



Sage Products LLC
Supplier Quality and Purchasing Standard
August, 2014

Table of Contents

1.0 Who We Are

- 1.1 Scope
- 1.2 Emphasis
- 1.3 Content

2.0 Sage Regulatory Environment

- 2.1 Animal Derivatives Disclosure

3.0 Quality System Concepts

- 3.1 Supplier's Responsibility for Their Quality
- 3.2 Supplier's Responsibility for Their Subcontractors
- 3.3 Item Certification
- 3.4 Approved Suppliers
- 3.5 Supplier Recognition

4.0 Sage Quality System Guidelines

- 4.1 Quality Policy
- 4.2 Quality Management
- 4.3 Quality Manual
- 4.4 Quality Plan
- 4.5 Quality Systems Procedures
- 4.6 Inspection and Tests
- 4.7 Personnel Training
- 4.8 Internal Audits
- 4.9 Sage Audits
- 4.10 Product Specification Requirements
- 4.11 Process/Product Changes
- 4.12 Process Control

5.0 Business Practices

- 5.1 Confidential Information
- 5.2 Environmental
- 5.3 Supplier Diversity

6.0 Purchasing Policy

- 6.1 Sales Appointment
- 6.2 Hours
- 6.3 Purchase Orders
- 6.4 Invoicing
- 6.5 Gifts and Gratuities
- 6.6 Delivery Information
- 6.7 Price Changes



1.0 Who We Are

Sage Products (“Sage”) is a worldwide leader in disposable healthcare products. Our core belief is in prevention—that evidence-based interventions will lead to improved outcomes. Our industry leading, innovative products make it easier for busy nurses to deliver essential patient care. These simple interventions are backed up with proven clinical evidence—and help improve patient safety by preventing skin breakdown, healthcare-associated pneumonias, surgical site infections and other adverse nosocomial events.

Innovation

Sage is much more than just a healthcare manufacturing company. We are true innovators and have been that way from the very beginning. We don't just take existing concepts and make them our own. We develop new concepts and products that address the challenges of the ever-changing healthcare industry. We take ideas, turn them into clinically relevant products and bring them to the marketplace as quickly as possible. But we don't just do this in a lab or boardroom. We take a hands-on approach to developing and improving our products, spending time in facilities listening to those people who use our products every day. We rely on feedback from clients and experiences in the field to develop products that will ultimately enhance patient care.

Service

Healthcare is a business, but to us it's personal. Our seasoned sales team truly cares about the customer and their patients. Whether in the hospital, alternate care or retail arena, we take the time to listen and respond to the needs of the rapidly changing healthcare market. Our customer service teams ensure responsive, personalized service for the length of customers' relationship with Sage. Our customers demand total satisfaction from Sage's products and service, and Sage demands that our people give them that satisfaction.

Manufacturing

Our current 603,000-square-foot facility in Cary, Illinois, is a state-of-the-art testament to quality, manufacturing hundreds of products all under one roof. Everything in our facility is automated to the highest degree, incorporating integrated vision systems designed to keep only the best products in the hands of our customers. Our manufacturing and operations personnel, many who have been at Sage 10 or more years, are the backbone of our success. At end of the day, we are truly a manufacturing company. In a time when more and more products are being manufactured overseas, we take great pride in the fact that our products are made right here in Cary, Illinois, USA!

Quality

Our philosophy is to continually meet and exceed our customers' expectations. From manufacturing to administration to executive management, every member of the Sage team is completely focused on maximizing quality. All products are manufactured under current Good Manufacturing Practices (GMP), as required by the Food and Drug Administration (FDA). Employees are trained extensively—not just to make products—but to fully understand all quality requirements. By integrating quality and regulatory compliance systems into all aspects of the product life cycle, Sage manufactures superior, reliable products that consistently meet high performance standards.



Community

In addition to being a leader in the healthcare industry, Sage is also a leader in the community. We derive so many benefits from the community including our labor force, vendors and customers. For that reason, it's imperative that we give back. We pride ourselves on doing everything we can to make the difference in the lives of our customers and associates

This Sage Supplier Quality and Purchasing Standard is intended to present the minimum quality requirements of Sage and is a supplement to, but does not replace or alter, other terms and conditions covered by purchase contracts or documents, specified warranty agreements, or requirements of engineering drawings or specifications.

1.1 Scope

The purpose of this Standard is to provide important information to the many companies that supply goods and/or services to Sage. This is being done because Sage considers our suppliers to be partners with us in fulfilling our Quality Policy:

“We are dedicated to providing extraordinary products and services that deliver superior value to our customers.”

This Standard applies to Sage suppliers who provide any of the following items:

A) Raw materials that are part of Sage finished product, including:

- Packaging
- Assemblies
- Printed materials

B) Services that can impact product quality

C) Finished Goods

1.2 Emphasis

This Standard emphasizes:

A) The importance of both parties agreeing to jointly defined requirements

B) The expectation that supplier's products and services consistently meet defined requirements through the development and maintenance of a system of control that results in consistent conformance to requirements

C) A culture of continuous improvement, which will mutually benefit the supplier and Sage

D) The need for open communications between Sage and its suppliers

1.3 Content

This Standard contains:

A) Description of basic quality requirements for a successful supplier/customer relationship

B) Key guidelines for meeting these quality requirements

In addition to the focus on the quality, Sage expects its suppliers to offer competitive pricing, on-time delivery performance, and exceptional service.



2.0 Sage Regulatory Environment

Medical device and pharmaceutical manufacturers such as Sage are obligated to follow many regulations and standards relating to quality. Regulations followed by Sage include but are not limited to cGMP in Manufacturing, Processing, Packing, or Holding of Drugs and Finished Pharmaceuticals, Quality System Regulation for Medical devices, and Electronic Records; Electronic Signatures as described by FDA, MHRA, and Health Canada.

2.1 Animal Derivatives Disclosure

Suppliers must identify if any of the components used in the manufacture of Sage products contain animal derivatives. Suppliers will be asked to certify this information in writing to Sage.

3.0 Quality System Concepts

Sage requires that our suppliers establish and maintain a quality system that is appropriate for the specific product being manufactured that ensures that the users of Sage’s products—medical practitioners and patients—receive and use safe, effective, and reliable medical products and drugs.

We intend that this document supplements or otherwise clarifies any contractual agreements that may exist between Sage and our suppliers. It is also intended to help Sage work with knowledgeable partners in our supply chain to enable us to meet our obligations for safety, quality, and reliability.

3.1 Supplier’s Responsibility for Their Quality

Sage views our suppliers as an extension of our own processes. We intend to partner with suppliers who consider Sage as a true extension of their processes. Suppliers must ensure that their products or services complies with all the mutually agreed to requirements with Sage. Suppliers are fully accountable for the value of the products and services they provide as well as any significant value added in Sage manufacturing processes.

3.2 Supplier’s Responsibility for Their Subcontractors

Sage considers its suppliers solely responsible for the quality-related activities of their suppliers. Normally, Sage will not evaluate or audit these sources as we consider such an evaluation to be incumbent upon our suppliers. If necessary, Sage may request supporting data of these evaluations.

3.3 Item Certification

Item certification means that Sage will use these items without routine incoming inspection. Eligibility for classification as a Certified Item includes the following criteria:

- A) Applicable quality system requirements for the item are implemented
- B) An acceptable quality history has been established for that particular item or commodity
- C) Equivalency of the supplier’s testing methods with Sage’s test methods is established
- D) A thorough understanding and acceptance of the supplier’s manufacturing process has been established
- E) Accurate certification documentation

Certified Items may become decertified if there is failure to meet certification requirements or if Sage receives non-conforming product.



3.4 Approved Suppliers

Sage will purchase raw materials, parts, assemblies, printed materials, certain services and equipment, and finished goods only from suppliers approved by Sage. Approved suppliers are those that have demonstrated consistent capability to meet our requirements and are specific to each supplier's manufacturing location.

3.5 Supplier Recognition

Sage will formally recognize suppliers who demonstrate their commitment by meeting our supplier performance criteria using the following criteria:

- A) Quality of products or materials provided
- B) Delivery performance
- C) Service performance

4.0 Quality System Guidelines

We want our suppliers to have a Quality System in place, but how it is implemented depends upon your company and the type of component that you supply to Sage. Below are listed minimum requirements for a quality system, which we use as a guideline when we evaluate the product or processes of our suppliers. Your company is the best judge of how to develop a quality system appropriate for your products.

4.1 Quality Policy

Management with executive responsibility is to establish the supplier's policy and objectives for, and commitment to, quality. Management with executive responsibility is to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

4.2 Quality Management

The executive manager is to appoint a member of the executive staff who, irrespective of other responsibilities, is the supplier's management representative for quality. This manager shall have the overall responsibility to ensure that the quality system is effectively established and being maintained. This individual is to be able to be contacted by a representative of Sage whenever issues of product quality arise.

4.3 Quality Manual

Where appropriate for the size of the organization, the supplier shall document how the quality system has been established and describe how the quality system functions in a quality manual.

4.4 Quality Plan

A plan defining how the specified requirements, including quality requirements, will be met shall be established and maintained. This plan shall include the practices, resources, and activities relevant and appropriate for the product being manufactured for Sage.



4.5 Quality System Procedures

The supplier shall have documented procedures and instructions to effectively implement the established quality system and support the quality plan.

4.6 Inspections and Tests

The supplier is responsible for conducting all appropriate inspections and tests necessary to conclude that the product made for Sage meets all of its specified requirements and quality attributes. These inspections and tests are to be included in the quality plan.

4.7 Personnel Training

The supplier is responsible for maintaining sufficient personnel with the necessary education, background, training, and experience to assure that the established quality system and quality plan are correctly implemented. Personnel are to be adequately trained to perform their assigned responsibilities according to an established training plan. Training shall be documented.

4.8 Internal Audits

Internal audits are to be performed to ensure that the established quality system is being maintained and that the quality plan is being followed. Management with executive responsibility is responsible for timely corrective actions to resolve discrepancies found during internal audits.

4.9 Sage Audits

To ensure the effectiveness of the supplier's quality system to deliver conforming product, Sage may require representatives to perform quality audits at the supplier's facility. The supplier's executive management shall support such audits and ensure that prompt corrective actions are taken to address any discrepancies found.

4.10 Product Specification Requirements

The supplier is responsible for addressing any incomplete, ambiguous, or conflicting specification requirements received from Sage prior to starting production operations.

4.11 Process/Product Changes

In order to enable Sage to determine if any proposed change in the product(s) will have any effect on the safety and/or efficacy of any of the product(s), supplier has agreed to notify Sage in writing 90 days prior to making a change in any of the following aspects of the product(s):

- A) Composition of any raw material
- B) Source of any raw material
- C) Method of producing, processing, or testing
- D) Change in subcontractors for producing, processing or testing
- E) Site of manufacture



4.12 Process Control

Suppliers are expected to support Sage’s objective to achieve zero defects. The use of Statistical Process Control (SPC) is recognized method for achieving process control and is a practice that supports successful manufacturing of products that conform to requirements. Sage believes that the strategy of SPC is applicable to most manufacturing processes.

5.0 Business Practices

5.1 Confidential Information

Suppliers will not disclose or use confidential information obtained from Sage in any way not directly related to the business activities of Sage. When it is necessary to discuss confidential matters, a Mutual Confidentiality Agreement form will be executed between Sage and the supplier before exchanging any information.

5.2 Environmental

Company decisions involving the use of energy and materials must all be considered with regard to the effect they will have on the environment. At Sage, we know that being a responsible member of the community involves recognizing our impact on the environment and adopting environmentally sustainable practices. We are committed to environmental stewardship and ongoing development of new green initiatives. Sage suppliers should be environmentally conscious and demonstrate continuous improvement with regards to:

- A) Recycled content of materials and products supplied to Sage
- B) Contribution to environment by using less energy and generating less pollution
- C) Working with Sage to identify potential waste reduction techniques in our current and future products and processes.

5.3 Supplier Diversity

At Sage, we believe in creating opportunities for people to succeed—in our products, in our workplace, and among our suppliers. As part of that goal, we are committed to Supplier Diversity, which includes seeking certified small Minority-Owned, Women-Owned, Service-Disabled Veteran-Owned, Veteran-Owned, Small Disadvantaged Businesses and HUB Zone business concerns from which to purchase competitively priced quality goods and services.

6.0 Purchasing Policy

The following information is provided to assist suppliers in understanding some of Sage’s procedures, policies, and practices that are designed to lend continuity to our supplier/customer relationships. This brief outline is intended to be a general overview and not all-inclusive. The purchasing staff will be able to provide additional details when necessary.

6.1 Sales Appointments

Our goal is to provide an environment that facilitates productive time management for Sage associates and potential suppliers. Accordingly, it is company policy not to see sales people without an appointment. While we cannot provide names or extensions to individuals making cold calls, we gladly forward pertinent information to appropriate parties for further consideration.



6.2 Hours and Appointments

Business hours are 8 a.m. to 4:30 p.m., Monday through Friday. We ask that our visitors sign in at the front desk (inside the North entrance of the building) upon arrival for an appointment. The receptionist will provide you with a visitor's badge and contact the party you wish to see.

6.3 Purchase Orders

Before merchandise may be shipped, or any service performed, a purchase order must be issued. Purchase Order numbers must appear on all shipments, packing slips, correspondence, and invoices. Additionally, individual box/container numbers are required on all multiple box shipments (i.e. 1 of 9, 2 of 9, etc.). All purchase orders issued are "Confirming Contract" documents.

6.4 Invoicing

Invoices are paid based on the terms stated on the purchase order, after receipt to dock of goods and following product release by the Quality Assurance Department. We cannot make payment without a supporting invoice showing our purchase order number. Prompt payment discounts are taken from date of receipt of invoice or date of actual release of materials, whichever is later. Invoices may be mailed to the attention of Accounts Payable, 3909 Three Oaks Road, Cary, IL 60013, faxed to 815-455-7095 or emailed to A/PInvoices@sageproducts.com.

6.5 Gifts and Gratuities

We require the highest ethical standards of business at all times. Therefore, Sage employees are not permitted to accept gifts or gratuities from suppliers which could be perceived as a conflict of interest.

6.6 Delivery Information

Sage suppliers are measured on their ability to deliver the right product and the right time. Consequently, it is essential that we receive shipments on the agreed upon date and time. Deliveries should be made to 3909 Three Oaks Road on the west (right) side of the building. Delivery hours are 7:00 a.m. to 5:00 pm, Monday through Friday, except holidays. Deliveries at other times can be arranged through the appropriate contact person at Sage. Only authorized persons can receive goods on behalf of Sage. Unless otherwise stated, we will allow a ten percent maximum under or over on individual shipments. Any over shipment in excess of ten percent may be returned at the supplier's expense. All shipments are to be made FOB supplier's dock, freight collect, unless otherwise stated. A list of approved carriers will be provided. Any deviation from the prescribed routing, without authorization, which results in excess freight charges will be billed directly to the supplier.

6.7 Price Fluctuations

Sage expects our suppliers to commit to work with us in developing long-term strategic plans to afford cost benefits to both companies. When necessary, any proposed price increase must be substantiated and presented to Purchasing, in writing, for review at a minimum sixty (60) days prior to the effective date of change. Proposed price increases that are driven by an increase in a specific commodity will only apply to the material content of the item supplied and must include confirmation that the price will be reduced when the commodity price decreases.