**Purpose**

The purpose is to check the validation of computerized systems, which provides documented evidence that the system works in a reliable and reproducible manner in accordance with the applicable internal directives, user and regulatory requirements.

**Scope**

This procedure applies to the validation activities of all GxP computerized systems built, supported and managed by ITS during the entire life cycle from project initiation to system decommissioning. All employees and subcontractors in charge of or participating in the validation of a GxP regulated computerized system supported by ITS must be trained on this procedure according to the Training Management procedure applicable to the trainee. Any Third Party provided documentation must comply with this procedure. General validation principles listed in this procedure apply to the qualification of infrastructure components supported and managed by ITS. However, in order to take into account specificities, infrastructure qualification activities and responsibilities are detailed in specific quality document.

**Out of Scope**

This procedure does not apply to computerized systems, which are not implemented or supported by ITS example laboratory or manufacturing computerized equipment.This procedure does not apply to nonGxP computerized systems.

**Business System Owner (BSO)**

Person accountable for the business process supported by the Computerized System, and ensuring the GxP compliance of the system and associated data (QGQD003024). The BSO is equivalent to the System Owner (SO) as defined in the Responsibilities section of this document.

**Deviation (in the context of CS validation activities)**

Nonconformance with planned activities (example Validation Plan, Test Design), SOPs or approved acceptance criteria. Any unresolved testing anomalies must be addressed as deviations. All unresolved deviations must be classified as critical, major or minor in the system release deliverables (Conformity Certificate, Authorization For Use, Validation Report).

**Minor Deviation**

A deviation not classified as critical or major, which potentially impacts a GxP system, utility, equipment, material, component, environment or documentation, but does not affect product quality, safety or efficacy.

**Major Deviation**

A noncritical deviation, which potentially affects the quality, safety, efficacy of a product or the ability to meet GxP requirements.

**Critical Deviation**

A deficiency in material, product, system or service that can affect significantly the quality, safety or efficacy of a product or can lead to health threatening conditions in a product. Alternatively, any deficiency that can lead to a noncompliant product or to a situation that may be cited by regulatory authorities as critical.

**GxP Critical System (C)**

A system is GxP Critical if failure of at least one of its functions causes a violation of GxP or other healthrelated regulations with direct impact on Product Quality, Patient and Consumer Safety, or Data Integrity.

**GxP Major System (M)**

A system is GxP Major if failure of at least one of its functions causes a direct violation of GxP or other healthrelated regulations, with no direct impact on Product Quality, Patient and Consumer Safety, or Data Integrity.

**GxP Minor System (m)**

A system is GxP minor if failure of at least one of its functions causes an indirect violation of GxP or other healthrelated regulations, with no direct impact on Product Quality, Patient and Consumer Safety, or Data Integrity.

**Global Computerized System**

It is a computerized system with a global governance that is used by more than one entity within or across Sanofi operational units, sites or countries.

**Distributed Global Computerized System**

It is a global computerized system with multiple installations.

**Centralized Global Computerized System**

It is a global computerized system with a single installation hosting business application and data.

**Installation Qualification (IQ)**

Validation activity to verify that the hardware and software components of the system are installed according to specifications and suppliers recommendations.

**Local Computerized System**

It is a computerized system used exclusively within one site, country or department.

**NonGxP System**

It is a system is Non GxP if none of its functions is used to comply with the GxP regulations.

**System Document**

Any documentation issued through the project that will have to be maintained and updated throughout the maintenance process, post golive, during the entire system life cycle. System Documents may also be created during the operation and maintenance of a system.

**System Integration Test (SIT)**

It is an activity performed by ITS to verify that the software operates according to its specifications.

**Technical System Owner (TSO)**

Person responsible for design, delivery, availability, support, and maintenance of GxP Computerized Systems and security of the associated data (typically from Engineering or Information Systems departments) (QGQD003024). Activities related to this role are addressed by IPL, PTC, AEX, ASE and ISE from Responsibilities section of this document.

**User Acceptance Test (UAT)**

Validation activity performed by user representative to verify that the software operates according to the user and functional requirements.

**User Process Monitoring (UPM)**

Validation activity verifying in the Production environment that users are able to perform and control the processes supported by the system according to performance criteria.

**AEX**

Application Expert.

**ASE**

Application Support Expert.

**ASU**

Application Support User.

**BQR**

Business Quality Representative.

**CAPA**

Corrective Action / Preventive Action.

**CS**

Computerized System.

**GxP**

Generic term used to designate all healthrelated regulations issued by government agencies. For example Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good distribution Practices (GDP), Good Clinical Practices (GCP), and Pharmacovigilance (example adverse event reporting).

**IPL**

ITS Project Leader.

**ISE**

Infrastructure Support Expert.

**ITS**

Information Technology & Solutions global function.

**PM**

Project Manager.

**PTC**

Project Technical Coordinator.

**PUMA**

Project Unified Methodology Approach – name of project methodology used at Sanofi to design, build and deliver computerized systems.

**Q&C**

Quality & Compliance.

**SO**

System Owner.

**UPL**

User Project Leader.

**UR**

User Representative.

**VEX**

Validation Expert.

**Computerized System Lifecycle Overview**

The lifecycle of computerized systems involves three phases where validation activities are required. The Project phase, the Operation and Maintenance phase, and the Decommissioning phase. The Project phase involves the Initiation, Requirements definition, Design, Build, Acceptance, and Release and Deploy stages.

**Purpose of Initiation Stage**

The purpose of the Initiation stage is to formalize / refine the business scope and to define the initial project organization needed to fulfil the project request.

**Prerequisite of Initiation Stage**

The prerequisite includes identification of System Owner and Business Quality Representative.

**Validation Activity of Initiation Stage**

The main validation deliverable of this phase is the System Criticality Assessment (SCA) that is used to evaluate new or updated computerized systems to determine regulatory requirements and compliance risk levels, including GxP criticality level (Critical, Major, minor or nonGxP). This deliverable relies upon a reasonably detailed system description (intended use) and the process which it supports. The GxP assessment portion of the SCA will be used to determine the validation strategy and the deliverables that are required for the validation of the system.

**Prerequisites for Requirements Definition Stage**

The prerequisites require an approved system criticality assessment.

**User Requirements for Requirements Definition Stage**

The development of the User Requirements is an early step in the validation of a computerized system. It defines expected system characteristics (independent of a technical solution) to support business processes including applicable regulatory requirements. Each requirement will be uniquely identified to facilitate inclusion in the Traceability Matrix, clearly and unambiguously listed, testable and measurable.

**Vendor Audit Report for Requirements Definition Stage**

A Vendor Audit Report is created to document the evaluation of the suppliers Quality Management System and as necessary the software development lifecycle (SDLC) dossier for the supplied solution. The decision to perform an audit is based on the riskbased approach as defined in GDSOP014100. The vendor audit results, the confidence in its quality management system and the SDLC dossier allow to leverage the specification and verification activities as part of the validation effort. A quality agreement or equivalent must be established with the Third Party, including clear statement of the responsibilities of the third party, according to QOQS013976.

**Validation Plan for Requirements Definition Stage**

A Validation Plan is created to formalize the rationale for the validation strategy (including global vs local activities when applicable), the validation scope and acceptance criteria, validation deliverables taking into account the criticality and the complexity of the system, applicable procedures, roles & responsibilities and the release strategy (including approaches to authorize deployment if applicable and use) applicable to the computerized system. If a validation strategy different than defined in this SOP is to be followed, it must be specified, justified and approved in the Validation Plan.

**Purpose of Design Stage**

The purpose of this stage is to complete a detailed set of specifications for the selected solution, from a functional, technical and operational services view point.

**Prerequisites for Design Stage**

The prerequisites include approved user requirements, approved functional specification, and a documented mapping of user requirements to functional specifications (Traceability Matrix).

**Validation Activities for Design Stage**

During this phase the Functional Specifications, Detailed Specifications and Architecture Specifications are created and approved to describe the functional and technical requirements needed to meet the user requirements. Each specification must be uniquely identified to facilitate inclusion in the Traceability Matrix, clearly and unambiguously listed, testable and measurable. The design review is conducted by initiating the Traceability Matrix to ensure that user requirements are addressed by the specifications and any gaps are identified and justified or addressed. Unresolved gaps are then handled as deviations in Conformity Certificate, Authorization for Use, or Validation Report.

**Functional Risk Assessment in Design Stage**

A detailed Functional Risk Assessment is performed to ensure a risk based approach to validation. For each key functionality or coherent group of functions of the system, a risk assessment, relying on the initiated Traceability Matrix, is performed to determine the GxP relevance, the business and GxP failure consequence, the potential consequences of erroneous or incorrectly entered data and impact on data integrity. The Traceability Matrix is used to help assess the GxP failure consequence by understanding the linkage between the user requirement and the functionality. The results are used to determine the appropriate level of testing.

**Test Strategy in Design Stage**

A strategy for testing must be developed for all systems. The Test Strategy document formalizes the strategy for all test activities including Installation Qualification, System Integration Testing, and User Acceptance Testing. For each test type the following topics are addressed applicability (justified when not applicable), environment(s) that will be used for the testing, responsibilities, prerequisites, the documentation required and a summary of the test coverage. The test coverage must be based on the GxP criticality and business failure consequence. The Test Strategy can be documented either in the Validation Plan or in a dedicated Test Strategy document (this decision must be documented in the validation plan) and must be based on the Functional Risk Assessment.

**Installation Qualification (IQ) Design in Design Stage**

Based on the testing strategy, the Installation Qualification (IQ) Design is created describing the hardware and software components to be qualified taking into account the component failure impact on system availability / data integrity, the target environments to be qualified, the required evidence and the acceptance criteria. The applicable Installation Procedures and IQ Forms are also identified and initiated, if not already available. At a minimum, the Installation Qualification must be performed for the test and production environments.

**System Retirement Plan in Design Stage**

A System Retirement Plan is created, if the new system replaces an existing system. It is approved before execution, completed and then approved after execution.

**Data Migration Plan in Design Stage**

A Data Migration Planmust be created only if legacy data has to be moved from an existing system to the new system. The purpose of Data Migration Plan is to describe the processes that will be used for migrating data from the current system to the target system and to explain how to check and ensure the integrity of the migrated data (the qualification of the migration tools can be leveraged to reduce the effort of manual data verification by the users).

**Technical Recovery Plan (TRP) in Design Stage**

A Technical Recovery Plan (TRP) is created if recovery requirements are included in the User Requirement Specification. The TRP describes the recovery procedure and supporting details required at the time of disaster for effective recovery. The TRP must be tested and approved before system acceptance, to ensure it is valid, accurate and ready to be used in case of required recovery during system Operation and Maintenance phase.

**Purpose of Build Stage**

The purpose of the Build stage is to develop the solution and verify that it meets the specifications, and to prepare the solution components, associated procedures, training and acceptance testing.

**Code Review in Build Stage**

During this phase, a Code Reviewis performed for critical GxP functions of the application, which are custom developed. It is performed by a qualified person other than the developer. The objective of the code review is to verify that coding standards have been followed, and to identify corrective action plans.

**Installation Qualification (IQ) Report in Build Stage**

The Installation Qualification (IQ) Report for the test environment is created and approved to summarize the installation following approved Installation Procedures identified in the IQ Design. Installation Qualification is performed in order to ensure that hardware and software components are installed according to specifications and that the required documentation is available. Preapproved IQ formsare executed for each component identified in the scope to verify successful installation and to identify deviations. The IQ Report summarizes the results of IQ activities and corrective action plans, as needed. As soon as the test environment is qualified, any changes must be managed under a formal change management process.

**System Integration Test Design in Build Stage**

Based on the test strategy defined in the Validation Plan, the System Integration Test Design can be used to leverage the validation effort provided that it is performed in a qualified environment according to approved System Integration Test Case(s). Upon completion of the System Integration Testing, a System Integration Test Report is created and approved summarizing the results of the testing and corrective action plans, as needed.

**User Acceptance Test (UAT) Design in Build Stage**

The User Acceptance Test (UAT) Design is created in accordance with the testing strategy describing the testing to be implemented to ensure the system is compliant with specifications and user requirements. User Acceptance Testing is performed in a qualified environment according to approved User Acceptance Test Case(s). The User Acceptance Tests Casesare used to check that application functionalities are operational and conform to the specifications. Test Cases may verify business processes or functions, interfaces, data migration (ensuring data integrity), access processes and performance criteria specific to the system (example disconnection, attempted access, structure of passwords), etc User Acceptance Test Cases prove that the acceptance criteria and objectives of tests defined in the User Acceptance Test Design are met. User Acceptance Test Cases describe the acceptance criteria and objectives of tests to achieve, all the steps to be performed, the expected result and the result obtained for each step together with the conclusion. Automated testing tools may be used as far as these are qualified. The associated test report must be verified, approved and retained as per manual testing documentation.

**Training in Build Stage**

Users and personnel involved in operation, administration and maintenance of the system must be trained on the appropriate operational procedures. The training strategy must be documented in a separate Training Plan document or in the Validation Plan. Training materials and User Guides must be available. Training evidence (example attendance sheets, certificates, quizzes, etc) must be retained.

**Purpose of Acceptance Stage**

The purpose of the Acceptance stage is to obtain system acceptance, ensure production readiness and obtain a GO decision to perform transition to production for a given version.

**User Acceptance Test Report in Acceptance Stage**

During this stage, the User Acceptance Testing is performed by user representative(s) to verify that the software operates according to user requirements. It is performed in a qualified environment according to an approved User Acceptance Test Design and preapproved User Acceptance Test Cases(s). Test results must be documented (print screens, printouts, etc) for the steps of tests demonstrating the achievement of the objectives of tests / acceptance criteria. Upon completion, the User Acceptance Test Reportis created and approved summarizing the results of the testing and corrective action plans, as needed.

**Traceability Matrix in Acceptance Stage**

The Traceability Matrix is developed throughout the project to document user requirements traceability through testing. This traceability is verified during test review which includes verification of coverage and test level as defined in the Functional Risk Assessment. A final check is made to ensure testing of requirements and the document approval is obtained. Unresolved gaps are then handled as deviations in the appropriate Conformity Certificate, Authorization for Use, or Validation Report.

**Conformity Certificate in Acceptance Stage**

For global computerized systems with configuration specific to entities or manufacturing sites and requiring multiple local deployments, a Conformity Certificate may be required, as specified in the Validation Plan. When required, the Conformity Certificate is created and approved by the global team to verify the completion of the validation activities, deliverables and procedures up to and including User Acceptance. It summarizes all resolved and unresolved deviations. Unresolved deviations must include corrective action plans and justifications. An overall conformity decision (Authorized, Authorized under conditions or Not Authorized) is also made. The Conformity Certificate is used to authorize the deployment into the production environment and other next steps (example site or entity specific activities, data migration, user access creation, etc) as defined in the Validation Plan. Further validation activities may be approved by entity or site specific team members.

**Installation Qualification (IQ) Report in Acceptance Stage**

The Installation Qualification (IQ) Report for the production environment is created and approved to summarize that hardware and software components are installed according to specifications and that the required documentation is available. Preapproved IQ forms are executed for each component identified in the scope. The IQ Report summarizes the results of IQ activities and corrective action plans, as needed.

**Data Migration Report in Acceptance Stage**

When legacy data is to be migrated, the Data Migration Plan is executed and verifications are performed. If applicable, a Data Migration Report is created to summarize the completion of the migration activities. It designates the verification results, deviations found and errors generated during the migration process and corrective action plans, if not resolved.

**Authorization for Use in Acceptance Stage**

An Authorization for Useis created and approved to verify the completion of the validation activities, deliverables and procedures identified in the Validation Plan prior to production use of the system. It summarizes all resolved and unresolved deviations and also includes the following checks verification of user training, user accesses, enduser procedures (covering system administration and use), data migration (as applicable), restoration test performed, performance monitoring job scheduled, ITS computerized systems inventory update, support and maintenance organization readiness (support groups defined) as well as operational documentation readiness (application and infrastructure operation manuals available).

**Validation Activities in Acceptance Stage**

If all deviations are adequately resolved, then an overall conformity decision can be made to Authorize for Use and then release the system for use. If there are any unresolved minor deviations, then an overall conformity decision can be made to Authorized for Use under Condition. If there are any unresolved Critical or Major deviations with no workaround the system cannot be Authorized for Use under any condition. Therefore, in the case of critical or major deviations with no workaround, the Authorization for Use form can be signed as not authorized. Once deviations are addressed, then a new version of Authorization for Use must be issued and signed. If any unresolved deviations exist with workarounds, the associated corrective action plans and justifications of why these will not affect the validated status of the computerized system must be provided. Then the decision can be made to Authorized for Use under Condition. The resolution of the deviations must be documented in the Validation Report. This includes a summary of the performed changes. If a Conformity Certificate was created previously, it must be referenced in the Authorization for Use document.

**Purpose of Release and Deploy Stage**

The purpose of the Release and Deploy stage is to release into production and deploy a solution that supports associated business processes and IS services. In addition to manage and support the post golive period including project closeout. During this phase, the following activities may occur according to the *Validation Plan*.

**User Process Monitoring in Release and Deploy Stage**

It monitors how well the system performance supports the business process after the rollout and during a given period of time, or agreed number of data generated, through specific indictors, acceptance criteria, and/or tests. The necessity to perform a User Process Monitoring is driven by the impact of the system implementation on the business organization and/or processes (critical operations automated). The decision to perform it is documented in the Validation Plan and the results of the User Process Monitoring are reported in the Validation Report with any deviations found and their corrective actions, as needed.

**System Retirement Plan in Release and Deploy Stage**

The approved System Retirement Plan (for legacy systems) is executed and the results are approved.

**Validation Report in Release and Deploy Stage**

The Validation Reportis created and approved to verify the completion of all validation activities as defined in the Validation Plan and the resolution of all deviations. The Validation Report may point to the Conformity Certificate and/or the Authorization for Use if previously created. If not then the Validation report must contain the content of the Conformity Certificate and/or the Authorization for Use as specified in this procedure. Any deviation remaining open in the Validation Report must be tracked under the ITS CAPA management process or ITS Change Management process. When all deviations are closed, an update of the Validation Report must be issued and approved.

**Deviation Management**

At the issuance of last validation deliverable gathering and assessing deviations (that is Conformity Certificate, Authorization for Use or Validation Report) required according to strategy, if deviations remain open with action plans defined, these action plans must be tracked under the ITS Change Management process if the resolution of the deviation requires functional modification of the computerized system, and the ITS CAPA Management process in any other cases.

**Leverage Suppliers Specification and Verification Activities**

The specification & verification (or testing) activities and documentation supplied by the vendor can be leveraged as part of the validation effort during the project phase and associated stages. The decision to rely on as well as the level of controls on suppliers specification & verification activities and documentation must be based on the confidence with the suppliers quality management system and the Software Development Lifecycle dossier (as per audit results). The rules, including responsibilities and controls, for leveraging suppliers specification & verification activities and documentation must be defined in the quality agreement or the validation plan. The defined rules must allow to ensure the completion, accuracy and reliability of validation deliverables in accordance with this procedure.

**Effect of System Type (Global / Local), Architecture and Hosting on Validation Strategy**

The validation activities across the various project stages are carried out at global level or local level depending on the computerized system type (global or local), the computerized system architecture and hosting (centralized or distributed), and the degree of specific configuration addressing local requirements.In the context of implementation of global computerized systems with specific configuration addressing local requirements, the validation plan issued at global level must define the need, the scope, the extent and the responsibilities for local validation activities during local deployment. The validation strategy designed at local level for a given deployment must comply with the strategy specified in the global validation plan for the local deployments

**Effect of Iterative Project Approach on Validation Strategy**

The project phases described in this procedure follow a sequential project approach that allows to implement a computerized system addressing all the user requirements through a single release. Nevertheless, an iterative project approach (example Agile) with multiple releases can also be used to implement GxP computerized systems provided that the following principles are followed. For each iteration, involve quality representatives (ITS or Business) on specification and testing activities in accordance with this procedure. User requirements and system specifications are maintained upto date across all iterations. Testing activities covering GxP risks are executed in a controlled environment corresponding to a user requirements and system specifications baseline and according to preapproved test design and test cases. Evidence of nonregression between the various iterations is provided to ensure that test results of each iteration remain valid. The choice to move forward with an iterative project approach must be a project team decision and documented in the validation plan defining specific roles and responsibilities and how each iteration will be managed from specification to release.

**Operation and Maintenance Phase**

The Operation and Maintenance phase starts after golive and will continue until the system is decommissioned. The objective of the Operation and Maintenance activities is to ensure that the computerized systems remain in validated status. Therefore, the processes listed hereafter as well as the associated Roles and Responsibilities must be described in procedures.When global ITS procedures are defined to support the execution of the processes required for Operation and Maintenance phase, they must apply to all GxP Computerized Systems supported and managed by ITS.

**Responsibilities of Operation & Maintenance Team**

The Operation & Maintenance team is responsible for implementing, maintaining and applying the following procedures Access Rights Management and Monitoring, Training, Change Management, Periodic Review, Backup and Restore, and Business Continuity.

**Access Rights Management and Monitoring**

The system access must be limited to authorized and trained individuals and periodically monitored and must include record of creation, change, and cancellation of access authorizations.

**Training**

Training must be provided to users and training records maintained. Incident Management the Business system owner and/or Key users must declare all incidents related to the Computerized System. They must be recorded, investigated and according to defined criteria escalated to the Problem Management process or the Quality Risk Management process.

**Change Management**

Modification to a computerized system must be managed via a formal review and approval process. As a result of these changes, system lifecycle and validation deliverables must be updated to reflect the current state and use of the system. It is about all the documents describing the business requirements (User Requirements), the computerized system (Functional Specifications, Detailed Specifications and Architecture Specification…) and allowing demonstrated adherence to user requirements through a risk based approach (System Criticality, Functional Risk Assessment, Traceability Matrix, Test Cases…). As necessary created to deal with the specific validation strategy associated to the change (Validation Plan, new Test Cases, Validation Report…) – The Validation Report must list all the deviations applicable to the system since previous versions.

**Periodic Review**

They must be performed to ensure the system is monitored to demonstrate that it is still operating properly and in a validated state.

**Backup and Restore**

Backups must be periodically performed and tested to ensure successful recovery of data after a system failure.

**Business Continuity**

Based on risk and needs, procedures including Disaster Recovery Plan (DRP) may be required to ensure business operation during a computerized system failure. Maintenance and monitoring must be in place to ensure proper functioning of the computerized system according to its intended use and to secure the system and the GxP data it manages.

**Decommissioning Phase**

Decommissioning is performed to retire the system that is no longer used and to ensure archiving of GxP data for their retention period. The preapproved System Retirement Plan issued in the context of the project phase for the deployment of a new system is executed, documented and approved after the retirement activities are performed.

**Records Management**

All deliverables (example documents, supporting evidence of activities execution) issued from validation activities are GxP records and must be managed according to the global procedure GDSOP014183 ITS Project and Application records management.

**Responsibilities of System Owner (SO)**

The system owner (also known as Business System Owner) is a manager or manager representative of the organization owning the business process supported by the system in production.The SO provides support teams with functional and crossfunctional process information to support and maintain the application integrity and quality.The SO has the ultimate responsibility for ensuring the GxP compliance of the system and associated data.When validation deviations remain open and workarounds impacting business process are implemented to move forward within the computerized system lifecycle (that is move to production or release for use), he is accountable for the proper GxP impact assessment and documentation of those workarounds.The SO is from the Global Function or GBU owning the system.

**Responsibilities of Project Manager (PM)**

The project manager is responsible for managing the project and delivering on time, within the budget a solution that meets user requirements. He is responsible for managing the compliance of the system with the predefined requirements.

**Responsibilities of ITS Project Leader (IPL)**

The ITS Project Leader is responsible for defining, building, delivering and maintaining a reliable solution that meets defined user requirements.

**Responsibilities of Project Technical Coordinator (PTC)**

The project technical coordinator is responsible for infrastructure related expertise, analyzing and implementing technical components and coordinating the various organizations that are involved throughout the entire system life cycle.

**Responsibilities of Application Expert (AEX)**

The application expert participates in the analysis, specification and selection of application components and their integration into the defined architecture in the build of the application solution that fulfills the user requirements.

**Responsibilities of User Project Leader (UPL)**

The user project leader is responsible for defining user requirements, organizing training, organizing and ensuring user acceptance testing and deployment of the solution from a user perspective.

**Responsibilities of User Representative (UR)**

The user project leader is responsible for defining user requirements, organizing training, organizing and ensuring user acceptance testing and deployment of the solution from a user perspective.

**Responsibilities of User Representative (UR)**

The user representative represents the entity for which the system is delivered and that operates at least one of its functions. The UR participates in providing his/her Business expertise, User Requirements definition, to the User Acceptance Testing preparation as well as their execution.

**Responsibilities of Application Support Expert (ASE)**

The application support expert is responsible for Level 23 support from the IS application side and acts as the Subject Matter expert. The ASE manages the changes in the computerized system from the IS application side and is part of the Operation & Maintenance Team(equivalent to IPL/AEX from project phase).

**Responsibilities of Infrastructure Support Expert (ISE)**

The infrastructure support expert is responsible for Level 23 support from the Infrastructure side and coordinates with the appropriate Infrastructure Subject Matter Experts.The ISE Manages the changes in the computerized system from the Infrastructure side and is part of the Operation & Maintenance Team (equivalent to PTC from project phase).

**Responsibilities of Application Support User (ASU)**

The application support user represents the users of the application to ensure the proper use of the application and is in charge of Level 23 support from the user side.The ASU manages the changes occurred on the application, provides training, performs administration and is part of the Operation & Maintenance Team (equivalent to UPL from project phase).

**Quality Roles**

In the context of local validation activities, (that is the local deployment of a global computerized system or the implementation of a local computerized system), the quality roles BQR and VEX can be merged as appropriate to ensure the proximity of Quality support with the execution of the validation activities and to optimize the ways of working.

**Responsibilities of Business Quality Representative (BQR)**

The business quality representative ensures that the quality requirements related to business processes are addressed by the project / system in compliance with applicable GxP and health related regulations. The BQR provides regulations expertise along the project & system lifecycle.The BQR role can be handled either by an Operational or Site Quality representative, or a Global Quality representative.

**Responsibilities of Validation Expert (VEX)**

The validation expert provides expertise and guidance to ensure that the Computerized System is implemented, maintained and supported in compliance with applicable regulations that apply to ITS processes.The VEX provides computerized system validation expertise along project & system lifecycle.VEX also coordinates the risk assessment and ensures execution of validation activities based on assessed risk and in compliance with the methodology.For global validation activities, the VEX role is ensured by ITS Quality and Compliance representative.For local validation activities, the VEX role is typically ensured by local quality, but may alternatively be assumed by ITS Q&C per agreement between ITS Q&C and the affected operational quality unit.

**Infrastructure Qualification Activities**

For infrastructure component delivered by ITS in NGDC or Global Cloud/SaaS, and delivered and maintained by ITS in Local Infrastructure, the infrastructure qualification activities are conducted globally and supported by ITS Q&C as VEX. A global qualification package is delivered and maintained through the entire infrastructure component lifecycle.For infrastructure component not delivered by ITS in Local Infrastructure, there is no ITS or ITS Q&C involvement.

**Validation Activities for Global Configuration**

For Global System with Centralized Hosting (NGDC or Cloud/SaaS), all validation activities are conducted globally and supported by ITS Q&C as VEX, and Business Quality as BQR. A global validation package is delivered and maintained through the entire CS lifecycle.Not applicable for Global System with Distributed Hosting, and Local System.

**Validation Activities for Global and Local Configuration for Global System with Centralized Hosting**

For Global System with Centralized Hosting (NGDC or Cloud/SaaS), the global validation activities are complemented by local validation activities to address local configuration impacts. The global validation activities are conducted globally and supported by ITS Q&C as VEX, and Business Quality as BQR.The local validation activities conducted at local level must be limited, and are supported by Local Quality as VEX (or ITS Q&C as VEX in specific case of agreement with Local Quality to ensure this role), and Local Quality as BQR.The required minimum local validation activities are specified in the global validation strategy, all or part of Local User Requirements to complement Global User Requirements, Local Validation Plan, Local Functional Risk Analysis and Traceability Matrix, Local Testing on Local configuration, Local Data Migration plan and report, Local Authorization for Use, and Local Validation Report.If the VEX role is assumed by local/site Quality, an ITS Q&C representative can be involved in these local validation actions to provide assistance to the local project team to apply this procedure and to apply the validation strategy defined within the global validation plan for local deployments.During the lifecycle, local impact analysis of changes & releases and quality events, and local part of Periodic reviews and Retirement plan.The full validation package consists in a global validation package complemented with all the local validation packages.The global and local validation packages are maintained through the entire CS lifecycle.

**Validation Activities for Global and Local Configuration for Global System with Distributed Hosting**

For Global System with Distributed Hosting, the global validation activities are complemented by local validation activities to address local configuration impacts as well as local installation. The global validation activities are conducted globally and supported by ITS Q&C as VEX, and Business Quality as BQR. The local validation activities conducted at local level must be limited, and are supported by Local Quality as VEX (or ITS Q&C as VEX in specific case of agreement with Local Quality to ensure this role), and Local Quality as BQR.The required minimum local validation activities are specified in the global validation strategy, all or part of Local User Requirements to complement Global User Requirements, Local Validation Plan, Local Functional Risk Analysis and Traceability Matrix, Local Installation Qualification on business application local components and configuration, Local Testing on Local configuration, Local Data Migration plan and report, Local Authorization for Use, and Local Validation Report. If the VEX role is assumed by local/site Quality, an ITS Q&C representative can be involved in these local validation actions to provide assistance to the local project team to apply this procedure and to apply the validation strategy defined within the global validation plan for local deployments.During the lifecycle, local impact analysis of changes & releases and quality events, and local part of Periodic reviews and Retirement plan.The full validation package consists in a global validation package complemented with all the local validation packages.The global and local validation packages are maintained through the entire CS lifecycle.

**Validation Activities for Global and Local Configuration for Local System**

For the Local System, all the validation activities are conducted locally and supported by Local Quality as VEX (or ITS Q&C as VEX in specific case of agreement with Local Quality to ensure this role), and Local Quality as BQR. A local validation package is delivered and maintained. In the context of systems supported and managed by ITS, the ITS validation process applies. If the VEX role is assumed by local/site Quality, an ITS Q&C representative can support the local project team to ensure that all validation deliverables are provided according this procedure.