RxLogix Corporation

Glossary

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Revision History

Version	Author	Issue Date	Description of Change
1.0	Linda D. Mier	28-Dec-2016	Initial document
2.0	Linda D. Mier	15-Feb-2017	Updated to include additional definitions, including: auditor, Engagement Manager (EM), RxLogix Managed Services, RxLogix Professional Services, Acceptance Testing, Acceptance Test Plan (ATP), Acceptance Test Report (ATR), Central Processing Unit (CPU), Good Documentation Practices (GDP), Random Access Memory (RAM), System Test Plan (STP), Test Script, Validation Plan (VP), Validation Report (VR), Validation Summary Report (VSR) Expanded the definition of DevOps.
3.0	Linda D. Mier	23-Mar-2017	Updated to include additional definitions including Acceptance Test Report, bespoke system, custom built system, out-of-the-box (OOB), SaaS. Added cross references between System Testing and OQ, Acceptance Testing and PQ.
4.0	Linda D. Mier	04-Apr-2017	Removed invalid cross reference from Test Plan. Split Executive and Executive Staff into two separate entries. Changed “RxLogix Professional Services” to “Professional Services”. Definitions added, including: Clinical trial, comparator, company core data sheet (CCDS), Computer System Validation (CSV), European Economic Area (EEA), Executive management, hardware (HW), healthcare professional, individual case safety report (ICSR), medicinal product, periodic safety update report (PSUR), post-authorization study, protocol, Qualified Person for Pharmacovigilance (QPPV), reporter, Risk Management System (RMS), software (SW), solicited source of Individual Case Safety

			Reports, sponsor, spontaneous report, supplier, vendor.
5.0	Mustafa Abdallah	28-Jul-2017	Corrected a couple of typos in acronym HW in v4.0 Revision History. Definitions added, including: End of Study Unblinding (EOSU),Health Insurance Portability and Accountability Act (HIPAA), Design Specification (DS), Configuration Specification Document (CSD), Requirements Traceability Matrix (RTM)
6.0	Srividhya Sivakumar	21-Jan-2020	Revamped the Glossary as part of periodic revision

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1.0 PURPOSE

This Guideline is a glossary defining acronyms and terms used in RxLogix policies, procedures, guidelines and associated deliverables.

2.0 SCOPE

The scope of this Guideline includes definition of acronyms and terms used in RxLogix business practices. This glossary may be referenced by any RxLogix document.

Document-specific definitions may be included in individual documents and supersede the definitions in this Glossary.

3.0 GENERAL

3.1 Roles and Responsibilities

Applicable to all of RxLogix personnel

4.0 Guideline Information

Term / Abbreviation	Definition
Adverse Drug Reaction (ADR)	(EMA) A noxious and unintended response to a medicine.
Adverse Event (AE)	(1) FDA) An adverse event or drug reaction is also known as a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life- threatening, result in hospitalization or death, or are birth defects. (2) (EudraLex Volume 9A): Any untoward medical occurrence in a patient or clinical-trial subject administered a medical product and which does not necessarily have to have a causal relationship with this treatment (Article 2(m) of Directive 2001/20/EC). An adverse event can, therefore, be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. (3) (EMA) An untoward medical occurrence in a patient taking part in a clinical trial.
Adverse Reaction	(EudraLex Volume 9A) A response to a medical product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function (Article 1(11) of Directive 2001/83/EC). Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (see ICH E2A Guideline). Adverse reaction also includes adverse clinical consequences associated with use of the product outside the terms of the Summary of Product Characteristics or other conditions laid down for the marketing and use of the product (including prescribed doses higher than those recommended, overdoses or abuse).
AGILE	Agile is a time-bound, iterative approach to software delivery that builds software incrementally from the start of the project, instead of trying to deliver all at once.
Audit Criteria	Audit criteria are a set of policies, procedures or requirements against which collected audit evidence is compared.
Audit	(ISO 9000) Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Audit Observation	Statement of fact made during an audit and substantiated by objective evidence.

Term / Abbreviation	Definition
Auditee	An organization or part of an organization (business area/technical area) that is being audited.
Auditor	The person who conducts an audit.
BACKLOG	This is the collection of Epics and Stories awaiting development
Business Continuity Plan (BCP)	A set of activities to define how RxLogix can maintain critical operations in the event the applications, systems or IT Services used to support those activities are no longer available.
Business Critical Service	A functionality or service which if interrupted would cause the company to suffer financial, legal or other damages or penalties. RxLogix's Business Critical Services are those that support the day to day business operations, ongoing software development, client application hosting and client managed services.
CAPA	Corrective and preventive action
Change Management	(ICH Q10) A systematic approach to proposing, evaluating, approving, implementing and reviewing changes.
CIMS	Change and Issue Management System
Code of Federal Regulations (CFR)	An annual publication which contains regulations of Executive Departments and Agencies of the Federal government. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is divided into chapters that bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. FDA's regulations are in Title 21, Parts 1-1271.
Compliance	Conformity and adherence to policies, plans, procedures, laws, regulations, contracts, or other requirements. For audits: Affirmative indication or judgment that the supplier of a product or service has met requirements.
Computer System Validation (CSV)	Establishing documented evidence that provides a high degree of assurance that a computer system will meet the required specifications. A computer system consists of software, network components, hardware interfaces to other systems, the users, training and system documentation.
Configuration Specification Document (CSD)	A document that defines the construction and components build of a software product within a computerized system.
Conformance	For audits: An affirmative indication or judgment that a product or service has met the requirements of the specs or regulations
Consumer	EudraLex Volume 9A: A person who is not a healthcare professional, such as a Patient, lawyer, friend or relative/parents/children of a Patient.
Contract	A contract is a signed agreement especially one concerning employment, services, sales, or tenancy, that is intended to be enforceable by law.

Term / Abbreviation	Definition
Control of Records	Records to provide evidence are controlled Documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of quality records. Records must be legible, readily identifiable
Controlled Copy	A formal copy of the latest, approved version of a document. A controlled copy must be systematically tracked, updated and stored for use. This can be either in electronic format such as in Document Library, email , scanned pdf or in paper format.
Correction	Action to eliminate a detected nonconformity.
Corrective Action	Action to eliminate the cause of a detected non-conformity or other undesirable situation. Action to eliminate the cause of a nonconformity and to prevent recurrence
Corrective and Preventive Action (CAPA)	(1) (ISPE) A quality system defined by 21CFR 820.100; the policies, procedures, and support systems that enable a firm to assure that exceptions are followed up with appropriate actions to correct the situation, and with continuous improvement tasks to prevent recurrence and eliminate the cause of potential nonconforming product and other quality problems. (2) (21CFR 820.100) A systematic approach that includes actions needed to correct (“correction”), prevent recurrence (“corrective action”), and eliminate the cause of potential nonconforming product and other quality problems (preventive action)
Critical	Audits perspective : Any nonconformity which may result in hazardous or unsafe conditions for individuals using, maintaining or depending upon the product or prevent performance of a vital products. Application perspective: Application is accessible, however, there is loss of data/memory leak related issues or critical functionality is available, but the application cannot be accessed unless issue is resolved, or issues related to regulatory compliance.
Curriculum	Training item(s)/course(s) related to a job role or position.
Database	(ANSI) A collection of interrelated data, often with controlled redundancy, organized according to a schema to serve one or more applications. The data are stored so that they can be used by different programs without concern for the data structure or organization. A common approach is used to add new data and to modify and retrieve existing data.
Database Administrator (DBA)	A person who directs or performs activities related to maintaining a successful database environment.
DBA	Database Administrator
Defect	A defect reported against a particular product version. A defect may also be referred to as a “Bug”, “Variance”, “Problem” or an “Issue”
Demo	For software development: Demonstration of the outputs of a Sprint to the Product Owner

Term / Abbreviation	Definition
Design Specification (DS)	A document that details the technical layout, configuration and structure of the hardware/software that make up a computerized system/product.
Developer (DV)	A person, or group, that designs and/or builds and/or documents and/or configures the hardware and/or software of computerized systems.
Development Manager (DM)	Person responsible for managing the software development for an RxLogix product or project.
Deviation	A departure from the process/tasks in an approved SOP, WI, or Plan (such as a Validation or Test Plan).Deviation can be Approved Deviations or Non Conformance
DevOps	Development Operations and Infrastructure. The RxLogix DevOps team is responsible for configuring, monitoring, and maintaining infrastructure and applications in RxLogix and hosted environments.
Disaster Recovery Plan (DRP)	A document that lists the resources, actions, tasks and standard operating procedure / work instructions required to manage application and service recovery process in the event of a major disruption or crisis event.
Document Control	Ensuring that documents are reviewed for adequacy, approved for release, distributed to and used at the location where the prescribed activity is performed. Obsolete documents are to be retained.
Effective	For documents: version that is currently applicable.
Effectiveness Check	For CAPAs: Verification activity conducted after the corrective and preventive actions for a CAPA have been implemented to ensure that those actions were effective and fully resolved the CAPA root cause(s).
End of Study Unblinding (EOSU)	End of Study Unblinding is an optional module that can be installed for Oracle Argus Safety or Oracle ArgusJ to manage unblinding of clinical trial cases upon completion of the study.
End User	(ANSI) (1) A person, device, program, or computer system that uses an information system for the purpose of data processing in information exchange. (2) A person whose occupation requires the use of an information system but does not require any knowledge of computers or computer programming. See: user.
Epic	For software development: An epic is a high level collection of requirements that group together requirements for related system functions (known as Stories)
EudraLex	EudraLex is the collection of rules and regulations governing medicinal products in the European Union.
Finding	For audits: The results of an evaluation of the collected audit evidence against the audit criteria. Findings can indicate conformity or nonconformity with audit criteria or opportunities for improvement.
Form	A form is a place to record data. A form with data is now a record. A record provides objective evidence of data, activities, etc.,
Good Automated Manufacturing Practice (GAMP)	(ISPE) A system for producing quality equipment using the concept of prospective validation following a life cycle model. Specifically designed to aid suppliers and users in the pharmaceutical industry.

Term / Abbreviation	Definition
Good Clinical Practice (GCP)	(EMA) A code of international standards concerning the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials. Good clinical practice provides assurance that a study's results are credible and accurate and that the rights and confidentiality of the study subjects are protected.
Good Documentation Practices (GDP)	The handling of written or pictorial information describing, defining, specifying and/or reporting of certifying activities, requirements, procedures or results in such a way as to ensure data integrity.
Good Laboratory Practice (GLP)	(1) (EMA) A code of standards concerning the testing of medicines in laboratories during their development. (2) (MHRA) GLP embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.
Good Manufacturing Practice (GMP)	(EMA) A code of standards concerning the manufacture, processing, packing, release and holding of a medicine. (ISPE) A system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: a) Unexpected contamination of products, causing damage to health or even death. b) Incorrect labels on containers, which could mean that patients receive the wrong medicine. c) Insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.
Good Pharmacovigilance Practice (GVP)	(EMA) A set of measures drawn up to facilitate the performance of the safety monitoring of medicines in the European Union.
Guideline	(1) A guideline is a statement by which to determine a course of action. A guideline aims to streamline particular processes according to a set routine or sound practice. By definition, following a guideline is never mandatory. Guidelines are not binding and are not enforced. (2) (EMA) A document providing guidance on the scientific or regulatory aspects of the development of medicines and applications for marketing authorization. Although guidelines are not legally binding, applicants need to provide justification for any deviations.

Term / Abbreviation	Definition
GxP	General term for Good Practice as observed in the pharmaceutical industry, encompassing Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP)
GxP Record	Any document or record generated as required to be maintained under GxP predicate rules. These may be maintained electronically or in paper format. This applies to GxP Applications or Infrastructure that supports a GxP system.
Job Descriptions	A job description specifies the daily tasks and objective of a role. The job description organizes the list of responsibilities and authorities for each role and instructs us of what its responsibility.
Healthcare Professional	(Eudralex Volume 9A) For the purposes of reporting suspected adverse reactions, healthcare professionals are defined as medically qualified persons, such as physicians, dentists, pharmacists, nurses and coroners. In addition, the MHRA accepts reports from the following healthcare professionals: midwives, health visitors, radiographers and optometrists
Health Insurance Portability and Accountability Act (HIPAA)	A US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.
Human Resources (HR)	The area of the organization concerned with the hiring and welfare of employees.
Incident	(ITIL) An unplanned interruption or reduction in quality of an IT service (a Service Interruption).
Individual Case Safety Report (ICSR)	(Eudralex Volume 9A) A document providing the most complete information related to an individual case at a certain point of time. An individual case is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products to an individual patient at a particular point of time.
Infrastructure	The hardware, software, network resources and services required for the existence, operation and management of an enterprise IT environment.
Installation Qualification (IQ)	(FDA) Establishing confidence that process equipment and ancillary systems are compliant with appropriate codes and approved design intentions, and that manufacturer's recommendations are suitably considered.
Institute of Electrical and Electronic Engineers (IEEE)	An organization involved in the generation and promulgation of standards. IEEE standards represent the formalization of current norms of professional practice through the process of obtaining the consensus of concerned, practicing professionals in the given field.
Internal audit	An, independent, objective assurance and consulting activity designed to add value and improve an organization's operations.
Issue	An issue is an event or condition that, if left unattended can have negative consequences for a product/project. The term implies a situation that is recoverable or that can be mitigated in some way.
JIRA	Agile project management software package from Atlassian that is used to track requirements and manage defects.

Term / Abbreviation	Definition
Knowledge Management	(ICH Q10) Systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components.
Lifecycle	(ICH Q8) All phases in the life of a product from the initial development through marketing until the product's discontinuation.
Major	An absence of, or the total breakdown of, a system to meet the requirements of the QMS of RxLogix or any applicable regulatory and statutory requirements. A significant number of minors can represent a total breakdown and thus be considered as a major A significant non-compliance with the QMS standard requirement An absence/failure of a complete system
Market Authorization Holder (MAH)	(EMA) The company or other legal entity that has the authorization to market a medicine in one, several or all European Union Member States.
Medicinal Product	(Eudralex 9A) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, metabolic action, or to making a medical diagnosis (Article 1(3) of Directive 2001/83/EC).
Minor	An isolated witnesses incident of a failure to comply with a procedure/document or quality system requirement A minor problem area which warrants attention A minor nonconformance is defined as an incident that does not meet the QMS and other statutory and regulatory requirements, but that does not have any major consequences. This means, that the nonconformance will not result in a failure or majorly weaken your QMS.
Nonconformance	A non-conformance (or 'nonconformity') means that something went wrong. The non-conformance could be in a service, a product, a process, goods from the organization or a supplier, or in the management system itself. It occurs when something does not meet the specifications or requirements including statutory and regulatory requirements. A nonconformity is any failure to meet a requirement. A requirement can be that of a customer's, statutory or regulatory body, ISO requirements, RxLogix QMS.
Observation	A statement of fact made during an audit and substantiated by objective evidence and auditor's informational comments, as applicable, based on an assessment of the system/application in question
Obsolete	For documents: No longer used. Sometimes called "retired".
Operational Qualification (OQ)	(FDA) Establishing confidence that process equipment and sub-systems are capable of consistently operating within established limits and tolerances.

Term / Abbreviation	Definition
Out-of-the-box (OOB)	Out-of-the-box refers to commercially available software that can be purchased and installed for production use.
Performance Indicators	(ICH Q10) Measurable values used to quantify quality objectives to reflect the performance of an organization, process or system, also known as "performance metrics" in some regions.
Performance Metrics	(ICH Q10) Measurable values used to quantify quality objectives to reflect the performance of an organization, process or system, also known as "performance indicators" in some regions.
Performance Qualification (PQ)	(FDA) Establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety.
Periodic Safety Update Report (PSUR)	(Eudralex Volume 9A) Periodical reports containing the records referred to in Article 104 of Directive 2001/83/EC and in Article 24(3) of Regulation (EC) No 726/2004.
Personally Identifiable Information (PII)	Any information relating to an identified or identifiable natural person ('data subject') ; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological,genetic, mental, economic, cultural or social identity of that natural person
Pharmacovigilance (PV)	(EMA) Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
Policy	A policy sets forth general overarching guiding principles on key business practices to which the Company and its employees must adhere.
Post-authorization Study	(Eudralex Volume 9A) A pharmacoepidimiological study or a clinical trial carried out in accordance with the terms of the marketing authorization, conducted with the aim of identifying or quantifying a safety hazard relating to an authorized medicinal product (Article 1(15) of Directive 2001/83/EC).
Preventive Action	(Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.
Process	A series of repeatable actions or steps taken in order to achieve a desired result
Product	The result of activities or processes (i.e., hardware, software, manuals, and technical support services).
Product Owner	The Product Owner (PO) is a member of the Agile Team responsible for defining Stories and prioritizing the Product Backlog to streamline the execution of program priorities while maintaining the conceptual and technical integrity of the Features or components for the product.
Professional Services	Whole of the process instructed by means of guidelines, prepared and designed in systems along with corroborating practices which can be accomplished a product(s) of an organization to organize, supply, function as well as manage IT solutions provided to clients.

Term / Abbreviation	Definition
Project Manager (PM)	(ISPE) Person responsible for delivering the successful project outcome.
PS	Project Sponsor
Proposal	A business document that announces and provides details about a project, as well as solicits bids from contractors who will help complete the project.
Protocol	1) Computer Systems: (ISO) A set of semantic and syntactic rules that determines the behavior of functional units in achieving communication. 2) Clinical Trials: (FDA) A study done to answer a question. Other words to describe a protocol are “research,” “study,” and “experiment.” “Protocol” also refers to the plan that details what researchers will do during the study.
PSUR	Periodic safety update report
PV Central (PVC)	PV Central is a global monitoring and early detection tool developed by RxLogix enabling you to monitor, easily manage and control compliance, productivity, and signal management.
PV DataHub(PVD)	PV DataHub is a homogenized data warehouse solution that stores the data in one place for easy and faster access and allows the consumer to process or add value to the data. PV DataHub provides the safety data in a denormalized manner for faster querying and reporting for signal detection and analytics purposes. It can be integrated with multiple safety data/clinical data entry systems and provides the data in a E2B R3 based standard data model structure.
PV Intake (PVI)	PV Intake is a user friendly system developed by RxLogix providing the ability to enter cases from variety of sources using a Web Form as well as mobile devices. In addition, it provides ability to automate case transfer from a variety of systems such as Electronic Data Capture (EDC) or Call Center systems to a Safety system.
PV Reports (PVR)	PV Reports is an advanced, user-friendly and self-service tool developed by RxLogix for Regulatory Reports, Ad-HOC Reports, OOB Spotfire Integration and Visualizations.
PV Signal (PVS)	PV Signal is a signal detection and management solution developed by RxLogix. It is fully compliant with EU GPV Module IX regulations. It provides a dynamic data mining environment for detecting signals, uncovering patterns, and recognizing emerging trends in spontaneous adverse event report data.
QA	Quality Assurance
QMS	Quality Management System
Quality	(ICH Q9) The degree to which a set of inherent properties of a product, system or process fulfils requirements.

Term / Abbreviation	Definition
Quality Assurance (QA)	(1) (ISO) The planned systematic activities necessary to ensure that a component, module, or system conforms to established technical requirements. (2) All actions that are taken to ensure that a development organization delivers products that meet performance requirements and adhere to standards and procedures. (3) The policy, procedures, and systematic actions established in an enterprise for the purpose of providing and maintaining some degree of confidence in data integrity and accuracy throughout the life cycle of the data, which includes input, update, manipulation, and output. (4) (QA) The actions, planned and performed, to provide confidence that all systems and components that influence the quality of the product are working as expected individually and collectively. (5) (ISO 9000) Part of quality management focused on providing confidence that quality requirements are fulfilled.
Quality Management	(ISO 9000) Coordinated activities to direct and control an organization with regard to quality.
Quality Management System (QMS)	(1) A Quality Management System establishes standards, policies, procedures, and quality objectives and ways to achieve those objectives. (2) (ISO 9000) Management system to direct and control an organization with regard to quality.
Quality Manual (QM)	Document specifying the quality management system and information security system of RxLogix.
Quality Policy	(ISO 9000:2005) Overall intentions and direction of an organization related to quality as formally expressed by senior management.
Quality Record	A document that states results or shows evidence of performed activities.
RA	Risk Assessment
RCA	Root Cause Analysis
Release	(IEEE) The formal notification and distribution of an approved version.
Request for Proposal (RFP)	A document that solicits a proposal, often made through a bidding process, by an agency or company interested in procurement of a commodity, service or valuable asset, to potential suppliers to submit business proposals. Includes both the method proposed and the pricing.
Request for Quotation (RFQ)	A standard business process whose purpose is to invite suppliers into a bidding process to bid on specific products or services. Focuses on pricing.
Requirement	(IEEE) (1) A condition or capability needed by a user to solve a problem or achieve an objective. (2) A condition or capability that must be met or possessed by a system or system component to satisfy a contract, standard, specification, or other formally imposed documents. (3) A documented representation of a condition or capability as in (1) or (2).

Term / Abbreviation	Definition
Requirements Traceability Matrix (RTM)	A document that links all the requirements throughout the validation process to ensure that all requirements defined for a system/product are tested in the test protocols. The RTM is considered a living document that captures the entire set of requirements as the system/product evolves.
Reporter	(ICH E2B(R3)) A reporter is the source of the information, that is the person who reports the facts.
Resource	An employee or a contractor working on a project governed by RxLogix procedures
Retrospective	Software development: A review of lessons learned from completed Sprints
RFP	Request for Proposal
RFQ	Request for Quotation
Risk Management System (RMS)	(Eudralex Volume 9A) A risk management system shall comprise a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to medicinal products, including the assessment of the effectiveness of those interventions (Article 34 of Regulation (EC) No 1901/2006).
RMS	(1) RxLogix Managed Services (2) Risk Management System
Root Cause	(ASQ) A factor that caused a nonconformance and should be permanently eliminated through process improvement.
RTM	Requirements Traceability Matrix
RxLogix Managed Services (RMS)	RxLogix group that handles managed service projects. RxLogix Managed Services is a sub-group of RxLogix Professional Services
SaaS	Software as a Service
SCLM	System Configuration Management Plan
Scrum	A regular team meeting among the cross functional stakeholders to discuss project status, share information and decide on the next course of actions.
Software Development Lifecycle(SDLC)	Software Development Life Cycle (SDLC) is a process used by the software industry to design, develop and test high quality softwares.. SDLC is a framework defining tasks performed at each step in the software development process.
Senior Management	Personnel) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources within the organization.
Server	A computer or computer program that manages access to a centralized resource or service in a network.
Service Level Agreement (SLA)	A Service Level Agreement is a contractual agreement on the level of service to be provided by a service provider to a customer, commonly used in computer-related services
Service Request (SR)	A formal request from a user for something to be provided – for example, a request for information or advice; to reset a password; or to install a workstation for a new user.

Term / Abbreviation	Definition
Software as a Service (SaaS)	Software as a Service is a software licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted.
Solicited Source of Individual Case Safety Reports	(Eudralex Volume 9A) Organized data collection schemes which include clinical trials, registries, named-patients use programs, other patient support and disease management programs, surveys of patients or healthcare providers or information gathering on efficacy or patient compliance. For the purposes of safety reporting, solicited reports should be classified as ICSRs from studies and therefore should have an appropriate causality assessment by a healthcare professional or the MAH.
Source Code	(1) (IEEE) Computer instructions and data definitions expressed in a form suitable for input to an assembler, compiler or other translator. (2) The human readable version of the list of instructions [program] that cause a computer to perform a task.
Sponsor	(ICH E6) An individual, company, institution, organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Spontaneous Report	(Eudralex Volume 9A) An unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organization (e.g. World health Organization (WHO), a regional center, a poison control center) which fulfils the following three conditions: • It describes one or more suspected adverse reactions in a patient; • The patient was given one or more medicinal products; • It does not derive from a study or any organized data collection scheme. Healthcare professionals or consumers may be stimulated to report a suspected adverse reaction by several situations including • A Direct Healthcare Professional Communication; • Early Post-Marketing Phase Vigilance (EPPV), e.t. in Japan; • A report in the press; • Direct questioning of healthcare professionals by company representatives. In these circumstances, provided the report meets the three conditions above, it should be considered a spontaneous report.
Spotfire	A data analytics and visualization software marketed by Tibco.
SPRINT	Sprint is a timeboxed iteration of a continuous development cycle. Within a Sprint, planned amount of work has to be completed by the team and made ready for review
Software Versioning	Software versioning is a way to categorize the unique states of computer software/associated documents as it is developed and released. The version identifier can be a word, or a number, or both.
Standard Operating Procedure (SOP)	Set of interrelated or interacting activities that use inputs to deliver an intended result

Term / Abbreviation	Definition
Statement of Work (SOW)	A statement of work includes detailed requirements and pricing, with standard regulatory and governance terms and conditions.
Superseded	For documents: Replaced by a newer version.
Supplier	A source of materials, service or information input provided to a process. May also be referred to as a vendor.
System	(1) (ANSI) People, machines, and methods organized to accomplish a set of specific functions. (2) (DOD) A composite, at any level of complexity, of personnel, procedures, materials, tools, equipment, facilities, and software. The elements of this composite entity are used together in the intended operational or support environment to perform a given task or achieve a specific purpose, support, or mission requirement. (3) A system is the combination of people, processes, procedures and technology used to accomplish a set of functions. The technology used, be it paper, computer, a hybrid of paper and computer or other is not a defining factor.
System Administrator	The person that is charged with the overall administration, and operation of a computer system.
System Testing (ST)	(IEEE) The process of testing an integrated hardware and software system to verify that the system meets its specified requirements. Such testing may be conducted in both the development environment and the target environment. Can also be referred to as an Operational Qualification (OQ). System Testing is a level of software testing where a complete and integrated software is tested. The purpose of this test is to evaluate the system's compliance with the specified requirements.
Template	A file that is created with an overall layout or blueprint with a format to be used for a group of documents
Test Script	Documentation specifying inputs, predicted results, and a set of execution conditions for a test item.
Training record	Documented evidence that training was undertaken by a person/personnel
Unit Testing (UT)	Unit testing is a software testing method by which individual units of source code, sets of one or more computer program modules together with associated control data are tested to determine whether they are fit for use.
User	(ANSI) Any person, organization, or functional unit that uses the services of an information processing system. See: end user.
User Acceptance Testing (UAT)	Testing conducted to determine whether or not a system satisfies its acceptance criteria and to enable the customer to determine whether or not to accept the system.
User Accounts	User IDs used to access RxLogix Infrastructure

Term / Abbreviation	Definition
User Story	A term used in Agile software development to capture a description of a software feature from an end-user perspective. It describes the type of user, what they want and why. A user story helps to create a simplified description of a requirement
Validation	(1) (FDA) Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.
Validation Test Plan (VTP)	Validation Test Plan (VTP) For validation: The Validation Test plan describes the Validation testing strategy for a project assessed as requiring formal validation.
Validation Test Summary Report (VTSR)	For Validation: The Validation Test Summary Report summarizes the validation activities conducted for a project.
Vendor	A person or an organization that provides software and/or hardware and/or firmware and/or documentation to the user for a fee or in exchange for services. May also be referred to as a supplier.
Virtual Private Network (VPN)	A system or technology that uses a public network, usually the Internet, to transmit encrypted data between a private network and a remote authorized user.
Vital Records	Document, file, or record in any form or format, containing information that is: (1) essential to the operations and/or survival of the organization, (2) necessary to recreate the organization's legal and financial position, and (3) necessary to preserve its claims and rights and those of its stakeholders.
Work Instruction (WI)	Work Instruction is a document that provides specific instructions to carry out an Activity. A Work Instruction is a step by step guide to perform a single instruction

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Required Workflow Steps for this Category

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