

 	STANDARD OPERATING PROCEDURE		Page No.	1 of 5
			SOP No.	IPC/PvPI/TE/001
	Section	Training & Education (TE)	Revision No.	00
	Effective Date	01/06/2016	Review Date	31/05/2019
Title: SOP to conduct training under NCC-PvPI				

1.0 OBJECTIVE

1.1 To lay down the procedure for training programme under NCC-PvPI.

2.0 SCOPE

2.1 The SOP shall be applicable to NCC-PvPI.

3.0 RESPONSIBILITY

3.1 The personnel engaged in the PvPI activities shall be responsible for adhering to this SOP.

3.2 Training & Education section shall be responsible to organize & conduct training programme at NCC-PvPI.

3.3 Quality Manager/ Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer In-charge, Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 TE section shall be responsible to prepare a training plan for newly recruited Technical Personnel, newly inducted AMCs Coordinators, existing personnel & other stakeholders of PvPI. NCC-PvPI conducts training at three levels as given below:

- i) Induction-cum-Training Programme for technical personnel and Coordinator(s) of newly inducted AMCs
- ii) Continuing Medical Education (CMEs)
- iii) Advance Level Training

	Name	Designation	Signature	Date
Prepared by	Vaishali Bhardwaj	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr Pawan K. Salhi	S.O	[Signature]	17/05/2016
Approved by	Dr. Kalaiseivaran	PSO	[Signature]	18/05/2016

 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			Sign <i>[Signature]</i> Dt. 18/05/2016
	STANDARD OPERATING PROCEDURE		Page No.	2 of 4
	Section	Training & Education (TE)	SOP No.	IPC/PvPI/TE/001
	Effective Date	01/06/2016	Revision No.	00
		Review Date	31/05/2019	
Title: SOP to conduct training under NCC-PvPI				

5.2 Induction-cum-Training Programme for Technical Personnel

5.2.1 Induction-cum-Training Programme shall be conducted preferably between one to three month after the selection/ joining of technical personnel at NCC or AMC.

5.2.2 The Induction-cum-Training Programme shall be preferably for five days, which shall be conducted as per the agenda prepared by TE section.

5.2.3 Training programme shall be commenced with the conduct of pre assessment questionnaire

5.2.4 Technical sessions for the training cover the following: -

- i) Presentation on relevant topics
- ii) Hands on training for ADR reporting form filling
- iii) Case narrative exercise
- iv) Hands on training on VigiFlow software

5.2.5 One day field training shall be organized for the trainees at nearby AMC decided by the Officer In-charge, PvPI.

5.2.6 Post assessment & feedback shall be conducted at the end of training.

5.2.7 After Induction-cum-Training Programme following documents are compiled by TE section with the coordination of concern trainers assigned by the Officer- In-charge PvPI.

- i) **Training Activities Record** shall be filled by the trainers for the assigned trainees & submitted to the TE section next day after the completion of training programme as per annexure (Format No.IPC/PvPI/TE/001-F01)
- ii) **Training Evaluation Record** shall be filled by the trainers & submitted to the TE section next day after the completion of training programme as per annexure (Format No.IPC/PvPI/TE/001-F02)

5.2.8 Certificates for trainees/ participants shall be prepared and distributed by TE section.

	Name	Designation	Signature	Date
Prepared by	Vaishali Bharchway	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr Pawan K. Saini	S.O.	[Signature]	17/05/2016
Approved by	Dr. Kalwalewan	PSO	[Signature]	18/05/2016

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	STANDARD OPERATING PROCEDURE		Page No.	3 of 4
			SOP No.	IPC/PvPI/TE/001
	Section	Training & Education (TE)	Revision No.	00
	Effective Date	01/06/2016	Review Date	31/05/2019
Title: SOP to conduct training under NCC-PvPI				

5.3 Induction-cum-Training Programme for Coordinator of newly inducted AMCs

5.3.1 The duration of training programme shall be for one or two days & training shall be conducted as per the agenda prepared by TE section.

5.3.2 Technical sessions for the training shall cover the following topics: - Presentation on relevant topics, Hands on training for ADR reporting form filling and demonstration/ Hands on training of VigiFlow software.

5.4 Continuing Medical Education (CMEs)

5.4.1 CMEs shall be conducted by the RTCs & AMCs with prior intimation to NCC-PvPI as per the "SOP for functioning of RTC under PvPI" (SOP No. **IPC/PvPI/TE/002**).

5.5 Advance Level Training

5.5.1 Advance level training shall be conducted by NCC-PvPI and RTCs & frequency of training shall be decided & approved by the Officer In-charge, PvPI as per the requirement of personnel.

5.6 Miscellaneous activities of TE section

5.6.1 Preparation and documentation of all training related documents regarding Induction-cum-Training Programme or any other training programmes organised at NCC-PvPI for the individual trainees/ participants/ technical personnel.

5.6.2 Compilation of the documents like advance level training, CMEs or awareness programmes organized by RTCs or AMCs.

5.6.3 Preparation of calendar of events for Training and Education programmes organised every year.

	Name	Designation	Signature	Date
Prepared by	Vaishali Bharelwaj	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr Pawan K. Saini	S.O.	<i>[Signature]</i>	17/05/2016
Approved by	Dr. Kalai Selvan	PSO	<i>[Signature]</i>	18/06/2016

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STANDARD OPERATING PROCEDURE

Page No.

4 of 4

SOP No.

IPC/PvPI/TE/001

Section

Training & Education (TE)

Revision No.

00

Effective Date

01/06/2016

Review Date

31/05/2019

Title: SOP to conduct training under NCC-PvPI

5.6.4 Maintaining record of on job training, workshops and others training attended by Technical Personnel of NCC-PvPI.

Note: -If any Coordinator(s)/ Technical Personnel interested to participate in the unplanned training of Pharmacovigilance (e.g. Hands on training for ADR reporting form filling, Hands on training on VigiFlow) they shall approach the RTC of their respective region.

6.0 SAFETY AND PRECAUTION

- 6.1 Do not use SOP, if it is not signed & issued by QA personnel or the authorized signatories.
6.2 Do not use adhesive tape or whitener on SOP.
6.3 Do not share the SOP information outside the organisation.

7.0 REFERENCES: In- House

8.0 ABBREVIATION

- AMC : Adverse Drug Reaction Monitoring Centre
NCC-PvPI: National Coordination Centre-Pharmacovigilance Programme of India
QA : Quality Assurance
RTC : Regional Training Centre
TE : Training and Education

9.0 ANNEXURE(s)

- Annexure-I- Training Activities Record : Format no. IPC/PvPI/TE/001-F01
Annexure-II-Training Evaluation Record : Format no. IPC/PvPI/TE/001-F02
Annexure III-Attendance Record : Format no. IPC/PvPI/TE/001-F03

Table with 5 columns: Name, Designation, Signature, Date. Rows include Prepared by (Vaishali Bhardwaj), Reviewed by (Dr. Kuman K. Saini), and Approved by (Dr. Kalaiselvan).

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	National Coordination Centre-Pharmacovigilance Programme of India	
Annexure-I Training Activities Record		

Format no. IPC/PvPI/TE/001-F01

Name of Trainee:

Designation:

Venue:

S. No.	Date	Title	
		Pre assessment Questionnaire	
		Presentation on the following topics:	
		•	
		•	
		Hands on training on ADR Reporting form filling	
		Case Narrative Exercise	
		Hands on training on VigiFlow	
		Report ID	Report Title:-
		Field Training	
		Hands on training on VigiFlow	
		Report ID	Report Title:-
		Presentation on the following topics:	
		Post assessment Questionnaire	
		Feed Back Questionnaire	
		Open Discussion & Resolution of Queries	
		Closing Ceremony & Certificate distribution	

Signature of Trainee

Name & Signature of the Trainer

	Name	Designation	Signature	Date
Prepared by	Vaishali Bhardwaj	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr Pawan K. Saini	S.O.		17/05/2016
Approved by	Dr. Kalpana	PSO		18/05/2016



Annexure-II

Training Evaluation Record

Format no. IPC/PvPI/TE/001-F02

Name of Trainee	
Designation	
Training Date	
Venue	

Training Evaluation Criteria:

Grade	Score
Excellent	16- 20
Very Good	13 - 15
Good	10 - 12
Satisfactory	6 - 9
Poor	1 - 5

Grade for Pre assessment

Excellent Very Good Good Satisfactory Poor

Grade for Post assessment

Excellent Very Good Good Satisfactory Poor

Grade for Filling of ADR form

Excellent Very Good Good Satisfactory Poor

Grade for Case Narrative

Excellent Very Good Good Satisfactory Poor

VigiFlow Data Entry

Excellent Very Good Good Satisfactory Poor

Comments by the Trainer (If any):

.....
.....

Signature of Trainer

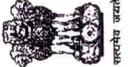
Signature of TE section Representative

Signature of Officer In-charge, PvPI

	Name	Designation	Signature	Date
Prepared by	Vaishali Bhargava	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr Pawan K. Saini	S.O.	Pw	17/05/2016
Approved by	Dr. Kalaiselvan	PIA	Ky	18/05/2016

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Annexure-III
ATTENDANCE RECORD

Format no. IPC/PvPI/TE/001-F03-00

Topic
Venue
Date

S.No.	Name	Designation	Contact Details (Email Id/phone no.)	Signature

	Name	Designation	Signature	Date
Prepared by	Vaishali Bhardway	Technical Associate	Vaishali	16/05/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	MJ	17/05/2016
Approved by	Dr. K. Rajiv Ran	PSO	UR	18/05/2016