 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-005-06	Effective Date:	15.06.2019
	Supersedes :	SOP-QA-005-05	Next Review Date:	14.06.2022
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<b>TITLE: CHANGE CONTROL</b>				

## 1.0 PURPOSE:

To lay down the procedure to control, review, approval and implementation of all changes connected with the Quality systems, manufacturing and testing of products during their life cycle.

## 2.0 SCOPE:

The procedure is applicable for all planned changes that may affect to product quality and the quality system at Discovery Laboratories Pvt. Ltd.

## 3.0 RESPONSIBILITY:

### 3.1 Initiator:

3.1.1 Initiator is responsible for initiating the change through Change control form (CCF) along with adequate supporting data and shall circulate the CCF to all concerned departments for their review and comments.

3.1.2 Implement the change after approval and conduct the post change review by completing necessary documentation as required.

### 3.2 Quality Assurance:

3.2.1 Responsible for issue the CCF to initiating department. After initiation allot the CCF number and update details into change control log.

3.2.2 Responsible to assess the proposed change, classification of change, approval or rejection of the change. shall

3.2.3 Responsible to identify the departments from which evaluation of change is required and recommend the function wise tasks along with target completion dates.

3.2.4 Responsible to ensure that the change is executed as per proposed.


### 3.3 All the departments/ personnel identified to evaluate the change shall be responsible to:

3.3.1 Evaluate the proposed change to recommend or not.

3.3.2 Indicate any additional activities/ documents affected by proposed change.

3.3.3 Complete necessary documentation as required.

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#### 4.0 DEFINITIONS:

4.1 **Major:** A change that has a substantial potential to have an adverse effect on the identification, strength, quality, and purity of the product

Is likely to have an impact on the critical attributes of the process, procedure or product; could shift the process significantly affecting the quality and yield.

4.2 **Minor:** A Minor change is described as a change which:

A change that has a minimal potential to have an adverse effect on the identification, strength, quality, and purity of the drug substance

#### 5.0 PROCEDURE :

5.1 The initiator shall fill the necessary details in the Change control form and forward it to respective Head of the initiating department. Wherever necessary, comparative evaluation against existing system / procedure with proper justification and support data shall be prepared and shall send the data along with the CCF.

5.2 The Head of initiating department or designee shall evaluate the change then forward to QA.

5.3 Upon receipt of change control form, QA personnel shall assign the number and shall enter the details such as Initiation Date, change details into Change control log (QA005-FM081).

5.4 QA shall maintain logs for all changes i.e. General and Product wise. The sequential number starts from every calendar.

5.5 The numbering system for General change controls is as follows:

CCF/GEN/ YYNNN

Where,

CCF represents : Change control form.


GEN represents : General.

YY represents : Last two digits of calendar year.

NNN represents : Sequential number starts from 001.

Ex: CCF/GEN/19001

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5.6 The numbering system for Product wise change control as follows

CCF/PPP/YNNNN

Where,

CCF represents : Change Control Form

PPP represents : Product code

YY represents : last two digits of Calendar year

NNN represents : Sequential number starts from 001 for each product

Ex: CCF/DAH/19001.

#### 5.7 Impact Assessment & Approval of CCF by QA:

5.7.1 QA representative shall review the proposed change to assess for potential impact on various items and shall identify the actions required such as Identification of customer where specific Customer agreements which require notification/ approval of change, Calibration, Validation/ Qualification, hold time, Stability studies, Training, Documents to be revised before change is effective etc....


5.7.2 QA shall evaluate the change and shall define the tasks to be performed during implementation of change and shall recommend the function wise tasks along with target completion dates.

5.7.3 Once the assessment is completed, QA personnel shall identify the concerned departments and advise initiating department to circulate the proposed CCF to concerned departments within the location for their review comments and assess the impact on existing system against proposed change.

5.7.4 Concerned department personnel shall review the change and shall recommend for the implementation or shall not recommend with justification.

5.7.5 After review and comments by the concerned departments within the location, if any review comments/approval required for customer / regulatory, the CCF shall be send

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along with the format (QA005-FM145). The scanned copies of the comments shall be enclosed to the CCF.

- 5.7.6 Head-QA or designee in co-ordination with concerned department heads shall review the change proposal for impact on validation status and shall define the action plan / follow-up actions required depending on the regulatory impact.
- 5.7.7 QA HOD/Designee shall access the proposed change along with all supporting data and the comments received from cross functional teams, the change shall be classified as 'Major' or 'Minor'.
- 5.7.8 Additional data may seek from initiator and the same shall be provided by initiating or respective departments.
- 5.7.9 Head - QA or designee shall approve or reject the change after reviewing and assessing the data and same shall be communicated to the initiating department for further actions.
- 5.7.10 Any major changes related to Site, Process, Analytical methods, engineering systems, Packing methods and labels etc. shall be informed to customers / Regulatory based on Quality agreement before permanent implementation.

## 5.8 Implementation & Evaluation of Change:

- 5.8.1 Head of the initiating department and concerned departments shall implement the change. The necessary inputs, guidance, advice shall be provided by Head - QA or designee in co-ordination with concerned departments for effective implementation of change.
- 5.8.2 After the change is implemented, Head of the initiating department / Designee shall review the effectiveness of change outcome and shall complete the necessary documents and shall submit to QA for closure of change.

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## 5.9 Review & Closure of Change Control:

5.9.1 QA shall review the results and proposed actions are implementation status

5.9.1.1 Are all the applicable documents revised and distributed

5.9.1.2 Is change implemented as per the proposal

5.9.1.3 Are validation / qualification/ calibration/ stability / training needs fulfilled.

5.9.2 After implementation of change the effectiveness of change against change proposal shall be reviewed before closure of change control, if necessary additional tasks shall be defined to ensure the effectiveness and the same shall be implemented by extending change control and / or by initiating new change control.

5.9.3 CCF shall be closed within 90days, after approval of change proposal. Otherwise justified.

5.9.4 The status of CCF shall be reviewed timely at Management Review Meetings.

## 6.0 FORMATS / ANNEXURE(S):

6.1 Change Control Form : QA005-FM001

6.2 Change Control Log : QA005-FM081

6.3 Comments and Approval for CCF : QA005-FM145

6.4 Requisition for Extending CCFfor more than 90 Days: QA005-FM146

6.5 Annexure-1 : Typical Examples of Change


6.6 Annexure-2 : Change Control Flow Chart

## 7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01-06-2007	New SOP is introduced.	---
01	01-07-2009	SOP format changed and reviewed for more clarity.	---
02	10.01.2011	Formats changed for more clarity.	---
03	01.01.2014	1. Temporary change control log book & detailed.	---

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Revision No.	Effective Date	Details of Revision	Ref. CCF No.
		2. Detailed Major& Minor changes included. 3. SOP revised more clarity.	
04	15-02-2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. General change control numbering changed. 3. Definitions are modified. 4. Impact assessment procedure included. 5. Review & Closure of change control procedure elaborated. 6. Change control flow included. 7. Typical examples of changes prepared as separate Annexure. 8. Change control form contents were modified. 9. Following formats included. - Comments and Approval for CCF. - Review of Temporary Approval for CCF. - Requisition for Extending CCF for more than 90days. 10. Altogether procedure has been rephrased for better clarity.	QA-CRF-014/16
05	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17037
06	15.06.2019	1. 5.7.2 and 5.9.2 columns are included 2. Altogether procedure has been rephrased for better clarity.	CCF/GEN/19024

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