

Saimax Healthcare & Surgicals

Documents Required for MDQMS

Sr. No.	Documents Required	Remarks
1	Internal Audit Records	
2	Training Certificates of Internal Auditors	
3	Training Plan & Record	
4	MRM Records	
5	Sales Plan	
6	Sales Order	
7	Sales Invoices	
8	Purchase Plan	
9	Purchase Order	
10	Approved Supplier List	
11	Supplier Agreement	
12	Supplier Evaluations	
13	Supplier Rating	
14	Products Specification	
15	Sampling Plan	
16	Quality Plan	
17	Store Inward & Outward Record	
18	Product Issue record (Store to production)	
19	Production Plan	
20	All Batch Manufacturing Record	
21	Preventive Maintenance Records	
22	Calibration record	
23	Calibration Plan	
24	Complaint Record with CAPA & closer	
25	Customer Feedback	
26	Medical Fitness of Chemist & Director	
27	Pest Control Records	
28	Validation Plan	
29	Process Validation	
30	Sterilizer Validation Record	If Required
31	Packing Validation Record	For Each type packing material
32	Previous Audit NC, compliance evidence	
33	Quality Manual	
34	Device Master File	For each products
35	Design History File	For each products
36	List of Procedures	
37	List of records	
38	All Legal Documents	