	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			
	STANDARD OPERATING PROCEDURE		Page No.	1 of 4
			SOP No.	IPC/PvPI/QA/018
	Section	Quality Assurance	Revision No.	00
	Effective Date	24/10/2016	Review Date	23/10/2019
Title: SOP for functioning of Quality Review Panel				

1.0 OBJECTIVE

1.1 To lay down a procedure for functioning of Quality Review Panel.

2.0 SCOPE

2.1 This SOP shall be applicable for operational aspects of the Quality Review Panel under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

3.1 All members of the QRP shall be responsible for the implementation of this SOP.

3.2 Quality Assurance section shall be responsible for coordination with Quality Review Panel.

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 The QRP shall function under the aegis of IPC. The QRP shall perform the following activities:

5.1.1 Review the ICSRs those qualify clinically for signal detection.

5.1.2 To make recommendations to the Working Group after data analysis of ICSRs and other Quality related issues.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Sr. Associate		05/10/2016
Reviewed by	Dr Pawan K. Saini	Scientific officer		06/10/2016
Approved by	Dr. Kalaiselvan	Principal Scientist		7/10/2016

5.1.3 Devise formats, guidance documents for follow up actions after implementation of recommendations.

5.1.4 Review and recommend the quality related document/SOPs and timely up-gradation of the same.

5.1.5 Review and recommend the content and quality of resource materials for Adverse Drug Reaction Monitoring Centres (AMCs).

5.2 Quorum of the QRP

5.2.1 Minimum 4 members shall be required to complete a quorum.

5.2.2 The maximum number of members in the QRP shall be 12.

5.3 Constitution of the QRP

5.3.1 QRP shall be a multi disciplinary panel, constituted by DCG(I) w.r.t. Government of India notification with representation of the following: Medical pharmacologists, Pharmacists, Regulatory authority representative, Industries representatives and any other experts from relevant field.

5.3.2 The Member secretary shall be from the NCC-PvPI, IPC and co-ordinate all activities of the QRP.

5.3.3 Tenure of the panel shall be for the period of 3 years. Special invitees e.g. subject experts shall be invited to attend meetings but shall not have any voting rights.

5.4 Decision making

5.4.1 Decision shall be reached based on a majority vote of the QRP members, provided a quorum has been met.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Jr. Associate		05/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		06/10/2016
Approved by	Dr. Kaleiselvan	PSO		07/10/2016

5.5 Schedule of meetings

5.5.1 The QRP shall meet at least twice in a year.

5.5.2 In order to fix a meeting date, a mutual consensus will be obtained from the members.

5.5.3 If any member unable to attend three consecutive meetings, his/her candidature may be considered as cancelled.

5.5.4 All members shall sign a confidentiality disclosure agreement form before the start of first QRP meeting as a member.

5.5.5 If the members unable to attend the meeting then he/she shall give reason for not attending the meeting in writing.

5.5.6 The Member Secretary would intimate the meeting details preferably **21 days** in advance.

5.5.7 The NCC-PvPI shall maintain records of all its meetings, correspondence and other proceedings for a minimum period of **five years** in the **Quality Assurance section** at NCC.

5.6 Communication of the meeting outcomes

5.6.1 A draft minutes of meeting shall be communicated by the member secretary in consultation with the chairperson and shall be circulated to all members of the QRP for comments.

5.6.2 The members shall offer their comments (if any) within 5 working days.

5.6.3 The final minutes of meeting shall be approved by Secretary-cum Scientific Director.

6.0 SAFETY AND PRECAUTIONS

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pv. Associate		5/10/2016
Reviewed by	Dr Pawan K. Sahu	S.O.		06/10/2016
Approved by	Dr. V. Kalaiselvan	PSO		07/10/2016

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 outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
QRP	:	Quality Review Panel
IPC	:	Indian Pharmacopoeia Commission
QA	:	Quality Assurance
ICSRs	:	Individual Case Safety Reports
DCG(I):		Drugs Controller General (India)
AMCs	:	Adverse Drug Reaction Monitoring Centres

9.0 ANNEXURE: Not applicable

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Sr. Associate		5/10/2016
Reviewed by	Dr Pawan K. Saini	S.O.		06/10/2016
Approved by	Dr. Kalaiselvan	PSO		07/10/2016