugs and medicines)
2. Health systems research & development

Types of activity:
1. Training and education
2. Development and application of appropriate technology
3. Providing technical advise to WHO

WHO Outputs:
4.3.3 - Improved quality and safety of medicines and other health technologies through norms, standards and guidelines, strengthening of regulatory systems, and prequalification

Responsible Officer: PAL Shanthi Narayan
Phone: +41 22 791 1318
Email: pals@who.int

Technical Counterpart: GUPTA Madhur
Phone: +911142595600
Email: guptamadh@who.int

Access to annual progress reports and the current workplan (this is accessible to WHO Staff Members only):
Link to eWork

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Training Calendar 2018

Duration of the training programme is 10 days and the training is available round the year as per training calendar.

State/Union Territory
• Uttar Pradesh • Uttarakhand
• Manipur • Chandigarh • Delhi

Training Date
15th -24th January

Last Date for Application
05th January 2018

JANUARY 2018

M	T	W	T	F	S	S
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				

MARCH 2018

M	T	W	T	F	S	S
			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	

State/Union Territory
• Himachal Pradesh • Tripura
• Arunachal Pradesh • Bihar
• Jammu & Kashmir

Training Date
5th -14th March

Last Date for Application
20th February 2018

State/Union Territory
• Madhya Pradesh • Nagaland
• Tamil Nadu • Meghalaya
• Puducherry • Odisha • Haryana

Training Date
7th -16th May

Last Date for Application
20th April 2018

MAY 2018

M	T	W	T	F	S	S
	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			

State/Union Territory
- Chhattisgarh • Karnataka
- Andhra Pradesh • Assam
- Dadra and Nagar Haveli
- Lakshadweep • Goa

Training Date
2nd -11th July

Last Date for Application
20th June 2018

JULY 2018

M	T	W	T	F	S	S
						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					

SEPTEMBER 2018

M	T	W	T	F	S	S
					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

State/Union Territory
- Maharashtra • Kerala
- Telangana • Mizoram
- Sikkim • Rajasthan

Training Date
3rd -12th September

Last Date for Application
20th August 2018

State/Union Territory
- West Bengal • Daman & Diu
- Gujarat • Jharkhand • Punjab
- Andaman & Nicobar

Training Date
12th -21st November

Last Date for Application
20th October 2018

NOVEMBER 2018

M	T	W	T	F	S	S
			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		

Venue:
Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
WHO Collaborating Centre for Pharmacovigilance in Public Heath Programmes & Regulatory Service
Ministry of Health & Family Welfare, Govt. Of India
Sector- 23, Rajnagar, Ghaziabad-201002, Email: pvpi.ipcindia@gmail.com, pvpi.ipc@gov.in
Tel: 0120-2783400, Extn.- 156, Fax: 0120-2783311

World Health Organization

IPC

Note: Aspirants are encouraged to apply as per the schedule of their respective States/UTs. However, the request may be considered in the other slots depending on the availability of seats.

Objective

To enhance Pharmacovigilance knowledge and skills of the healthcare professionals which in turn promote patient safety.

Background

Pharmacovigilance (PV) is a science relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. To track Adverse Drug Reactions (ADRs) in Indian Population, Ministry of Health & Family Welfare (MoHFW), Government of India, has launched Pharmacovigilance Programme of India (PvPI). This programme has a pan-India outreach, but only a small proportion of the healthcare professionals have formal training on PV. As per the recent amendments to Drugs & Cosmetics (D&C) Rules, 1945, the inclusion of PV in undergraduate pharmacy curriculum as per Pharmacy Council of India (PCI) notification and order from MoHFW to all states/UTs Government regarding strengthening of PV in particular states, the avenues in PV sector have widened and it has become now a priority area. As per the theme of Pradhan Mantri Kaushal Vikas Yojana, IPC has taken initiative for skill development and capacity building programme by imparting training to young healthcare professionals in the field of Pharmacovigilance.

Target group

- Young Pharmacy/Medical/ Paramedical/other health-care professionals seeking career in field of PV
- Existing professionals in Pharmacovigilance
- Faculties from Medical/ Pharmacy/Allied Health Science institutions

Career Prospects

- Offering adequate knowledge and skills on PV to the participants for their employment opportunities in this emerging field.
- Providing a platform for being an entrepreneur in PV
- Capacity building and strengthening of QPPV (Qualified Person for Pharmacovigilance) as per recent amendments in D&C Rules 1945.

Expected Outcome

- Creating a workforce at national/international level to meet challenges in PV
- Acquiring basic knowledge in PV
- Generating a trained pool of faculties at Pharmacy institutions as per the undergraduate curriculum approved by PCI.
- Providing trained PV professionals who are well versed with Good Pharmacovigilance Practices.

How to Apply

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

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

Faculties

Renowned experts from:

- Government Teaching & Corporate Hospitals
- Regulatory Authority
- WHO
- Pharmaceutical Industries
- Academic & Research Institutions

Training Fees

- Professionals from Academia, Industry & Corporate Hospitals: ₹15,340/- (₹13,000 course fee +18% GST)
- Other Professionals: ₹10,030/- (₹8,500 course fee + 18% GST)

Fees include

- Resource material (Electronic/Printed)
- Field visits and cultural tours
- Lunch & refreshments
- Social events

Course Content

- PV: Basics, Objectives & Methods
- Pharmacovigilance Programme of India
- ADRs: Understanding, Prevention & Reporting
- Understanding Individual Case Safety Reports
- Causality Assessment & Quality Review
- PV based Regulatory Action
- Application of IT tools
- Signal Detection & Assessment
- Benefit-Risk Assessment
- Optimization of Drug Safety through Research
- Periodic Safety Reports: PSURs/PBRERs
- Role of PV in Public Health Programmes
- Vaccines Pharmacovigilance
- Materiovigilance

Note: Aspirants have to make their own arrangements for travelling & Accommodation

Workshop on “Scope for Integration of Pharmacy Institutions with National Pharmacovigilance Centres” for South-East Asia Region

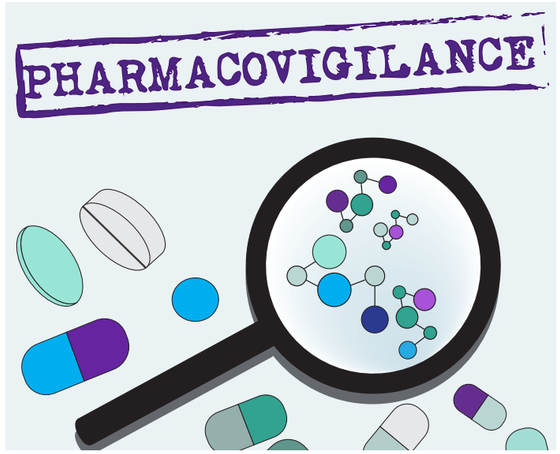
Date: October 26-27, 2018

VENUE:

Indian Pharmacopoeia Commission, Ghaziabad

OBJECTIVE:

The workshop is aimed at prompting and promoting pharmacy institutions for integration with National Pharmacovigilance Centres to boost Pharmacovigilance education and its advocacy and also to enhance career avenues of the pharmacy professionals in Pharmacovigilance sector.



BACKGROUND:

The pharmacy institutions are intended to produce qualified and trained pharmacists who could join hands with other healthcare professionals, thus providing proper healthcare to the patients. Pharmacovigilance being one amongst the major responsibilities of the pharmacists, the universities and institutions are required to lay stress on Pharmacovigilance as an integral and important part of the curriculum and be equipped with the tools of capacity building.

Since the employment opportunity for pharmacy professionals in Pharmacovigilance has been growing exponentially, it is incumbent upon pharmacy institutions to impart adequate knowledge and skills to the students, enabling them to face PV challenges successfully. The workshop is best equipped with the means and avenues aimed at bridging the gap between pharmacy institutions and National Pharmacovigilance System.

TARGET GROUP/AUDIENCE:

- University Vice-chancellors
- Directors/Principals/HODs/Teachers of Pharmacy Institutions
- Chairman, Managing Directors of Pvt. Institutions

Fee: INR 10,000

Total no. of Participants: 250

FACULTIES/SPEAKERS:

Renowned experts from-

- University (Vice chancellors)
- Pharmacy Council of India
- Central Drugs Standard Control Organisation(CDSCO)
- WHO

MODULES OF THE WORKSHOP:

- Understanding the elements of Pharmacovigilance to improve patient-safety.
- Amendment to Pharmacy curriculum with respect to Pharmacovigilance – Institutions preparedness in effective implementation.
- Undertaking research projects on Pharmacovigilance, ADR-monitoring for ease of regulatory decision-making process.
- Alignment of Pharmacy Institutions with PvPI for monitoring, reporting and preventing adverse drug reactions.
- Reachout of Pharmacovigilance to Public Health Programmes & community health programmes through National Health Programmes.
- Pharmacy Institutions partnership with District hospitals to function as Adverse Drug Reaction Monitoring Centres (AMCs).
- Role of Pharmacy institutions in Pharmacovigilance education & advocacy.
- Enhancing employment opportunities for pharmacy professionals in Pharmacovigilance.

EXPECTED OUTCOME:

- Integration of Pharmacy institutions with Pharmacovigilance system for Pharmacovigilance education and ADR reporting.
- Pharmacy institutions linkage/engagement with district hospitals.
- Optimization of Drug safety through research-based Pharmacovigilance – Engagement of PharmD interns/Pharmacy professionals with PvPI.
- Pharmacy profession will have greater value in terms of serving the patients for safer treatment.

Regional Training on “Pharmacovigilance System Establishment & Capacity Building at Pharmaceutical Industries”

BACKGROUND:

Pharmaceutical Industries play an important role for patient safety by collecting Adverse Drugs Reactions (ADRs) due to the use of pharmaceutical products and sending them to the Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India. As per the recent amendment to Schedule Y, Drugs & Cosmetics Rules, 1945, notified vide Gazette Notification No. G.S.R. 287 (E) dated March 8, 2016, Pharmacovigilance has been made mandatory for Marketing Authorization Holders (MAHs) in India. In order to ensure the effective implementation there is need to understand the issues and challenges for the MAHs as well as PvPI in terms of managing ADRs and to set up a Pharmacovigilance system at MAHs’ organization.

OBJECTIVE:

To sensitize new drugs/generic manufacturers, importers, distributors and other stakeholders about Pharmacovigilance system setup/strengthen as per “Pharmacovigilance Guidelines for MAHs of Pharmaceutical Products” at their site.

TARGET PARTICIPANTS:

Professionals in Pharmacovigilance, Quality Assurance (QA) and Regulatory Affairs (RA) in Pharmaceutical Industries and Healthcare Systems.

EXPECTED OUTCOME:

- Obtain information about requirements to set up/ strengthen the Pharmacovigilance system.
- Obtain information to improve the Pharmacovig ilance system in compliance with the regulatory requirements.
- Obtain information about quality management system at MAHs’ site.
- Any other issues/challenges for Pharmaceutical Industries for reporting of ADRs to IPC, NCC-PvPI.

TRAINING CALENDAR:

The tentative training schedule for Year 2018 is:

S. No.	State/ UT	Venue*	Month
1.	Gujarat	Ahmedabad	March 23, 2018
2.	Karnataka	Bengaluru	May 25, 2018
3.	Sikkim	Sikkim	August 10, 2018
4.	Uttar Pradesh (National Meeting)	NCC-PvPI, IPC, Ghaziabad	October 12, 2018
5.	J & K	Jammu	October 26, 2018
6.	Tamil Nadu	Chennai	December 7, 2018

* Venue & Time will be made available at our website 15 days prior to the event

TERMS AND CONDITIONS FOR REGISTRATION:

1. 1. Payment shall be made either by Demand Draft drawn in favour of “Indian Pharmacopoeia Commission” payable at Sanjay Nagar, Ghaziabad or NEFT to “Indian Pharmacopoeia Commission, Bank of Baroda, Sanjay Nagar, Ghaziabad, Bank Account Number: 21860100013540, Branch IFSC Code: BARB0SANGHA (fifth character is zero), Type of Bank Account: Current.
2. Registration Fee: Rs. 2,500/ (GST included) GST # of IPC is **GSTIN 09AAATI7017F2ZR.**
3. Demand draft has to be sent by post to “Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Rajnagar, Ghaziabad, Uttar Pradesh, 201002, India”. Please mention **“Name of Programme”** on top of the envelope.
4. Scanned copy of duly filled Application form must be sent to: pvpi.ipc@gov.in.
5. Registrations will be accepted based on ‘first-come-first serve’ basis.
6. Amount will not be refunded under any circumstances.

Brainstorming session on "Role of State & UT Drug Regulators for effective utilization of Indian Pharmacopoeia Commission (IPC) services"

BACKGROUND:

IPC is dedicated to setting of standards for drugs and providing Indian Pharmacopoeia Reference Substances (IPRS) for quality control of medicines in India. IPC publishes Indian Pharmacopoeia (IP) in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and the Rules there under. IPC provides technical support to the CDSCO/State Drug Regulators in implementation of Pharmacopoeial standards under Pharmacovigilance.

As per the requirements under sub para (2) of Para 28 of Schedule M (Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products) of Drugs and Cosmetics Act and Rules: "Reports of serious Adverse Drug Reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority." Also, as per the recent amendment in Drugs & Cosmetic Rules 1945, Schedule Y and the Gazette notification GSR 287 (E) dated March 8, 2016 the setting up of Pharmacovigilance system is mandatory for all MAHs.

In this regard, NCC-PvPI in collaboration with CDSCO has developed "PV Guidance Document for MAHs of Pharmaceutical Products", which was released by the then Secretary (Health) on September 29, 2017 and will be effective from January 1, 2018.

OBJECTIVE:

State/UT Drug Regulators are primarily responsible for licensing, manufacturing and sale/distribution of drugs. For effective implementation of IPC services i.e. IP, IPRS and PvPI including the PV guidelines for MAHs, there is an urgent need to discuss the role and responsibilities of State/ UT Drug Regulators as they have to play a crucial role in ensuring outreach of the IPC services to the public.

VENUE:

Conference Hall, Indian Pharmacopoeia Commission, Raj Nagar, Sector-23, Ghaziabad.

Date: February 2, 2018

Time: 10:00 AM to 04:30 PM

EXPECTED OUTCOME:

- Leveraging the services of IPC to the public.
- Effective implementation of Pharmacovigilance system at MAHs' site in State/UT (s) as per Pharmacovigilance Guidelines.
- Enhancing working relation between IPC and state/UT's regulators.

Workshop on "Compliance of Good Pharmacovigilance Practices for Low-Middle Income Countries (LMIC)"

BACKGROUND:

The Pharmacovigilance Division, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India has been designated as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services vide WHO CC No. IND-145. The compliance of Good Pharmacovigilance Practices (GVPs) especially in the Low and Middle Income Countries is the need of the hour. In order to ensure the effective implementation of GVPs it is imperative to understand the issues and challenges facing National Regulatory Authorities and Marketing Authorization Holders (MAHs) as well as National Pharmacovigilance Centres in terms of managing Adverse Drugs Reactions (ADRs) and set up a sustainable Pharmacovigilance system at MAHs.

OBJECTIVE:

To sensitize National Regulatory Authorities, National Pharmacovigilance (PV) Centres and MAHs of LMICs to the need for, and essence of efficient handling of Individual Case Safety Reports (ICSRs), Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Reports (PBRERs) etc. This training aims to provide skills and develop the competency of the staff in ensuring Good Pharmacovigilance Practices (GVP).

TRAINING CALENDAR:

Tentative Training Calendar 2018 for LMIC

S. No.	Tentative Dates	Venue
1.	April 2-3, 2018	IPC, Ghaziabad, India
2.	August 23-24, 2018	IPC, Ghaziabad, India

WHO CAN ATTEND:

- National Pharmacovigilance Centre, Regulatory Authority and MAH representatives.

EXPECTED OUTCOME:

- To understand and simplify the Adverse Drug Reaction (ADR) reporting procedures.
- To understand the duties and acquire the skills of the personnel responsible for Pharmacovigilance auditors & auditee.
- Ensuring Good Pharmacovigilance Practices

TOPICS TO BE COVERED:

Day 1	
Session	Topic
1	Introduction: Need For Pharmacovigilance
2	Adverse Event/Reaction: Collection, Management and Submission
3	Pharmacovigilance Regulatory Guidelines
4	Aggregate reports: PSUR and PBRER
5	Pharmacovigilance Master File (PvMF): Basic Need
6	Quality Management System (QMS) in MAHs
Day 2	
7	Post-marketing Safety Studies (PMS)
8	Post-authorization Safety Studies (PASS)
9	Signal Detection
10	Benefit-Risk Assessment
11	Risk-Management Plan
12	Audit and Inspection of Pharmacovigilance system in MAHs

TERMS AND CONDITIONS FOR REGISTRATION:

1. Payment shall be made either by Demand Draft drawn in favour of "Indian Pharmacopoeia Commission" payable at New Delhi or NEFT/TT to "Pharmacovigilance Programme of India", IPC, Bank of Baroda, Rajnagar, Ghaziabad, Uttar Pradesh, India, Bank Account Number: 21860100013540, Branch IFSC Code: BARB0SANGHA (fifth character is zero), SWIFT Code: BARBINBBGHA, Type of Bank Account: Saving.
2. Registration Fee- including GST, GST no. GSTIN 09AAATI7017F2ZR of IPC.

   For Indian Delegates: 10,030 INR (8,500 INR course fee (+ 18 % GST)

   For Foreign Delegates: 200 U$D (inclusive of 18% GST)
3. Registration fee for Two participants from National Regulatory Authorities of LMIC will be waived off.
4. Demand draft has to be sent by post to "Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Rajnagar, Ghaziabad, Uttar Pradesh, 201002, India". Please mention "Name of the Programme" on the top of envelope.
5. Scanned copy of duly filled form must be sent to: pvpi.ipc@gov.in.
6. Maximum 50 registrations will be accepted based on 'first-come-first serve' basis.

Workshop on "Challenges, Solutions and Recommendations for Integrating Pharmacovigilance with National Health Programmes in South-East Asia Region"

Date: April 5-6, 2018

VENUE:

Indian Pharmacopoeia Commission (IPC), Ghaziabad

Objective:

To understand the modalities in integration of Pharmacovigilance with public health programmes and utilization of Adverse Drug Reactions (ADRs) data for better patients-safety outcomes.

TARGET GROUP/AUDIENCE:

National Pharmacovigilance Centres

- WHO-Country Office, India
- PvPI

Maximum Participants: 30

FACULTIES/SPEAKERS FROM:

National PV centres

- Academicians
- WHO
- Public health Programmes

MODULES OF THE WORKSHOP:

- Systems & Procedures
- ADR data monitoring & reporting
- Causality Assessment
- IT Tools, Bridge application and seamless data flow
- Challenges in the application of data
- Recommendations to WHO

BENEFITS OF ATTENDING:

- Data utilisation
- Importance of Pharmacovigilance

EXPECTED OUTCOME:

- Better understanding of Pharmacovigilance system in SEAR countries and its utilisation for public health safety
- Help the attendees to establish/strengthen the integration of Pharmacovigilance systems with public health programmes.
- Effective utilization of the PV data by the public health programmes.

Workshop on "ADR-Monitoring for Kala Azar (KA) treatment and its integration with Pharmacovigilance Centres"

Date: August 21, 2018

VENUE:

Indian Pharmacopoeia Commission

BACKGROUND:

As per the recommendation of WHO the national Pharmacovigilance centre should be integrated with public health programmes to monitor the safety of medicines used in the respective health programmes. The medicines used in public health programmes may not be used in the private sectors. To monitor the safety of the medicines used in PHPs, the integration with national Pharmacovigilance centres may play a major role in monitoring the safety of medicines.

TARGET GROUP/AUDIENCE:

- National Pharmacovigilance Centres
- WHO Country Office India
- PvPI

Maximum Participants: 30

FACULTIES/SPEAKERS FROM:

- National PV centres
- Academicians
- WHO
- Public health Programmes

MODULES OF THE WORKSHOP:

- Kala Azar ADR reporting form
- Systems & Procedures
- ADR data monitoring & reporting
- Data Analysis
- Challenges in the application of data
- Challenges in ADR reporting
- Recommendations to WHO

BENEFITS OF ATTENDING:

- Better understanding of ADRs with anti-KA drugs
- Data utilisation
- Importance of Pharmacovigilance for anti-KA drugs

EXPECTED OUTCOME:

- Better understanding of Pharmacovigilance data and its utilisation for public health safety
- Help the attendees to establish/strengthen pharmacovigilance systems in their countries

Workshop-cum-Training programme on Pharmacovigilance for NABH-accredited Hospitals

BACKGROUND:

A Memorandum of Understanding (MoU) has been signed between Indian Pharmacopoeia Commission, National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) with National Accreditation Board for Hospitals and Healthcare Providers (NABH), Quality Council of India (QCI) to promote ADRs reporting.

OBJECTIVE:

To train NABH-accredited hospitals staff on Pharmacovigilance and ADRs reporting.

Maximum Participants: 50

Registration Fee: Rs. 2,000 + 18% GST

OUTCOME

- Enhancing corporate hospitals involvement in monitoring and reporting of ADRs to PvPI.
- Reputation of hospitals is enhanced as a part of the safety monitoring system.
- Bolster the hospitals in NABH accreditation.
- At large promoting patient-safety.

TRAINING SCHEDULE:

Tentative training Schedule for NABH Accredited Hospitals for the year 2018 is as follows

S. No.	Venue	Month (Year-2018)
1.	Bhubaneswar	January
2.	Ludhiana	February
3.	Lucknow	March
4.	Bengaluru	April
5.	Jodhpur	May
6.	Ranchi	June
7.	Gurugram	July
8.	Noida	August
9.	Kozhikode	September
10.	North east	November

* Venue & Time will be made available at our website 15 days prior to the event

TERMS AND CONDITIONS FOR PARTICIPANTS:

1. The Registration will be done on 'first-come-first serve' basis.
2. Maximum two participants from one hospital can attend the programme, which include one from Management side and one may be clinician/Clinical Pharmacist.
3. Payment shall be made either by Demand Draft drawn in favour of "Indian Pharmacopoeia Commission" payable at Sanjay Nagar, Ghaziabad or NEFT to " Indian Pharmacopoeia Commission, Bank of Baroda, Sanjay Nagar, Ghaziabad, Bank Account Number:21860100013540, branch IFSC Code: BARB0SANGHA(fifth character is zero), Type of Bank Account: Super Saving
4. GST no. of IPC is GSTIN 09AAATI7017F2ZR.
5. Demand draft has to be sent by post to "Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Rajnagar, Ghaziabad, Uttar Pradesh, 201002, India". Please mention "Name of Programme" on the top of envelope.
6. Scanned copy of duly filled Application form must be send to: qa.nccpvpi@gmail.com
7. Maximum 50 registrations will be accepted based on first come first serve basis.
8. Amount will not be refunded in any circumstances.

Advance-level Training by Regional Training Centres (RTCs)

OBJECTIVE:

To embark upon discussions on advances in Pharmacovigilance, rationality in prescription of drugs & drug safety in vulnerable population. Expanding Pharmacovigilance activities & strengthening the PV network in the region.

VENUE:

PvPI -- Regional Training centres (RTCs)

PARTICIPANTS:

AMC Coordinators, Deputy Coordinators & PvAs

S. No.	Regional training Centres (RTCs)	Month/Date
1.	BJMC, Ahmedabad	March 22-23
2.	KEM, Mumbai	March 23-24
3.	AIIMS, Bhopal	October 12
4.	PGIMER, Chandigarh	October
5.	AIIMS, Rishikesh	October
6.	JSS, Mysuru	November
7.	IPGMER, Kolkata	December

* Venue & Time will be made available at our website 15 days prior to the event

MODULE:

- Adverse Drug reactions (ADRs) in Special Population
- Risk-Benefit Assessment
  - Key parameters & considerations for Risk-Benefit Assessment
  - Importance during the lifecycle of Drugs
- Risk-Management Plan
- Challenges for Fixed Dose Combinations (FDCs)
- Medication Error and its importance: A wider Scope for Pharmacovigilance
- Vaccine error
- Challenges in coding ADRs
- Causality Assessment of ADRs: Logic & Methods
- Signal Detection in Pharmacovigilance: Methodology & Tools
- Strategies to enhance patient safety by effective Pharmacovigilance

HANDS-ON TRAINING:

- Workshop on Causality Assessment

Induction-cum-Training Programme on Pharmacovigilance

OBJECTIVE:

To Cope up with Good Pharmacovigilance Practices (GVPs) and quality management system of PvPI and implement the same at Adverse drug reaction Monitoring Centres (AMCs) with a view to monitoring and ensuring patient safety.

PARTICIPANTS:

- Coordinators of newly-recognized AMCs & newly-recruited Pharmacovigilance Associates

VENUE:

Indian Pharmacopoeia Commission

SCHEDULE:

Based on enrolment of New AMCs

Duration: Five days

MODULES OF THE TRAINING:

- Basics & Concepts of Pharmacovigilance
- Understanding & Reporting of ADRs and Terminologies in Pharmacovigilance
- How to assess Adverse Drug reactions: Clinical Relevance & Judgement
- Quality Management System in PvPI
- An Effective Pharmacovigilance System & Good Pharmacovigilance Practices (GVPs)
- Role of AMCs & their Coordinators in developing an effective Pharmacovigilance system
- Introduction to Suspected ADR Reporting Form & consumer Reporting Form: What, Where, How & Whom to Report
- VigiFlow: An Introduction & Data entry
- Documentation Grading – Report Completeness
- Causality Assessment: The Logic & Methods
- Integration of PvPI – AEFI in vaccine safety monitoring & handling of AEFI cases
- Introduction to Public Health Programmes (PHPs) and their integration with PvPI
- Signal Detection by PvPI: Logic & Methods
- Pharmacovigilance Programme of India: An Overview & Updates
- Role of CDSCO in PvPI – Recommendations & Regulatory action
- Hands on Training:
- Exercise on 'How to fill an ADR Reporting Form'
- Exercise on Causality Assessment
- Hands-on Training on Vigiflow
- Exercise on Case processing, Narrative writing & Documentation at AMCs

FIELD VISIT:

- Visit to Adverse Drug Reaction Monitoring Centres (AMCs)

Pharmacovigilance Skill and Knowledge Enhancement Seminar (PV-SKES) for Year 2018

OBJECTIVE:

To enhance the knowledge of PvPI/IPC staff and acquaint them with latest developments in Pharmacovigilance.

PARTICIPANTS:

45 (all belonging to PvPI/IPC)

VENUE:

Indian Pharmacopoeia Commission

SCHEDULE:

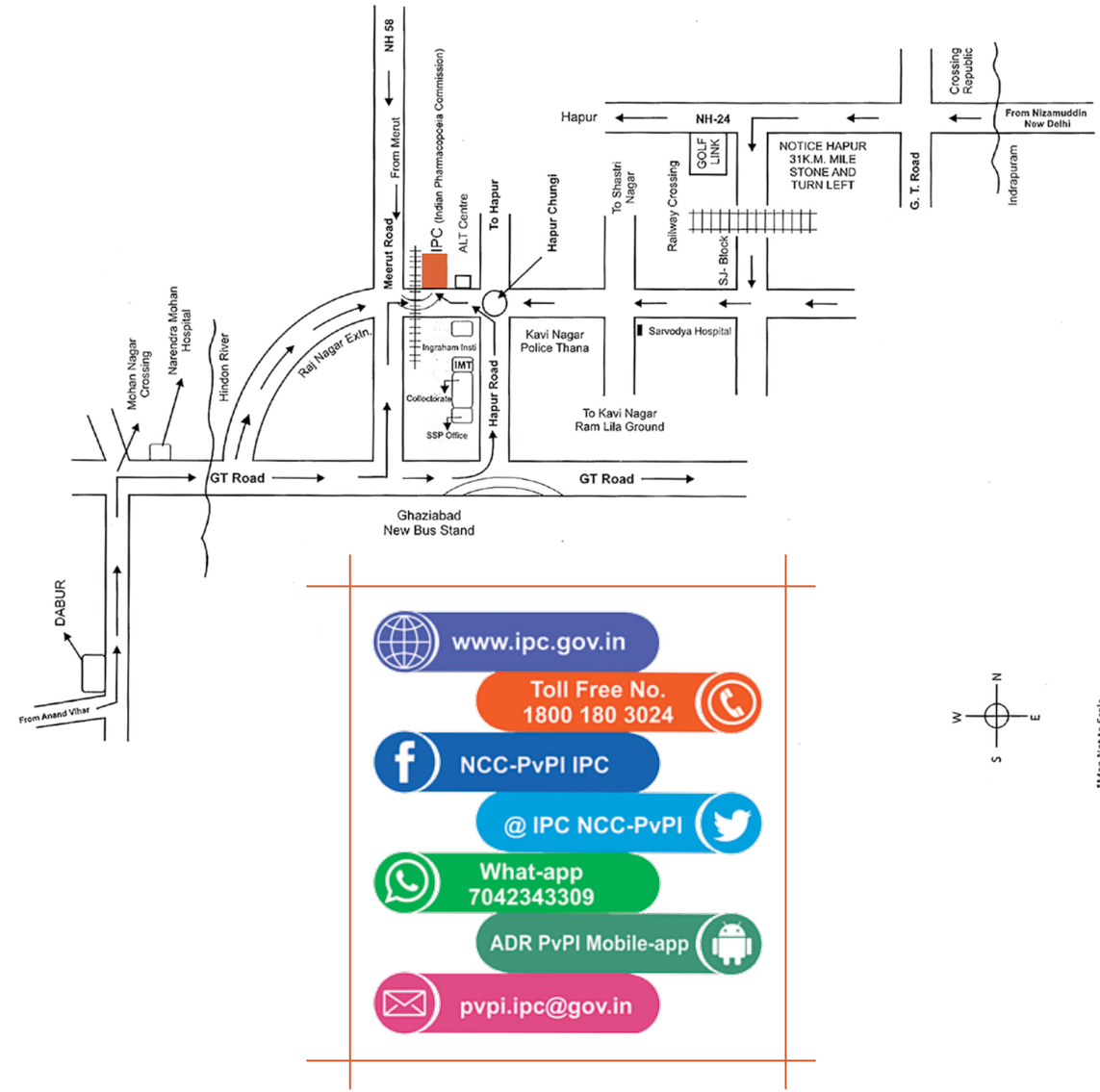
A seminar on 2nd and 4th Friday is scheduled.
A tentative schedule is as follows:

PV-SKES	Tentative date
1st PV-SKES	January 12
2nd PV-SKES	February 9
3rd PV -SKES	March 23
4th PV -SKES	April 13
5th PV -SKES	May 25
6th PV -SKES	June 22
7th PV -SKES	July 13
8th PV -SKES	August 10
9th PV -SKES	September 21
10th PV -SKES	October 5

PvPI Training Calendar 2018

S No.	Name of the Event	Month & Date	Venue
1.	Skill Development Programme on Basics & Regulatory Aspects of Pharmacovigilance- "Optimising medicine Safety is our Goal"	January 15-24	IPC, Ghaziabad
		March 5-14	
		May 7-16	
		July 2-11	
		September 3-12	
		November 12-21	
2.	Workshop on "Scope for Integration of Pharmacy Institutions with National Pharmacovigilance Centres for South-East Asia Region"	October 26-27	IPC, Ghaziabad
3.	Regional Training on "Pharmacovigilance System Establishment & Capacity Building at Pharmaceutical Industries"	March 23	Ahmedabad
		October12	NCC-PvPI, IPC, Ghaziabad
		May 25	Bengaluru
		July 13	Sikkim
		December 7	Chennai
4.	Brainstorming session on "Role of State & UT Drug Regulators for effective utilization of Indian Pharmacopoeia Commission (IPC) services"	February 2	IPC, Ghaziabad
5.	Workshop on "Compliance of Good Pharmacovigilance Practices for Low-Middle Income Countries (LMIC)"	April 2-3	IPC, Ghaziabad
		August 23-24	IPC, Ghaziabad
6.	Workshop on "Challenges, Solutions and Recommendations for Integrating Pharmacovigilance with National Health Programmes for South-East Asia Region"	April 5-6	IPC, Ghaziabad
7.	Workshop on "ADR-Monitoring for Kala Azar (KA) treatment and its integration with Pharmacovigilance Centres"	August 21	IPC, Ghaziabad

8.	Workshop-cum-Training programme on Pharmacovigilance for NABH-accredited Hospitals	January	Bhubaneswar
		February	Ludhiana
		March	Lucknow
		April	Bengaluru
		May	Jodhpur
		June	Ranchi
		July	Gurugram
		August	Noida
		September	Kozhikode
		November	North East
9.	Advance-level Training by Regional Training Centres (RTCs)	March 22-23	BJMC, Ahmedabad
		March 23-24	KEM, Mumbai
		October 12	AIIMS, Bhopal
		October	PGIMER, Chandigarh
		October	AIIMS, Rishikesh
		November	JSS, Mysuru
		December	IPGMER, Kolkata
10.	Induction-cum-Training Programme on Pharmacovigilance	-	IPC, Ghaziabad
11.	Pharmacovigilance Skill and Knowledge Enhancement Seminar (PV-SKES)	January 12	IPC, Ghaziabad
		February 9	
		March 23	
		April 13	
		May 25	
		June 22	
		July 13	
		August 10	
		September 21	
		October 5	



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सत्यमेव जयते

IPC

World Health Organization

Venue:
Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
WHO Collaborating Centre for Pharmacovigilance in Public Heath Programmes & Regulatory Services
Ministry of Health & Family Welfare, Govt. Of India
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