S.No.	Record Category	Description	Example	Retention Period

JHS SVENDGAARD LABORATORIES LIMITED

DOCUMENT RETENTION POLICY

1	Administrative Records	Documentation relating to routine administrative activities performed by most departments, regardless of function, such as correspondence, agendas, diaries, etc.	Activity Reports· Agendas / Itineraries· Annual / Semi-annual Reports· Attendance Records· Calendars / Diaries· Catering Requests· Chronological / Running Files· Conference Room Requests· Correspondence· Departmental Files· Meeting Files / Minutes· Monthly / Status Reports· Service Requests· Telephone Messages / Logbooks· Travel / Trip Reports· Vacation Schedules	No longer than one year
2	Equipment Records (Non-regulated)	Documentation accumulated as a result of the purchase and use of non-regulated equipment.	Calibration Records:· Designs & Specifications:· Maintenance Records:· Operator Instructions:· User Manuals:· Warranty / Guarantee	No Longer Than 1 Year after Life of Equipment
3	Financial Planning and Reporting Records Company leval and Departmental	(A) Documentation that examines the Company's internal operations to determine financial decisions and direction. (B) Documentation maintained locally by departmental managers / administrators to manage departmental budgets and to track and forecast expenditure.	Budget Files:· Capital Expenditure Decision Making Records· Cost Centre Reports· Economic Analysis Records· Financial Analysis Files· Financial Summaries· Forecast Files· Gross Profit Records· Journal Entries· Profit & Loss Statements· Sales Schedules· Approval / Authority Forms :· Capital Appropriation Requests:· Charge Back Records:· Cheque Requests:· Cost Justification Files:· Expense Reports:· Fixed Assets Inventories:· Forecast Files:· Invoices:· Mileage Reimbursement Records:· Purchase Orders / Requisitions:· Receipts	For not less than 8 years immediately preceding current year
4	Inventory Records (Non-regulated)	A detailed list of all goods and materials in stock.	Discrepancy Reports :· Inventory Lists	For not less than 8 years immediately preceding current year
5	Personnel/Supervisory Records	Documentation maintained by line managers to facilitate the day-to-day management of their	Professional Development Records:· Update Meeting Notes	No Longer than Employment Ends.

		employees. (Company official employee records are covered elsewhere on the Schedule.)		
6	Planning Records	Documentation relating to non-regulated departmental or programme planning, including documentation on objectives, strategies, and tactics, etc. for a specified period of time.	Benchmarking / Survey Records:· Departmental Planning Records:· Strategic Reports:· Tactical Reports.	No Longer Than 5 Years.
7	Policies / Procedures (Non-regulated)– Company level and departmental	Policies and procedures governing significant Company, business unit, region, area or function and deparmental operations that are not regulated.	(A) Company Guidelines:· Corporate Policies· Corporate Standards· Standard Operating Procedures (SOPs) (B) Departmental Policies & Procedures:· Guidelines:· Process Instructions:· Schedules of Regular Activities·	(A) - Compamy level - 7 Years after Superseded by New Version (B) Departmental level - No Longer Than 3 Years after Superseded by New Version
8	Programme / Operational Records (Non-regulated) - Departmental	Records of ongoing departmental programmes where those programmes are non-regulated.	Metrics:· Programme Correspondence:· Programme Descriptions:· Programme Meeting Minutes / Notes :· Publicity:· Reports	No Longer Than 3 Years
9	Project Records (Non-regulated)- Departmental	Records of a specific and time bound task and related activities, where that task is non-regulated.	Committee / Task Force Files:· Contract Supplier Management Records:· Cross Functional Project Records:· Project Initiation Records:· Project Operation Files:· Project Planning, Monitoring & Control Records:· Project Review &	No Longer Than 3 Years after Completed

			Reporting Records:· Requests for Information / Proposal / Quotation	
10	Reference Materials	Current Published and internal information used for ready reference.(This category excludes records that provide evidence of business activities or transactions, as such records are covered elsewhere in the Schedule)	Association / Professional Organisation Records:· Brochures:· Bulletins:· Catalogues:· Conference / Convention / Seminar / Symposium Files, Materials, etc.:· Emergency Contact Lists:· Journals / Reprints:· Laws / Regulations / Rulings and Registers of Applicable Legislation· Manuals· Manuscripts / Abstracts· Newsletters· Organograms / Organisation Charts· Presentation Files· Public Domain Information· Software Manuals· Supplier Files· Telephone Directories· Vendor / Consultant Records	Review Annually and Destroy Outdated Material
11	Training / Education Records (Non-regulated)	Records of internal and external training received by an individual for a non-regulated function, documentation detailing the content of training and education provided to employees, and summary evaluation and attendance records.	Completion Certificates:· Course Outlines:· Handbooks:· Presentation Materials:· Registration / Enrolment Forms	Review Annually and Destroy Outdated Material
12	Data Warehouse	Structured information from different originating systems that has been consolidated for query and analysis within a data warehouse environment from which outputs are generated. (This category excludes records that are required to be kept in order to provide evidence of business activities or		Review Annually and DestroyOutdated Material

		transactions. Primary records from originating systems and records produced as outputs should be managed according to the retention period for the relevant record category.)		
13	Disaster Recovery Back-ups	Copy created for disaster recovery purposes only (i.e., Not as an archive.)	· Computer System Back-ups:· Vital Record / Security Back-ups	No Longer Than 60 Days after Superseded
14	E-mail – Uncategorised	Transitory electronic communication stored in unstructured parts of an email system including inboxes, sent folders, draft folders and trash folders.[(E-mail business records should be managed according to the retention period listed for that record category.)]	· Administrative Records with Short-Term Value:· Information Copies:· Reference Copies:· Spam (i.e. Unsolicited E-mail from Parties outside the Company):· Working Documents	No Longer Than 60 Days
15	Voice Mail	Transitory voice communication sent and received by telephony systems.		No Longer Than 60 Days
<u>Discover, Research and Develop Drugs/Products</u>				
1	Adverse Event Records	Documentation reporting adverse events to the Company's investigational / marketed products.		7 Years after Life of Product Line
2	Alliance / In-Licensing	Records generated during the		10 Years after

	Research &Development Records- Terminated	research and / or development of a compound, technological process or equipment, produced as a result of an alliance, collaboration, joint venture, academic liaison or other association, arrangement or grant with one or more companies or third party / parties.		All Contractual Obligations have Expired(unless otherwise specified in the relevant agreement)
3	Audit / Inspection Records	Documentation relating to the examination of internal and external controls, compliance with policies and procedures and improved process recommendations pertaining to GxP.		7 Years after Audit is Closed
4	Clinical Compliance and Quality Assurance (QA)Records	Documentation pertaining to quality assurance testing and compliance controls related to clinical projects and studies		30 Years
5	Clinical Study Records	Key documents (e.g. ICH GCP Essential Documents) and any other documentation detailing significant actions, agreements and decision points produced during the management and execution of clinical studies or groups of clinical studies.		30 Years after Initial Approval in First Market or Non-Submitted Closure

6	Computer System Documentation - Research &Development Applications /Systems	Documentation relating to the design, development, validation, installation, implementation, use and retirement of regulated computer applications/systems.		30 Years after Life of System
7	Discovery Records	Documentation generated in the course of research and discovery of new compounds except for laboratory notebooks and/or supplemental data.		30 Years
8	Drug / Product /Portfolio Development Records	Documentation detailing development strategy, significant actions, agreements and key decisions on the selection, progression or termination of programmes, active alliances or projects at the programme, alliance or portfolio level.		30 Years after Report Issued
9	Human Biological Sample Management Records	Records that provide traceability of the acquisition and management of human biological samples obtained by the Company for use in research and development. (Records limited in scope to Company sponsored clinical trials should be managed according to the retention period for Clinical		30 Years after Sample Exhausted or Disposed off.

		Study Records.)		
10	Labelling Records	Documentation relating to labelling approvals and subsequent changes and approvals.		7 Years after Life of Product Line
11	Laboratory Animal Health Records(Regulated)	Records related to the acquisition, care and maintenance of animals, generated outside of a defined GxP study. (GxP records are covered elsewhere in the Schedule		10 Years after Disposition
12	Laboratory Animal Management Records	Documentation detailing the management, environment and licenses for conducting animal studies where regulated procedures are carried out. (GxP records are covered elsewhere in the Schedule)		5 years
13	Laboratory Notebooks and/or Supplementary Data	Recorded sets of ideas, experimental designs, test observations, results analyses and / or conclusions derived from experiments or studies performed during the research and development of a compound / drug /product		65 years
14	Manufacturing Records - Preclinical and Clinical Development	Documentation pertaining to the development and manufacture of compounds /		30 Years

		drugs / products used in preclinical or clinical trials.		
15	Organisation Charts and Job Descriptions (Regulated)	Documents which define reporting lines and responsibilities of individuals involved in the discovery, research and development of drugs / products.		30 Years after Superseded by New Version
16	Policies / Procedures(Regulated)	Documentation of GxP regulated methods, processes and procedures.		30 Years after Superseded by New Version
17	Preclinical Non-Study Specific Records	Documentation supporting GxP compliance related to preclinical activities.		30 Years
18	Preclinical Study Records	Documentation created during the management and execution of preclinical GxP studies or groups of studies.		30 Years from Initial Approval or Non-Submitted Closure
19	R&D Facility(Premises, Equipment, Utilities)Records	Records validating the quality of R&D facilities, equipment and utilities systems and procedures, which may be produced once only, periodically or generated via ongoing processes.		30 Years after Life of Facility, Premises, Equipment, Utility
20	Research Reports /Technical Documents	Summary information pertaining to company sponsoredresearch, development and medical		30 Years

		activities.		
21	Specimens -Preclinical - Laboratory AnimalSciences - Slides	Raw specimens collected during preclinical or healthscreening purposes		2 Years after ProcessingComp leted
22	Specimens -Preclinical - Laboratory AnimalSciences - WetTissue, Blocks	Raw specimens collected during preclinical or healthscreening purposes.		6 Months
23	Specimens -Preclinical - Slides	Raw specimens collected during preclinical studies.		20 Years after Report Issued orSpecimen Archived
24	Specimens -Preclinical - Tissuesand DNA Samples	Raw specimens collected during preclinical studies.		10 Years after Report Issued orSpecimen Archived GRS032
25	Specimens -Preclinical - WaxBlocks and ElectronMicroscopy Blocksand Grids	Raw specimens collected during preclinical studies.		15 Years after Report Issued orSpecimen Archived
26	Submission /CommunicationRecor ds	Documents, dossiers and all records of communicationbetween the Company and regulatory agencies in supportof a request		7 Years after Life of Product Line(unless otherwise specified in

		for, and maintenance of, a marketingapproval for a product.		anyapplicable license, sale or transferagreements)
27	Supportive RegulatoryInformation	Key records relating to obtaining and maintaining productregistrations but not submitted to an agency or 3rd party.		7 years
28	Training / EducationEmployee Records -R&D (Regulated)	Records of internal and external training and experiencethat demonstrate staff ability to carry out processes inaccordance with regulations.		30 Years after Employment Ends
29	Training / EducationMaterials Records -R&D (Regulated)	Records of training / education course design,development and content used in the delivery of internaland external training events.		15 Years after Superseded
<u>Manage the Organisation</u>				
1	Accounting Records	Documentation detailing payment / receipt transactions within the Company or between the Company and others.	Account Analysis:· Account Reconciliation Files:· Accounts Payable Batch Files:· Accounts Receivable Files:· Balance Sheets· Bank Statements· Cash Receipts· Cheque Registers· Cheque Requests· Credit Cardholder Files· Credit Case Files·	For not less than 8 years immediately preceding

			Education Reimbursement Forms· Expense Reports· Invoices· Monthly Account Control Reports· Purchase Orders · Purchase Requisitions· Travel & Entertainment Files· Voided Cheques	current year
2	Audit Records, Audit Schedules	a) Documentation relating to the examination of compliance with internal and external controls, policies and procedures, laws and regulations, by the Company and its external suppliers and contractors; and improved process recommendations. b) Audit schedules for internal (Company) and external suppliers and contractors.	a) Action Plan & Resolution Records:· Audit Findings:· Audit Plans:· Audit Reports:· Audit Schedules· Audit Timetables· Compliance Overview Documents· Self-Assessments of Compliance required by the Company and its Regulators b) Audit Plans:· Audit Timetables	7 Years after Audit is Closed
3	Benefits Programme Records	Documentation detailing the Company's various benefit programmes including pension fund membership, retirement savings plans, health and life insurance plans.	Benefit Plan Documents:· Cash Balance Plan Documents:· Employee Assistance Programme Files:· Matching Gift Programme Files:· Pension Files· Retirement Savings Plan Files	12 Years after Life of Programme
4	Business Continuity Planning Records	Documentation detailing plans and preparations necessary to minimise loss and maximise the continuity of critical business functions in the event of an unforeseen business interruption.	Business Impact Analysis Documents:· Contingency Resource Information:· Disaster Recovery Plans:· Emergency Response Plans:· Findings Reports· Mock Disaster Project Files	Until Superseded by New Version
5	Communication	Communication materials	Briefing Books:· Company Promotional Information:·	5 Years

	Records – External	prepared by or for the Company for external use with investors, stock analysts, corporate regulators and the general public.	Executive Biographies :· Government Relations Files:· Investor Relations Files· Lobbying Records· Press Releases / Kits· Product Information· Public Relations Records· Request / Reply Letters· Speeches – External· Submissions to Corporate Regulators	
6	Communication Records – Internal	Internal Company communication materials that are widely distributed throughout the organisation or within large business areas.	Bulletins / Announcements:· Company Newsletter / Publications:· Employee Communications	3 Years
7	Compensation Programme Records	Documentation detailing terms and conditions of the Company's various compensation programmes.	Bonus Programme Records:· Compensation Surveys:· Salary Range History Records· Sales Incentive Programme Records· Special Incentive Programme Records· Stock Option Programme Records	10 Years after Superseded by New Programme
8	Computer System Documentation – Regulated (non-GxP) Applications / Systems	Documentation relating to the design, development or selection, implementation, use, and retirement of computer applications / systems that are used for regulated processes other than GxP. (Computer systems used for GxP regulated processes are covered in other sections of the Schedule).	Access Management Records:· Business Requirements :· Change Control Documentation· Compliance Determination & Review Reports· Configuration Management Documents· Date Migration Records· Decommissioning Records· Deployment Documentation· Design Specifications & Review Reports· Incident Management Records· Installation Documentation· Programming Standards· Qualification Documents (Installation, Operation & Performance)· Quality Plans & Reports· Service Requirements & Specifications· Source Code & Review Reports· System Requirements & Specifications· User Documentation· Testing Documentation· Validation Plans &	5 Years after Life of System
9	Contracts / Agreements	Documentation detailing the legally binding terms and conditions of agreements between the Company and	Agency Contracts:· Confidentiality Agreements:· Consulting Agreements· Fleet Lease Agreements · License Agreements, Leave and License Agreement· Management Services Contracts· Research Contracts· Service Contracts· Software	To be destroyed 6 years after termination or 8 years following

		other people / organisations.	License Ownership Documentation (License Certificates / Software Reseller Reports / Paid Invoice showing product description & quantity)· Stock Purchase Contracts· Supply Agreements· Vendor Contracts, Distributors Contracts.	the year, in which the last transaction was entered into (whichever is longer)
10	Contributions / Charitable Donations	Records relating to various Company community or charity programmes that provide cash donations, product donations, gifts in kind, or other contributions or donations.	Community / Special Events Files:· Corporate Sponsorship Records:· Matching Gift Programme Files· Patient Assistance Files· Product Donation Records	For not less than 8 years immediately preceding current year
11	Corporate Secretariat Records	Agenda, Notices of Meetings, Resolutions passed by Circulations, Proof of service of Notices	Agenda of Board Meeting, Committees, Notices send to Directors of other persons for such meetings and Proof of services of Notices and Agendas	For such period as the Board may decide but not later than three years from the date of the meeting.
12	Corporate Secretariat Records	Records of the formation and maintenance of the Company and its subsidiaries, including Company formation documents, records of members / shareholders to track the issued share capital of the Group, and records of decisions taken by Company Boards and Board Committees (includes Boards of Company Subsidiaries).	Annual Report & Accounts:· Minutes of Board Meeting, Minutes of General Meeting, Committee Meetings, Exhibits / Attachments / Papers:· Certificates of Incorporation· Corporate Governance Charter· Memorandum & Articles of Association (or equivalent)· Statutory Registers (e.g. Register of Directors, Register of Members / Shareholders, Register of Offices, Share Register)	Permanent

13	Dispute Case Files	Documentation generated during the management of a legal dispute, including claims, litigation and arbitrations.	Discovery Documents· Expert Reports· Key Pleadings, Briefs and Correspondence	6 Years after: Case is Closed, Any Affirmative Obligations Arising from the Case have Expired, or the Statute of Limitations Arising from the Facts of the Case has Run (whichever is longer)
14	Dispute Resolution and Settlement Records	Documentation of the settlement or close of a legal dispute, including claims, litigation and arbitrations.	Dismissal Records:· Judgements:· Releases· Settlement Agreements	20 Years after Settlement / Close
15	Employee Benefits Records	Records documenting individual employee benefits and outcomes.	Insurance Records:· Disability Insurance Records:· Life Insurance Records· Long Term Care Insurance Records· Medical Insurance Records· Pension Records· Savings Plan Records	9 Years after Final Benefit has been Received
16	Employee Health Records	Records of employees' health status and occupational health risks, including documentation of health assessments, case management, work accommodations and absences for work related and non-work related illnesses and injuries.	Case Management Records:· Clinical Histories:· Exposure Limit Records· Exposure Records (Area & Personal)· Exposure Risk Assessments (e.g. Chemical, Noise & Radiation Exposures)· Health Assessment & Surveillance Records· Medical Consultation, Diagnosis, Treatment & Follow-up Records· Preventative & Corrective Action Records· Medical Leave Records	40 Years after Employment Ends

17	Employee Records	Documentation concerning terms and conditions, and employment status of individual employees.	Contract of Employment:· CVs / Resumes:· Employee Background Checks· Employment Terms & Conditions· Employment Eligibility Records· Evidence of Qualifications· Exit Checklist & Interview Records· Global Assignment Agreements· Immigration Records · Job Applications (Successful Applications Only)· Job Descriptions· Maternity Leave Records· Performance & Development Plans (PDPs)· Performance Reviews· Promotion Approvals· Resignation Letters· Salary / Pay Increases & Bonuses· Secondment Agreements· Sign-on Bonus Agreements· Stock Option Grants· Termination Records· Unpaid Leave Authorisations	7 Years after Employment Ends
18	Engineering and Specification Records	Final documentation showing details of buildings and facilities design, specifications and construction.	Building Design & Plans:· Construction Data:· Installation Records· Plant Specifications· Process Hazard Analyses & Associated Action Records· Technical Specifications	6 Years after Life of Building
19	Environment, Health and Safety (EHS) Management Records	Documentation demonstrating compliance with environment, health and safety regulatory requirements and Company policies and standards.	Adverse Event Investigation Records:· Environmental Risk & Impact Assessments:· Health & Safety Risk Assessments· Management Reviews & Programme Reviews· Material & Waste Consignment Records· Material Safety Data Sheets· Performance Data e.g. Environmental Releases, Injury & Illness Rates, etc.· Preventative & Corrective Action Records· Workplace Inspection Records	10 Years
20	Executive Committee Meeting Records	Minutes and exhibits documenting decisions taken by the Company's senior executive team in its operation of the Company.	Corporate Executive Team Minutes:· Meeting Exhibits / Attachments / Papers	25 Years
21	Facilities Management Project Records	Documentation accumulated during the management and execution of building and	Maintenance Project Records:· Mechanical / Electrical Plant Installation & Decommissioning Records· Permits-to-Work· Project Planning, Risk Assessment, Monitoring &	3 Years after Project is Completed

		facilities projects and operations including relocations and refurbishments.	Implementation Files	
22	Fixed Asset Records	Documentation related to long-term tangible assets acquired for use in the operation of the business.	Cost Segregation Files:· Depreciation Schedules· Fixed Asset Registers	For not less than 8 years immediately preceding current year
23	Fleet Records	Documentation relating to employees and their Company owned/leased vehicles received for business purposes.	Driver History Records:· Driver Training Records· Motor Vehicle Records	6 Years after Employment Ends
24	General Ledger Records	Year-end summaries of the profit and loss account and balance sheets that support the published accounts of the Company and its subsidiaries, and the accounts of each Company-defined financial reporting entity.	Year-end Profit & Loss Account & Balance Sheet Summaries	Permanent
25	Grant Records	Documentation relating to grants given to clinical research organisations, investigator sites, and other agencies ororganisations relating to drug / product development.		For not less than 8 years immediately preceding current year
26	Human Resources (HR) Programme Records	Documentation detailing the initiatives and measures of the Company's Human Resources or Personnel programmes other	Diversity Programme Records:· Fitness Centre Records· Organisational Effectiveness Records· Training & Development Records· Wellness Programme Files	3 Years

		than compensation and benefits.		
27	Import / Export Records	Records of movement of goods in cross-border trade including all documents relating to importing and exporting any commodity.	Bills of Lading:· Certificates of Origin· Customs Entry Declaration Records· Export Documentation & Declarations· Hazardous Goods Declarations· Inventories· Invoices· Letters of Credit· Licenses· Packing Lists· Permits· Waybills	For not less than 8 years immediately preceding current year
28	Insurance Records – Claim Records and Programme Records	Documentation detailing insurance claims and management of Company insurance programmes.	Certificates of Insurance:· Insurance Claim Records · Insurance Policy Files (e.g. Bonds, Construction All Risks, Fidelity, Goods-in-Transit, Personal Accident, Property Damage & Business Interruption, Product Integrity, Sports & Social Clubs)· Insurance Rating Adjustments	6 Years after Completed or Expired
29	Insurance Records – Long Latency Liability Insurance Policies	Policy documentation issued to the Company by its insurers for long latency liability cover.	Aviation:· Clinical Trial Phase 1 Volunteers Personal Accident· Directors & Officers Liability· Employers Liability / Workers Compensation· Employment Practices Liability· Excess Liability· Medical Professional Liability· Motor Third Party / Business Auto· Multimedia Professional Liability· Pension Trustees / Fiduciary Liability· Pollution Liability· Product Liability· Professional Indemnity · Public Liability / General Liability	Life of Business
30	Intellectual Property Records	Documentation detailing applications to Intellectual Property Offices for granted intellectual property rights and evidence of intellectual property ownership (e.g. copyrights, patents, trademarks, etc.) excluding abandoned applications.	Copyright Records:· Patent Applications & Renewals· Patent Certificates· Service Marks & Logos· Trademark Applications & Renewals· Trademark Certificates	6 Years after Life of Copyright, Patent or Trademark
31	Legal Project Records	Documentation detailing legal	Agreement Negotiation Files:· Consumer Promotional	6 Years after

		opinions or transactions involving the Company.	Material Review Records· Due Diligence Records· In-licensing & Out-licensing Records· Joint Venture Records· Legal Opinion Records· Legal Research· Mergers, Acquisitions & Divestiture Records	Project Completed
32	Payroll Records	Records relating to payroll disbursements made by the Company to its employees.	Adjustment Records:· Base Pay Records· Bonus Records· Contributions & Loan Payment Files· Garnishment Files· Payroll Deduction Files· Reconciliation Files· Salary Reporting Files· Sales Incentive Records· Special Incentive Records· Supplemental Thrift Reporting Files· Tax Allowance / Exemption Records	For not less than 8 years immediately preceding current year
33	Real Estate Records	Documentation pertaining to land and building holdings and related issues.	Lease Records:· Liens· Master Site Plans, Drawings & Maps· Mortgages· Planning Permissions· Survey Reports· Title Deeds	6 Years after Life of Property
34	Recruitment Records	Documentation pertaining to staffing of vacant positions with internal or external applicants.	CVs / Resumes:· Employment Applications · Interview Notes· Job Advertisements / Postings· Job Descriptions· Work Permit Files	2 Years after Vacancy is Filled or Cancelled
35	Security Investigation Records	Documentation related to various types of investigations, including those pertaining to misconduct by an employee or contractor, fraud, and product tampering.	Counterfeiting Investigation Files:· Employee Background Investigation Files· Findings Records & Action Plans· Intelligence Reports· Investigative Case Files· Product / Competitor / Regulatory Authority Complaints &/or Inquires· Product Tampering	6 Years after Investigation is Completed
36	Site Contamination Assessment Records	Documentation generated as a result of contamination assessments, asbestos surveys and soil and groundwater investigations, including the decommissioning, disposing of or closing of Company sites.	Asbestos Inventories:· Asbestos Survey Records· Contamination Survey Records for Buildings, Facilities & Equipment· Due Diligence Assessments · Material / Equipment Disposal Records· Remediation & Decontamination Records · Soil & Groundwater Investigation & Monitoring Records· Summary of Activities Undertaken at Company Facilities	40 Years after Site Closed
37	Tax Records	Documentation detailing	Benefit Records – Government Filings:· Customs Files ·	Permanent

		Company tax liabilities.	Employee Relocation Files· Income Tax Returns· International Assignment Files· Property Tax Reports· Retirement Savings Plan Files· State Research Files· Summary Annual Reports· Tax Audit Files· Tax Credit Files· Tax Payer Identification Files· Tax Payment Files· Tax Work Papers· Transfer Pricing Files· Value Added Tax (VAT) Files	
<u>Manufacture Products</u>				
1	Audit Records – External Suppliers and Contractors	Documentation relating to the examination of external suppliers and contractors to determine compliance with GMP.	Action Plans & Resolution Records:· Audit Finding Records· Audit Planning Files· Contractor Audit Records· Vendor Audit Records	7 Years after Audit is Closed
2	Audit Records – GMP Regulatory	Records relating to regulatory GMP audits of facilities manufacturing products, intermediates or active pharmaceutical ingredients (APIs) for JHS.	Agreed Actions arising from audits (e.g. Corrective Actions, Preventative Actions):· Audit Reports· Commitments Correspondence· Correspondence between Manufacturing Site and a Regulatory Agency Concerning Regulatory Audits· Follow-up Correspondence e.g. Action Progress Reports, Form of Observations, Audit Findings· Formal Inspection Reports· Observations Correspondence	10 Years after Audit Report Received
3	Batch Related Records - Active Pharmaceutical Ingredients (API)- (A) With Expiration Dates (B) With Retest Dates	Documentation held as evidence of batch quality including raw material supply, testing, dispensing and investigation, and batch preparation, processing, environmental monitoring, testing, storage and	Calibration Equipment Maintenance Records:· Cleaning & Sanitation Records· Deviation Records· Distribution & Shipping Records· Environmental Monitoring Records· Equipment Logbooks· Investigation Reports· Laboratory Test Records· Out of Specification Reports· Packaging Component Supply Records· Process Control Records· Production Control Records· Raw Materials Supply Records· Raw Materials Test	(A) With Expiration Dates - 1 Year after API Batch Expires (unless otherwise specified in the

		distribution.	Records / Certificates· Starting Materials & Intermediates Records	technical terms of supply) (B) With Retest Dates - 3 Years after API Batch is Completely Distributed (unless otherwise specified in the technical terms of supply)
4	Batch Related Records– Intermediate Product, Bulk Product, Filled Product and Finished Product– (A) With Expiration Dates (B) With No Expiration Dates	Documentation held as evidence of batch quality including raw material supply, testing, dispensing and investigation, and batch preparation, processing, environmental monitoring, testing, storage and distribution.	Calibration Equipment Maintenance Records:· Cleaning & Sanitation Records· Deviation Records· Distribution & Shipping Records· Environmental Monitoring Records· Equipment Logbooks· Investigation Reports· Laboratory Test Records· Out of Specification Reports· Packaging Component Supply Records· Process Control Records· Production Control Records· Raw Materials Supply Records· Raw Materials Test Records / Certificates· Starting Materials & Intermediates Record	(A) With Expiration Dates - 1 Year after Finished Product Batch Expires (B) With No Expiration Dates - 4 Years after Batch is Released
5	Computer System Documentation – Manufacturing Applications / Systems	Documentation relating to the design, development, validation, installation, implementation, use and retirement of regulated computer applications / systems.	Access Management Records:· Business Requirements· Change Control Documentation· Compliance Determination & Review Reports· Configuration Management Documents· Data Migration Records· Decommissioning Records· Deployment Documentation· Design Specifications & Review Reports· Incident Management Records· Installation Documentation· Programming Standards· Qualification	7 Years after Life of System

			Documents (Installation, Operation and Performance)· Quality Plans & Reports· Service Requirements· Source Code & Review Reports· System Requirements & Specifications· Testing Documentation· User Documentation· Validation Plans & Reports	
6	Controlled Drugs Records	Documentation demonstrating compliance with controlled substances. (Drugs and Precursors) regulations other than batch specific records.	Annual Returns to Government Departments:· Controlled Drug Register Records· Export / Import / End-user Certificates· Export Summaries· Records of Disposals· Supply Registers.	Permanent
7	Manufacturing Facility (Premises, Equipment, Utilities) Validation Records	Records validating the quality of facility (premises, equipment, utilities) systems and procedures, excluding IT systems, which are not batch-specific. May be once only, produced periodically or generated via ongoing processes.	Change Control Records – Non-Product Specific:· Engineering Drawings & Specifications· Equipment Logs· Facility & Equipment Validation Records· System Validation Records· Vendor Files	7 Years after Life of Facility, Premises, Equipment, Utility
8	Manufacturing Process Validation Records	Records validating the quality of product and process systems and procedures. May be once only, produced periodically or generated via ongoing processes.	Analytical Specifications :· Change Control Records – Product Specific· Method Validation Records· Periodic Product Review Reports· Process Validation Records· Validation Master Plans· Validation Protocols· Validation Reports & Batch Records	1 Year after Last Manufactured Batch of Finished Product Expires (Closing sites archive copies for 7 years after facility closes. Transfer originals to

				receiving site for Product).
9	Master Manufacturing Specifications & Procedure Records	Master records of standard definitions, descriptions or instructions to be followed in order to maintain statutory or regulatory compliance.	Indexes of Master Specifications & Procedures:· Master SOPs (incl. Local SOPs)· Master Batch Records & Master Formula Records· Master Product Packaging Specification Records· Technical Terms of Supply	7 Years after Superseded by New Version
10	Organisation Charts & Job Descriptions (Regulated)	Documents which define reporting lines and responsibilities of individuals with quality and GMP responsibilities at the time of manufacture.	Organisation Charts:· Organograms· Role Specifications	7 Years after Superseded by New Version
11	Product Incident Management Records – Active Pharmaceutical Ingredients (API)	Documentation accumulated during the management of product complaints, product recalls or any other product related incidents.	· Action Plans:· Complaint Records· Evaluation & Decision Records· Findings Reports· Incident Management Reports· Recalls Records· Root Cause Investigations	– With Expiration Dates - 1 Year after Batch Expires or 1 Year after Receipt of Complaint (whichever is longer) – With Retest Dates - 3 Years after Batch is Distributed or 1 Year after Receipt of Complaint (whichever is

				longer)
12	Product Incident Management Records – Intermediate Product, Bulk Product, Filled Product and Finished Product	Documentation accumulated during the management of product complaints, product recalls or any other product related incidents.	· Action Plans:· Complaint Records· Evaluation & Decision Records· Findings Reports· Incident Management Reports· Recalls Records· Root Cause Investigations	– With Expiration Dates- 1 Year after Batch Expires or 1 Year after Receipt of Complaint (whichever is longer) – With No Expiration Dates- 4 Years after Batch is Released or 1 Year after Receipt of Complaint (whichever is longer)

13	Training / Education Employee Records - Manufacturing (Regulated) Training / Education Material Records – Manufacturing (Regulated)	Records of internal and external training and experience that demonstrate an individual's ability to carry out processes in accordance with regulations. Documentation detailing the content of training and education provided to employees and summary evaluation and attendance records.	Competency Assessments:· Completion Certificates· CVs· Environment, Health & Safety Training Records· Lists of Training Undertaken (Procedures, GMP, Technical / Non-technical Training for Role.) · Evaluation Summaries:· Handbooks· Master Presentation Materials· Master Registration / Enrolment Records· Training Completion Records	7 Years after Employment Ends 7 Years after Superseded
Market & Sell Products				
1	Advertising and Promotion Approval Records	Files created and maintained by in-house marketing groups documenting development and internal approvals of promotional materials.	Advertising, Art & Design Records:· Job Bags / Job Jackets· Project Descriptions· Requests for Regulatory Agency Approval & Supporting Documentation· Sample Advertising / Promotional Materials· Specification Sheets	7 Years after Internal Approval
2	Business / Commercial Plans	Information documenting business plans, objectives, strategies, strategic intent, etc. for a specified period of time.	Competitive Analysis Reports:· Contracting Strategy Files· Corporate Strategy Files· Marketing Plans· Product Strategies· Promotion Plans· Situation Analysis Files· Strategic Plans· Tactical Plans	5 Years after Completed
3	Business Development Records	Information reflecting potential business / collaboration and/or licensing opportunities.	Compound/Product Acquisition Records:· Co-Promoted Product Records· In-Licensing / Out-Licensing Records· Joint Venture Records· Partnership Records· Strategic Market Development Records	3 Years after Closed
4	Competitive Information	Information about competitors, their products and/or pipelines.	Competitive Marketing Information:· Competitive Response Files· Competitive Trends Records· Competitor Profiles· Product Competition Files	1 Year after Reference Completed

5	Convention / Symposia Programme Records	Information pertaining to the Company's participation in a convention requested by a product manager or logistics of any symposia event.	Authorisation Letters:· Convention / Symposium Materials and Content· Meeting Planning Records· Promotional Programme Files· Speaker Event Files· Vendor Records	For not less than 8 years immediately preceding current year
6	Customer Interface Records	Transactional information with buying groups, hospitals, physicians, and other customers.	Charge Back Records:· Cost Containment / Frozen Incentive Records· Credit Memos· Free Issue Stock Records· Good Will Credits· Incentive Records· Rebate Files· Rebate Remittance Files· Sales Invoices·	For not less than 8 years immediately preceding current year
7	Customer Interface Records	Transactional information with buying groups, hospitals, physicians, and other customers.	Sales Orders	Routine records - 2 years
8	Healthcare Education Records	Information pertaining to educational resources and programmes provided to healthcare professionals on a range of therapeutic and practice management issues.	Continuing Education Course Records:· Speaker Training Event Files· Sponsorship / Grant Records	For not less than 8 years immediately preceding current year
9	Market Research Studies – Consumer Healthcare Products	Summary reports based on information gathered from questionnaires, surveys, interviews, focus groups, etc. or a specific research study when there is no pre-existing research available.	Internal Reports:· Primary Research Studies· Secondary Research Studies· Vendor Reports	10 Years
10	Market Research Studies – Prescription	Summary reports based on Information gathered from	Internal Reports Analyses:· Primary Research Studies· Secondary Research Studies· Vendor Reports	5 Years

	Products	questionnaires, surveys, interviews, focus groups, etc. or a specific research study when there is no pre-existing research available.		
11	New Product Marketing Records	Information pertaining to the marketing of new products.	Brand Name Market Research:· Commercial Assessment Files· Forecasting Records· Product Viability Records· Trade Naming Documents	5 Years after Product Launch
12	Pricing Information Records	Documentation used to support pricing decisions regarding Company products based on their value and competitiveness.	Backup Pricing Information:· Pricing Meeting Minutes· Pricing Research· Price Lists	16 Months
13	Pricing History Records	Documentation of product pricing from product launch to current price.	Price Lists:· Pricing History Files	Life of Product
14	Product Bids / Contract Records	Documentation of pricing requests and agreements for specific products with group purchasing organisations (GPO), cities, counties, states, sales representatives, individual hospitals, etc. or a public health service (PHS) entity.	Administrative Service Fees Records:· Formulary Activity Files· Government Contract Records· Local / State Entitlement Files · Managed Care Contract Records· National Account Files	For not less than 8 years immediately preceding current year
15	Sales Reporting and Analysis Records	Company sales information including, raw data, market share reports, territory rankings reports etc.	Drug Distribution Data Reports:· End of Month Sales Reports· Hospital Reports· Market Share Trend Reports· Non-Retail Sales Data· Percent Quota & Market Reports· Ranking Reports· Retail Sales Data· Sales Data from Sales Force Automation Systems	2 Years
16	Sample Accountability Records	Documentation of sampling activities for sales	Physical Inventory Reports:· Physician Signature Cards· Sample Accountability Detail Run	3 Years – Presently under

		representatives including documentation of a physician's receipt of product samples.		Litigation hold

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