6. Appendix 1

A1 GMP DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
REGULATORY DOCUMENTATION - SMF - DMF - Regulatory Authority inspection reports/documentation	Indefinite	
MANUFACTURING DOCUMENTATION - Raw Mat. Receipts - Dispensing information - Batch Prod. Record - Packaging Prod. Record - In process controls (+ raw data) - Deviation reports/investigations - Hygiene controls - Distribution records - Returns information - Equipment usage + cleaning logs. - Cleaning records - Temperature/humidity records (inc. Transit) - Master batch production records - Master packaging production records		 Full change history Full change history
APIs	Retest/Expiry life + one year or three years after final distribution whichever is the longer	
FORMULATED PRODUCTS	Shelf life + one year or at least five years	

A1 GMP DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
ANALYTICAL DOCUMENTATION_ - Sampling records - Analytical results - Lab raw data - Certificates of Analysis - Hygiene controls - Deviation (e.g. O.O.S.) - Reference standards - Media records (micro) - Log books RAW MATERIALS APIs INTERMEDIATES EXCIPIENTS FORMULATED PRODUCTS	3 Retest/Expiry life + one year or three years after final distribution whichever is the longer Until stock is consumed and API released 10 Shelf life + one year or at least five years	
COMPLAINTS/PRODUCT DEFECT NOTIFICATION	10	
COMMERCIAL STABILITY TESTING	at least 10	Analytical documentation and Master Batch Documentation for 10 years. Completed batch records until expiry date & 1 year or at least 5 years
ANNUAL PRODUCT REVIEW (APRs)	6	

A1 GMP DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
AUDIT REPORTS (Self inspection)	6	
CHANGE CONTROL DOCUMENTS	Indefinite	Full change history
CONTRACTS (INTERNAL + EXTERNAL) - Pest Control - Analytical labs. - Service contracts - Cleaning - Manufacturing/Packaging/Storage/Distribution - QA Contracts	6	
PURCHASE AGREEMENTS	6	
QUALITY MANUALS etc. (ISO)	6	
SOPs	6	Full change history
TECHNICAL TRANSFER (Manufacturing and analytical)	Indefinite	
TRAINING RECORDS (Inc. Organograms, Job Descriptions & Personnel Qualifications)	Indefinite	For period of employment + 6 years
CONTRACT PERSONNEL & CONSULTANT RECORDS (eg. CVs and associated documents)	Indefinite	For period of contract + 6 years or in line with Validation and Facility Qualification documentation requirements.
VALIDATION - VMP, protocols, reports and certifications (VMRs)	Indefinite	
PRODUCT SPECIFICATIONS	Indefinite	Full change history
RECALL REPORTS	Expiry date + one year or at least five years	
CALIBRATION RECORDS	6	
MAINTENANCE RECORDS	6	

A2 MEDICAL DEVICE DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
QUALITY MANAGEMENT SYSTEM DOCUMENTS	5 years	
PRODUCT SPECIFYING DATA	Active life + 5 years	i.e. 5 years after manufacture of the product ceases.
BATCH HISTORY RECORDS	5years	
OTHER QUALITY RECORDS	5years	

A3 SAMPLES

WHAT	RETENTION PERIOD YRS	COMMENTS
RAW MATERIALS	N/A	
INTERMEDIATES	N/A	Typically until stock consumed and API released
APIs	Expiry date + one year or three years after the final distribution	
EXCIPIENTS	10	If stability permits. Exclude water, gases, highly corrosive or inflammable
FORMULATED PRODUCTS - Finished tablets/capsules - Dry powders (unlabelled final containers) - Bulk liquid - Semi solids (eg creams/ointment/suppositories - Placebos	Expiry date + one year	
FINISHED PRODUCTS - Tablets/capsules - Powders and inhalers - Liquids (sterile and non-sterile) - Semi solids - Parenterals - Medical devices - Aerosols	Expiry date + one year	
PACKAGING MATERIALS - Primary and printed	Expiry date + one year	
CUSTOMER COMPLAINTS	2	3 yrs for medical complaint samples
ROUTINE PRODUCTION STABILITY TESTING	Up to 6	Product dependant