

# Corporate Quality Management Capabilities



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## Corporate Quality Management Capabilities

Thank you for your recent inquiry. In order to serve you better, we would like you to know more about our products and us.

Sigma-Aldrich Corporation is a family of brands including Aldrich, Fluka, Sigma and others, organized into four business units: Research Specialties, Research Essentials, Research Biotech and Sigma-Aldrich Fine Chemicals (SAFC). Sigma-Aldrich distributes more than 130,000 products for use in life science and high technology applications. Approximately half of the products we offer are produced at our own manufacturing facilities. The remaining products are produced by other sources selected by us and purchased in accordance with Sigma-Aldrich's specifications. Sigma-Aldrich distributes its products directly in standard package sizes. Larger quantities and Custom solutions are available through the SAFC business unit.

Whether produced at our own manufacturing facilities or purchased from other sources, all products are subjected to Sigma-Aldrich quality control procedures to insure that they meet Sigma-Aldrich's standards. Many sites including most of our manufacturing facilities are certified to one or more ISO standard. Some products are currently produced in accordance with cGMP requirements. We will be pleased to provide you with information regarding the cGMP status of any specific products in which you may be interested.

We have enclosed answers to many of the questions most frequently asked by Sigma-Aldrich's customers regarding our Quality Management System and the quality of our products and services. We hope you find this information helpful.

Sincerely,



Steven G. Walton

Corporate Vice President Quality,

Safety, Compliance

## Corporate Quality Management Capabilities

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# Corporate Quality Management Capabilities

## Corporate Vision Statement

*“Accelerating Customers’ success through Leadership in Life Science, High Technology and Service”*



## Corporate Quality Management Capabilities

### Quality Policy Statement

Sigma-Aldrich is committed to being the preferred global supplier for research, development, and manufacturing in life science and high technology. To achieve our strategic vision we must meet or exceed customer requirements. We will realize this goal by establishing and maintaining outstanding Quality and Quality Assurance Systems. Every employee at Sigma-Aldrich is dedicated to defect-free work, following established procedures, and delivering products and services that are world-class!

The following principles guide our daily activities:

- **Passion for Process Improvement**
- **Obsession with Service**
- **Leadership in Life Science and High Technology**

The ultimate measure of our success can be found in the success of our Customers, Shareholders and Employees.

## Corporate Quality Management Capabilities

### Organization Information

Name: Sigma-Aldrich Corporation

Address: 3050 Spruce Street

City: St. Louis, Missouri

Country: USA

Zip Code: 63103

Website: [www.sigma-aldrich.com](http://www.sigma-aldrich.com)

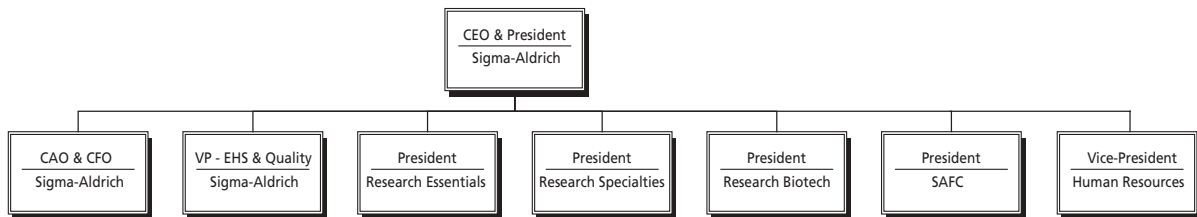
Telephone: 1-800-521-8956

Years in Business: >50 years

Ownership: Public

Total number of Employees: ~ 7200

### Corporate Organizational Chart



### Customer Requests

The purpose of this guide is to assist our customers with their supplier evaluation and incoming inspection processes. In addition to this guide customers are encouraged to visit our award winning website, [www.sigma-aldrich.com](http://www.sigma-aldrich.com) or contact us through one of our local subsidiaries for further information.

### Quality System Overview

Sigma-Aldrich is a global company with sales, manufacturing, and distribution facilities in 35 countries. Many of these locations have quality systems that adhere to the requirements of ISO 9001 or other ISO standards and have received third party accreditation. In addition, Sigma-Aldrich has multiple manufacturing facilities that are registered with the FDA and operate under cGMP. Other sites are currently working to enhance their current quality systems that would meet the requirements of a recognized standard.

### Regulatory Affairs

Where it is necessary Sigma-Aldrich has the capabilities and resources needed to address regulatory requirements such as Drug Master File (DMF) submissions, CE Mark technical files and Certificate of Suitability (Cofs) declarations to the appropriate governing body.

## Corporate Quality Management Capabilities

### Quality System Site Overview

Location	1ISO Registered Sites			OHSAS 18001	cGMP Sites
	9001	13485	14001		
Andover, UK	✓				✓
Arklow, Ireland					✓
Allentown, PA USA	✓				
Bellefonte, PA USA	✓				
Bornem, Belgium	✓				
Tingalbe [Brisbane], Australia	✓				
Broendby, Denmark	✓				
Buchs, Switzerland	✓				✓
Budapest, Hungary	✓				
Caseyville, IL USA	✓				
Denver, PA USA	✓				✓
Gillingham, UK	✓				✓
Hamburg, Germany	✓				
Haverhill, UK	✓		✓		
Helsinki, Finland	✓				
Ishikari, Ichikawa, Tokyo & Osaka, Japan	✓				
Irvine, UK	✓	✓	✓	✓	✓
Jerusalem, Israel	✓				✓
Kyoto, Japan	✓				
Lenexa, KS USA	✓				✓
Madison, WI USA					✓
Manchester, UK	✓				✓
Brooklyn [Melbourne], Australia	✓				
Miamisburg, OH USA	✓				✓
Milano, Italy	✓				
Milwaukee, WI USA	✓				
Mulberry, FL USA	✓				
Oakville, Canada	✓				
Oslo, Norway	✓				
Perryville, MO USA	✓				
Poole, UK	✓				
Poznan, Poland	✓				
Praha, Czech Republic	✓				
Rehovot, Israel	✓				



## Corporate Quality Management Capabilities

### Quality System Site Overview cont.

Location	1ISO Registered Sites			OHSAS 18001	cGMP Sites
	9001	13485	14001		
Saint Louis, MO USA	✓	✓			✓
Saint Quentin Fallavier, France	✓				
Schnelldorf, Germany	✓				
Seelze, Germany	✓		✓		
Selma, CA USA	✓				
Sheboygan, WI USA	✓				✓
Steinheim, Germany	✓				
Stockholm, Sweden	✓				
Taufkirchen, Germany	✓				
Wien, Austria	✓				
The Woodlands, TX USA	✓				
Zwijndrecht, Netherlands	✓				

<sup>1</sup> Site specific certificates are available at:

[http://www.sigmaaldrich.com/CustomerSupport/Customer\\_Service/Quality\\_Systems/ISO\\_Certification.html](http://www.sigmaaldrich.com/CustomerSupport/Customer_Service/Quality_Systems/ISO_Certification.html)

## Corporate Quality Management Capabilities

### Quality System Details

#### Strategic Plan and Management Review

In 1999 Sigma-Aldrich embarked on the process of developing and implementing a comprehensive strategic plan, which included an emphasis on enhancing the Quality Management System. This plan was significantly revised in 2005 to ensure Sigma-Aldrich objectives are achieved including an increased focus on meeting our customer's requirements. In addition, many locations also conduct Management Reviews of their site Quality Management System at prescribed intervals.

#### Quality Manuals

The majority of locations within Sigma-Aldrich maintain a site specific Quality Manual, which provides information on the elements of the Quality Management System including the sequences and interactions of the primary business processes.

#### Quality Policy

The global "One Company" Sigma-Aldrich Quality Policy can be found on page 5 in this guide.

#### Document Control

Quality Management System policies, procedures, and records are maintained under document control as appropriate. Site specific document management systems will describe the level of document control necessary, and may include documentation relating to administration, manufacturing, analytical methods, equipment operation and other areas as defined.

#### Training

Sigma-Aldrich sites have established training programs that include core and job specific requirements. Core training can include quality system, safety and developmental topics. In addition to job training, each position has a written job description that describes the necessary educational and experience qualifications to adequately perform the required tasks.

#### Corrective and Preventive Action

Each site has established a Corrective and Preventive Action system to identify areas for improvement to current products and processes, and also to eliminate nonconformities or prevent reoccurrence.

## Corporate Quality Management Capabilities

### Customer Complaints

Customer complaints are communicated to the appropriate site for resolution. Site specific procedures exist to define the process for complaint investigation, correction action, as well as any actions necessary to accomplish field corrections or recalls. In the event of a recall, affected customers will be identified and contacted.

### Audits

#### Internal Audits

Internal audit programs have been established at each Sigma-Aldrich location to ensure the integrity and continuous improvement of the Quality Management System.

#### Customer

Customer quality audits are permitted at our facilities. We request that adequate notification be provided (date to be agreed) and that an agenda be sent from the customer within 2-weeks of the requested audit date(s). Sigma-Aldrich reserves the right to cancel or revise the audit schedule.

#### Regulatory

Sigma-Aldrich is willing to offer full cooperation to all requests for Government or regulatory audits of our cGMP facilities.

### Supply Chain

#### Suppliers

Our supplier's (materials & services) can be qualified using a combination of criteria such as, assessment questionnaires, on-site audits, historical performance (quality, on-time delivery) and/or third party accreditation. A supplier may become "Rejected" after non-compliance with the Sigma-Aldrich expectations. New and alternate suppliers are qualified as necessary to maintain product supply, purity and competitiveness.

## Corporate Quality Management Capabilities

### Manufacturing Facilities

Location	# of QA/QC Personnel	Square Foot	Square Meter
Andover, UK	3	14,200	1,319
Arklow, Ireland	14	35,779	3,324
Bangalore, India	4	60,000	5,574
Bellefonte, PA USA	25	161,500	15,000
Tingalbe [Brisbane], Australia	See Melbourne	11,000	1,022
Buchs, Switzerland	45	402,400	37,400
Caseyville, IL USA	1	18,900	1,756
Castle Hill, Australia	1	35,000	3,252
Denver, PA USA	17	33,500	3,112
Gillingham, UK	11	55,000	5,100
Hamburg, Germany	11	200,000	18,581
Haverhill, UK	7	22,000	2,044
Ishikari, Japan	5	24,700	2,300
Irvine, UK	16	111,000	10,300
Jerusalem, Israel	5	45,000	4,180
Kyoto, Japan	2	5,759	535
Lenexa, KS USA	19	121,000	11,241
Lismore, Australia	1	2,000	186
Madison, WI USA	12	61,500	5,713
Brooklyn [Melbourne], Australia	5	20,000	1,858
Miamisburg, OH USA	8	61,500	5,700
Milwaukee, WI USA	41	1,336,000	124,200
Mulberry FL USA	see Caseyville	8,000	743
Natick, MA USA	2	30,000	2,800
Oakville, Canada	1.5	656	61
Perryville, MO USA	1	1500	139
Poole, UK	3	113,000	10,500
Rehovot, Israel	6	80,000	8,000
Seelze, Germany (in cooperation w/Honeywell)	40	5,200,000	485,000
Selma, CA USA	see Caseyville	3,600	334
Sheboygan, WI USA	27	427,000	39,700
Steinheim, Germany	12	640,500	59,500
St. Louis, MO USA	135	823,000	76,500
Sydney, Australia	2	882	82
The Woodlands, TX USA	12	68,000	6,400

## Corporate Quality Management Capabilities

### Process Control

#### Procedures

Documentation exists for providing appropriate instructions for producing and testing final product. If changes to the manufacturing or testing process is warranted the work instruction document(s) will reflect the procedural change and approval.

#### Equipment

Critical equipment, defined as a piece of equipment whose failure could compromise the quality, performance, or functionality of a product, is maintained in a calibration and testing program. Where applicable, traceable standards (e.g. NIST) are utilized. Documented procedures exist for equipment operation, calibration and maintenance, and can also include how equipment is cleaned. Where required, equipment and usage records are maintained and available. Equipment tags are also employed to further indicate equipment calibration and maintenance status.

#### Quality Records

Appropriate quality records for a product's lifecycle within Sigma-Aldrich are maintained and available. Quality records can include; customer communications including orders and complaints, raw material information, in-process manufacturing and testing data, packaging, final quality analysis, batch disposition, training and equipment. A product and batch identification system is employed to allow for traceability throughout the entire process.

#### Nonconformance

Procedures exist to prevent nonconforming product from unintended use or delivery. They provide for identification, documentation, evaluation, segregation (when practical) and disposition of nonconforming product, and for notification to all functions concerned. When material is determined to be nonconforming, it is "flagged" in our electronic systems and may also be physically labeled and/or segregated to reflect this "blocked" status so as to prevent shipment.

### Specification Control

#### Incoming Materials

For most materials from our suppliers, Certificates of Analysis are received and reviewed. In addition if warranted, incoming materials may also pass through a physical quality inspection and review process. These materials will be maintained in a "Quarantined" status until the review is complete.

#### Development

Research and Development, Manufacturing, Quality Control, Quality Assurance, Compliance, and Product Management/ Marketing functions are all involved with establishing product specifications. Customer and regulatory requirements, market demand, and process capability are considered in specification development.

#### Accessibility and Control

The majority of general catalog product's specifications are available to our customers and employees. A product specification is considered a controlled document, in either an electronic format and/or in hardcopy, and is handled as such, with revision control, approval and issuance. Any special customer specification(s) are maintained as confidential. Confidential specifications are disclosed only to personnel who are authorized access as part of their job function.

#### Change Management and Notification

Processes exist to manage internally driven changes including final product specifications. If a Change Notification Agreement exists between Sigma-Aldrich and a customer, communication of the change will be initiated. Contact our SAFC Division for details.

### Product/Batch Documentation

#### ***Product Specifications & Certificate of Analysis (CofA)***

The majority of Sigma-Aldrich products have established product specifications. A product's specification information may be found on the Certificate of Analysis, catalog listing and/or on the label. Certificates of Analysis report batch level information including:

- Formula & formula weight
- CAS number
- Grade
- Analytical test results
- QC release date
- Shelf-life (if available)
- Authorization signature from the site that released the batch.

Certificates of Analyses can be found at [www.sigma-aldrich.com](http://www.sigma-aldrich.com), requested from our Technical Service group and/or included in the shipment. Customers will need to contact Customer Service for further information on how to arrange for receipt of a Certificates of Analysis in the product shipment.

#### ***Analytical Test Methods***

A number of the analytical methods used by the Quality Control groups to test Sigma-Aldrich products are available. Specific analytical methods can be found at [www.sigma-aldrich.com](http://www.sigma-aldrich.com) or can be requested from our Technical Service groups. Sigma-Aldrich reserves the right to disclose certain information under a Confidentiality Disclosure Agreement depending upon the request.

#### ***Product Information Sheets***

Certain products include a product information sheet, which provides general product information or specific product usage instructions.

Product Information Sheets can be found at [www.sigma-aldrich.com](http://www.sigma-aldrich.com), requested from our Technical Service groups or may be included in the shipment.

## Corporate Quality Management Capabilities

### **Certificate of Origin**

See Sigma-Aldrich Certificate of Origin Policy (TSE/BSE) and Frequently Asked Questions at:  
[http://www.sigmaaldrich.com/CustomerSupport/Customer\\_Service/Quality\\_Systems.html](http://www.sigmaaldrich.com/CustomerSupport/Customer_Service/Quality_Systems.html)

Information regarding the origin of a particular product is provided on a Certificate of Origin. Information can include:

- Origination Country
- Source: Animal, Plant, Synthetic, etc.
- Biologic species: e.g. Bovine
- Tissue used: e.g. Plasma
- Additional source information (e.g. Age of animal)

Certificates of Origin can be found at [www.sigmaaldrich.com](http://www.sigmaaldrich.com) or by request from our Technical Service groups.

### **BSE/TSE Declaration**

Sigma-Aldrich has established an approach to assisting customers in assessing the risk regarding BSE/TSE, and when Animal Component Free is applicable at:  
[http://www.sigmaaldrich.com/CustomerSupport/Customer\\_Service/Quality\\_Systems.html](http://www.sigmaaldrich.com/CustomerSupport/Customer_Service/Quality_Systems.html)

### **Certificate of Suitability (CofS)**

When the details are known regarding potential exposure to animal origin materials during a product's manufacturing process, and the procedures are in-place to reduce the risk of cross contamination, Sigma-Aldrich will determine if a dossier will be filed with the European Directorate for the Quality of Medicines (EDQM) for that specific product. If requested, additional administration processing fees will apply.

## Corporate Quality Management Capabilities

### Container Label

Product information provided on the container label include:

- Product and Batch number
- Product Name
- Risk & safety statements in multiple languages w/pictograms
- Physical chemical properties
- Regulatory information incl. country of origin, usage claim
- <sup>1</sup>Storage and handling information
- <sup>2</sup>Customer PO and/or product number

<sup>1</sup>Sigma-Aldrich defines the following long-term storage conditions on the label:

Blank or RT = Room Temperature (Ambient)

2–8 °C = Refrigerator/Cooler

-20 °C = Freeze at or below; avoid frost-free freezers

-70 °C = Ultracold freezer at or below

<sup>2</sup>This option is available for bulk orders only; contact the SAFC Division for details.

### Retainers

Retained samples are available for retest for those batches in stock and may be used for retest purposes. Sample quantity availability is product specific and certain products may also have retained material from batches no longer available to customers. Contact the Technical Service group to inquire on availability of specific products.

### Batch Records

For inquires concerning batch information, there is no guarantee that the request can be fulfilled if the batch is more than 7 years past the release date and the customer's inquiry request is greater than 1 year after the order date.