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1. Purpose of the Quality manual for GCE suppliers

The purpose of this Quality Manual is to describe the requirements for GCE suppliers. This guide sets out the responsibilities of suppliers within their quality management systems as well as GCE's expectations, which have been defined to ensure that GCE products supplied to the market - high pressure regulators, portable oxygen concentrators, laboratory equipment for high purity gases, industrial cutting and welding applications - comply with industry standards and relevant legislation (e.g., European Parliament and Council Regulation (EU) 2017/745 on medical devices, TPED).

This Quality Manual applies to all suppliers involved in the design, development, manufacturing, and distribution of GCE final products or services.

1. General Quality Management System Requirements



6. 1. Quality Policy

GCE requires suppliers to adopt a written quality policy that demonstrates their commitment to meeting customer requirements, complying with applicable regulations, and continually improving their processes.

* 1. Organizational Structure and Responsibilities

Suppliers must define clear roles, responsibilities, and authorities within their organisation to ensure effective quality management and oversight.

* 1. Document Control

A robust document control system should be implemented to manage all quality related documents, including policies, procedures, work instructions, and specifications.



# Record Keeping

Suppliers are responsible for maintaining accurate and complete records of all quality-related activities, including production, testing, inspections, and complaints. Specifically, the required retention period is 15 years for parts supplied for medical applications, and 5 years for parts supplied for industrial applications.

# Training and Competence

Training programmes should be in place to ensure that staff have the necessary skills and knowledge to perform their tasks competently.

# Risk Management

Suppliers must identify and mitigate risks associated with their processes and products, with a particular focus on patient safety and product performance.

# Change Control

Any changes to products, processes, or systems must be controlled, documented, and assessed for their impact on product quality and regulatory compliance.

* 5. Deviations

Any deviation from the specification of the goods supplied shall be notified in writing to the Operative Purchaser prior to delivery of the goods. Deviation information should be accurate, clear and detailed, providing a full understanding of the nature and extent of the deviation, as well as the root causes identified, and mitigating actions taken.



# Complaint Handling

A complaint handling process shall be established to address GCE complaints, analyse root causes and implement corrective actions.

The expected response times for complaints are as follows:

1. Containment – within 24 hours
2. Root Cause Analysis / determination – 21 days
3. Implementation of Corrective Action – 30 days
4. Verification of the effectiveness of Corrective Action\* - within 30 days

\*Interim or containment actions must be maintained until the effectiveness of the permanent corrective action has been validated.

Suppliers shall use the Open One system for communication related to complaints. Each complaint is reported to a designated contact person at the supplier via an automatic e-mail notification. The system allows both sharing and storing of information related to the case. Access to the application is assigned to a single representative of the supplier, but it is possible to request access in case of a change of the designated person at the supplier's side. The request should be sent to the relevant GCE SQA.

# On-time delivery performance

Suppliers are expected to acknowledge the receipt of purchase orders promptly and confirm their ability to fulfil the order within 3 days. Suppliers must adhere to the agreed-upon delivery schedule communicated by GCE. Any changes to the delivery schedule must be promptly communicated and approved in advance. In the case of unexpected delays or disruptions, suppliers must immediately notify GCE and provide alternative delivery arrangements.

# Communication Channels

Effective communication is vital to the success of our partnership. For specific enquiries or concerns, please contact the designated process owner (Quality or Purchasing). Not sure who the right person is? - Ask a question to the whole team:

|  |  |
| --- | --- |
| Supplier Quality Assurance | sqa@gcegroup.com |
| Purchasing | Nakup@gcegroup.com |

1. Customer's Property

The property of GCE used by the supplier must be recorded, used and maintained in accordance with the terms and conditions agreed in the Contract for Work and Loan Contract.

1. Supplier Selection and Evaluation




7. 1. Supplier Evaluation Criteria

Suppliers are evaluated on their capability to meet product quality requirements, regulatory compliance, complaint handling process to address GCE complaints, root cause analysis and implementation of corrective actions, stability and overall performance history.

* 1. Supplier Prequalification

Relevant information is gathered on potential suppliers to assess their capability, suitability and compliance with specific requirements. GCE expects suppliers to implement and maintain processes that comply with the principles and standards set out in ISO 9001 (Quality Management Systems) / ISO 13485 (Medical Devices - Quality Management Systems). This is essential to reduce the risks associated with working with unsuitable or non-compliant suppliers and provides the basis for a more detailed evaluation and selection process.

* 1. Supplier Approval Process

The supplier approval process is defined by GCE's internal procedures.

Compliance with the following expectations is required for a supplier to be included in GCE's approved supplier portfolio. Suppliers are expected to comply with GCE's Code of Conduct for Business Partners. Invoice payment terms of 90 days are expected as standard, unless otherwise agreed. Supplier approval for critical items includes signing the Quality Agreement.

*Note: Information on the criticality of the item being requested is provided to the supplier as part of the request, along with a set of all relevant data (in the case of a critical item).*

Only approved suppliers are allowed to supply products and services to GCE. The approval process involves a thorough assessment of the supplier's quality management system and capabilities..

* 1. Ongoing monitoring of Supplier Performance

Supplier performance is regularly monitored to ensure continuous improvement.

* + 1. Monthly Supplier Evaluation

Monthly monitored indicators:

1. On Time Delivery
2. DPPM.

In the case of significant fluctuations in performance in a negative direction or a sustained decline in performance on any of the above indicators, GCE will communicate the identified situation and specific data to the supplier and expect the supplier to conduct a root cause analysis and implement corrective actions with the aim of improving performance.

* + 1. Annual Supplier Evaluation

The annual supplier performance evaluation is more comprehensive and includes indicators reflecting both performance in quality and timeliness of deliveries, as well as friendliness of the business terms offered and communication.

The final score obtained as a result of the annual evaluation places each supplier in one of the following performance groups:

1. Top Performer
2. Performing to target
3. Needs improvement
4. Not meeting expectation

Although the result achieved is communicated individually to the group of suppliers representing 80% of GCE's annual spend, the data is available to any supplier on request..

Only those suppliers who consistently demonstrate a high level of quality and reliability (i.e. Group 1 or 2) can become GCE's strategic partners for new development projects.

Suppliers with unsatisfactory performance (3 or 4) are encouraged to conduct a root cause analysis of the underlying issues. They are expected to define and implement comprehensive improvement plans with specific actions to address or mitigate the root causes. This proactive approach is in line with our commitment to continuous improvement and ensures a strong partnership for sustainable success.

1. Product and Service Requirements
3. 1. Product Specifications

Suppliers are responsible for meeting all defined requirements for the supplied product and must be able to clearly demonstrate compliance at all times. Suppliers must adhere to agreed product specifications and ensure that any changes are communicated and approved by GCE.

* 1. Material Requirements

All materials supplied must meet the requirements of relevant material standards. The supplier must have a material certificate for each batch of material supplied to or used in the manufacture of goods for GCE. Unless otherwise specified, the supplier must provide a material certificate for the relevant batch of material or components on request.

Suppliers must ensure that all substances and products supplied comply with the requirements of the

* [REACH Regulation (EC 1907/2006)](https://environment.ec.europa.eu/topics/chemicals/reach-regulation_en)
* [RoHS Directive](https://www.rohsguide.com/)
  1. Identification and Traceability

Suppliers shall establish and maintain systems to ensure full identification and traceability of materials and components used in their manufacturing process.

Identification is essential to ensure that production batches of materials, components or equipment can be distinguished from each other, and it helps to maintain accurate records during the manufacturing process, assembly, distribution and throughout the life cycle of the final product.

Traceability as the ability to trace the history, location or application of an item or product through various stages of its life cycle. It involves capturing and maintaining a record of the item's movement, processing and interactions within the supply chain or production process.

* 1. Packaging and Labeling

Packaging and labelling requirements, including Unique Device Identification (UDI) for medical devices, must be strictly adhered to in order to meet regulatory requirements. Packaging and labelling should include information to identify the component, such as part number, batch number, date of manufacture and any other relevant identifiers.

* 1. Calibration and Maintenance

Equipment used in the manufacturing process should be calibrated, maintained and regularly checked for accuracy.

* 1. Non-Conforming Product

Procedures should be in place to identify, segregate and dispose of non-conforming products to prevent their unintended use or distribution.

1. Manufacturing Process and Product Controls
3. 1. Process Validation

Processes critical to product quality must be validated and regularly monitored to ensure ongoing compliance and product consistency.

* 1. Monitoring and Control of Parameters

To ensure stable product quality, process and product parameters should be identified and controlled within predetermined limits.

* 1. Contamination Control

Measures must be taken to prevent contamination during the manufacture, handling and storage of parts to ensure compliance with cleanliness requirements, where such requirements are defined.

* 1. Product Quality Control

In order to ensure compliance with specific requirements, GCE expects the implementation of inspection, testing and validation of processes and products.

1. Continuous Improvement
3. 1. Key Performance Indicators (KPIs)

Suppliers should define and monitor KPIs to measure the effectiveness of their quality management system and regularly identify areas for improvement.

* 1. Continuous Improvement Approach

We expect from the supplier to have established a culture of continuous improvement across all areas, including but not limited to productivity, waste reduction, and overall operational efficiency.

* 1. Corrective and Preventive Actions (CAPA)

Suppliers must address nonconformities and prevent recurrence by establishing and implementing a robust CAPA process.

1. Management Review

Management reviews should be conducted periodically to assess the performance of the quality management system and to identify opportunities for improvement.

8. 1. Audits

GCE reserves the right to conduct process audits at the supplier's manufacturing facility. The purpose of these audits is to ensure compliance with agreed specifications, quality standards and regulatory requirements. The Supplier shall provide the necessary access, documentation and cooperation to facilitate the audit process. The results of such audits may be used for performance evaluation and continuous improvement purposes, benefiting both parties in our joint efforts to maintain product quality and end customer satisfaction.

1. Product Responsibility

GCE's incoming inspection does not replace the supplier's inspection system. It may not always detect all potential non-conformities or defects in the goods supplied. Suppliers should be aware that such defects may become apparent during assembly or testing of the end product at GCE, but may also pass through and become apparent only during use of the end product by the customer/end user. In the event of such a defect being caused by a component of the supplier, GCE reserves the right to seek compensation from the supplier for the damage or a reasonable part thereof, as well as for any additional costs incurred in handling the affected products.

It is essential that suppliers remain willing to cooperate in identifying the root causes of non-conformities and in proposing improvement actions to mitigate risks.

Through our joint efforts, we will continue to strengthen our partnership and maintain the excellent quality of GCE's products.

1. Confidentiality and Intellectual Property

4. 1. Protection of Confidential Information

Suppliers are required to treat all confidential information provided by GCE with the utmost care and to ensure that it remains protected.

* 1. Intellectual Property Rights

Suppliers must respect and protect the intellectual property rights of GCE and other relevant stakeholders.

This Quality manual for GCE suppliers serves as a guide for suppliers wishing to do business with GCE. By adhering to the requirements outlined and demonstrating a commitment to quality, compliance and continuous improvement, suppliers can strengthen their partnership with GCE and contribute to the production of safe and effective products.

This guide will be periodically reviewed and updated to reflect changes in regulations, industry best practices and company policies. Suppliers will be notified of any significant revisions.

If you have any questions or require further information, please do not hesitate to contact us.

1. Annexes

Annex A - Questionnaire for Suppliers GR 2.04.02 T3

1. Revision history

|  |  |  |
| --- | --- | --- |
| **Version** | **Release date** | **Changes from last revision** |
| 1.00 | 17.10.2023 | Initial release |
| 1.01 | 07.12.2023 | Order confirmation requirement modified to "within 3 days" |
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1. Annex A - Questionnaire for Suppliers GR 2.04.02 T3



