Global Supplier Standards Manual (GSSM)

Version 1.0
Released April 1, 2024

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1.0 OVERVIEW

1.1 PURPOSE

The purpose of this document is to ensure that external Baxter suppliers meet the requirements and expectations documented in this Global Supplier Standards Manual (GSSM).

1.2 SCOPE

This manual applies to all external Baxter Suppliers. Suppliers are also required to abide by any additional requirements specified in other agreements with Baxter. GSSM is not intended to replace (or alter) any contracts, drawings, specifications, or purchase orders by any means.

1.3 PERFORMED BY

The following role	Performs this task
Suppliers	Follow the requirements defined in this document
Baxter personnel	Support suppliers to meet these requirements

1.4 RESPONSIBILITY

Suppliers are responsible for reviewing new and revised Baxter Requirements including Customer Requirements and determining the impact on their Quality & Environmental Health & Safety Management System and promoting awareness of Baxter's GSSM at their locations.

2.0 GENERAL REQUIREMENTS

2.1 EXPECTATIONS

We view our suppliers as an extension of our own processes. Therefore, Baxter shall and intends to do business with only those suppliers who consider their customer as a true extension of their processes. Suppliers shall ensure that each of their products or services complies with all the requirements mutually agreed to with Baxter as well as all applicable requirements defined by applicable global regulatory agencies. Suppliers are accountable not only for the value of the products and services they provide but for the value added to our processes as well. Suppliers shall provide timely responses on all correspondence with Baxter e.g., Quality Agreement, SCAR, Non-Conformance, etc.

2.2 COMMUNICATION

The official business language for all documents and communication is English. Other languages may only be used as agreed.

2.3 PRIMARY POINT OF CONTACT

Designated Baxter Category Manager. Contact details can be found on the Contract, Master Supply Agreement (MSA) or Quality Agreement (QA), whichever is available.

3.0 GLOBAL TERMS AND CONDITIONS

3.1 https://www.baxter.com/partners-suppliers/baxter-suppliers/purchase-order-terms-conditions

3.2 SUPPLIER FINANCIAL HEALTH

Our supplier community is a critical component to our success hence it is important for Baxter to establish transparency and visibility into our suppliers financial stability. Baxter may require suppliers to provide financial records for Baxter's internal review. All reports provided by the supplier are treated with utmost confidentiality.

4.0 CORPORATE RESPONSIBILITY (CR)

As Baxter, we are focused on tackling the environmental, social and governance (ESG) topics that affect our patients, customers, employees, communities, and other stakeholders. We are committed to respecting the highest standards of labor and human rights, environmental and ethical conduct.

We achieve these commitments through our corporate responsibility program. Please refer to our 2030 Corporate Responsibility Commitment (https://www.baxter.com/our-story/corporate-responsibility-0) that outlines our goals.

4.1 EXPECTATIONS

We at Baxter have always considered our suppliers as an integral part of our business and critical to delivering the highest quality of products and patient care. We seek relationships with suppliers that operate in accordance with these expectations to bolster our mutual journey towards corporate responsibility. We will review this section annually and update as needed to reflect the evolution of our Corporate Responsibility program and the latest expectations from our suppliers.

4.1.1 **Principles**

Suppliers are expected to:

a) Operate in an environmentally responsible manner.
b) Respect human and labor rights.
c) Foster a culture of diversity, equity & inclusion.
d) Behave ethically and with integrity.
e) Establish effective data security systems and protect personal information.

4.1.2 **Standards**

Suppliers are expected to:

a) Uphold the Standards in the most efficient manner.
b) Make reasonable efforts to disclose information prescribed by these Standards (or as agreed with Baxter).
c) Demonstrate they have policies and management systems for priorities identified in this Standard.

d) Uphold similar requirements in their own supplier base and business relationships.

4.1.3 **Approach**

Baxter welcomes suppliers to engage with us as we strive to assist our business partners to build necessary capabilities in line with these Standards.

Supplier expectations are listed as:

a) "Expected" for mandatory requirements to qualify as responsible business operations and conduct business with Baxter.
b) "Encouraged" for expectations beyond minimum compliance and define additional expectation for responsible business operations.

4.1.4 **Monitoring**

Suppliers are expected to self-monitor their alignment with Baxter standards. Suppliers shall notify Baxter if any complications and conflicts exist when complying with the standards.

Baxter utilizes EcoVadis (www.ecovadis.com) to collect supplier data and assess performance. Suppliers are expected to complete an assessment on the EcoVadis platform, unless otherwise agreed with Baxter. Suppliers should also provide Baxter with any additional relevant sustainability reports, if available.

4.2 ENVIRONMENTAL RESPONSIBILITY

Suppliers are expected to operate in an environmentally responsible and efficient manner to minimize adverse impact on the environment. Suppliers are encouraged to help their own suppliers to adopt the same standards. Please refer to the Environment, Health and Safety section of Baxter's Ethics and Compliance Standards https://www.baxter.com/partners-suppliers/new-suppliers for additional information.

4.2.1 **Climate and Emissions**

Suppliers are expected to:

a) Comply with applicable laws and regulations governing climate risk assessment and emissions management.
b) Measure and disclose energy usage and greenhouse gas (GHG) emissions for their own operations (Scope 1 and 2), as requested.
c) Disclose the apportion or estimation of emissions attributed to Baxter's business, as requested.

Suppliers are encouraged to:

a) Set science-aligned goals or targets for GHG emissions reduction and share them with Baxter.
b) Implement a systematic approach for reducing energy usage and GHG emissions and monitor and report progress.
c) Measure and disclose the apportion or estimation of Scope 3 emissions attributed to Baxter's business, as requested.

4.2.2 **Water and Wastewater Management**

Suppliers are expected to:
Comply with all applicable law and regulations governing water withdrawal, usage, and effluent management.

Suppliers are encouraged to:
Implement a systematic approach that measures, documents, characterizes, and monitors water sources, use, and discharge.

4.2.3 **Waste Management**

Suppliers are expected to:
Comply with all applicable law and regulations governing waste, hazardous and toxic materials, and substances.

Suppliers are encouraged to:

a) Managed active pharmaceutical ingredient (API) and drug substance manufacturing effluents during production of products.
b) Implement a systematic approach to identify, manage, reduce and responsibly control disposal, and minimize waste to landfills from their operations.
c) Implement programs to reduce, reuse and recycle waste and promote recyclability and recycled content in packaging materials.
d) Foster circularity by effectively designing out waste by favoring sustainable sources, implement measures to improve process efficiency and managing and treating your waste.

4.2.4 **Pollution and Spills**

Suppliers are expected to:
Comply with applicable environmental laws and regulations and obtain the necessary permits, licenses registrations expected.

Suppliers are encouraged to:
Implement a systematic approach to identify and prevent air pollution, accidental spills, and release of hazardous materials into the local community and environment.

4.2.5 **Biodiversity**

Suppliers are encouraged to:

a) Understand and monitor the impacts of their operations and supply base on biodiversity.
b) Ensure business activities, including sourcing, are not conducted in “High Conservation Value Areas”, unless aligned with Baxter.
c) Implement programs to support biodiversity and reduce their negative impact, wherever possible.

4.3 HUMAN AND LABOR RIGHTS

Suppliers are expected to respect and comply with Baxter's Global Human Rights Policy across the Value Chain. https://www.baxter.com/policies-positions/global-human-rights in their own operations and their supply base and business relationships, wherever possible.

4.3.1 Local Community

Suppliers are expected to respect the right of local communities around their operations to a clean and healthy environment.

4.4 DIVERSITY EQUITY AND INCLUSION

Baxter is committed to diversity, equity, and inclusion across all aspects of its business. We work to develop mutually beneficial relationships with small and diverse suppliers as we strive to increase the diversity of our supplier base. We encourage our suppliers to actively participate in promoting diversity and inclusion within their operations.

Suppliers are encouraged to:

a) Provide information about your diverse certification, ownership and management structure, in accordance with our criteria for diversity.
b) Establish aspirational employee diversity representation goals and track progress within own operations.
c) Provide training to your employees to foster an inclusive workplace culture. This training should promote understanding, awareness, and appreciation for diversity and inclusion.
d) Collaborate with diverse businesses in your supply base.
e) Monitor and disclose spend (Tier 1 and Tier 2) with diverse and non-diverse suppliers.

Diverse supplier registration: Baxter Diverse Supplier Registration

4.5 HEALTH AND SAFETY

Suppliers are expected to provide a safe and healthy working environment for your workers. Suppliers working with Baxter or onsite at a Baxter location must work in a way that assures their own safety. This includes implementing appropriate health and safety measures to ensure the well-being and protection of employees. Please refer to the Environment, Health and Safety section of Baxter's Ethics and Compliance Standards https://www.baxter.com/partners-suppliers/new-suppliers.

4.6 ETHICS AND COMPLIANCE

Suppliers are expected to operate and conduct business responsibly, ethically, and act with integrity. Our Ethics and Compliance team works closely with teams across the regions to ensure that our activities adhere to applicable laws and to company policies. Suppliers are expected to abide by the local regulations, national policies, and other standards (Baxter's Ethics and Compliance Standards https://www.baxter.com/partners-suppliers/new-suppliers) as required by Baxter for compliance.

4.7 CORPORATE SOCIAL RESPONSIBILITY

Strong governance and management systems are the foundation to compliance with the corporate responsibility expectations in this standard. Suppliers are required to adhere to requirements and in addition comply with the following expectations.

Suppliers are expected to:

a) Manage their operations and activities systematically with internal oversight and management systems to support the conformance to these Standards.
b) Abide by Baxter's Ethics Policy or the supplier's own equivalent code of conduct, as aligned with Baxter.

Suppliers are encouraged to:

a) Identify dedicated personnel and their responsibilities to ensure compliance with corporate responsibility expectations and applicable laws and regulations.
b) Implement relevant corporate responsibility related ISO standards (for example, ISO 45001 (occupational health and safety management systems) and ISO 14001 (environmental management systems).
c) Develop mechanisms to identify and manage risk in all areas relevant for corporate responsibility, including risk arising from change management processes.
d) Establish mechanisms for conducting due diligence on their own supply chains to adhere to corporate responsibility expectations.
e) Provide necessary training to your employees to ensure awareness and understanding of implications of corporate responsibility expectations to your business operations and supply base.
f) Establish grievance mechanisms to report concerns, non-compliance and breaches.
g) Implement necessary corrective actions for deficiencies identified by internal or external assessments, inspections, and management reviews, including the recording and reporting of near-misses, incidents, and incident prevention opportunities.
h) Implement proper mechanisms to investigate any incidents or concerns relating to implementing the corporate responsibility expectations, and effectively communicating the findings to relevant stakeholders, including Baxter.

5.0 COUNTERFEIT PARTS

Supplier ensures that there is no risk of counterfeit products for supply to Baxter. Counterfeit products are defined as items that are, or contain, unlawful or unauthorized reproductions, substitutions or alterations that have been knowingly mismarked, misidentified or otherwise misrepresented to be an original manufacturer's part. The supplier must have strict procurement policies in place to ensure traceability for all items incorporated in the product.

6.0 CONFLICT MINERALS

Regarding the Baxter Engineering and Service Expectations, the following summarizes the expectations and compliance with processes:

6.1 Baxter must perform due diligence on and make disclosures concerning its use of conflict minerals originating in the Democratic Republic of the Congo and adjoining countries or any other high-risk country as defined by the legal authorities.

6.2 All Baxter suppliers are required to respond to information requests from Baxter regarding the uses and sources of conflict minerals in their products including information about minerals that are recycled or scrapped.

6.3 To respond to Baxter´s information requests, suppliers will need to make similar inquiries of their suppliers to investigate the source of materials in their products, and to provide Baxter the requested information based upon the results of such inquiries.

6.4 Baxter may be required, and may require its suppliers, to perform due diligence on the source and chain of custody of its conflict minerals in accordance with the "OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas." In addition, suppliers may be required to make certain representations/ certifications with respect to the use of conflict minerals.

6.5 Additional information on conflict minerals may be obtained through links on the SEC website (http://www.sec.gov) or the European Commission Trade website (http://www.ec.europa.eu/trade/).

7.0 QUALITY-IMPACTING SUPPLIER REQUIREMENTS

This section contains the high-level requirements and expectations that suppliers with quality impact shall meet for supply to Baxter. Suppliers' compliance with these requirements will be assessed as part of Baxter's supplier evaluation and ongoing monitoring activities.

7.1 QUALITY MANAGEMENT SYSTEM

7.1.1 Have an adequate Quality Management System (QMS) in place at all manufacturing sites.

7.1.2 It is preferred that the supplier's QMS is accredited by a third-party certification body to a recognized international standard, e.g., MedAccred, ISO13485, ISO9001, ISO17025, ISO27001 or ISO14001/ISO45001. The accreditation scope shall cover the product or service supplied to Baxter. Suppliers are required to supply copies of their current certifications to Baxter, as applicable.

7.2 SUPPLIER NOTICE OF CHANGE (SNC)

7.2.1 Baxter products undergo stringent regulatory assessments before they can be sold. The regulatory approval is based on a specified product build standard and production method. Therefore, if there are any changes to a product, Baxter has a legal requirement to assess those changes to ensure that the product continues:

a) to meet its specification,
b) be safe and effective, and
c) meet the regulatory requirements.

Suppliers are required to inform Baxter of all changes that meet our change definition and provide advance notification and gain written approval prior to implementation. Failure to do so could result in the supplier being placed on Conditional and New Business Hold Status. Any costs related to supplier-initiated changes will be at the expense of the supplier.

These changes may include, but are not limited to:

1) Company ownership or name change
2) Design or specification change
3) Manufacturing material, process, equipment, tooling, or service change
4) End-of-life availability status
5) Manufacturing location (address change)
6) Packaging, labeling, storage-condition change
7) Changes to supplier base including subcontractors, sub-assembly suppliers, direct material suppliers, etc.
8) Manufacturing process change (temporary or permanent)
9) Changes to the control plan

7.2.2 Change Expectations:

a) Verbal changes and approval are not acceptable.
b) Supplier is responsible for submitting changes via the method agreed with Baxter.
c) Do not assume that any changes are minor.
d) 180 Day advance notification from implementation date unless otherwise specified and agreed upon with Baxter.

7.3 PROCEDURES AND RECORDS

7.3.1 Maintain procedures and records for all activities performed for Baxter. This will include at a minimum the following processes:

a) Production activities, including inspection/testing.
b) Training and competence
c) Document and record control
d) Data integrity principles
e) Internal Audits
f) Control of Nonconformance, including Field Actions
g) Corrective and Preventive Action (CAPA) to address quality issues and improvement initiatives.
h) Annual Quality Reporting (APQR) for drugs, excipients and API

7.3.2 Control documents with identification of document approval, distribution, revision, and changes. This includes documents of external origin such as Baxter agreements, specifications, and drawings.

7.3.3 Retain all documents and records associated with the manufacture of the product for Baxter for a minimum period of ten years from the date of manufacture unless otherwise specified and be made available to Baxter upon request in a timely manner.

7.4 LEGAL REQUIREMENTS

7.4.1 Suppliers are expected to understand and comply with all applicable laws, rules, and regulations. These include laws covering bribery, the manufacture of medical devices, fraud, and abuse, kickbacks, intellectual property (including patents, copyright, trademarks, and confidentiality), labor and employment laws (including prohibitions against child labor, exploitation of children and forced or involuntary labor), insider trading, antitrust prohibitions, foreign corrupt practices, occupational health and safety, environmental hazards, offering or receiving gratuities and information privacy.

7.4.2 Baxter suppliers are required to abide by the requirements in:

a) Component specification/s
b) Purchase Order Terms and Conditions (PO Ts&Cs)

7.4.3 In addition, some suppliers will also be required to abide on one or more agreements, for example:

a) Master Supply or Service Agreement (MSA)
b) Quality Agreement (QA)
c) Non-Disclosure Agreement (NDA)
d) Development Agreement
e) Statements of Work
f) Applicable Privacy documents

7.4.4 Suppliers need to support regulatory filings, providing, and updating corresponding documentation.

7.5 RESTRICTED MATERIALS AND ENVIRONMENTAL COMPLIANCE REQUIREMENTS

7.5.1 Background

The international community's concern about the health and environmental risks posed by the products they purchase has led to the introduction of local and international laws which affect the importation of articles into many countries. The products Baxter manufactures must comply with these directives and regulations.

7.5.2 Some applicable material restrictions legislation may include, but not limited to:

All components and materials:

1) EU REACH Regulation (EC No 1907/2006)
2) EU Persistent Organic Pollutants Regulation (Regulation EU 2019/1021)
3) US iMERC Hg Registration and Labelling
4) California Proposition 65
5) California Management of Perchlorate Materials (22 CCR § 67384.1)
6) Canada Prohibition of Certain Toxic Substances Regulation
7) Canada Products Containing Mercury Regulations
8) Australia Asbestos Restriction & Canadian Asbestos Regulation
9) EU Medical Device Regulation (Regulation EU 2017/745)

Components and materials incorporated into electrical and electronic products:

1) EU RoHS Recast (Directive 2011/65/EU)
2) EU RoHS Recast Amendment 2015/863 regarding phthalates.

Batteries or components and materials incorporated into batteries:

1) EU Battery Directive (2006/66/EU) Packaging & Waste disposal
2) EU Packaging Directive (94/62/EC)
3) WEEE 2012/19/EU
4) US Toxics in Packaging Restrictions

7.5.3 Baxter will collect materials declarations from our suppliers to enable us to proactively respond to changing regulations.

7.5.4 Suppliers are expected to respond to material declaration requests in a timely manner.

7.6 PURCHASING REQUIREMENTS

Purchasing information describes or references the component purchased. Baxter typically uses these documents to provide purchasing information to the supplier:

a) the purchase order containing the standard terms and conditions.
b) the component specification at a defined revision number, including referenced documents, e.g., processes and test requirements.
c) this document, Baxter Global Supplier Standards Manual (GSSM).

7.6.1 Provide details of Key Contacts. The supplier shall promptly notify their Baxter Category Manager of any changes to the Key Contacts.

7.6.2 By accepting the purchase order, this is a formal acceptance that the supplier will satisfy all the requirements on the specification and drawing, including referenced documents e.g., Test requirements.

7.6.3 Purchase orders cannot be processed prior to the supplier being approved and listed in the Approved Entity List.

7.7 ASSET CONTROL AND MANAGEMENT REQUIREMENTS

7.7.1 Maintain the security and confidentiality of and prevent any damage or loss to all Baxter equipment and ensure that all equipment is identifiable and integrated with the suppliers' asset/equipment database and/or quality system. Prompt communication with Baxter is required if damage has occurred to any equipment.

7.7.2 Supplier shall not alter Baxter equipment without prior consent. Any labels affixed by Baxter must remain with the equipment. Suppliers will advise Baxter if labels are out-of-date and/or damaged.

7.7.3 If a label is not provided with the equipment, then the supplier should mark the equipment with the appropriate Baxter equipment number and wording “Property of Baxter” in a visible location that does not interfere with the function of the equipment.

7.7.4 Provide reasonable advanced notice to Baxter when any additional equipment is required for purposes of; interim replacement when the current equipment requires calibration or when the available capacity on the existing equipment is below 1.8 times the current demand.

7.7.5 Only use Baxter equipment solely in the performance of its obligations to Baxter and no other purpose. The supplier assumes all risk of loss or damage to Baxter equipment and will, at Baxter’s request, immediately restore or replace any damaged or lost Baxter equipment with an equivalent item.

7.7.6 Supplier shall ensure that appropriate steps are identified in managing all tooling either furnished to, fabricated, or procured by the supplier under a Baxter purchase order or other authorizing document, and includes tooling located at a supplier’s lower tier supplier.

7.7.6.1 Suppliers are responsible for performing all maintenance work, repairs, and component replacements as necessary to ensure tooling remains in good working condition and suitable for its intended use.

7.7.6.2 Suppliers must ensure that the tooling is inspected to applicable data (engineering data, engineering drawings, master layouts, tool design, control tool, etc.) as specified in the purchase order prior to release to production.

7.7.6.3 Failure to meet these requirements may result in the loss of existing or future business with Baxter. All costs associated with the supplier’s failure to comply with this standard will be the responsibility of the supplier.

7.8 SUPPLY CHAIN RISK MANAGEMENT & BUSINESS CONTINUITY PLANS

Baxter expect Suppliers to build resilience in their supply chain, which is the ability of a supplier to plan, prepare and respond to disruptions within their supply chain.

Disruptions could occur due to many reasons, some of them being weather conditions, shortages in material or labor, geo-political factors, material / component end of life, manufacturing site issues, tooling/equipment failure etc.

Baxter expects its suppliers to:

a) build a deep understanding of risks in your supply chain and prioritize them (e.g., High probability and high consequence events are the highest priority to plan for)
b) build a strong collaboration and partner network in your supply chain and with Baxter.
c) establish, maintain, and periodically test business continuity plans for their site(s).
d) consider crisis management, disaster, business recovery and contingency plans.
e) identify a back-up site/resource for each relevant site specific to Baxter’s business.

f) notify all Baxter receiving sites and the Baxter Buyer immediately if an impending production interruption is known in advance.

7.9 DELIVERY REQUIREMENTS

7.9.1 Immediately report all unexpected events that may delay the supply of goods to Baxter.

7.9.2 Only deliver components in accordance with what is stated on the purchase order. This includes keeping to the Baxter item number and revision level.

7.9.3 Provide/attach a Certificate of Conformance (CoC) and/or Certificate of Analysis (CoA), when necessary. The CoC/CoA can be forwarded via email but must be sent at the time components are dispatched from the suppliers' site.

7.10 CAPACITY MANAGEMENT

7.10.1 Suppliers are responsible for its own capacity management and planning. Capacity planning includes allocating required equipment, tooling and resources and accounting for their utilization in current Baxter business and shared capacity with other customers. Capacity verification may include Baxter's review of supplier and sub-supplier production capacity to peak demand requirements.

7.10.2 Suppliers are responsible for managing their own supply chain (including sub-suppliers of components and raw materials) and shall identify, communicate, and resolve any constraints that prevent an uninterrupted flow of product to Baxter's manufacturing locations.

7.10.3 Suppliers shall review and submit capacity studies annually as required.

7.10.4 Suppliers shall provide a quote based on their capacity meeting Baxter's annual volume projection with an additional 20%.

7.11 WARRANTY

Suppliers are required to implement a warranty management process supporting the analysis of all part returns from Baxter customers as requested by Baxter. All issues are to be addressed with the appropriate containment, root cause and corrective action(s) in the timeframe specified as per customer specific requirements (CSR). Any charges incurred from Baxter customers due to supplier issues will be communicated and passed on to the supplier.

7.12 NON-CONFORMITY MANAGEMENT

If Baxter identifies quality issues with a supplied component, the supplier may be required to provide on-site support to perform sorting, failure analysis, and corrective action reporting. By mutual agreement, on-site support can be provided at Baxter or an Authorized Third Party's location(s).

Material identified as non-conforming shall not be reworked and supplied to Baxter as new material without prior written authorization.

A Supplier Corrective Action Request (SCAR) can be issued by Baxter to address product quality concerns or supplier audit findings. SCAR responsiveness will be used by Baxter as one of the Key Performance Indicator for suppliers.

The 8D Problem Analysis is highly encouraged as a root cause analysis methodology. However, other appropriate tools such as fishbone diagram, 5 Whys, etc. are acceptable.

Please note that there are some Baxter facilities that must supplement the problem-solving documentation with Baxter customer specific problem-solving documents / procedures. Contact your Baxter Quality representative to obtain the appropriate problem-solving documentation / format.

7.12.1 Sorting

Parts may be sorted at the appropriate location (supplier or Baxter site). If suspect parts are removed from a Baxter location and sorted off-site (at the supplier's or a third-party facility), the supplier must report actual reject totals daily (identified during the sort) to the affected Baxter facility.

If determined to be a supplier issue, all costs incurred from sorting activities are the responsibility of the supplier. These costs could include, but are not limited to:

a) Administrative costs
b) Additional labor / Overtime
c) Material handling
d) Floor space utilization
e) Additional packaging
f) Tooling and equipment
g) Scrapped materials
h) Expediting charges (shipping, sterilization, etc.)

7.13 NEW PRODUCT INTRODUCTION

The foundation of Baxter's growth is supported by the development and innovations delivered in new products. Open collaboration between Baxter and its suppliers is imperative in achieving our new product introduction goals, which are:

a) Ensure that the relevant commercial and legal agreements are executed.
b) Solicit the schedule, deliverables, and requirements of the projects.
c) Identify where your organization fits in the supply chain design.
d) Organize regular meetings with Baxter (i.e., action tracker, commercial review, etc.)
e) Establish a regular meeting with your critical sub-tier suppliers.

7.14 AUDITS

Baxter expects suppliers to maintain, execute, and record internal audits of its operations to ensure compliance with written processes, procedures, standards, and agreements.

Baxter conducts supplier assessment and surveillance audits as part of its supplier management program. Baxter will endeavor to provide the supplier advance notice ahead of audits, however under some circumstances this may not be feasible.

Supplier shall agree to support and negotiate the same rights of access for Baxter representative with prior notice to any of the suppliers' sub-suppliers who are involved in the supply of Baxter products for the purpose of carrying out an audit.

7.15 KEY PERFORMANCE INDICATORS (KPIS)

Baxter uses Key Performance Indicators to measure the effectiveness of processes. Baxter will define KPIs that are relative to the supplier operation, set targets for these parameters, measure them relative to the established targets, report on the findings, and develop improvement plans based on the results. KPIs are to be regularly reviewed by the management and communicated to all team members.

Examples of KPIs that are relevant to a manufacturing facility may include (but are not limited to):

Quality Measurable

a) Product Acceptance or Parts Per Million (PPM)
b) SCARs
c) Nonconforming Part Incidents
d) Field Actions

Business Measurable

a) On-Time Delivery

7.16 COMPONENT QUALIFICATION

The purpose of Component Qualification is to provide a consistent set of requirements for qualifying a component and to ensure that there are robust and capable manufacturing processes at suppliers to meet Baxter's product requirements. Component Qualification shall be completed before use of a component in production.

Component Qualification deliverables may include but not limited to the following:

1) Cover Sheet & Checklist
2) Drawing/Specification
3) Design for Manufacturability (DFMA)
4) First Article Inspection Report (FAIR)
5) Measurement System Analysis (MSA)/Gage R&R Studies
6) Process Capability (Cpk/Ppk)
7) Process Flow Chart
8) Manufacturing/Assembly Instructions
9) Control Plan
10) Process Control Charts and Statistical Techniques
11) Process Failure Mode and Effect Analysis (PFMEA)
12) Validation (IQ/OQ/PQ)
13) Sub-tier Supplier FAIR
14) Design Review

Deliverables will be dependent on the component under qualification and upon Baxter discretion. Full details of requirements will be provided by Baxter prior to the start of any component qualification.

In general, Baxter considers its suppliers fully responsible for the quality related activities of their suppliers, subcontractors, service providers, and/or material sources throughout their supply chain. Typically, these sources will not be subject to evaluation or an audit, however Baxer reserves the right to do so when needed to ensure supply chain safety or understand other potential impacts to Baxter. We consider such an evaluation incumbent upon the supplier to document, clarify, and verify, by whatever means deemed necessary, that the subcontractors' facilities, procedures, materials, and controls meet or exceed the requirements set forth in this manual as well as applicable requirements defined by global regulatory agencies. Baxter may request supporting data of these evaluations as needed.

8.0 REFERENCES

[1] Baxter's Public Website, https://www.Baxter.com
[2] Baxter's Partners and Suppliers Website, https://www.baxter.com/partners-suppliers/baxter-suppliers
[3] Baxter's Code of Business Conduct and Ethics, http://www.Baxter.com/ethics
[4] Baxter's Corporate Responsibility Commitment, https://www.baxter.com/our-story/corporate-responsibility-0

9.0 GLOSSARY OF TERMS

Terms	Definition
Biodiversity	The variability among living beings from all sources, including, inter alia, aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species and ecosystems
Bribery	The offering, giving, soliciting, or receiving of any item of value as a means of influencing the actions of an individual holding a public or legal duty
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.
Circularity	A systems solution framework that tackles global challenges like climate change, biodiversity loss, waste, and pollution. It is based on three principles, driven by design: eliminate waste and pollution, circulate products and materials (at their highest value), and regenerate nature
Component	Any ingredient intended for use in the manufacture of a product, including those that may not appear in such product. This includes any raw material, substance, piece, part, software, firmware, labeling or assembly.
Complaint	(1) Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, effectiveness, or performance of a product after it is released for distribution or related to a service that affects the performance of such product.

Terms	Definition
	(2) Written electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices
Corruption	The abuse of entrusted power for private gain and / or illicit benefits.
Drug Component	Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product
Due Diligence	(1) The process of investigation and evaluation performed relating to the details of a potential incident (or complaint). Examples of due diligence are phone calls or written correspondence to the account/reporter to verify facts. (2) Due diligence is the investigation or exercise of care that a business takes before entering into an agreement or contract with another party. The degree of due diligence investigation will vary depending on the nature of the proposed agreement.
External Stakeholder	A person or an organization outside a particular company who has a personal stake in and / or is affected by its activities, including customers, suppliers, investors, or local communities
First Article Inspection	A Report consisting of all requirements as outlined on the component or assembly drawing
Greenhouse Gas (GHG) Emissions	Emissions from the six GHGs covered by the United Nations Framework Convention on Climate Change (Carbon dioxide (CO2); Methane (CH4); Nitrous oxide (N2O); Hydrofluorocarbons (HFCs); Perfluorocarbons (PFCs); and Sulphur hexafluoride (SF6)) which contribute to global warming and climate change.
High Conservation Value Areas	Critically important natural habitats due to their high biological, ecological, social or cultural values and hence, need to be appropriately managed to maintain or enhance their value.
Human Rights	As laid out in the United Nations Guiding Principles on Business and Human Rights (UNGPs), human rights are defined, at a minimum, as the rights expressed in the International Bill of Human Rights and the International Labor Organization's Declaration on Fundamental Principles and Rights at Work.
Internal Stakeholder	A person who works for and / or owns a company.
Living wages	Minimum income level that allows individuals or families to afford basic needs i.e., adequate shelter, food, and other necessities.
Local Community	The people living and / or working in areas around a company's operations and activities.
Non-Conforming Material, Finished Good or Service	Any raw material, production material, finished good or service that does not conform to requirements (specifications, AQL's, contracts/agreements, etc.) established between the supplier and the applicable Baxter unit. The nonconformance will be categorized into three levels of risk:

Terms	Definition
	Critical: Significant impact to business, customer safety, product efficacy and purity; Major: Impact on material or product performance or function; Minor: Impact does not directly impact customer safety, product efficacy and purity.
Product	(1) Result of a process Raw materials, in-process materials (components/constituent parts) and finished goods, including returned devices. (2) In BAXLIMS, a Product Test Data object that is used to create the batch record. (3) Output of an organization that can be produced without any transaction taking place between the organization and the customer
Purchase Order (PO)	A Baxter generated records that authorizes a purchase transaction. When accepted by the supplier, a Purchase Order becomes a Contract binding on both parties.
Quality Agreement	A written document defining the cGMP and regulatory compliance roles and responsibilities of Baxter and a Client or Supplier. A Quality Agreement may be a separate agreement or be part of a Contract.
Quality Management System (QMS)	(1) Formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement. (2) Part of a management system with regard to quality
Rework	(1) A manufacturing step involving technique or technology that is not a part of the approved process sequence. (2) Action on a nonconforming product or service to make it conform to the requirements
Supplier Corrective Action Request (SCAR)	This report documents the background, investigation, corrective and/or preventative action(s) and verification of effectiveness pertaining to a supplier nonconformance.
Supplier	Any entity that provides goods and/or services to Baxter.
Sustainable Resource Use	Use of resources in a way and at a rate that does not lead to the long-term degradation of the environment, thereby maintaining its potential to meet the needs and aspirations of present and future generations
Terms and Conditions (T&C)	General and special arrangements, provisions, requirements, rules, specifications, and standards that form an integral part of an agreement, purchase order, or contract between Baxter and its supplier
Tooling/Tools	All test equipment, test fixtures, measuring devices, molds, jigs, dies, patterns, taps, gages, templates and other manufacturing aids made for and limited to the production of particular detail parts and assemblies for Baxter
Validation	(1) Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. (2) Confirmation, through the provision of objective evidence, that requirements for a specific intended use or application have been fulfilled

10.0 REVISION HISTORY

Revision	Originator	Description of Change
1.0	Noel Caguiat	Initial Release