



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Trend Preparation for QMS Documents	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the Procedure for Preparation of QMS trends.

2.0 SCOPE:

This SOP is applicable for Preparation of trends related to QMS documents like change control, incident & deviation to be followed at

3.0 RESPONSIBILITY:

QA (Officer/ Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP.
Preparation of trends related to QMS documents.

4.0 ACCOUNTABILITY:

Head QA: Approval, ensure Training and Implementation of this SOP. Approval of trend data prepared for QMS documents and give review comments.

5.0 DEFINITIONS:

- 5.1 Deviation:** It is a departure from Approved Procedure, Specifications or Protocols.
- 5.2 Incident:** An event which may or may not affect the product quality but is a violation of cGMP.
- 5.3 Change Control:** It is a systematic approach to managing all changes made to a product or system, to ensure that changes are carry out in a controlled and organized manner. Changes can be related to facility, documentation, system, equipment, instrument, procedure, layouts and products etc.

6.0 PROCEDURE:

- 6.1** QA Officer/Executive shall maintain the log of QMS documents like change control, deviation & incident as per their respective SOP's.
- 6.2** On the basis of log of QMS documents, QA Officer/Executive shall prepare the trend of QMS documents quarterly as per format presented in Annexure-I, II & III for trend charts.



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ANNEXURE-I

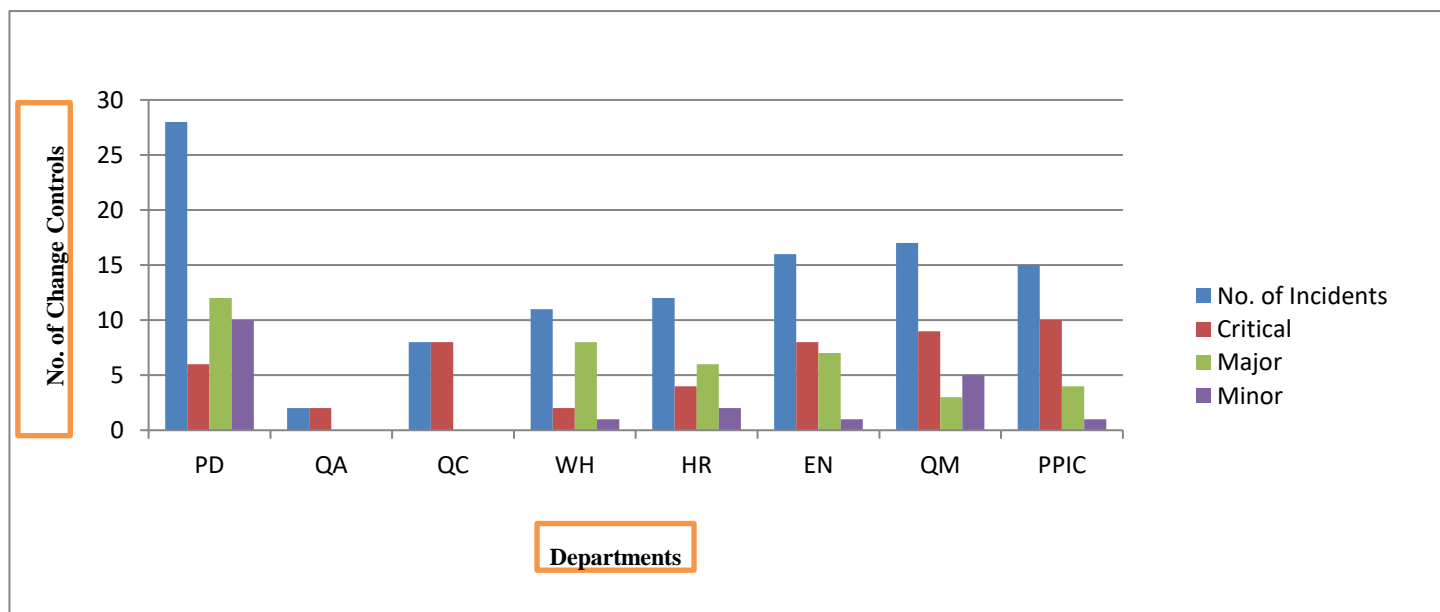
TREND CHARTS FOR CHANGE CONTROL

Trend between No. of Change Controls & Category of Change Controls:

Year: _____ **Month:** _____ **Frequency:** Quarterly

S.No.	Department	Total No. of Change Controls	Number of Change Controls Category wise		
			Minor	Major	Critical
1.					
2.					
3.					

No. of Change Controls Vs Category of Change Controls from _____ to _____ Month Department wise



Review Comments:

Prepared By:
Officer/Executive QA
(Sign & Date)

Reviewed By:
Manager QA
(Sign & Date)

Approved By:
Head QA
(Sign & Date)



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE-II

TREND CHARTS FOR DEVIATION

Trend between No. of Deviations & Category of Deviations:

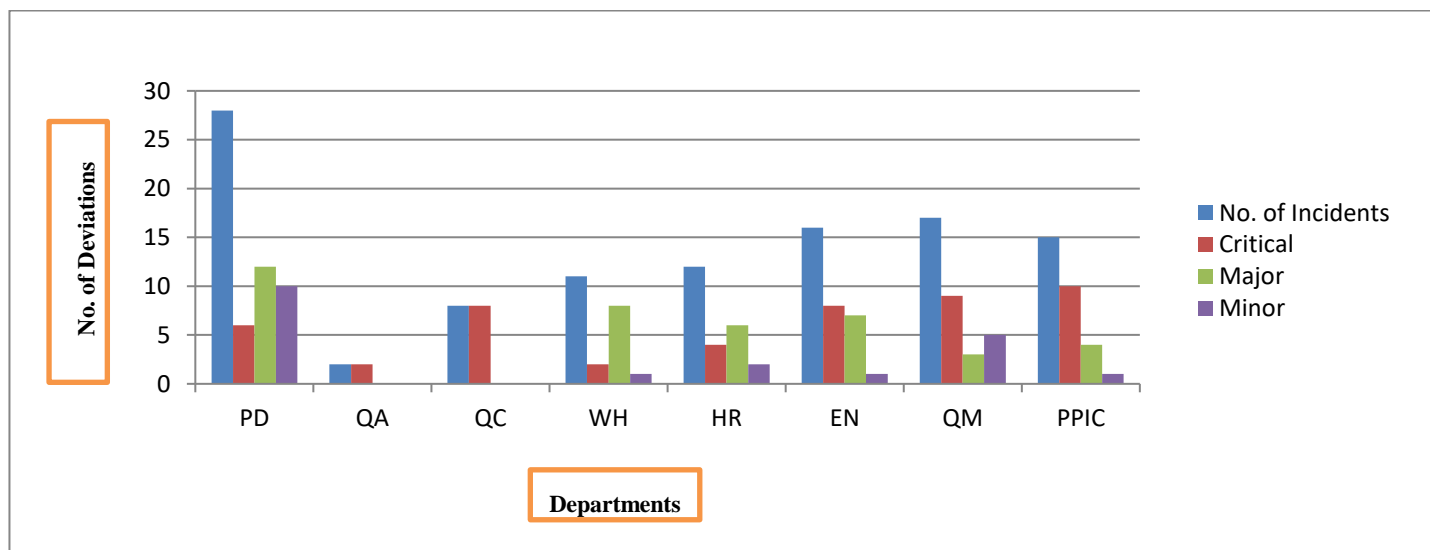
Year:

Month:

Frequency: Quarterly

S.No.	Department	Total No. of Deviations	Number of Deviations Category wise		
			Minor	Major	Critical
1.					
2.					
3.					

No. of Deviations Vs Category of Deviations from _____ to _____ Month Department wise



Review Comments:

Prepared By:
Officer/Executive QA
(Sign & Date)

Reviewed By
Manager QA
(Sign & Date)

Approved By:
Head QA
(Sign & Date)



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ANNEXURE-III

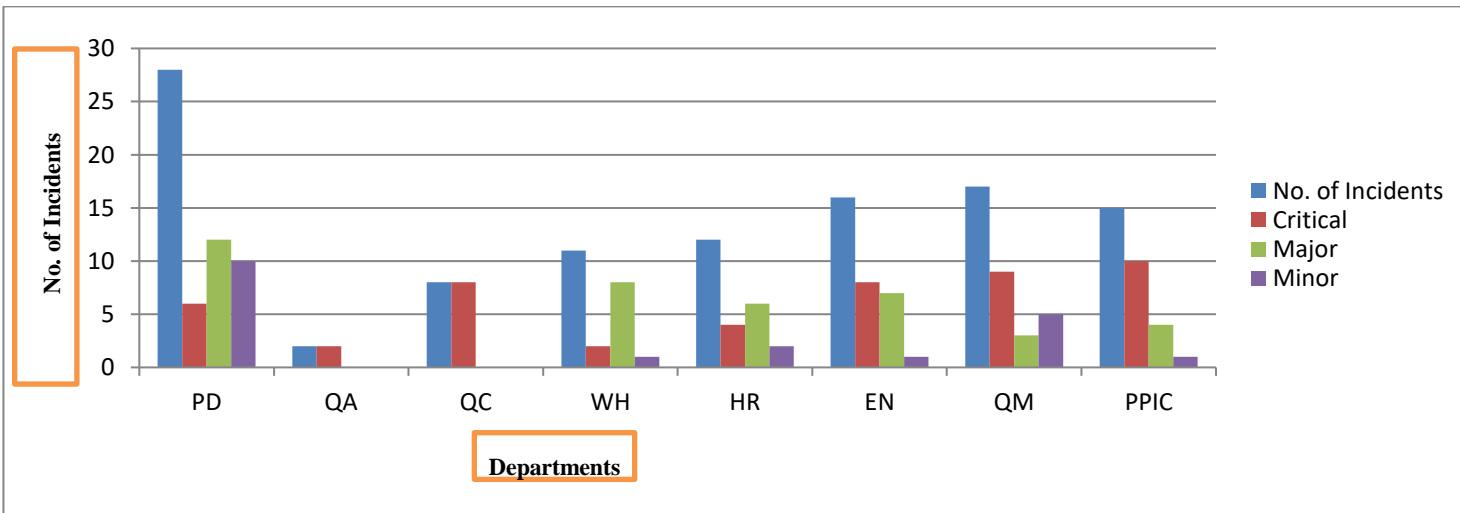
TREND CHARTS FOR INCIDENT

Trend between No. of Incidents & Category of Incidents:

Year: _____ **Month:** _____ **Frequency:** Quarterly

S.No.	Department	Total No. of Incidents	Number of Incidents Category wise		
			Minor	Major	Critical

No. of Incidents Vs Category of Incidents from _____ to _____ Month Department wise



Review Comments:

Prepared By:
Officer/Executive QA
(Sign & Date)

Reviewed By:
Manager QA
(Sign & Date)

Approved By:
Head QA
(Sign & Date)