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 सत्यमेव जयते 	<b>INDIAN PHARMACOPOEIA COMMISSION</b> National Coordination Centre-Pharmacovigilance Programme of India		
	<b>STANDARD OPERATING PROCEDURE</b>		Page No. 1 of 3
			SOP No. IPC/PvPI/QA/008
	Section All sections	Revision No. 00	Effective Date 01/09/2016
Effective Date	01/09/2016	Review Date 31/08/2019	
<b>Title: SOP for Management Review Meeting</b>			

**1.0 OBJECTIVE:**

1.1 To lay down the procedure for management review to evaluate the effectiveness of quality system.

**2.0 SCOPE:**

2.1 This SOP shall be applicable to all elements of PvPI quality system.

**3.0 RESPONSIBILITY:**

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

**4.0 ACCOUNTABILITY:**

4.1 Officer Incharge - Pharmacovigilance Programme of India

**5.0 PROCEDURE:**

5.1 Quality Manager shall circulate the meeting notification along with the agenda of the meeting at least one week in advance as per Annexure-I (Format No. IPC/PvPI/QA/010-F01).

5.2 Management review meeting shall be once in a year.

5.3 Normally the meeting shall be attended by the following persons:

	Name	Designation	Signature	Date
Prepared by	Saurabh K Jain	PV Associate	Saurabh	16/08/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer	[Signature]	17/08/2016
Approved by	Dr. V. K. Gaiswani	Prin. sc. officer	[Signature]	18/08/2016

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			SOP No.	IPC/PvPI/QA/008
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- a. Officer Incharge
- b. Quality Manager
- c. Technical Manager
- d. Section Incharge
- e. QA Staff
- f. Representative from parent body ( if desired)

5.4 The meeting is chaired by Officer Incharge -PvPI.

5.5 The point for the meeting shall be as follows:

- a. Suitability of policies and procedures
- b. Reports from Managerial and supervisory personnel
- c. Matters arising from the previous reviews
- d. Outcome of recently conducted audit
- e. Corrective and preventive actions
- f. Assessment by external bodies If any
- g. Stakeholder feedback
- h. Recommendation for improvement
- i. Quality review panel (QRP) recommendation review
- j. Signal review panel (SRP) recommendation review
- k. Core training panel (CTP) recommendation review
- l. Personnel training
- m. Amendment / review of documents
- n. Planning of new PvPI activities
- o. Adequacy of resources due to changing circumstances.
- p. Any other relevant matter with the permission of Officer Incharge -PvPI

	Name	Designation	Signature	Date
Prepared by	Sauabhk Jain	Pr Associate	<i>[Signature]</i>	16/08/2016
Reviewed by	Dr. Pawan K. Sahni	S.O.	<i>[Signature]</i>	17/08/2016
Approved by	Dr. V. Kalaiselvan	P30	<i>[Signature]</i>	18/08/2016

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5.6 The minutes of meeting and outcome shall be recorded as per **Annexure-II (Format No. IPC/PvPI/QA/010-F02)** and copy of the same is circulated to concern members by Quality Manager after taking due approval from Officer Incharge -PvPI.

5.7 Sometimes a special management review meeting shall be called as an outcome of a special audit being carried out because of some major non conformances raised in the audit.

#### 6.0 SAFETY AND PRECAUTION:

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

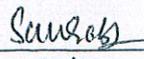
#### 8.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
NCC	:	National Coordination Centre
PvPI	:	Pharmacovigilance Programme of India
QA	:	Quality Assurance

#### 9.0 ANNEXURE(s):

Annexure- I Management review notification: **IPC/PvPI/QA/010-F01**

Annexure- II Minutes of meeting and Outcome: **IPC/PvPI/QA/010-F02**

	Name	Designation	Signature	Date
Prepared by	Srusabk kv Jain	PVASSOC Jata		16/08/2016
Reviewed by	Dr. Bawan K. Saini	S.O.		17/08/2016
Approved by	Dr. Kalraj Ivan	PSO		18/08/2016

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	<b>Annexure-I</b> <b>MANAGEMENT REVIEW NOTIFICATION</b>

Format No. IPC/PvPI/QA/008-F91-00

Ref. No :

Date:

Name:

Designation:

To- All concerned

Subject: Management review meeting regarding-

Dear Sir

Management review meeting is being scheduled on

(Date).....at(Place)..... From (Time) .....to.....

You are hereby requested to attend the meeting.

The point for the meeting shall be as follows:

- a. Suitability of policies and procedures
- b. Reports from Managerial and supervisory personnel
- c. Matters arising from the previous reviews
- d. Outcome of recently conducted audit
- e. Corrective and preventive actions
- f. Assessment by external bodies If any
- g. Stakeholder feedback
- h. Recommendation for improvement
- i. Quality review panel (QRP) recommendation review
- j. Signal review panel (SRP) recommendation review

	Name	Designation	Signature	Date	
Prepared by	<i>Saurabh K. Jain</i>	<i>PR Associate</i>	<i>[Signature]</i>	<i>16/08/2016</i>	Page 1 of 2
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>[Signature]</i>	<i>17/08/2016</i>	
Approved by	<i>Dr. V. Kalaise Wan</i>	<i>PSO</i>	<i>[Signature]</i>	<i>18/08/2016</i>	

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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I

MANAGEMENT REVIEW NOTIFICATION

Format No. IPC/PvPI/QA/008-F01-00

- k. Core training panel (CTP) recommendation review
- l. Personnel training
- m. Amendment / review of documents
- n. Planning of new PvPI activities
- o. Adequacy of resources due to changing circumstances.
- p. Any other relevant matter with the permission of Officer Incharge -PvPI

With Kind Regard

Name:

Signature:

Date:

Copy to:

	Name	Designation	Signature	Date	
Prepared by	<i>Saurabh K Jain</i>	<i>Pr Associate</i>	<i>Saurabh</i>	<i>16/08/2016</i>	Page 2 of 2
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>M</i>	<i>17/08/2016</i>	
Approved by	<i>Dr. Kalaise Ivan</i>	<i>PSO</i>	<i>U</i>	<i>18/08/2016</i>	

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	<b>Annexure-II</b>

**MINUTES OF MEETING AND OUTCOME**

Format No. IPC/PvPI/QA/008-F02-00

Ref No. : .....

Date: .....

Meeting held on:

Attended by:

.....  
.....  
.....  
.....  
.....  
.....

Minutes of Meeting: (If require additional sheet attach)

Sr. No	Agenda	Discussion held on	Outcome	Remark

	Name	Designation	Signature	Date	Page no 1 of 2
Prepared by	<i>Santosh Kr Jain</i>	<i>Pr Associate</i>	<i>[Signature]</i>	<i>16/08/2016</i>	
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>Sec</i>	<i>[Signature]</i>	<i>17/08/2016</i>	
Approved by	<i>Dr. Kalisekhar</i>	<i>Pls</i>	<i>[Signature]</i>	<i>18/08/2016</i>	

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	Annexure-II MINUTES OF MEETING AND OUTCOME

Format No. IPC/PvPI/QA/008-F02-00

Management Review (Remarks):

.....  
.....  
.....  
.....  
.....

Details of Corrective action taken/ required /proposed:

.....  
.....  
.....  
.....  
.....

Prepared by:

Approved by:

Signature/Date

Signature /Date:

Copy to:

	Name	Designation	Signature	Date	
Prepared by	<i>Ramesh K. Jain</i>	<i>Pr Associate</i>	<i>[Signature]</i>	<i>16/08/2016</i>	Page no 2 of 2
Reviewed by	<i>Dr. Pawan K. Saini</i>	<i>S.O.</i>	<i>[Signature]</i>	<i>17/08/2016</i>	
Approved by	<i>Dr. Kalaiselvan</i>	<i>PSO</i>	<i>[Signature]</i>	<i>18/08/2016</i>	