

# RECORDS AND PERSONAL DATA RETENTION SCHEDULE



Record Code	Record Type	Description	Retention Period (Years)	Associated Personal Data
30123	ANNUAL PRODUCT REVIEWS	Summary of decisions and timelines for new products added to the pipeline following annual new product selection review.	IND	
40217	ASBESTOS & OSHA CERTIFICATES	Chemical Information sheets, emergency procedures for chemical spills/ingestion. Asbestos abatement/demolition project records; survey records, training records.	30	
40218	AUDIT REPORTS & RECORDS	Audit reports & supportive documentation for both internal & external audits. Includes; Audit committee materials, summary of audit activities, reports & responses, regulatory examination reports & procedures, risk management reports & procedures, safety health & security audit reports, SAS 70 documents, written records of a problem identified by audit documentation of the testing of selected controls documented in FDICIA control matrices, includes internal control documentation for critical business units. Various compliance notebooks and logbooks, correspondence, memorandum, & documents relating to internal control, company policies & the like. Compilation of findings regarding adherence to various regulatory issues. Agency audit information, incoming and outgoing correspondence; USDA related documentation; Site Compliance & Sarbanes Oxley compliance records, Investigation case files (closed).	7	
40241	BLOOD/PLASMA SAMPLES	Blood or Plasma samples used in clinical studies. Retention is 5 years from the date application was approved or 5 years (if not approved) following the date of completion of study from which reserve sample was obtained.	6	Biosamples Clinical Studies

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40219	BUSINESS INFORMATION & ANALYSIS	Business reports & summaries, industry reports & information; Letters of Intent, competitor information, annual product reviews & summary of decisions & timelines for new products added to pipeline following annual new product selection review; portfolio review meeting minutes. Supporting documentation for budget & forecasts for each operating unit. Market research, polls, surveys, analysis & reports. Financial analysis regarding potential new products; Screening documents regarding potential new products including all product opportunities, difficulty rating files & PowerPoint summaries; Tooling related to project plans & deliverables for new product development & sustaining operations. Documents received or created in connection with any portfolio matter; reports providing status of pipeline projects not in active development; summary of development timelines; information supporting special portfolio projects. Product catalogs; specifications; product lists; product pricing sheets; correspondence, data requests, special pricing records & supporting documentation. Sales tracking reports; POS & Ecommerce Sales; Sales history reports; Sales commission reports; Sales forecasts; Operating forecasts/Plans; Distributor sales forecasts; Sales & expense forecasts for new product opportunities; information on sales orders, due dates and back orders.	4	
40246	COMMERCIAL BATCH RECORDS	Commercial Manufacturing batch records not used for validation protocols.	5	

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40227	COMPANY FINANCIAL & TAX RECORDS	Filed Federal & State Tax returns & correspondence; Annual reports to investors forms & reports required by the IRS. Includes:1099s, Form 5500, exemption worksheets, property tax records, etc.; Sales Tax registers; Tax statements; Tax work papers; Tax forms, supporting schedules, assessment notices, tax bills & billing schedules; Employee tax summaries; sales & use tax audit work papers; W2s & unemployment tax files. Official paid checks & check reports; Void check registers. reports on expenses, travel & entertainment payment files. Billing files, vendors correspondence & invoices, credit memos, sales Invoices; relocation expense invoices; union bills annual reports, monthly & quarterly reports, SEC reports; bank statements; balance sheets, account numbers, Monthly, Quarterly & YTD averages, statements of income; depreciation schedules; financial statements; journal entries, documents created or received in connection with any promissory or other financial obligatory document to which the Company is a party. Account reconciliations & back up documentation, general ledger balance sheets, ledger tickets, & daily proof of general ledger balance to accounts. Includes check processing, Accounts payable aging & unvouchered receipts; expense documentation. Amortization records, receipts & invoices for office equipment, work orders & supporting documents concerning bank properties & fixed asset invoices & corresponding setup information, additions to fixed asset system, wire transfer request forms. Cash receipts and wire transfers.	9	
40237	COMPUTER VALIDATION RECORDS - ACTIVE	For validation records only - Project binders for various IT projects, project charters, user requirement specs, project plans, test plans, test scripts, matrices, implementation plans, training plans, hardware & software installation, removal or new security configuration needs. Includes maintenance requests for existing application or systems.	IND	

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40247	COMPANY FINANCIAL & TAX RECORDS (PUERTO RICO)	Retention starts 10 years from the required filing date (9 months past the close of the financial reporting period).Records include filed Fed. & State Tax returns & correspondence; Annual reports to investors forms & reports required by the IRS.1099s, Form 5500, exempt. worksheets, property tax records; sales tax registers; tax statements; tax work papers & forms, supporting schedules, assessment notices, tax bills & billing schedules; employee tax summaries; sales & use tax audit work papers;W2s & unemployment tax files. official paid checks & reports; void check registers. reports on expenses, travel & entertainment payment files, billing files, vendors correspondence & invoices, credit memos ,sales invoices; relocation expense invoices; union bills annual reports, monthly & quarterly reports, SEC reports; bank statements; balance sheets, account numbers, monthly, quarterly & YTD averages, statements of income; depreciation schedules; financial statements; journal entries, documents created or received in connection with any promissory or other financial obligatory documents to which the Company is a party. account reconciliations & back up documentation, general ledger balance sheets, ledger tickets & daily proof of general ledger balance to accounts. check processing, accounts payable aging & unvouchered receipts; expense docs. Amortization records, receipts & invoices for office equipment, work orders & supporting docs. concerning bank properties & fixed asset invoices & corresponding setup information, additions to fixed asset systems, cash receipts, wire transfers.	11	
40244	COMPUTER VALIDATION RECORDS - EXPIRED	For validation records only - Project binders for various IT projects, project charters, user requirement specs, project plans, test plans, test scripts, matrices, implementation plans, training plans, hardware & software installation, removal or new security configuration needs. Includes maintenance requests for expired applications or systems. Retention begins on day system expires.	8	

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Record Code	Record Type	Description	Retention Period (Years)	Associated Personal Data
30054	CONTRACT FILES - ACTIVE	Executed contracts and/or agreements either between the company and third parties or intercompany. Files containing materials prepared or received in the course negotiating or administering any contract. Includes service agreements, CDAs, maintenance contracts, employee agreements including relocation agreements, etc. Notes, drafts, correspondence, memoranda and other documents related to leases of company property. Purchase order forms, requisitions, quotes, supporting documentation. Union contracts and arbitrations.	IND	Employee data - employment purposes; HCP data - KOL relationship management; 3rd party providers data
30105	CONTRACT FILES - EXPIRED	Executed Contracts and or agreements between the Company and third parties or intercompany. Files containing materials prepared or received in the course of negotiating or administering any contract whether executed or expired, includes service agreements, CDAs, maintenance contracts, Employee Agreements including relocation agreements, etc. Notes, drafts, correspondence, memoranda and other documents related to Leases of Company property. Purchase order forms, requisitions, Quotes, supporting documentation. Union contracts and arbitrations.	15	
30106	CORPORATE RECORDS	Corporate records containing shareholder and board minutes, articles, bylaws, stock records, and the like for existing entities; management review meeting records; company information prepared for internal or external release.	IND	
40220	CUSTOMER ACCOUNT & VENDOR FILES	Reports & information provided by the raw material supplier on a specific drug which includes composition, COAs, MSDS and methods; Lab certificates of analysis, raw material C of A, monographs. Files on vendors who sell products or perform services to the company (Not including contracts); Correspondence to vendors for approval of our specs. Information pertaining to current customers, including customer history, Contact information on dealers, distributors, retailers. Customer care logs; Complaint records information regarding orders submitted by customers.	3	

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Record Code	Record Type	Description	Retention Period (Years)	Associated Personal Data
40242	DEA FILES	All DEA records and files required to be kept under this part must be kept by the registrant and be available, for inspection and copying by authorized employees of the Administration. CFR 1304.04 A	3	
40226	EHS/ENGINEERING/FACILITIES RECORDS	Environmental audit reports & related responses, memos, notes, checklists; environmental performance reports, reports from Fire Marshall, hazardous materials business plan, testing, wastes manifests, waste profile sheets, hazardous material transportation, disposal documentation, cleanup records, CERCLA records, waste facility liability records & records related to liability (Cercla and others) associated with facilities used for waste disposal, EPCRA Sections 312 & 313 Tier 2 & 3 annual reporting of hazardous chemical inventory, EPCRA Section 302 notification to SERC and LEPC of listed EHS exceeding established thresholds, Spill Prevention Control & Countermeasure Records, Spill/incident reports, waste facility inspection reports/forms; waste determination records; waste manifests; exception reports; waste reports and related correspondence. Air quality monitoring documents, air sample reports, air permit compliance reports, certifications, & supporting documentation, emission reports & supporting documentation, emission monitoring system records. Building inspections, reports & supporting documentation, includes building & floor layout plans, updates, & redesigns, emergency action plans. Various Compliance notebooks & logbooks, correspondence, memorandum, & documents relating to internal control, company policies, compilation of findings regarding adherence to various regulatory issues. Agency audit information, incoming & outgoing correspondence, USDA docs. State Licenses & Permits (expired)	9	

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Record Code	Record Type	Description	Retention Period (Years)	Associated Personal Data
40228	EMPLOYEE BENEFIT RECORDS	Documentation for active employee enrollment in medical, insurance & 401K plans. Includes disability records, claim forms & unemployment claims pending or settled (not job related injuries). Records relating to active insurance policy operation & management including all note, correspondence, memoranda & policies. Includes pension & 401K plan designs, COBRA files and union benefits.	6	Employee Data - compensation, payroll, and benefits
30170	INFORMATION TECHNOLOGY (IT) - EXPIRED PROJECT DOCUMENTATION - NON VALIDATION RECORDS	(excluding validation records) Project binders for various IT projects. Includes project charters, user requirement specs, project plans, test plans, test scripts, matrices, implementation plans, training plans. Hardware & software installation, removal, or new security configuration needs. Includes maintenance requests for existing applications or systems. IT customer service logs.	7	
40221	INSURANCE	Records relating to active insurance policy operation & management including all notes, correspondence, memoranda & policies. Includes Certificates of Insurance or evidence of insurance coverage for suppliers/vendors or other parties, revised/replaced and outdated policies, directives, instructions & guidelines, expired insurance policies, incident reports, concentra injury & staus reports. WC carrier injury reports, additional physician & physical therapy reports for all closed WC matters.	8	Employee Data - compensation, payroll, and benefits
40222	INTELLECTUAL PROPERTY FILES - EXPIRED	Prior art, opinions, correspondence, amendments, applications, disclosures, work notes, etc. in connection with expired Company patents. Applications, certificates, & registrations with respect to patents filed by or on behalf of the Company. Patent and Trademark Prosecution files, internal and external correspondence, registration, opinions, renewal information, proof of use or otherwise for prosecution of trademark infringement. Trademark application records. RETENTION BEGINS ON DAY THAT PATENT EXPIRES.	10	

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40245	LEGAL HOLDS	All paper and electronic records that have been placed on Legal Hold (once the hold ends, records must be re-coded to the correct record type).	IND	
40229	LITIGATION FILES (EXPIRED)	All complaints, subpoenas, pleadings & other documents prepared, received or otherwise in our possession with respect to settled, dismissed, or otherwise disposed of litigations in which the company has/had been named a party (includes arbitration or mediation). All documents created or received in connection with a bankruptcy proceeding in which the company is a named party.	8	
70000	MANAGED CARE - REIMBURSEMENT FROM FEDERAL HEALTH CARE PROGRAMS	All documents and records relating to reimbursement from the Federal health care programs, pricing documents and managed care contracts	10	
40230	MARKETING & SALES RECORDS	Documentation & supporting material for marketing campaigns, promotional materials & products. Brochures (past copies), advertising records & direct mail. Monthly sales meeting materials, sales promotional slides, fees for service including-speaker training & attendance, payment to speakers, consultant attendance, evaluation forms, customer orders, Patient Assistance Program (PAP) documents, convention fund requests, physician signature audits, inventory reconciliations, physician acknowledgement of deliveries.	10	HCP Data - product detailing, product promotion, product service and sales, KOL management; Employee Data - compliance; Patient Data -- patient engagement, request fulfillment; Consumer data - responding to request

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40235	MSDS RECORDS/OSHA MEDICAL & EMPLOYEE EXPOSURE RECORDS	MSDS records, reports & information provided by the raw material supplier on a specific drug which includes composition, COAs, methods; lab certificates of analysis, raw material C of A, monographs. OSHA - Medical & employment questionnaires, medical history, medical diagnosis, doctor medical opinions/recommendations/progress notes, first aid records, current & previous medication taken, medical treatment, medical complaints, medical claims, environmental & biological workplace monitoring, material safety data sheets, chemical inventory. Incident investigations, citations, injury reports, OSHA logs, summary of occupational injuries & illnesses, safety records & inspections, records of accident or incidents that happen on the job for internal & OSHA uses. Documents & files relating to closed incident/case investigations, EEO case files.	30	Employee Data - compensation, benefits and regulatory reporting
40240	PERSONNEL RECORDS - APPLICANTS NOT HIRED	Employment application from applicants who were not hired.	3	Employee Data - workforce recruiting
40223	PERSONNEL RECORDS - HIRED	Employee attendance recs. time sheets, personal leave/vacation/disability records, alternative & reduced work arrangements, labor distribution records, company org charts. employee drug screening results & reports, tuition reimbursement guidelines, course of study applications, grade reports & documentation, garnishments, liens & levies served on the bank or issued against bank customer accounts, legal reviews & advice regarding same. VISA forms & correspondence applications/extensions, work permits & immigration status, job descriptions, position requisitions, candidates interviewed, no interest resumes, new hire forms, AA/EEO info (race & ethnicity), EEO tracking log, vital statistics rpts, names of applicants received through agencies and referrals, recruiting files; Exit interview questionnaires. Payroll registers, earnings logs, transaction forms, financial institution retirement funds, report of contributions & defined contributions plant participant statements, Master controls, Labor distributions, severance worksheets, check registers; salary ledgers, enrollment forms & work papers regarding deferred payment instructions, status reports for listing earnings and deductions withholding information. Offer letter, confidentiality agreement, application, resume, acknowledgement forms, background check forms, medical recs and complaints, FMLA docs, retirement data, deceased retiree files.	9	Employee Data - workforce recruiting, employment purposes.

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Record Code	Record Type	Description	Retention Period (Years)	Associated Personal Data
20052	PUBLIC RELATIONS/CORPORATE COMMUNICATIONS	Records relating to news releases, press releases, newspaper submissions and slide presentations and speeches.	10	
40238	QA/QC LABORATORY COMPLIANCE-PRODUCT RELATED - ACTIVE VALIDATION RECORDS	Active validation records, compliance certificates, clinical trial records-study completed-no FDA application filed, clinical trial records-IND withdrawn, active batch records (executed), calibration records (active equipment), executed change control forms, clinical trial records-NDA approved.	IND	Clinical Trial Subject Data
40224	QA/QC LABORATORY COMPLIANCE-PRODUCT RELATED FOR EXPIRED VALIDATION RECORDS	(Does not include active validation records). Retired project documentation and computer/IT systems. Completed Master Formula & docs for manufacturing of NDA product batches for submissions/Validation. Packaging data paper recs to support commercial batch/lot. Bioequivalency studies, change requests to update GMP docs, various compliance notebooks/logbooks, correspondence/memo/docs relating to internal control & drug products, company policies. Compilation of findings for adherence to various regulatory issues. Agency audit info, incoming/outgoing correspondence; USDA related docs, executed component & commodity specs, testing docs to printed components, customer care logs, complaint records, docs that investigates manufacturing deviations, original documentation for discontinued products including master formula, batch records, methods/validation records, & specs, field alert reports & docs, diverse types of printed material generated or used by incoming dept. cycle counts, inventory adjustments, physical inventory records for all products, storage areas info for temperature/humidity, various testing descriptions, internal test data, all forms & inventory control recs by QC Lab, tabulated schedule logbooks on stability, packaging & compounding processes recs/logs (including record machine, product & line info) packaging batch recs, raw material release data, product manufacturing instructions, calibration recs, quality reports, specification sheets, QA snapshots, scorecards, metrics, procedure change requests and stop ship requests.	10	Clinical Trial Subject Data

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<b>40239</b>	QA/QC SAMPLE PRODUCTS	Finished product samples; complaint sample retention.	<b>4</b>	Clinical Trial Subject Data - AE and Complaint reporting; Patient Data - AE and Complaint reporting
<b>30148</b>	R&D-ANALYTICAL DEVELOPMENT RECORDS	R&D files pertaining to analytical data generated in the development of a product including testing results, chromatograms, research batches, method/process validation & development, raw data, stability records, stability testing including room temperature studies, cool heat studies, accelerated studies, packaging compatibility, finished product stability hard cards, stability risk analysis, visual exam stability samples, retained sample inspection forms, retain sample request forms, sample result summary stability test reports. analytical reports-information & testing in the development of a product, analytical development reports used to support ANDA submissions, special testing studies done for an analytical product, original signed DV versions of specifications and methods.	<b>10</b>	Clinical Trial Subject Data - Phase 1-3 Clinical Studies
<b>30030</b>	REBATE PROCESSING FILES/GOVERNMENT PRICING	Monthly, quarterly payments, via credit or check with supporting WRS and MFG/PRO reports, Medicaid invoices & payment records for rebates paid for governmental programs.AMP calculations (from date of submission), best price calculations, FAMP & FCP calculations, Industrial Funding Fee - calculations & payments.	<b>10</b>	
<b>30078</b>	RECALL FILES	Product recall information & supporting documentation.	<b>10</b>	Patient Data - regulatory reporting

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<b>30113</b>	REGULATORY FILES/R&D FILES	Corporate file copy of documents submitted to the FDA for the approval of the drug product for commercial marketing including original submissions, back-up documentation, supplements, annual reports submitted to FDA, inserts & outsert text for all NDAs, Job tickets associated with tracking a labeling submission, old label records & labeling destruction reports. Original documents submitted to FDA for withdrawal of drug product from commercial marketing, documents associated with listing drug products with the FDA for commercial marketing, docs associated with the approval of drug products onto various state & Medicaid formularies. Pharmacovigilance, adverse event reporting.	<b>IND</b>	Clinical Trial Subject Data
<b>40231</b>	SHIPPING & RECEIVING RECORDS	Pink slips, shipping request forms, shipment detail reports, shipment logs, customs documents, waybill forms, packing lists & bills of lading, delivery receipts, air bills, import documentation.	<b>5</b>	
<b>3992</b>	STORAGE TANK RECORDS	Storage tank install/close records, registration records, and tank release detection records.	<b>IND</b>	
<b>1452</b>	TRAINING DOCUMENTATION	Training Records for GMP, Regulatory and Pharmacovigilance including documents & materials, basic written records, field training records, classroom written records, inhouse/outside training database & reports, continuing education, certificates.	<b>9</b>	Employee Data - employment purposes

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40233	TRAINING DOCUMENTATION 2	Training Records for EHS, Employee Training & Development, IT, Ethics & Compliance including documents & materials, basic training written records, field training and classroom written records, inhouse/outside training database & reports, continuing education, certificates. Sales recorded quality control messages used for training.	3	Employee Data - employment purposes
40225	TRANSACTIONAL DOCUMENTS	Documents that have been prepared, received, or gathered in connection with any due diligence conducted on behalf of or in relation to any transaction in which the company is a potential party. Files containing correspondence, notes, drafts, memoranda, opinions, with respect to legal matters not in litigation; Includes legal reference books, copies of forms, and other legal resource materials. Correspondence, analysis sheets, and materials relative to important transactions, notes, organizational charts, monthly and quarterly financials, legal correspondence and settlements. Documents received or created in connection with any Portfolio matter; reports providing status of pipeline projects not in active development; summary of development timelines; information supporting special portfolio projects. Product catalogs; specifications; product lists; product pricing sheets; correspondence, data requests, special pricing records and supporting documentation.	9	Employee, HCP, other data -- Merger & Acquisition Data
40234	WORKERS COMPENSATION - INACTIVE	WC - claims, medical claims, denied claims for permanently & totally disabled workers, medical review files, contested WC case hearing.	12	Employee Data - compensation, payroll and benefits; regulatory purposes

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