STANDARD OPERATING PROCEDURE	
Procedure #: SOP-FLS-CORP-0032	**TITLE**
Revision: 3	Life Sciences Quality Manual

1. INTRODUCTION

Saint-Gobain Life Sciences (LS) 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. Quality is measured and judged by both external and internal customers, including interested parties, 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 LS Leadership Team is accountable for the quality of the 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 and AS9100, the Plant Quality Manager role is the site's management representative. Business leaders within LS 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 LS 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 AS9100D, 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. Any exclusion(s) to the standards or regulations will be documented and justified within each individual site's Quality Manual. For the LS Laboratory, the following exclusions shall apply: ISO / IEC 17025:2017(E), Sections 7.3 and 7.8.5. The range of laboratory activities that are within the scope of the ISO 17025 standard shall be managed as a separate document.

The Quality Manual is binding for all LS 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 LS product portfolio. This includes functional groups such as Design, Information Systems (IS/IT), Purchasing, Human Resources, and Supply Chain Management.

The scope of this Quality Manual is applicable to all of the Saint-Gobain Life Sciences manufacturing sites. Refer to LST-FLS-CORP-0005, *SGLS Manufacturing Site List*.

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 the LS and local level shall demonstrate leadership and commitment with respect to the quality management system by:

- taking accountability for the effectiveness of the quality management system;
- ensuring that the quality policy, quality manual and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- establishing measurable and meaningful quality objectives and associated metrics that aim to improve customer satisfaction;
- ensuring the integration of the quality management system requirements into the organization's
- business processes;
- promoting the use of the process approach and risk-based thinking;
- ensuring that the resources needed for the quality management system are available;

- ensuring that responsibilities and authorities are defined, documented and communicated within the organization;
- communicating the importance of effective quality management and of conforming to the quality management system requirements;
- ensuring that the quality management system achieves its intended results;
- engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- promoting improvement
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;
- establishing a review process according to the Management Review Governance Structure model (refer to Management Review Section below);
- ensuring prompt communication, handling, and resolution of out of specification investigations and events within their areas of responsibility.
- product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

Management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- the focus on enhancing customer satisfaction is maintained.

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 (SOPs).

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 LS lab. The responsibilities are mandated by standards, defined in SOPs and / or outlined in customer test requests. These lab responsibilities include:

- Identification of risks of 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.
- Communication to customers in advance of information it intends to place in the public domain.
- Notification to the customer concerned, unless prohibited by law, the release of confidential information.
- The authority and responsibility to disposition all test results.
- Review and approval of Events per SOP-FLS-CORP-0007, *Event Process*
- Review and approval of out of specification (OOS) investigation reports per SOP-FLS-CORP-0047, *Procedure for Handling Out of Specification Test Results*.
- Approval of test methods, specifications, equipment, utilities, suppliers and SOPs using the change management system outlined in SOP-FLS-CORP-00009, *Change Management*.
- Overall creation and maintenance of the operation of the lab.
- Adherence to ALCOA principles following good laboratory practices and data integrity principles as outlined in SOP-FLS-CORP-0030, *Policy on Data Integrity*.

4.5 **Employees:** Every employee is responsible for understanding and supporting the quality objectives and adhering to policies and procedures. Completing all quality training required for the specific position and adhere to the principles of Data Integrity. 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.

- Employees are obligated and empowered to speak up when quality issues are observed.

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

Interested Parties	Interested parties include (but not limited to):
	• ***Internal Parties*:**
	  ○ Saint-Gobain employees
	  ○ Group internal Audit
	  ○ SGLS manufacturing sites
	• ***External Parties*:**
	  ○ External providers (e.g. Suppliers)
	  ○ Customers
	• ***Public Parties*:**
	  ○ Notified Bodies
	  ○ Regulatory Agencies (e.g. Federal Aviation Administration – FAA; Food and Drug Agency – FDA; European Food Safety Authority, European Union Aviation Safety Agency – EASA; National Medical Products Administration – NMPA; National Health and Family Planning Commission (China NHFPC); China Inspection and Quarantine (CIQ); The Ministry of Health, Labor, and Welfare (Japan MHLW); The Food Safety Commission of Japan (FSCJ), European Chemicals Agency (ECHA), European Commission (EC); Office of Environmental Health Hazard Assessment (OEHHA); California Attorney General's Office; US Securities and Exchange Commission (SEC) and Toxics in Packaging Clearinghouse (TPCH)
	  ○ Export Authorities

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 (AS9100D, ISO 9001:2015 or ISO 13485:2016 depending on the LS site; ISO 17025 for LS Laboratory). For the purposes of this manual, Management refers to the Plant Manager and his/her immediate staff. LS Senior Management refers to the CEO / President of LS and his/her immediate staff and / or the CEO's immediate staff's teams (N-2).

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.
WCM Management	Saint-Gobain's World Class Manufacturing (WCM) is the approved continuous improvement framework that defines the logic, rigor and detail of how sustained improvements in operational performance and customer satisfaction can be achieved.

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. The committees will be provided Quality Key Performance Indicators (KPIs) consolidated in dashboards. Quality Management Review is covered in Management Review sections below as interpreted from AS9100D, 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 LS organization. The LS 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 seven categories:

- Management Responsibility Process (MRP1), providing a framework for management review of process performance and product quality / services to drive continual improvement and ensure resource needs are supported, and
- Measurement, Analysis and Improvement Processes (MAP1), providing monitoring of process performance and product quality / services and the associated CAPA system
- Product Realization Processes (PRP), a sequence of processes required for successful product delivery without compromise to quality which is broken up into two sub categories
    - PRP1 – product development and transfer
    - PRP2 – commercial production
- Resource Management (RMP) a group of processes that ensure provision and control of resources required to achieve quality objectives, including the training and change management systems which is broken up into three sub categories:
    - RMP1 – resource management of personnel
    - RMP2 – resource management of materials
    - RMP3 – resource management of work environment and machines

7.3 Design of WCM Management

7.3.1 WCM is comprise of eight (8) Pillars with each Pillar focusing on a different set of losses. The Pillar role is to identify, eradicate and set up systems to prevent these losses from re-occurring.

Saint-Gobain World Class Manufacturing Model:

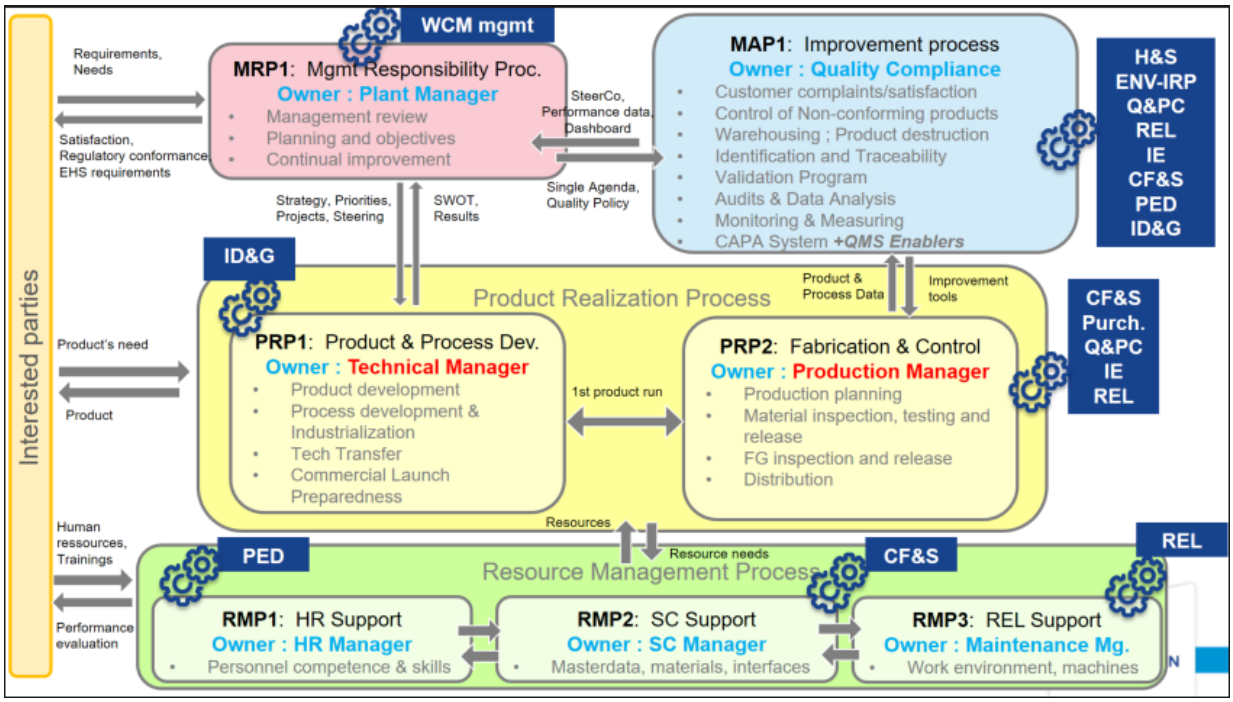
- Health & Safety
- Environment & risk Prevention
- Reliability
- Industrial Efficiency
- Quality & Process Control
- Customer Focus & Service
- People Development
- Innovation Development & Growth

7.3.2 The WCM model contains a set of toolkits to ensure operational problems are solved with logic, pace, rigor, and with sustained long term success.

7.3.3 WCM Pillar Boards, Systems Methodologies, and Tools have been developed and designed to provide logical roadmaps and analysis with rigorous and detailed application to ensure sustained results. Refer to the Saint-Gobain World Class Manufacturing Policy.

The general sequence and interrelation between the seven groups and individual processes, within each group utilizing the WCM framework and tools is illustrated in the QMS Process Map in Figure 1 below.

Figure 1: QMS Process Map



8. QMS PROCESSES

8.1 Management Responsibility Processes (MRP1)

Saint-Gobain LS 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 the Quality Objectives that are aligned with the Quality Policy and communicates them throughout the organization. The requirements, risks, opportunities, strengths, weaknesses, external and internal issues of interested parties are leveraged when constructing the Life Sciences SWOT Analysis and Quality Objectives. The Quality Objectives are documented and communicated to the LS organization appropriately (e.g. through the use of a Quality Dashboard and / or Single Agenda). Resource needs are defined and provided to support

achievement of all Objectives outlined in the LS Single Agenda. 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 LS 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 LS 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 within 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 Senior 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 Global Regulatory Affairs and Quality Director, LS Operations Director, and General Management for that business. 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 requirement outlined in SOP-FLS-CORP-0041, *Management Review*. Management Review occurs on three levels. 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 (Quality Management Review). The review consists of the Plant Manager, Plant Quality Manager and other members of the site leadership team as defined in SOP-FLS-CORP-0041, *Management Review*. 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 Senior Management level. This review consists of the leaders with oversight at a business level and includes but is not limited to the, LS CEO, General Managers, Operations Director(s), R&D Management, Supply Chain Director, and LS Quality Management depending on the LS Senior Management Review Meeting taking place. This review is a roll up of key information from the Site QMRs as appropriate. This review evaluates the overall performance of the LS 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 shall be generated by a designated scribe at each meeting forum then archived after approval. Action items are captured, 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 (e.g. LS Single Agenda) to identify areas of focus for performance improvement and effective execution for the following year.

8.2 Measurement, Analysis, and Improvement Process (MAP1)

8.2.1 The following controls are in place to support providing monitoring of process performance and product quality / services within the production realization process:

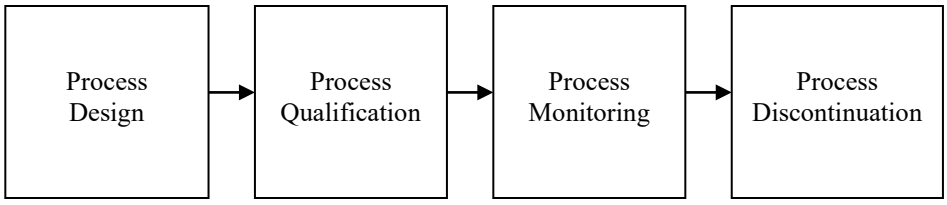
- Identification and Traceability

  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 documenting and handling and investigating product complaints in accordance with SOP-FLS-CORP-0062, *Customer Complaint Handling*. 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 non-conformances).

- Environmental Monitoring

  In LS 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 according to SOP-FLS-CORP-0008, *CAPA Procedure*. 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.

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.

8.2.2 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*.

8.2.3 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.)

8.2.4 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

8.3 Product Realization Processes (PRP1 & PRP2)

The following product realization processes represent the upfront product development and transfer processes associated with PRP1:

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-0009, *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.

The following product realization processes represent the hand off of the product transfer and commercialization processes associated with PRP2:

8.3.3 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.

8.3.4 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 (CoA) 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 (CoC) is issued stating the lot has been manufactured in accordance with approved procedures and specifications.

8.3.5 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 CoC stating that the batch was manufactured in accordance with the sites' QMS.

8.3.6 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.

8.4 Resource Management Processes (RMP 1, RMP2, & RMP3)

8.4.1 RMP1 - 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.

8.4.2 RMP2 – Master data, materials, and interfaces

- 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.

8.4.3 RMP3 - Facilities, Equipment, Utilities 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 Good Manufacturing Practices (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 Policy*.

- 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 Occupational Safety and Health Administration - OSHA, Environmental Protection Agency - 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 Policy*. 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*.

9. INTERNAL REFERENCES

Document Number	Document Title
SOP-FLS-CORP-0012	Good Documentation Practices for Validation Activities
SOP-FLS-CORP-0001	Validation Master Plan Policy
SOP-FLS-CORP-0010	Quality Risk Management Policy
ENG-FLS-CORP-0021	Cleanroom Control Program
SOP-FLS-CORP 0008	CAPA Procedure
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
SOP-FLS-CORP-0047	Procedure for Handling Out of Specification Test Results
LST-FLS-CORP-0005	SGLS Manufacturing Site List
N/A	Saint-Gobain World Class Manufacturing Policy

10. EXTERNAL REFERENCES

- AS9100 Revision D, Quality Management Systems – requirements for Aviation, Space and Defense Organizations
- 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

STANDARD OPERATING PROCEDURE

Procedure #: SOP-FLS-CORP-0032	**TITLE**
Revision: 3	Life Sciences Quality Manual

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.
2	22 November 2019	1-15, 20, 22-23	Update procedure format to current practice. Add in AS9100 Revision D throughout document. Add in exclusions for ISO 17025 standard. Define interested parties. Update the management definition. Add in use of quality dashboards and single agenda as examples for capturing quality objectives. Update management review and responsibilities sections. Update titles in Approval section. Define abbreviations. Add OOS procedure reference.
3	01 December 2021	All	Update Interested Parties definition, Employees responsibilities, and reference to LST-FLS-CORP-0005 to align with Saint-Gobain ICQRF requirements. Revised the QMS Process Map to integrate the WCM methodologies and incorporated the references to WCM. Revision to the content to support the QMS Process Map updates.

15. PROCEDURE APPROVAL SIGNATURES

Prepared By	Job Title	Date Approved
Allison Vereb — Digitally signed by Allison Vereb Date: 2021.12.01 12:03:13 -05'00'	Allison Vereb Worldwide Quality Systems Manager	Refer to e-signature
Approved by	**Job Title**	**Date Approved**
Ernst Breinig — Digital unterschrieben von Ernst Breinig Datum: 2021.12.15 16:30:50 +01'00'	Ernst Breinig LS Vice President of Operations	Refer to e-signature
Narendar, Yeshwanth — Digitally signed by Narendar, Yeshwanth Date: 2021.12.15 08:49:57 -05'00'	Yeshwanth Narendar LS Vice President R&D & Innovation	Refer to e-signature
Hanff, Polly — Digitally signed by Hanff, Polly Date: 2021.12.15 13:50:56 -05'00'	Polly Hanff LS Global Regulatory Affairs & Quality Director	Refer to e-signature