USER REQUIREMENT SPECIFICATION

FOR

DOCUMENT MANAGEMENT SYSTEM

APPROVAL :

	Prepared By	Checked By	Approved By	Authorized By
Signature / Date	14/01/21	15/01/21	15/01/21	15/1/21
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Designation / Department	Asst. Manager - QA	Manager - Q.A	DGM - QA	Technical Director

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ABBREVIATIONS:

Sr. No.	Abbreviation	Full Form
1.	BMR	Batch Manufacturing Record
2.	BPR	Batch Packing Record
3.	DMS	Document Management System
4.	EDP	Electronic data processing
5.	HOD	Head of Department
6.	IQ	Installation Qualification
7.	MFR	Master Formula Record
8.	MPR	Master Packing Record
9.	OQ	Operational Qualification
10.	PQ	Performance Qualification
11.	QA	Quality Assurance
12.	SOP	Standard Operating Procedure
13.	URS	User Requirement Specification

1.0 OBJECTIVE:

1.1 To create, modify, review and approval of Master Documents in software system in computer.

2.0 SCOPE:

2.1 The Document Management System shall be applicable to cGMP related documents - Standard Operating Procedures (SOP's), Master Formula Records (MFR's), Master Packing Records (MPR's), Batch Manufacturing Records (BMR's), Batch Packing Records (BPR's), Specifications (Raw materials, Packaging Material, Bulk Products, Finished Products, Stability), Protocols, Artworks etc. in phased manner

3.0 RESPONSIBILITY:

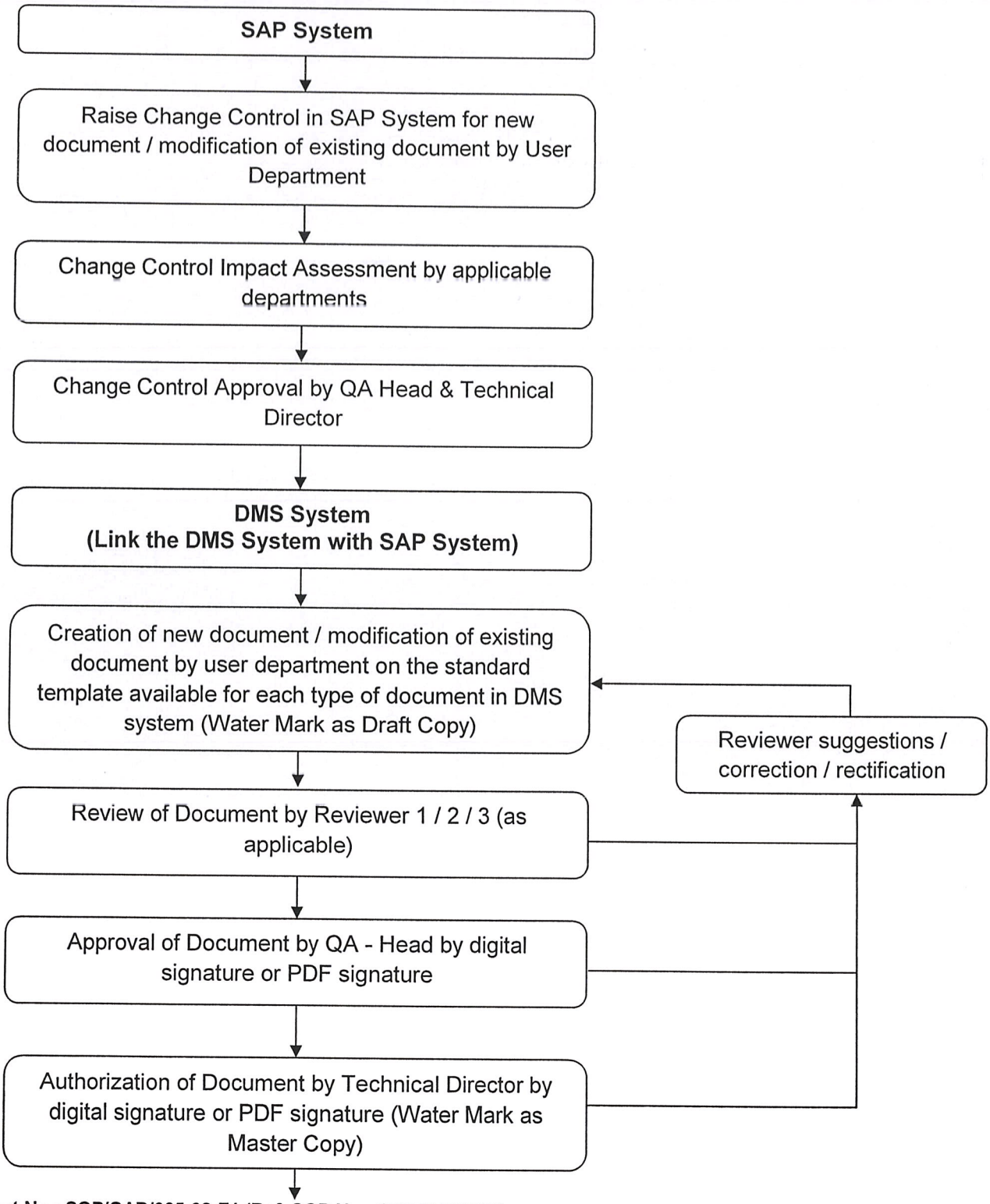
3.1	**EDP Department**	: To provide all infrastructure & support for installation & maintenance of software.
3.2	**User Department**	: To Create, Modify the documents in system & to get approved.
3.3	**QA Department / Head - Q.A**	: To maintain all documents in the computer system.
3.4	**Service Provider**	: To provide Software, Qualification and Trouble shooting.

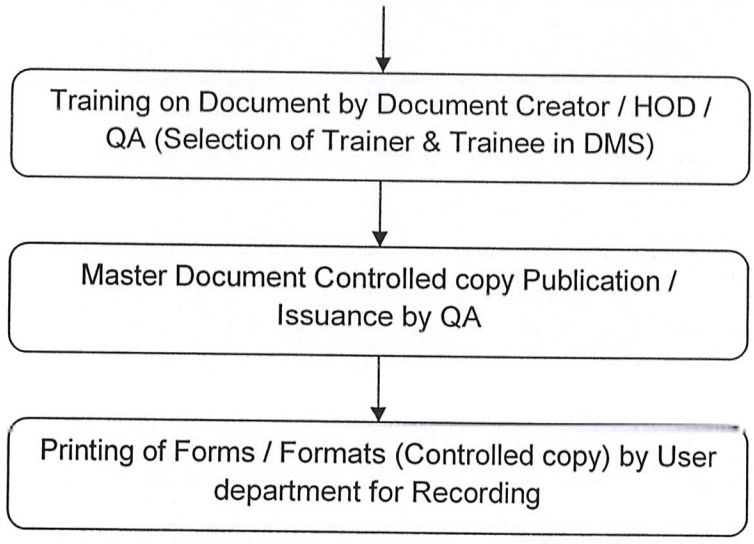
4.0 SYSTEM DESCRIPTION :

4.1 Document Management System is required to have online creation, modification and approval of master documents instead of physical movement of documents for these processes.

5.0 LOCATION: The Document Management System shall be implemented at Blue Cross laboratories Pvt. Ltd. Nashik Plant, Goa Plant and Mumbai Head Office.

6.0 GMP DOCUMENT FLOW DIAGRAM :





7.0 SYSTEM FEATURES: DMS Software shall have following features

7.1 Creation of new document / modification of existing document on the standard templates.

7.2 Document number system Auto / Manual.

7.3 Circulation of draft document to related stake holders, alert mails to all.

7.4 Getting suggestions / corrections in the draft document either in same document or separately during review / approval.

7.5 Inprocess document tracking by controller / author.

7.6 Alert / Auto task reminder email to all selected stake holders.

7.7 Final draft copy shall be forwarded for approval.

7.8 Provision of Signatures of all stake holders at the designated place on the document.

7.9 Linking of DMS with change control system.

7.10 QA shall be controller of all documents & shall have the authority to change the author / reviewer / approver.

7.11 Version control of all master documents. Document change history viewing facility.

7.12 Provision to upload / attach reference documents.

7.13 Printing control to QA for printing numbers of copies.

7.14 Audit trail for printing.

7.15 Control for view, edit & printing of document, access control.

7.16 Master document training record provision (SOP's / Protocols).

7.17 Files to get converted in PDF / PDF Format at the time of publication.

7.18 Provision to make document Obsolete.

7.19 Water mark on the Master copies / Obsolete copy.

7.20 DMS to be integrated with SAP system.

7.21 Existing master word / excel document shall be able to upload in DMS.

7.22 Interlinking identification of documents.

7.23 DMS System shall have auto backup facility.

7.24 Facility to Archive the Obsolete documents.

8.0 INSTALLATION: Installation shall be performed by service provider representative along with BCL team.

9.0 QUALIFICATION AND COMMISSIONING: Qualification shall be performed by service provider representative along with BCL team.

10.0 DOCUMENTATION: Qualification documents, Operational manual shall be provided by service provider.

11.0 TRAINING: Training on operation of system shall be provided by service provider representative after installation.

12.0 SUPPORTING DOCUMENTS REQUIRED:

12.1 DMS System Qualification documents.

12.2 Operational manual.