Annexure-II

Retention Period of Quality Related Documents

Company Logo Here

XX PHARMACEUTICALS LIMITED

117 Adams Street, Brooklyn, NY 11201, USA

Retention Period of Quality Related Documents

Document Type	Document details	Retention period
Administrative Records	Documentation relating to routine administrative activities performed by most departments, regardless of function, such as correspondence, agendas, diaries, etc.	No Longer Than 1 Year
Equipment Records (Non-regulated)	Documentation accumulated as a result of the purchase and use of non-regulated equipment.	No Longer Than 1 Year after Life of Equipment
Inventory Records (Non-regulated)	A detailed list of all goods and materials in stock.	Until Superseded by New Version
Personnel / Supervisory Records	Documentation maintained locally by departmental managers to manage employees. (Company official employee records are covered elsewhere on the Schedule.)	No Longer than Employment Ends
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.	No Longer Than 5 Years
Policies / Procedures (Non-regulated) – Departmental	Policies and procedures outlining departmental operations that are not regulated.	Until Superseded by New Version
Programme / Operational Records (Non-regulated)	Records of ongoing departmental programmes where those programmes are non-regulated.	No Longer Than 3 Years

Project Records (Non-regulated) – Departmental	Records of a specific and time bound task and related activities, where that task is non-regulated.	No Longer Than 3 Years after Completed
Adverse Event Records	Documentation reporting adverse events relating to the Company's investigational /marketed products.	7 Years after Life of Product Line
Audit / Inspection Records	Documentation relating to the examination of internal and external controls, Assurance with policies and procedures and improved process recommendations.	7 Years after Audit is Closed
Clinical Assurance and Quality Assurance Records	Documentation pertaining to quality assurance testing and Assurance controls related to clinical projects and studies.	30 Years
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
Discovery Records	Documentation generated in the course of research and discovery of new compounds,	30 Years
Labeling Records	Documentation relating to labeling approvals and subsequent changes and approvals.	7 Years after Life of Product Line
Policies / Procedures (Regulated)	Documentation of GXP regulated methods, Processes and procedures.	30 Years after Superseded by New Version

Submission / Communication Records	Documents and dossiers submitted to a regulatory agency in support of a request for marketing approval, related correspondence between the Company and the regulatory agency.	7 Years after Life of Product Line
Submission / Communication Records – Out licensed / Sold / Transferred	Documents relating to product / project for which the development / marketing is sold or parts licensed to a third party.	7 Years after Life of Product Line, unless otherwise specified in the license, sale or transfer agreement
Supportive Regulatory Information	Key records relating to obtaining and maintaining product registrations but not submitted to an agency or 3rd party.	7 years
Training / Education Records – R&D (Regulated)	Records of internal and external training and experience that demonstrate staff ability to carry out processes in accordance with regulations.	30 Years after Employment Ends
Audit Records	Documentation relating to the examination of Internal controls, Assurance with policies and procedures, improved process recommendations and financial audits.	3 Years after Audit is Closed
Communication Records – Internal	Internal Company communication materials that are widely distributed throughout the organization or within large business areas.	3 Years
Compensation Programme Records	Documentation detailing terms and conditions of the Company's various compensation programmes.	10 Years after Superseded by New Programme

Computer System Documentation	Documentation relating to the design, development or selection, implementation, use, and retirement of computer applications / systems that are used for regulated processes	5 Years after Life of System
Contracts / Agreements	Documentation detailing the legally binding terms and conditions of agreements between the Company and other people / organizations.	6 Years after expiry of the agreement.
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.	10 Years after Employment Ends
Employee Records	Documentation concerning terms and conditions, and employment status of individual employees.	7 Years after Employment Ends
Engineering and Specification Records	Final documentation showing details of buildings and facilities design, specifications and construction.	6 Years after Life of Building
Environment, Health and Safety (EHS) Management Records	Documentation demonstrating Assurance with environment, health and safety regulatory requirements and Company policies and standards.	10 Years
Facilities Management Project Records	Documentation accumulated during the management and execution of building and facilities projects and operations including relocations and refurbishments.	3 Years after Project is Completed

Human Resources (HR) Programme Records	Documentation detailing the initiatives and measures of the Company's Human Resources or Personnel programme.	3 Years
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.	10 Years after Life of Copyright, Patent or Trademark
Policies and Procedures	Policies and procedures governing significant Company, business unit, region, area or function operations.	5 Years after Superseded by New Version
Real Estate Records	Documentation pertaining to land and building holdings and related issues.	6 Years after Life of Property
Recruitment Records	Documentation pertaining to staffing of vacant positions with internal or external applicants.	2 Years after Vacancy is Filled or Cancelled
Audit Schedules	Audit schedules for internal (Company) and external suppliers and contractors.	7 Years
Audit Records – External Suppliers and Contractors	Documentation relating to the examination of external suppliers and contractors to determine Assurance with GMP.	7 Years after Audit is Closed

Batch Related Records - Active Pharmaceutical Ingredients (API) - With 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.	1 Year after API Batch Expires
Batch Related Records – Intermediate Product, Bulk Product, Filled Product and Finished Product – With 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.	1 Year after Finished Product Batch Expires or minimum five years from the date of manufacturing whichever is the longest period
Manufacturing Facility Validation Records	Records validating the quality of facility systems and procedures which are not batch-specific. May be once only, produced periodically or generated via ongoing processes.	7 Years after Life of Facility
Master Manufacturing Specifications & Procedure Records	Master records of standard definitions, descriptions or instructions to be followed in order to maintain statutory or regulatory Assurance.	7 Years after Superseded by New Version
Organization Charts & Job Descriptions (Regulated)	Documents which define reporting lines and responsibilities of individuals with quality and GMP responsibilities at the time of manufacture.	7 Years after Superseded by New Version

Product Incident Management Records – Active Pharmaceutical Ingredients (API) – With Expiration Dates	Documentation accumulated during the management of product complaints, product recalls or any other product related incidents.	1 Year after Batch Expires or 1 Year after Receipt of Complaint (whichever is longer)
Product Incident Management Records – Finished Product – With Expiration Dates	Documentation accumulated during the management of product complaints, product recalls or any other product related incidents.	1 Year after Batch Expires or 1 Year after Receipt of Complaint (whichever is longer)
Training / Education Employee Records – Manufacturing (Regulated)	Records of internal and external training and experience that demonstrate an individuals ability to carry out processes in accordance with regulations.	7 Years after Employment Ends
Training / Education Material Records – Manufacturing (Regulated)	Documentation detailing the content of training and education provided to employees and summary evaluation and attendance records.	7 Years after Superseded
Annual Product Review Reports	Documentation detailing the annual product quality review of the batches manufactured in the calendar years.	7 Years

Equipment/ instrument calibration records	Calibration master plans & reports.	10 years
Log Books	Duly filled/completed logbooks kept in QA Archive Room.	10 years