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ISO 22716:2007

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

GUIDE

Document Master List

Controlled list of every document supplied in the ISO 22716:2007 kit, with its revision status and owner.

Document control

Document number	GDE-02	**Revision**	0
Document title	Document Master List	**Issue date**	[Date]
Document owner	Management Representative	**Next review**	[Date]
Management system	Cosmetics Good Manufacturing Practice System	**Classification**	Internal
Standard clauses	7.5	**Status**	For approval

	Name	Position	Signature / Date
Prepared by	[Name]	[Position]	
Reviewed by	[Name]	[Position]	
Approved by	[Name]	[Position]	

Rev.	Date	Description of change	Author
0	[Date]	First issue.	[Name]

Before you issue this document

Replace every highlighted placeholder such as [Organisation Name] with your own details, delete any clause that does not apply to your scope, and have the document approved by the roles named above. Record the approval in the revision history — an auditor will ask who approved it and when.

This master list records every document in the ISO 22716:2007 Complete Documentation Kit. It is the register required by the standard's documented-information clause: when [Organisation Name] adopts the kit, update the revision and issue-date columns as each document is approved, and add any document created locally.

How to use this list

Keep one controlled copy. Every time a document is revised, raise its revision number here and on the document's own cover page. An auditor will normally ask for this list first and sample from it.

Doc. No	Document title	Clause(s)	Owner
00 Read Me First			
GDE-01	Kit Guide and Implementation Roadmap	3.3, 7, 16	Quality Director
01 Manual			
MAN-01	Cosmetics Good Manufacturing Practice Manual	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17	Managing Director
03 Procedures			
PRO-01	GMP Training and Competence Procedure	3.3.2, 3.4, 3.4.2, 3.4.4	Quality Director
PRO-02	Personnel Hygiene, Health, Gowning and Visitor Control Programme	3.3.1.3, 3.4.3, 3.5, 3.6	Quality Director
PRO-03	Document and Record Control Procedure	17.1, 17.2, 17.3, 17.4, 17.5	Quality Director
PRO-04	Site Layout, Area Flows and Waste Management Procedure	4.2, 4.3, 4.4, 11.2, 11.3, 11.4, 11.5	Quality Director
PRO-05	Premises Cleaning, Sanitisation, Maintenance and Pest Control Programme	4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13	Quality Director
PRO-06	Equipment Register, Calibration, Maintenance and Access Control Procedure	5.2, 5.3, 5.4, 5.6, 5.7, 5.8, 5.9	Quality Director
PRO-07	Equipment Cleaning, Sanitisation and Cleaning Verification Protocol	5.5, 4.10.3	Quality Director
PRO-08	Supplier Evaluation, Purchasing and Approved Supplier List	6.2	Quality Director
PRO-09	Goods Receipt, Material Status Control and Release Procedure	6.3, 6.4, 6.5	Quality Director
PRO-10	Storage, Stock Rotation, Inventory and Material Re-evaluation Procedure	6.6, 6.7, 8.3	Quality Director
PRO-11	Finished Product Release, Shipment and Returned Goods Procedure	8.1, 8.2, 8.4, 8.5	Quality Director
PRO-12	Quality Control Laboratory Procedure with Test Methods, Result Review and Reagent Control	9.1, 9.2, 9.4, 9.6	Quality Director
PRO-13	Sampling Plan, Sample Labelling and Retained Sample Register	9.7, 9.8	Quality Director

Doc. No	Document title	Clause(s)	Owner
PRO-14	Out-of-Specification Investigation, Rejected Product Disposition and Reprocessing Procedure	9.5, 10.1, 10.2	Quality Director
PRO-15	Subcontracting Procedure with Contract Giver and Contract Acceptor Quality Agreement	12.1, 12.2, 12.3, 12.4, 12.5	Quality Director
PRO-16	Internal Audit Procedure	16.1, 16.2, 16.3	Quality Director
PRO-17	Deviation and Change Control Procedure with Separate Registers	13.1, 13.2, 15	Quality Director
PRO-18	Complaint Handling and Product Recall Procedure	6.4, 7.2.3, 7.3.3, 8.3.4, 14.1, 14.2, 14.3	Quality Director
04 Forms, Registers & Templates			
FRM-01	Raw Material, Packaging, Bulk and Finished Product Specifications	6.1, 9.3, 8.1	Quality Director
FRM-02	Master Formula and Manufacturing Instruction Template	7.2.1	Quality Director
FRM-03	Batch Manufacturing Record with Weighing, Dispensing and Bulk Hold	7.2.1, 7.2.3, 7.2.4, 7.2.6, 7.2.7	Quality Director
FRM-04	Batch Packaging Record	7.3.1, 7.3.3, 7.3.4, 7.3.7, 7.3.8	Quality Director
FRM-05	Competence Matrix and Training Record	3.4, 3.4.4	Quality Director
FRM-06	Internal Audit Plan and Report	16.2, 16.3	Quality Director
FRM-07	Document Change Request	17.3, 17.4	Quality Director
04 Forms, Registers & Templates			
REG-01	Authorised Personnel, Quality Unit Independence and Signature Authority Matrix	3.2.1, 3.3, 3.3.1.3, 5.8, 6.5.2, 8.2.2, 9.5, 9.7.1, 10.1, 10.2, 14.2.1, 14.3.1, 15, 16.2.1, 17.3.3	Quality Director
REG-02	Cosmetic Regulatory Requirements Register and Product Information File GMP Statement	9.8.2, 17.5.2	Quality Director
REG-03	Corrective Action Register with Effectiveness Check	6.6.8, 13.2, 14.1.2, 16.3	Quality Director
05 Plans & Programmes			
PLN-01	Water System Specification, Sanitisation and Monitoring Plan	6.8	Quality Director
PLN-02	In-Process Control Plan and Record	7.2.5, 7.3.5, 7.3.6	Quality Director
PLN-03	Microbiological Control Plan	9.2, 9.3	Quality Director
PLN-04	GMP Implementation Plan	7, 16	Quality Director
PLN-05	Annual Internal Audit Programme	16.2	Quality Director

Doc. No	Document title	Clause(s)	Owner
PLN-06	Training Needs Analysis and Annual GMP Training Plan	3.3.2, 3.4, 3.4.2	Quality Director
06 Checklists			
CHK-01	Line Clearance Checklist for Manufacturing and Packaging	7.2.2, 7.3.2	Quality Director
CHK-02	ISO 22716:2007 Gap Analysis Checklist	—	Quality Director
CHK-03	Internal Audit Checklist	16	Quality Director
CHK-04	Certification Readiness Checklist	—	Quality Director
07 Internal Auditor Training Pack			
TRN-01	Internal Auditor Participant Handbook	16	Quality Director
TRN-02	Trainer's Guide	16	Quality Director
TRN-03	Presentation Slides Outline	16	Quality Director
TRN-04	Exercises and Case Studies	16	Quality Director
TRN-05	Examination	16	Quality Director
TRN-06	Examination Answer Key and Marking Scheme	16	Quality Director
TRN-07	Course Forms	16	Quality Director
TRN-08	Certificate of Training Template	16	Quality Director

Revision status

Record the approved revision of each document as it is issued. Rows are pre-filled at revision 0 (first issue).

Doc. No	Rev.	Issue date	Approved by	Next review
GDE-01	0	[Date]	[Name]	[Date]
MAN-01	0	[Date]	[Name]	[Date]
REG-01	0	[Date]	[Name]	[Date]
REG-02	0	[Date]	[Name]	[Date]
PRO-01	0	[Date]	[Name]	[Date]
PRO-02	0	[Date]	[Name]	[Date]
PRO-03	0	[Date]	[Name]	[Date]
PRO-04	0	[Date]	[Name]	[Date]
PRO-05	0	[Date]	[Name]	[Date]
PRO-06	0	[Date]	[Name]	[Date]
PRO-07	0	[Date]	[Name]	[Date]
PRO-08	0	[Date]	[Name]	[Date]
FRM-01	0	[Date]	[Name]	[Date]
PRO-09	0	[Date]	[Name]	[Date]

Doc. No	Rev.	Issue date	Approved by	Next review
PRO-10	0	[Date]	[Name]	[Date]
PLN-01	0	[Date]	[Name]	[Date]
FRM-02	0	[Date]	[Name]	[Date]
FRM-03	0	[Date]	[Name]	[Date]
CHK-01	0	[Date]	[Name]	[Date]
PLN-02	0	[Date]	[Name]	[Date]
FRM-04	0	[Date]	[Name]	[Date]
PRO-11	0	[Date]	[Name]	[Date]
PRO-12	0	[Date]	[Name]	[Date]
PRO-13	0	[Date]	[Name]	[Date]
PLN-03	0	[Date]	[Name]	[Date]
PRO-14	0	[Date]	[Name]	[Date]
PRO-15	0	[Date]	[Name]	[Date]
PRO-16	0	[Date]	[Name]	[Date]
FRM-05	0	[Date]	[Name]	[Date]
FRM-06	0	[Date]	[Name]	[Date]
REG-03	0	[Date]	[Name]	[Date]
PRO-17	0	[Date]	[Name]	[Date]
PRO-18	0	[Date]	[Name]	[Date]
FRM-07	0	[Date]	[Name]	[Date]
PLN-04	0	[Date]	[Name]	[Date]
PLN-05	0	[Date]	[Name]	[Date]
PLN-06	0	[Date]	[Name]	[Date]
CHK-02	0	[Date]	[Name]	[Date]
CHK-03	0	[Date]	[Name]	[Date]
CHK-04	0	[Date]	[Name]	[Date]
TRN-01	0	[Date]	[Name]	[Date]
TRN-02	0	[Date]	[Name]	[Date]
TRN-03	0	[Date]	[Name]	[Date]
TRN-04	0	[Date]	[Name]	[Date]
TRN-05	0	[Date]	[Name]	[Date]
TRN-06	0	[Date]	[Name]	[Date]
TRN-07	0	[Date]	[Name]	[Date]
TRN-08	0	[Date]	[Name]	[Date]

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ISO 22716:2007

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

GUIDE

Clause Cross-Reference Matrix

Shows which kit document answers each clause of ISO 22716:2007 — the table certification bodies ask for at stage 1.

Document control

Document number	GDE-03	**Revision**	0
Document title	Clause Cross-Reference Matrix	**Issue date**	[Date]
Document owner	Management Representative	**Next review**	[Date]
Management system	Cosmetics Good Manufacturing Practice System	**Classification**	Internal
Standard clauses	—	**Status**	For approval

	Name	Position	Signature / Date
Prepared by	[Name]	[Position]	
Reviewed by	[Name]	[Position]	
Approved by	[Name]	[Position]	

Rev.	Date	Description of change	Author
0	[Date]	First issue.	[Name]

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Use this matrix to demonstrate that every requirement of ISO 22716:2007 is addressed by documented information. Complete the final column with the evidence or record that proves the requirement is being met in practice, and take it to the stage 1 audit.

Good practice

Auditors use a matrix like this to plan their sample. A complete, honest matrix shortens stage 1 considerably; an aspirational one invites a deeper audit.

Clause	Kit document(s)	Evidence / records in use
1	MAN-01	
2	MAN-01	
3	MAN-01	
3.2.1	REG-01	
3.3	GDE-01, REG-01	
3.3.1.3	PRO-02, REG-01	
3.3.2	PLN-06, PRO-01	
3.4	FRM-05, PLN-06, PRO-01	
3.4.2	PLN-06, PRO-01	
3.4.3	PRO-02	
3.4.4	FRM-05, PRO-01	
3.5	PRO-02	
3.6	PRO-02	
4	MAN-01	
4.2	PRO-04	
4.3	PRO-04	
4.4	PRO-04	
4.5	PRO-05	
4.6	PRO-05	
4.7	PRO-05	
4.8	PRO-05	
4.9	PRO-05	
4.10	PRO-05	
4.10.3	PRO-07	
4.11	PRO-05	
4.12	PRO-05	
4.13	PRO-05	
5	MAN-01	

Clause	Kit document(s)	Evidence / records in use
5.2	PRO-06	
5.3	PRO-06	
5.4	PRO-06	
5.5	PRO-07	
5.6	PRO-06	
5.7	PRO-06	
5.8	PRO-06, REG-01	
5.9	PRO-06	
6	MAN-01	
6.1	FRM-01	
6.2	PRO-08	
6.3	PRO-09	
6.4	PRO-09, PRO-18	
6.5	PRO-09	
6.5.2	REG-01	
6.6	PRO-10	
6.6.8	REG-03	
6.7	PRO-10	
6.8	PLN-01	
7	GDE-01, MAN-01, PLN-04	
7.2.1	FRM-02, FRM-03	
7.2.2	CHK-01	
7.2.3	FRM-03, PRO-18	
7.2.4	FRM-03	
7.2.5	PLN-02	
7.2.6	FRM-03	
7.2.7	FRM-03	
7.3.1	FRM-04	
7.3.2	CHK-01	
7.3.3	FRM-04, PRO-18	
7.3.4	FRM-04	
7.3.5	PLN-02	
7.3.6	PLN-02	
7.3.7	FRM-04	
7.3.8	FRM-04	

Clause	Kit document(s)	Evidence / records in use
8	MAN-01	
8.1	FRM-01, PRO-11	
8.2	PRO-11	
8.2.2	REG-01	
8.3	PRO-10	
8.3.4	PRO-18	
8.4	PRO-11	
8.5	PRO-11	
9	MAN-01	
9.1	PRO-12	
9.2	PLN-03, PRO-12	
9.3	FRM-01, PLN-03	
9.4	PRO-12	
9.5	PRO-14, REG-01	
9.6	PRO-12	
9.7	PRO-13	
9.7.1	REG-01	
9.8	PRO-13	
9.8.2	REG-02	
10	MAN-01	
10.1	PRO-14, REG-01	
10.2	PRO-14, REG-01	
11	MAN-01	
11.2	PRO-04	
11.3	PRO-04	
11.4	PRO-04	
11.5	PRO-04	
12	MAN-01	
12.1	PRO-15	
12.2	PRO-15	
12.3	PRO-15	
12.4	PRO-15	
12.5	PRO-15	
13	MAN-01	
13.1	PRO-17	

Clause	Kit document(s)	Evidence / records in use
13.2	PRO-17, REG-03	
14	MAN-01	
14.1	PRO-18	
14.1.2	REG-03	
14.2	PRO-18	
14.2.1	REG-01	
14.3	PRO-18	
14.3.1	REG-01	
15	MAN-01, PRO-17, REG-01	
16	CHK-03, GDE-01, MAN-01, PLN-04, TRN-01, TRN-02, TRN-03, TRN-04, TRN-05, TRN-06, TRN-07, TRN-08	
16.1	PRO-16	
16.2	FRM-06, PLN-05, PRO-16	
16.2.1	REG-01	
16.3	FRM-06, PRO-16, REG-03	
17	MAN-01	
17.1	PRO-03	
17.2	PRO-03	
17.3	FRM-07, PRO-03	
17.3.3	REG-01	
17.4	FRM-07, PRO-03	
17.5	PRO-03	
17.5.2	REG-02	

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