
Supplier Quality Process

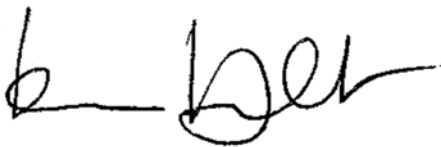
Quality Objectives

Carestream Health's Quality Objectives are to:

- ▶ Effectively maintain and consistently execute our quality system processes.
- ▶ Provide reliable products and robust services and solutions that meet the needs of our customers.
- ▶ Maintain global regulatory compliance.

Quality Policy

Carestream Health is committed to delivering high quality products, services, and solutions that meet our customers' needs and applicable regulatory requirements. This is accomplished through the maintenance of an effective quality management system.



Kevin Hobert
Chief Executive Officer
Carestream Health, Inc.

Supplier Quality Process

It is evident from Carestream Health, Inc.'s Quality Policy and Objectives that Carestream Health demands consistent quality that meets customer needs and regulatory requirements. In turn, Carestream Health expects its suppliers to consistently meet standards of performance in quality, reliability, cost, and delivery of the products and services provided to us. This is accomplished by utilizing appropriate process improvement techniques (Lean, Six Sigma, etc.) in a manner that delivers improved productivity and the optimal deployment of resources.

Carestream Health will manage our supply base to maintain a strategic and competitive advantage in the marketplace. The method used by Carestream Health to achieve this objective is through the Supplier Quality Process, or SQP.

SQP utilizes a number of different elements to select, measure, improve, and recognize Carestream Health Suppliers. The flexible design of SQP allows it to be applied to the specifics of each Carestream Health Supplier relationship. The SQP Improvement Team (consisting of the Commodity Manager, Supplier, and Client within Carestream Health) work together to resolve performance issues required to meet Carestream Health's expectations. The improvements gained should benefit all suppliers' customers and eliminate unnecessary costs.

Each supplier is expected to measure their performance in a way that is consistent with Carestream Health's business needs, and they are responsible for driving continuous improvement within their operations. Effective quality improvement is hardly easy, but if SQP has been deployed well, the following results should occur for both Carestream Health and our suppliers:

- ▶ Defect trends will decrease and overall performance improve
- ▶ Number of supplier "corrective action" requests will decrease
- ▶ Productivity/Cost of Quality (COQ) savings will result
- ▶ Number of recognized "Certified" Suppliers will increase

Carestream Health is committed to continue its utilization of the Supplier Quality Process to meet year-over-year performance improvement with our supplier base.

Major Elements of the Supplier Quality Process including the following:

Element of SQP	Description
Supplier Quality Assessment (SQA)	The purpose of the SQA is to evaluate the effectiveness of the supplier's quality management system and continuous improvement processes. Assessments take place wherever the product or service is "produced" and are most commonly one day in length.
Measuring Supplier Performance	To keep Carestream Health's suppliers performing at or above the stated levels, a number of criteria are measured including, minimum performance for a quality management system, product or service quality performance, delivery performance, lead-time, and productivity performance.
Supplier Process and Performance Improvement	Carestream Health expects the processes and the performance of their supply base to continuously improve from year-to-year. This is critical for both the supplier and for Carestream Health to remain competitive. Carestream Health will work with suppliers as necessary in a team environment to achieve continuous improvement.
Supplier Certification	<p>Carestream Health Supplier Certification Program recognizes suppliers who meet Carestream Health's established requirements, and are producing excellent levels of cost, quality, and delivery performance. To be considered for this recognition, suppliers must show evidence of a sound and effective quality management system, provide Carestream with consistent benchmark quality levels (or <300 DPPM), meet standards for delivery (>97%) lead-time (max. 21 days or as agreed), and year-over-year productivity.</p> <p>Through the improvement and certification effort, the Supplier benefits from:</p> <ul style="list-style-type: none"> ▶ Improvements, which potentially increase the supplier's competitiveness. ▶ First consideration for new business. ▶ Visible recognition by Carestream Health, Inc. <p>And Carestream Health benefits from:</p> <ul style="list-style-type: none"> ▶ Products/Services that consistently meet Carestream Health's requirements. ▶ Products/Services are received, when needed. ▶ Productivity Improvements realized on a year-over-year basis.

Supplier Performance Expectations

Quality

- ▶ Have a documented and effective quality management system capable of meeting the ISO 9001 standard or appropriate medical device standards (i.e. ISO 13485, U.S. Quality System Regulator - QSR).
- ▶ Consistently strive to deliver goods and services to Carestream Health at a Six-Sigma level of quality, using continuous improvement methods.
- ▶ Use process controls and stress defect prevention rather than defect detection.
- ▶ Strive for designs and processes that result in $Cp \geq 1.5$.
- ▶ Endeavor to assure high levels of reliability in products and services, assuring that products and processes perform at a high level over a given time, minimizing life cycle costs.
- ▶ In cases, where the supplier is principally a Service Provider, the supplier must have an agreement with Carestream Health specifying what constitutes defect-free "quality".
- ▶ Maintain records that support lot traceability and/or evidence for compliance to service agreements.
- ▶ Characterize all processes (define process capability).

Delivery

- ▶ Keep commitments to deliver the proper material on time, to the correct location, and with the proper quantity.
- ▶ Lead-times are consistent with industry benchmarks.
- ▶ Comply with applicable Carestream Health specifications for packaging, labeling, storage, shipping, and tracking.

Productivity

- ▶ Achieve year-over-year productivity improvements that result in lower costs for Carestream Health.
- ▶ Strive to achieve lowest total life cycle cost through quality, requiring no incoming inspection, no adjustments or repairs, and only planned service of the product.
- ▶ Work with own second and third tier suppliers, and other Carestream Health suppliers, as either a customer or supplier, to create the lowest total cost for Carestream Health.

Product and Technology Leadership

- ▶ Participate in the development and design of Carestream Health products and services, consistent with Carestream Health's practice of Early Supplier Involvement.
- ▶ Notify Carestream Health of any specifications that are not a good match for supplier's processes. Supplier accepts accountability for any consequences that may result from accepting work from Carestream Health that is not a good match for own processes.
- ▶ Use processes, tooling, and manufacturing technologies that are state-of-the-art.
- ▶ Provide items that give Carestream Health products and services features and quality that lead the industry.

- ▶ Share technology directions and intentions with Carestream Health.
- ▶ Provide system solutions, not just component solutions.
- ▶ Understand and embrace the principles of Lean Manufacturing.

Service and Support Leadership

- ▶ Conduct business consistent with Carestream Health's values.
- ▶ Accept no purchase orders from Carestream Health or supply agreements with Carestream Health unless Carestream Health's Purchasing Organization is involved.
- ▶ Promptly notify Carestream Health when there is a change to nature of goods or services supplied, source of supply, manufacturing processes, business operations, or any other conditions which have the potential to impact or application and/or business relation
- ▶ Notify Carestream Health of intentions to discontinue supply of an item or service at least one year before a "last-time-buy" order will be accepted.

Regulatory Compliance

- ▶ Comply with applicable worldwide regulatory requirements and respond in a timely manner to requests for documentation to demonstrate compliance.
- ▶ Assure compliance with worldwide registrations for use, importations, and exportation of materials, equipment, parts, and components.
- ▶ Inform Carestream Health when specifications or requirements jeopardize compliance with applicable regulations.
- ▶ Work with own suppliers to ensure regulatory compliance throughout the supply chain.



Carestream Health, Inc.,
150 Verona Street,
Rochester, NY 14608

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