

 सत्यमेव जयते 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			CONTROLLED COPY 19/05/2016
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			SOP No.	IPC/PvPI/TE/002
	Section	Training & Education (TE)	Revision No.	00
Effective Date	01/06/2016	Review Date	31/05/2019	
Title:				SOP for functioning of Regional Training Centres under PvPI.

1.0 OBJECTIVE

1.1 To lay down a procedure for functioning of Regional Training Centres.

2.0 SCOPE

2.1 This SOP shall be applicable to Regional Training Centres under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

3.1 All Technical Associates working at RTCs, Coordinators of respective RTCs shall be responsible for adhering to this SOP.

3.2 Training and Education section shall be responsible for Coordination with RTCs.

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

4.0 ACCOUNTABILITY

4.1 Officer In charge-Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 RTC shall provide training and technical support to AMCs of their respective region for conducting CMEs & other awareness programmes.

	Name	Designation	Signature	Date
Prepared by	Kinnari Dabhi	Technical Associate	R.J. Dabhi	16/05/2016
Reviewed by	Dr. Ramesh K. Saini	S.O.		17/05/2016
Approved by	Dr. Kalaiselvan	P.S.O.		18/05/2016

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- 5.2 RTC shall conduct at least one CME at any AMCs under their region on rotation basis and one advance level training on Pharmacovigilance (PV) at RTC in the year with prior approval from NCC.
- 5.3 RTC shall be coordinating with RNTCP, ART and AEFI under their respective region.
- 5.4 RTC shall review the status of existing AMCs from time to time and take corrective measures for improving their performance.
- 5.5 RTC shall assist the NCC for identifying and evaluating proposal for new AMCs as when required.
- 5.6 RTC shall send tentative agenda to NCC one month in advance for conducting CME or advance level training programme.
- 5.7 RTC shall be follow guidelines issued for financial Assistance to RTCs for conducting CME.
- 5.8 Coordinator of RTC shall inform to nearby hospitals about the role of centre regarding pharmacovigilance by distributing resource material with the help of Technical Associates.
- 5.9 RTC shall work according to the training modules provided by NCC.
- 5.10 If any Coordinator(s)/ Technical Personnel interested to participate in the unplanned training of Pharmacovigilance (e.g Hands on training on VigiFlow, ADR reporting form filling) they shall be approach to the RTC of their respective region.
- 5.11 RTC shall send original copy of attendance sheet, feedback form and registration form & other training document after conducting CME or Advance level training.
- 5.12 RTC shall send detailed report of the programme with evaluation analysis from the participants regarding the programme to the NCC-PvPI. Problem faced by the organizers and suggestion for the programme improvements, are also required to be sent to NCC.

	Name	Designation	Signature	Date
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Approved by	Dr. Kaladeivan	PSO	[Signature]	18/05/2016

 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			Sign by <i>[Signature]</i> Date <i>16/05/2016</i>
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5.13 Certificate for CME and Advance level training shall be prepared by responsible AMCs/RTC and approved by officer in charge of PvPI.

6.0 SAFETY AND PRECAUTIONS:

- 6.1 Do not use any SOP if it is not signed and 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 to outside the organization.

7.0 REFERENCES: In-house

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
RTCs	:	Regional Training Centres
CME	:	Continuing Medical Education
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
AMCs	:	Adverse Drug Reaction Monitoring Centres

9.0 ANNEXURE

Annexure I: List of RTC & states under their purview

	Name	Designation	Signature	Date
Prepared by	<i>Kinnari Dasni</i>	<i>Technical Associate</i>	<i>K.J. Dasni</i>	<i>16/05/2016</i>
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Approved by	<i>Dr. V. Kalaithevan</i>	<i>P&O</i>	<i>[Signature]</i>	<i>18/05/2016</i>



National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I
List of Regional Training Centres & states under their purview

List of Regional Training Centres & states under their purview	
Existing RTC	States/ UT(s) under purview
1. PGIMER, Chandigarh	Jammu and Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh & Delhi
2. Seth GS Medical College & KEM Hospital , Mumbai	Maharashtra, Goa, Dadra and Nagar Haveli
3. JSS Medical College Hospital , Mysore	Karnataka, Kerala, Tamil Nadu Puducherry & Lakshadweep
4. Institute of Postgraduate Medical Education & Research , Kolkata	Andaman Nicobar, West Bengal, Jharkhand, Bihar & Odisha
Newly identified RTC	States/ UT(s) under purview
1. All India Institute of Medical Sciences, Bhopal	Madhya Pradesh & Chhattisgarh
2. B. J Medical College, Ahmedabad	Gujarat, Rajasthan, Daman & Diu
3. All India Institute of Medical Sciences, Rishikesh	Uttarakhand & Uttar Pradesh
4. Nizam's Institute of Medical Sciences, Hyderabad	Andhra Pradesh & Telangana
5. Silchar Medical College & Hospital, Silchar	Assam, Arunachal Pradesh, Nagaland Manipur, Meghalaya, Mizoram Tripura & Sikkim

	Name	Designation	Signature	Date
Prepared by	Kinnari Dabhi	Technical Associate	K.J. Dabhi	16/05/2016
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