STANDARD OPERATING PROCEDURE	
Procedure #: SOP-FLS-CORP-0032	**TITLE**
Revision: 1	Life Science Quality Manual

1. INTRODUCTION

Saint-Gobain Life Science sector of activity considers quality, compliance, and employee health and safety as indispensable core values in providing safe and effective products. Compliance is interpreted as adherence to applicable regulations, internal standards (e.g. SOP's, policies), and registrations for the ultimate purpose of reducing risk and ensuring product quality. Any exclusion(s) to the standards or regulations will be documented and justified within each individual site's Quality Manual. For the Life Science Laboratory, there are no exclusions to note within ISO 17025. The range of laboratory activities that are within the scope of the ISO 17025 standard will be managed as a separate document.

Quality is measured and judged by both external and internal customers and indicates the degree to which customers are satisfied and their objective needs, expectations, and requirements are met. The QMS described in this Manual assures compliance with this commitment.

The Saint-Gobain Life Science (LS) Leadership Team is accountable for the quality of the Life Science (LS) product portfolio and for compliance to all applicable regulations. This accountability is achieved through an effective QMS (Quality Management System). Responsibility for the QMS is delegated to the Head of LS Quality. For sites governed by ISO 13485, the Plant Quality Manager role is the site's management representative. Business leaders within Life Science are responsible for ensuring that the principles defined in the QMS are adequately applied and resourced within their areas of responsibility.

Each plant must demonstrate ongoing compliance to the QMS by developing local Quality Manuals based on the Life Science Quality Manual. Saint-Gobain expects that all employees understand and actively follow the requirements of the QMS. In addition, Saint-Gobain's Quality Policy and Quality Vision Statement constitute fundamental inputs to the annual Business and Quality objective setting process to cascade Quality Objectives throughout the organization to the individual level.

2. QUALITY VISION STATEMENT

We live a culture of quality supported by a globally harmonized, ISO-based Quality Management System.

Our Management supports employees in living our quality culture by providing appropriate training, resources, business processes, and systems.

We foster an environment in which our employees understand and embrace their responsibility for product quality and employee health and safety.

We believe that excellence in innovation, technology, and processes are key to our commitment of providing safe and effective products to our customers.

3. SCOPE OF THE QUALITY MANUAL

With the exception of the exclusions outlined herein, this Quality Manual contains the requirements as outlined in ISO 13485:2016, ISO 17025:2017 and ISO 9001:2015 required to manage the product life cycle and the end-to-end supply chain of our products, components and laboratory services. The Quality Manual is binding for all Life Science sites and business units manufacturing and distributing products. In addition, the QMS is binding for all global and local functions involved in managing the end-to-end supply chain for, and lifecycle of, the Life Science product portfolio. This includes functional groups such as Information Systems (IS/IT), Purchasing, Human Resources, and Supply Chain Management.

4. RESPONSIBILITIES

4.1 **Management**: It is management's responsibility, regardless of level, to establish and adhere to quality and compliance standards. Senior management at LS and a local level must:

- Establish a Quality Policy and respective Quality Manuals as guiding documents.
- Establish measurable and meaningful quality objectives and associated metrics that aim to improve customer satisfaction.
- Establish a review process according to the Management Review Governance Structure model (refer to Management Review Section below).
- Establish a process to share quality objectives with the employees, for example, through the individual goal setting process.
- Ensure prompt communication, handling, and resolution of out of specification investigations when applicable and nonconformities within their areas of responsibility.
- Create and maintain an environment where continuous improvement and quality decision making is recognized and rewarded.
- Provide necessary resources to maintain and continuously improve the effectiveness of the QMS.

4.2 Senior Management:

- Provides a forum whereby exceptional decisions may be made for exceptional situations where actions taken may be outside Standard Operating Procedures.

4.3 **Quality:** The Quality Unit is responsible for specific activities related to quality oversight. The responsibilities are mandated by regulations, standards and defined in SOPs. These responsibilities include:

- The authority and responsibility to disposition materials and products.
- Review and approve deviations and investigation reports.
- Assess and determine the need for market action.
- Approve test methods, manufacturing/packaging/ labeling records, specifications, SOPs, change controls, and CAPAs.
- Facilitate the overall creation and maintenance of the quality system.

4.4 **Analytical Services & Quality Control (ASQC):** The laboratory unit is responsible for specific activities related to the oversight of the Life Science lab. The responsibilities are mandated by standards, defined in SOPs and / or outlined in customer test requests. These lab responsibilities include:

- The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.
- The laboratory shall inform the customer in advance, of the information it intends to place in the public domain.
- When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.
- The authority and responsibility to disposition all test results.
- Review and approve deviations and out of specification (OOS) investigation reports
- Approve test methods, specifications, equipment, utilities, supplier and SOPs using the appropriate change management system
- Facilitate the overall creation and maintenance of the operation of the lab.
- Ensure adherence to ALCOA principles following good laboratory practices and data integrity principles as outlined in the corporate procedures

4.5 **Employees:** Every employee is responsible for understanding and supporting the quality objectives and adhering to policies and procedures. It is every employee's responsibility to immediately act on any issue that could have an impact on product quality and compliance. To act on means:

- Resolve issues within their control and scope of responsibility.
- Escalate issues outside their control and scope of responsibility to their superior who in turn will consult the respective quality person or Senior Management where applicable.

4.6 **Approved Delegates**: The hiring manager of every role within Saint-Gobain has the authority to sign for that position under their management provided the hiring manager has the appropriate qualifications, training and training record evidence where needed. An exception to this policy is with the Quality department roles associated with the Medical or Pharmaceutical markets. Where the Plant Quality Manager (PQM) role is involved, any member of the PQM's quality department and corporate Quality are approved delegates provided the appropriate training has occurred and has been documented if needed. For Corporate Quality roles, any member of the corporate team can sign for the other corporate role provided he / she has the qualifications and training.

5. DEFINITIONS

Term	Definition or Abbreviation
Quality Management System	A quality management system (QMS) is a collection of business processes focused on achieving quality policy and quality objectives to meet customer requirements. It is expressed as the organizational structure, policies, procedures, processes and resources needed to implement quality management.
Quality Objectives	A means to translate the quality policy strategies into measurable activities. What will we do to meet the goals stated in the quality policy?
Quality Policy	Overall intentions and directions of an organization related to quality as formally expressed by LS Senior Management.
Quality Risk Management	A systematic process for the assessment, control, communication and review of risks to the quality of the product across the product lifecycle.

Term	**Definition or Abbreviation**
Management	Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources within the company or site (ISO 9001:2015 or ISO 13485:2016 depending on the LS site; ISO 17025 for Life Science Laboratory). For the purposes of this manual, Management refers to the Plant Manager and his/her immediate staff and the General Manager and his/her immediate staff. LS Senior Management refers to the CEO / President of LS and his/her immediate staff.

6. SG LS QUALITY GOVERNANCE STRUCTURE

Saint-Gobain has established a Quality Governance model to ensure transparency of quality status and issues to all levels of leadership within the organization. Information is cascaded upward to successively higher levels through a system of Quality Review Committees. At each level, the quality function chairs a cross-functional Quality Committee. The committees will be provided Quality Key Performance Indicators (KPIs) consolidated in dashboards. Quality Management Review is covered in Management Review section below as interpreted from ISO 17025:2017, ISO 9001:2015 or ISO 13485:2016.

To reinforce Quality Unit's role with respect to independent oversight of operations and facilitate an appropriate escalation process, the LS Leadership Team has established a 'dotted-line' reporting structure for the Plant Quality Manager to the LS Quality Systems Manager.

7. THE QUALITY MANAGEMENT SYSTEM

7.1 Hierarchy of the Quality Manual

The LS Quality Manual defines the minimum standards required across the Life Science organization. The Life Science Leadership Team expects all plants or functional units to comply with this Quality Manual.

7.2 Design of the QMS

7.2.1 The QMS is designed to achieve three primary objectives:

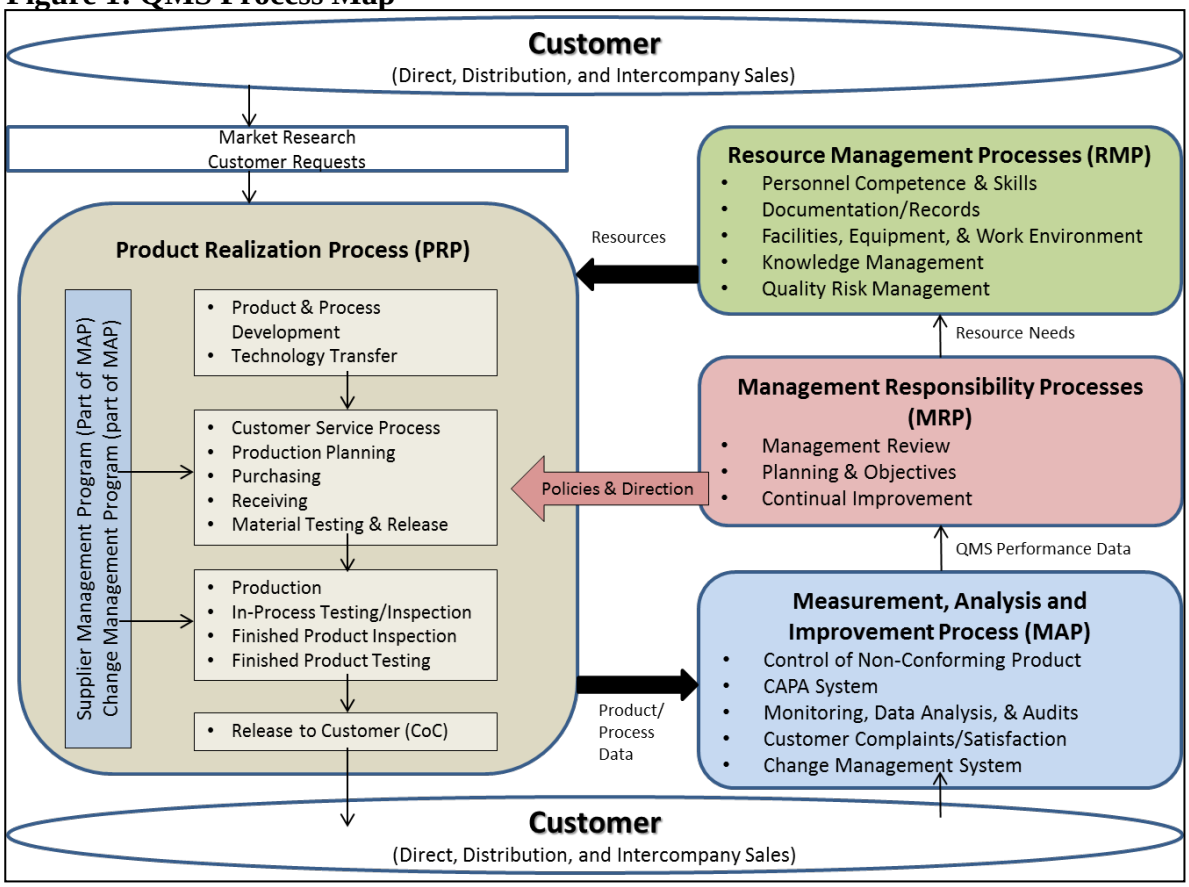
- Achieve product realization: The QMS shall facilitate delivery of products and services that meet the needs of customers without compromise to quality.
- Establish and maintain a state of control: The QMS shall effectively monitor and control process performance, product quality and service quality.
- Facilitate continual improvement: The QMS shall support identification and implementation of process improvements to improve consistent delivery of products and services meeting quality requirements.

7.2.2 The QMS is made up of groups of interrelated processes that, together, support achievement of these objectives. These processes can be grouped into the following four categories:

- Product Realization Processes (PRP), a sequence of processes required for successful product delivery without compromise to quality
- Measurement, Analysis and Improvement Processes (MAP), providing monitoring of process performance and product quality / services and the associated CAPA system
- Management Responsibility Processes (MRP), providing a framework for management review of process performance and product quality / services to drive continual improvement and ensure resource needs are supported, and
- Resource Management Processes (RMP), a group of processes that ensure provision and control of resources required to achieve quality objectives, including the training and change management systems.

The general sequence and interrelation between the four groups and individual processes within each group are illustrated in the QMS Process Map in Figure 1 below.

Figure 1: QMS Process Map



8. QMS PROCESSES

8.1 Management Responsibility Processes (MRP)

Saint-Gobain Life Science Management is responsible for ensuring successful implementation and maintenance of the QMS. The Management Responsibility Processes described below drive continual improvement and provide policies and direction for the Product Realization and Resource Management Processes.

8.1.1 Planning and Objectives

LS Senior Management sets Quality Objectives that are aligned with the Quality Policy and communicates them throughout the organization. Resource needs are defined and provided to support achievement of the Quality

Objectives. Performance indicators are used to measure progress and are acted upon as required.

8.1.2 Management Oversight and Management Review

The intent of Management Oversight and Management Review is to actively engage, drive ownership, and hold responsible all levels of management, the Quality Unit, and all Life Science employees in their respective responsibilities for quality and compliance to include: reporting, action, review, and communication. By providing the right information at the right time and at the right level, the organization, including management, is enabled to take the right action by recognizing and focusing on what's important.

Proper Management Oversight and Management Review assure awareness, provide control and drive continuous improvement in the manufacture, testing, warehousing, and distribution of Saint-Gobain products and analytical services through:

- Adequate identification and, as appropriate, escalation of issues;
- Assessment, reporting, review, and control measures to assure the overall performance of the SG quality system; and
- Thorough effective communications from and to all levels of the organization, including Senior Management and the shop floor.

Management is responsible to assure that all necessary enablers are in place to allow for fulfillment of Management Oversight, to include the appropriate resources, objectives and direction, organizational structures and leadership, training, and communication forums. Additionally, Management is responsible to assure that the Quality System is implemented and effective and to maintain a formal Management Review process of that system.

- Quality Reporting

  Quality Reporting is required for identification of events, for the tracking and monitoring of the investigation and resolution of these events, and for the trending and reporting of the events. This reporting occurs via our established quality systems in accordance with procedures SOP-FLS-CORP 0007, Event Process and SOP-FLS-CORP 0008, *CAPA*.

- Quality Communication and Escalation

Quality Communication occurs through a cascade of meetings from the job board to Departmental Review meetings to Site Management Reviews and LS Management reviews. The cascade of information flows up and down to ensure issues are escalated and decisions are made and effectively enforced.

In cases where there are exceptional events that require exceptional decisions to the requirements in LS policies or plant SOPs, escalation is made to the LS Quality Representative and Business Management. Examples of exceptional events may be supplier issuance of Force Majeure, risk to patient, or employee safety risk. Decisions made in this forum are appropriately documented (e.g. event management, change management).

- Management Review

  Management Review is a formal ISO process. Management Review occurs on three levels at SG. The first two levels of review are at the plant. The first level review is considered a "Departmental" or "Job Board" or "Quality Board" review. Key quality indicators are reviewed on a frequent periodic basis (e.g. weekly/monthly). Examples of these reviews may be a Change Board or Material Review Board.

  The second level is called the Site Level QMR. Performance and trending information related to the key quality systems elements are prepared in a meaningful manner such that the health of individual quality system elements can be determined, that product and process related trends can be identified and most importantly, that actions can be identified and taken to remedy any issues. The following quality indicators are included in the scope of the Site QMR depending on the ISO certification that applies to the LS site or laboratory:
  - extent to which the quality objectives have been met (fulfillment of objectives)
  - changes in internal and external issues
  - suitability of policies and procedures
  - training
  - monitoring and measuring of processes or process performance
  - monitoring and measuring of products or conformances of products
  - deviations (product nonconformities)
  - complaints & handling

- customer satisfaction and feedback from relevant parties (e.g. personnel)
- maintenance & calibration
- audits (internal & external including assessments from external bodies)
- corrective actions
- preventive actions
- reporting to the regulatory authorities (where applicable)
- performance of external providers
- adequacy of resources
- the effectiveness of actions taken to address risks and opportunities
- results of risk identification
- outcomes of the assurance of the validity of results
- changes in the volume and type of work or in the range of laboratory activities
- changes that could affect the QMS
- recommendations (opportunities) for improvement
- applicable new or revised regulatory requirements
- status of actions from prior Management Reviews.

The third level of Management Review is the LS Management level. This review consists of the leaders with oversight at a business level and includes the Business Managers, Operations Directors, Application Engineering Management, R&D Management and LS Quality Management. This review is a roll up of key information from the Site QMRs as appropriate. This review evaluates the overall performance of the Life Science quality system and product and process quality performance. Decisions for necessary actions are made at this level including alignment on areas of highest risk, resources, and priorities. Actions necessary to mitigate risks are determined and the LS Quality Objectives are evaluated for necessary adjustments. Large capital expenditures and strategic resource necessary to address the LS Quality Objectives are identified at this level for input to the LS Strategic Plan and Budget Plan.

Minutes of all three Management Reviews should be maintained by the Quality Lead of the meeting and action items are tracked and monitored in the CAPA system where appropriate.

8.1.3 Continual Improvement

Meaningful Quality Objectives, appropriate resource planning, and the management review process drive continual improvement. Management objectives are reviewed and established annually to identify areas of focus for performance improvement and effective execution for the following year.

8.2 Resource Management Processes

8.2.1 Personnel Competence and Skills

Saint-Gobain and contracted employees shall have the education, documented training, and/or experience to perform their job duties. A job description is used for documenting what the required knowledge, skills, and abilities are for each function within the organization. An individual's training needs are determined by Management according to the knowledge and skills required to perform a specific job function. Site level training procedures describe the organization of, requirements for, and implementation of training and development for Saint-Gobain and contract employees.

Management and/or designated trainers evaluate training competency through activities such as on-the-job observation, employee performance reviews, and customer feedback (internal & external). Training records shall be maintained to document training appropriate to the job function has been performed.

8.2.2 Facilities, Equipment, and Work Environment

- Facilities are designed to be of a suitable size, construction, and classification to facilitate efficient and clean manufacturing operations to conform to product requirements. Procedures are in place to meet ISO and GMP (as applicable) requirements including room classification, pest control, material and personnel flow, sanitation, and maintenance according to the LS Engineering Standard, ENG-FLS-CORP-0021, *Cleanroom Control Program*. Utilities are designed, controlled, and maintained according to SOPs to support product quality.

  Commissioning, validation, implementation, subsequent changes to, and decommissioning of ISO or GMP facilities and utilities are managed through Saint-Gobain's Change Management Program, SOP-FLS-CORP-0009, *Change Management*. Requalification is performed as required according to the SOP-FLS-CORP-0001, *Validation Master Plan*.

- Environmental, Health, and Safety (EHS) procedures are in place to promote the health and well-being of personnel at SG facilities, and to meet regulations by agencies such as OSHA, EPA, ISO, and local ordinances. Processes are in place to identify and monitor exposure limits to hazardous materials and products. Safety Data Sheets (SDS) sheets are maintained in an appropriate system at the LS plants to be readily accessible. Safety orientation is conducted for all contractors, new SG employees, and visitors.

- Equipment, computerized systems, and software that supports production processes and facilitates business processes (e.g. QAD, Factivity, eQMS, etc.) are qualified for their intended use according to SOP-FLS-CORP-0001, *Validation Master Plan*. Implementation and subsequent changes to these systems are controlled through SG's Change Management Program.

- Equipment is protected from damage and deterioration. Preventive maintenance activities are planned and performed to maintain process capability and optimize availability for production. Maintenance activities are managed through a work order system. Calibration is managed and documented and if limits are exceeded, appropriate actions are taken to assess validity of previous measuring results utilizing the Event Process, SOP-FLS-CORP-0007. Damaged or deteriorated equipment is removed from use until repaired. Maintenance to equipment is made by qualified personnel. In the event equipment that was utilized in the manufacturing process is found to be defective, a product impact assessment will occur and appropriate actions taken and documented according to SOP-FLS-CORP-0007, *Event Process*.

8.3 Product Realization Processes

8.3.1 Product and Process Development

The Research & Development, Application Engineering, Advanced Concept Engineering, or plant-based technical departments are responsible for developing new materials, new applications to existing materials, new processes, and new engineered systems. Development activities, methods, and data are appropriately documented to enable ongoing support of product manufactured at Saint-Gobain. A stage/gate process coupled with the Design, Development and Change Control Checklist are employed in support of the development process following SOP-FLS-CORP-00009, *Change Management*.

8.3.2 Technology Transfer and Commercial Launch Preparedness

Saint-Gobain ensures that products, processes, and technology transfers to commercial production will meet the requirements of our customers and regulatory requirements through our Validation Program. The Validation Master Plan and Design, Development and Change Control Checklist describe the process and requirements for a technology transfer.

Commercial launch readiness from R&D projects is ensured through a systematic review and Design, Development and Change Control Checklist executed in the HPS (High Performance Solutions) Gate process at Gate 5. This is executed within the R&D database or other applicable site level procedure and tool by a Technical Project Leader. Both Regulatory Affairs and Quality Assurance have review and approval roles in this process.

8.3.3 Production Planning and Purchase/Receipt of Starting Materials

The Supply Chain organization is responsible for forecasting customer demand and putting in place both short and long-term feasible production plans based upon customer forecast data provided by the Marketing & Sales organization. Additionally, Supply Chain is responsible for forecasting long-term capacity requirements and alerting management to deficiencies. Saint-Gobain purchases starting materials that meet company (Internal Controls Reference Framework), Pharmacopoeia (USP, NF, EP, etc.), or agreed upon specifications as defined in material specifications, purchase orders, and Quality Agreements (where applicable). Materials are inspected upon receipt and stored in appropriately qualified access-controlled areas under designated storage conditions to maintain the quality and integrity of the materials. Procedures are established for handling damaged, mishandled, or incorrectly labeled materials. Materials that have not yet been tested and released are quarantined from released materials. Labeling and ERP are used as the primary means for quarantining nonconforming materials. Where physical space is available, separate areas are designated for physical storage of nonconforming materials.

A supplier management program is in place according to SOP-FLS-CORP-0032, *Supplier Quality Management*, to ensure the quality of goods and service provided to SG, and is described in the Measurement, Analysis and Improvement Processes section.

8.3.4 Material Testing/Inspection and Release to Production

All starting materials undergo inspection and release according to established procedures and material specifications. Depending on the material and specification, some may undergo testing. Only starting materials from approved suppliers that meet pre-determined specifications and have been approved for use by Quality may be used in Production. The material handlers assign released starting materials to production according to a system of first in-first out. Exceptions to this from specific customers are handled on a case-by-case basis. Inventories are managed through an ERP system (e.g. QAD), and are reconciled for each material.

8.3.5 Finished Product Testing

Commercial product manufactured and released by SG undergoes finished product inspection and for some products, testing according to established specifications. This testing may be performed by SG or by a contracted laboratory. Finished product testing (e.g. lot release testing) is performed by or contracted by SG, a certificate of analysis is issued for conforming product or the test reports are forwarded along with a certificate of conformance. For product that does not have testing performed, a certificate of conformance is issued stating the lot has been manufactured in accordance with approved procedures and specifications.

8.3.6 Product Release

The completed batch record for each product manufactured at SG consists of the executed manufacturing record and/or production router, as well as any relevant forms, system printouts, material CoA's, and reference to any deviation investigation(s). The completed batch record is reviewed by Quality for completeness, accuracy, and conformance to SOPs, manufacturing instructions, and specifications for all product manufactured for regulated industries. Conforming batches are released with a Certificate of Conformance (CoC) stating that the batch was manufactured in accordance with the sites' QMS.

8.3.7 Distribution

Finished product is stored in controlled warehouse environments if required in the storage requirements. Distribution records are maintained to ensure traceability should a recall or other market action become necessary. Procedures are in place describing the requirements for market action should this become necessary. Agreements are in place with distributors of SG

product that ensure cooperation and participation as necessary when market actions are undertaken. SOPs govern the handling and destruction of returned goods.

8.3.8 The following controls are in pace to support the production realization process:

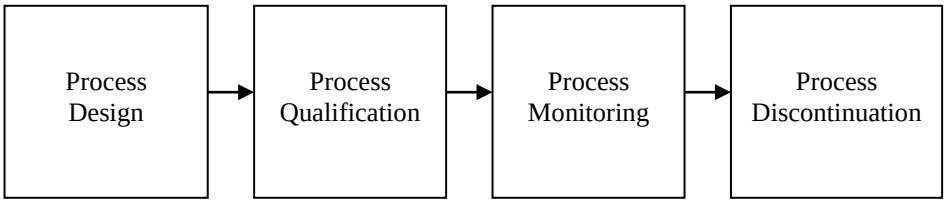
- Identification and Traceability

  Procedures ensure that identification of raw materials, components, and in-process product is maintained from receipt, through manufacturing and packaging, to release, warehousing and distribution. Where required, the use, cleaning, and maintenance of production equipment and areas are documented in site specific SOPs for traceability. Procedures are also in place to ensure the identification of test samples from receipt through proper disposal.

- Validation Program

  Validation is defined as the collection and evaluation of data, from the process design stage to process discontinuation, with established scientific evidence that a process is capable of consistently delivering quality products. Validation activities at SG are conducted using a lifecycle approach in four stages:

Figure 2: Validation Lifecycle



  - **Process Design** consists of building and capturing process knowledge, understanding and developing the strategy, and rationale for process control.
  - **Process Qualification** confirms that the Process Design is capable of reproducible commercial manufacturing.
  - **Process Monitoring** ensures that the process remains in a state of control during the operation of the system or manufacturing of product through review, trending, and analysis of relevant data, such as system

performance, process changes, raw material changes, and process deviations.
  - **Process Discontinuation** is the removal of commercial product from the SG portfolio and inactivation of the related documents.

- Monitoring & Measuring Equipment

  Measuring equipment is controlled, calibrated, and maintained. Equipment is uniquely identified and records are maintained that document the results of each calibration where calibration is required. Calibration of measuring equipment employs standards traceable to NIST, ASTM, or other appropriate standards.

  Where required, monitoring and measuring equipment is documented in site specific SOPs for traceability.

- Warehousing

  Raw materials, components, in-process product, and packaged finished goods are stored and transported to meet label requirements and customer specifications to ensure quality and integrity of the material or product is maintained throughout the shelf life. Warehouses are secure and access controlled, minimally by controlled access to the plant. Environmental conditions are monitored as appropriate. Inventory remains traceable from receipt through shipping or destruction. Appropriately segregated storage areas are used where appropriate.

- Product Destruction

  SOPs describe the requirements for handling and destruction of production waste, laboratory waste and finished goods to ensure conformance to GMP, EPA, and Foreign Trade Zone requirements.

- Control of Non-Conforming Product

  Deviations and non-conformances are identified, investigated, and documented according to SOP-FLS-CORP-0007, *Event Process*. Non-conforming product is withheld from use until appropriately dispositioned. Root cause is investigated and corrective and/or preventive actions (CAPAs) are implemented when appropriate.

- Customer Complaints/Satisfaction

The LS Leadership Team and site Management Teams monitor customer satisfaction through indicators such as on-time delivery, backorder levels, customer complaints, customer returns, customer surveys and customer-related corrective actions.

Procedures are established for handling and investigating product complaints. Required notifications are made within established timeframes to meet regulatory reporting requirements and customer Quality Agreements. A product complaint may be received in different ways to different employees. If an employee receives a product complaint via email, phone or other mode of communication, they must report it to Quality as soon as they become aware of it.

- Audits and Data Analysis
  - Internal Audits

    The performance of the QMS is measured according to site internal audit procedure with regular and systematic independent internal audits conducted by qualified auditors. The audit program uses a risk-based approach to determine frequency and depth of audits of each system or process.

  - A supplier management program is in place to assure the control of external providers and the quality of materials used in the manufacturing of products. The scope of the supplier management program includes all suppliers of goods and services to SG, including third-party contract manufacturers, materials, components, calibration and testing services, and sister sites. Assessment of suppliers may include paper assessments, review of regulatory or ISO inspection results, and/or an on-site audit. The supplier management program is described in SOP-FLS-CORP-0032, *Supplier Quality Management*.

- Monitoring & Measurement of Product

  Product is measured and monitored on a batch basis primarily through inspection by Quality Control and is documented in the batch record or production router. Product is monitored under the Management Review process by trending events (e.g. nonconforming material, product complaints, and audit nonconformances).

- Environmental Monitoring

  In Life Science facilities with an ISO classified cleanroom, the environmental monitoring program is managed and governed according to LS Engineering Standard ENG-FLS-CORP-0018, *Environmental Monitoring Program*. Monitoring data reviewed includes viable and non-viable particulate, temperature, humidity, and differential pressure. Compressed gases and facility water systems are also reviewed.

- CAPA System

  SG ensures that appropriate, timely corrective action is taken whenever systemic, major or critical non-conformities are discovered, and when preventative actions are identified. CAPAs are the means by which formal action is taken to address causes(s) (root, probable, or contributing) of any event (examples include deviations, trends, audit observations, and complaints).

  SG utilizes either an electronic QMS software tool or a manual, paper-based system to document CAPAs. The effectiveness of CAPAs is reviewed and documented within the same system.

  Corrective and Preventive actions which have the potential to impact the following examples are within the scope of the CAPA system: product registration, GMPs where applicable, product attributes, the state of validation of processes, equipment, instruments, facilities (design or cleanliness), record control, production and process controls, validations and systems.

8.4 QMS enablers

In order to support an effective and successful QMS, Saint-Gobain has established policies and procedures relating to data integrity, documentation practices, risk management and knowledge management.

8.4.1 Data Integrity

Saint-Gobain policy SOP-FLS-CORP-0030, *Policy on Data Integrity*, outlines the key elements necessary to help ensure the reliability and integrity of information and data throughout all aspects of a product's lifecycle.

Data integrity is the extent to which all data are complete, consistent, and accurate throughout the data lifecycle. Ensuring data integrity means collecting, documenting, reporting, and retaining data and information in a manner that accurately, truthfully and completely represents what actually occurred.

Employees shall adhere to established company procedures that describe documentation control and retention requirements, such as SOP-FLS-CORP-0012, *Good Documentation Practices for Validation Activities*, and SOP-FLS-CORP-0031, *Good Documentation Practices*.

8.4.2 Quality Risk Management

Saint-Gobain Corporate Policy SOP-FLS-CORP-0010, *Quality Risk Management Policy*, provides the model for risk management that is used at SG. Each site is expected to have a Risk Management Plan in alignment with the policy and implement the identified risk management practices into the sites Quality System Elements (e.g. CAPA, Change, Validation, etc.)

8.4.3 Knowledge Management

It is important to manage product and process knowledge throughout the product lifecycle. Mechanisms and examples of documents contributing to knowledge management and transmission at SG include:

- Product development studies
- Technology transfer documentation
- Process validation studies
- Raw material and finished product testing data
- Manufacturing history (executed batch records)
- Stability studies
- QMS data
    - Investigations
    - CAPA
    - Change controls
    - Complaint reports
    - Deviations
- Trend evaluation and reporting in Management Reviews
- Supplier audits

- Supplier Management dossiers
- Internal audits
- Employee training curricula
- Laboratory records

9. CROSS REFERENCES

Document Number	Document Title
SOP-FLS-CORP-0012	Good Documentation Practices for Validation Activities
SOP-FLS-CORP-0001	Validation Master Plan
SOP-FLS-CORP-0010	Quality Risk Management Policy
ENG-FLS-CORP-0021	Cleanroom Control Program
SOP-FLS-CORP 0008	CAPA
SOP-FLS-CORP-0009	Change Management
SOP-FLS-CORP-0007	Event Process
SOP-FLS-CORP-0032	Supplier Quality Management
ENG-FLS-CORP-0018	Environmental Monitoring Program
SOP-FLS-CORP-0030	Policy on Data Integrity
SOP-FLS-CORP-0031	Good Documentation Practices

10. EXTERNAL REFERENCES

- ISO 9001:2015 (E) Quality management systems—Requirements
- ISO 13485:2016 (E) Medical Devices – Requirements for Quality Management Systems – Requirements for Regulatory Purposes
- ISO 17025:2017 (E) General Requirements for the Competence of Testing and Calibration Laboratories
- ICH Q10 Pharmaceutical Quality System, International Conference on Harmonization of Technical Requirement for Registration of Pharmaceuticals for Human Use

11. ATTACHMENTS

None

12. APPENDICES

None

13. FLOW CHARTS

None

14. DIAGRAMS

None

15. REVISION INFORMATION

Revision	Revision Date	Page(s) Affected	Revision Description
0	January 31, 2017	All	Original Issue
1	14 Jan 2019	All	Updated title. Added in designation of management representative for ISO 13485 registered sites. Added ISO 13485 and 17025 to external references section and requirements where needed throughout document. Added in management review inputs from ISO 13485 and 17025. Updated product realization section to include new Design, Development and Change Control Checklist. Clarified primary means of quarantining product throughout LS. Added Prepared By signature in approval section and remove General Manager role. Updated titles to align with organizational change. Removed Quality Policy since it is controlled as a standalone document. Added Approved Delegates to Responsibilities section.

16. PROCEDURE APPROVAL SIGNATURES

Prepared By	Job Title	Date Approved
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Approved by	**Job Title**	**Date Approved**
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	Jim Ding LS R&D Director	
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15. REVISION INFORMATION

Revision	Revision Date	Page(s) Affected	Revision Description
0	January 31, 2017	All	Original Issue
1	14 Jan 2019	All	Updated title. Added in designation of management representative for ISO 13485 registered sites. Added ISO 13485 and 17025 to external references section and requirements where needed throughout document. Added in management review inputs from ISO 13485 and 17025. Updated product realization section to include new Design, Development and Change Control Checklist. Clarified primary means of quarantining product throughout LS. Added Prepared By signature in approval section and remove General Manager role. Updated titles to align with organizational change. Removed Quality Policy since it is controlled as a standalone document. Added Approved Delegates to Responsibilities section.

16. PROCEDURE APPROVAL SIGNATURES

Prepared By	Job Title	Date Approved
Genine Dale	Genine Dale Worldwide Quality System Manager	14JAN2019
Approved by	**Job Title**	**Date Approved**
	Ernst Breinig LS Operations Director	16 Jan 2019
	Jim Ding LS R&D Director	17/1/19
Polly Hanff	Polly Hanff LS Global Regulatory Affairs & Quality Director	16 Jan 2019