



Life Sciences Change Notification and Communication Policy

Saint-Gobain understands that the products supplied to our customers may be used in potentially critical applications, therefore, maintains a global quality system for Change Management and Change Notification to ensure timely, consistent, and transparent communication of changes that may impact product quality, regulatory compliance or supply continuity.

CHANGE NOTIFICATION

Saint-Gobain determines if a change notification is required based upon the market of the Product, industry expectations, existing agreements, and the risk assessment associated with the change and its potential impact on Product and recommended application.

Saint-Gobain commits to notifying impacted customers who purchase Product direct from Saint-Gobain in writing via a change notification document based upon the following requirements.

Notification Period	Scope	Notifiable Timeline	Notifiable Changes
Change Notification – Level 1	Change to: <ul style="list-style-type: none"> • Product form, fit, or function • The validated state of a product • Specification and critical quality attributes (dimensions, safety, identify, purity, product characteristics) • QMS certification status 	6-12 months advance notification	<ul style="list-style-type: none"> • Manufacturing location, equipment (excludes like for like changes), critical process parameters • Raw material change • Fluid path component change in a bioprocessing assembly • Product Discontinuation • Design or Dimensional changes • Product specification or claim modification or removal • Part Number change • Sterilization changes • Subcontractor change
Change Notification - Level 2	Changes that have no commercial production impact and minimal potential to negatively affect commercial product quality.	90 days advance notification	<ul style="list-style-type: none"> • Product documentation revisions with no impact to product quality criteria (e.g. Product Branding, Certificates, documentation typos) • Packaging changes that do not impact the critical quality attributes or product specifications • Second Sourcing components without change to specification, form, fit, or function. • Cosmetic changes to labeling/packaging • Non-fluid path component in a bioprocessing assembly change • Product release test method change
Change Notification - Emergency	Product impact is assessed during the change management process and documented in the notification.	As soon as possible	<ul style="list-style-type: none"> • A supplier initiates an unplanned change • There is an urgent quality or safety need • Continuity of supply cannot otherwise be maintained



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CHANGE APPROVAL

Saint-Gobain's policy for approval is based upon the type of Product supplied and the scope of change. Change approval requirements will be communicated within the change notification.

Product Type	Definition	Customer Approval
Standard/ Catalog	A standard product offered under any Saint-Gobain brand and/or listed on a publicly available product list. It is available for purchase by all customers without restriction. The product may also be configured using a predefined set of selectable options or features (for example, tubing ID/OD/length, packaging configuration, or post-processing) while still remaining part of the standard catalog offering.	Not Required
Custom	A Product exclusive to a unique customer due to tailored branding or exclusive design elements that are governed by customer specific agreements and pricing terms.	Required

CUSTOMER COMMUNICATIONS

Saint-Gobain determines the risk of complaints, non-conformities and critical events for impact to the safety, quality, and efficacy of Product manufactured and requires customer communications meeting Saint-Gobain internal policies and procedures and existing Quality Agreements. Saint-Gobain commits to the following customer communications for Product supplied direct to customers.

Type	Communication Requirements
Complaints	<ul style="list-style-type: none"> • Complaint Acknowledgement within 24 hours • Complaint Investigation Response <ul style="list-style-type: none"> ○ 30 calendar days (routine complaints) ○ 45 calendar days (investigations requiring microbiological) <p><u>Note:</u> Interim complaint investigation responses will be supplied to the Customer in the event the above timelines cannot be met.</p>
Non-Conformities	For non-conformities identified affecting Product quality after the Product has been shipped to a customer a Quality Alert will be communicated within three (3) business days.
Critical Event	For internal events identified to have negative impact on Customer or Product supplied communication will occur within three (3) business days

Recipients of any of the above notifications or communications within this policy have the responsibility to further distribute as necessary within their supply chain and in accordance with their applicable requirements.