SIGMA-ALDRICH®

Quality and Supply Chain Transparency Guidelines

for Life Science Applications

Work with a supplier that can help solve regulatory challenges in manufacturing

SAFC®

Manage Supply Chain Risk

with a partner that understands manufacturing and regulatory requirements

Global shifts in chemical markets and production centers over the past few decades have increased the complexity of today's supply chain. This trend has led to reduced knowledge and understanding of risk in the biopharmaceutical manufacturing process.

SAFC's Quality and Supply Chain Guidelines bring clarity to this complex process. Designed to meet our customers' evolving needs in understanding and managing risk, SAFC provides an appropriate level of service that works in accordance with the assigned quality level of a product and its recommendation for use. It is a part of our constant effort to provide customers with reliable services for their risk management needs.

Quality and Supply Chain Transparency Guidelines:
Bringing clarity to raw materials for life science applications

SAFC, a member of the Sigma-Aldrich family, is dedicated to solving manufacturing challenges by providing customers with tailored quality and regulatory support for product applications.

We classify the majority of the Sigma-Aldrich products under one of the four levels of our Enhanced Quality Program, from the non-regulated, non-GMP raw materials to highly-regulated GMP products.

Each level has associated quality support and documentation, along with recommended use and change notification parameters.

Standard and **Premium** levels provide helpful information for customers, such as product specifications and certificates of analysis easily available on the Sigma-Aldrich website. Products with either **Standard** or **Premium** quality levels include a comprehensive range of change notification parameters that may be relevant to multiple industrial or commercial specialties. Products with these levels of quality meet the needs of a market that demands innovation and a broad variety of chemicals, along with Just-In-Time delivery. However, the **Standard** and **Premium** quality levels are not recommended for regulated applications, such as biopharmaceutical manufacturing. We provide clear features of quality and documentation support linked to the quality levels, so our customers can make an informed decision on the quality profile appropriate for their application.

Products classified under **Elite** and **GMP** levels have been manufactured and tested to meet the requirements of the biopharmaceutical and pharmaceutical regulated manufacturing processes, as well as other applications requiring highly controlled raw materials. We provide quality documentation supporting our customers' regulatory requirements, as well as manufacturing site quality overview and certifications. The decision on which of these quality profiles is most appropriate is driven by customer need for controlled **(Elite)** or validated processes **(GMP)**.

Our Quality and Supply Chain Guidelines provide clear features to enable the selection of appropriate quality level for applications and provide an understanding of the implications of that decision.

Defining the Right Level of Quality Support

SAFC's Quality Guidelines can be used by customers to develop their own risk assessment for the products they use, and to assist in the process of choosing new raw materials.

These defined quality levels allow for comparison of quality support and documentation available for raw materials.

SAFC Quality Guidelines

Attributes	Standard Quality Level	Premium Quality Level	Elite Quality Level	GMP/Compendia Quality Level
Product Use	Research, Industrial and Chemical Specialities	Research, Industrial and Chemical Specialities	Upstream and Downstream Biopharma Processing	API, BPE, IVD, Biopharma Applications
Raw Material Regulatory Requirements	Non-Regulated Applications	Non-Regulated Applications	Regulated Applications	Regulated Applications
Quality Systems Controls	ISO 9001	ISO 9001	ISO 9001 plus other Controlled Processes	ICH Q7, IPEC, 21 CFR, 13485
Sourcing Information	Proprietary	Discretionary Confidential Information Shared Under CDA	Confidential Information Shared Under CDA	Confidential Information Shared Under CDA
Documentation Available				
Analytical Methods	●	●	●	●
Certificate of Analysis	●	●	●	●
CCN	●	●	●	●
Product Specification	●	●	●	●
Certificate of Origin		●	●	●
Expiry or Retest Date		●	●	●
Vendor Assessment		●	●	●
Critical Control Parameter (CCP)			●	●
QA Batch Review			●	●
Lot Sample Retained			●	●
Vendor Management			●	●
Validation				●

SAFC Quality Guidelines: Levels and Recommended Use

Standard Quality Level Details	
Product Use	**Recommended for research use, non-registered manufacturing use, and non-regulated industrial applications, with limited change notification requirements.**
Features	• ISO 9001 Quality Management System - *does not include GMP guidance* • Certificate of Analysis (CofA) and MSDS available • Certificate of Origin (CofO) may be available • Analytical Method may be available upon request • Sourcing information remains proprietary
Change Notification*	Analytical release specifications and/or method, vendor (could be different from manufacturer), manufacturing site if produced by Sigma-Aldrich, packaging site, testing site, product deletion. Notification timeline: 2 weeks

*Change notification is a service available at all Quality levels and must be requested by customer for individual products. Fees may apply.

SAFC Quality Guidelines: Levels and Recommended Use, continued

Premium Quality Level Details	
Product Use	**Recommended for non-registered manufacturing use and non-regulated industrial applications, with limited change notification requirements.**
Features	• ISO 9001 Quality Management System - *does not include GMP guidance* • Certificate of Analysis (CofA) and MSDS available • Certificate of Origin (CofO) available • Analytical Method available upon request • Expiry or Recommended Retest Date supplied • Vendor Assessment • Sourcing information disclosure at discretion of SAFC
Change Notification*	Analytical release specifications and/or method, vendor (could be different from manufacturer), manufacturing site if produced by Sigma-Aldrich, packaging site, testing site, product deletion, type of manufacture. Notification timeline: 4 weeks

Elite Quality Level Details	
Product Use	**Recommended for upstream and downstream processing, registered starting materials and raw materials (material can be in regulatory filing). This level does not support the use of the product as an API or Excipient.**
Features	• Quality Management System, including some elements of industry standards • Controlled Manufacturing process, not validated • Internally qualified analytical method. If compendial methods are used, they are validated by definition. • Certificate of Analysis (CofA) and MSDS available • Certificate of Origin (CofO) available • Expiry or Recommended Retest Date supplied – supported by Sigma-Aldrich data • Manufacturing and risk assessment. Residual solvents, melamine, and BSE TSE statements available. • Retained sample • Quality review of batch records • Manufactured by Sigma-Aldrich or by qualified supplier who commits to notification of changes and transparency • Sourcing information disclosed under confidentiality agreement
Change Notification*	Analytical release specifications and/or method, manufacturing site, packaging site, testing site, type of manufacture, significant manufacturing process changes. Notification timeline: 12 weeks

GMP Quality Level Details	
Product Use	**Recommended for upstream and downstream processing, registered starting materials and raw materials (material can be in regulatory filing). Some products at this level are suitable for use as API's or Excipients.**
Features	• Quality Management System at GMP level • Validated and controlled manufacturing process • Internally qualified analytical method. If compendial methods are used, they are validated by definition. • Certificate of Analysis (CofA) and MSDS available • Certificate of Origin (CofO) available • Expiry or Recommended Retest Date supplied – supported by Sigma-Aldrich data • Manufacturing and risk assessment. Residual solvents, melamine, and BSE TSE statements available. Meets compendial requirements where indicated in name or Product ID. • Retained sample • Quality review of batch records • Manufactured by Sigma-Aldrich or by qualified supplier who commits notification of changes and transparency • DMF's or Quality Dossiers may be available • Certificates of suitability may be available
Change Notification*	Analytical release specifications and/or method, manufacturing site, packaging site, testing site, type of manufacture, significant manufacturing process changes, and primary packaging component or closure. Notification timeline: 12 weeks

*Change notification is a service available at all Quality levels and may need to be requested by customer for individual products. Fees may apply.

SAFC International Sites

Global Email: safcglobal@sial.com

Argentina
Tel: +54 11 4556 1472
Fax: +54 11 4552 1698
Email: info-argentina@sial.com

Australia
Free Tel: 1800 800 097
Free Fax: 1800 800 096
Tel: +61 (0)2 9841 0555
Fax: +61 (0)2 9841 0500
Email: anzcs@sial.com

Austria
Tel: +43 (0)1 605 81 91
Fax: +43 (0)1 605 81 20
Email: atorders@sial.com

Belgium
Free Tel: +0800 99560
Free Fax: +0800 99561
Tel: +31 (0) 78 6205414
Fax: +31 (0) 78 6205424
Email: nldsaf@sial.com

Brazil
Tel: +55 11 3732 3100
Fax: +55 11 3733 5151
Email: brasafc@sial.com

Canada
Free Tel: +1 800 565 1400
Free Fax: +1 800 265 3858
Tel: +1 905 829 9500
Fax: +1 905 829 9292
Email: canada@sial.com

China
Tel: +86 400 620 3333
Fax: +86 6141 5567
Email: ordercn@sial.com

Czech Republic
Tel: +420 246 003 200
Fax: +420 246 003 291
Email: czeorders@sial.com

Denmark
Tel: +45 43 565 900
Fax: +45 43 565 905
Email: nordicsafc@sial.com

Finland
Tel: +358 9 350 9250
Fax: +358 9 350 92555
Email: finorder@sial.com

France
Tel: +33 (0)4 74 82 2882
Fax: +33 (0)4 74 82 2890
Email: frasafc@sial.com

Germany
Tel: +49 (0)89 6513 1920
Fax: +49 (0)89 6513 1919
Email: deusafc@sial.com

Greece
Tel: +30 2 10 994 8010
Fax: +30 2 10 994 3831
Email: grcustsv@sial.com

Hungary
Tel: +36 (06) 1 235 9066
Fax: +36 (06) 1 235 9050
Ingyenes zöldtelefon: 06 80 355 355
Ingyenes zöld fax: 06 80 344 344
Email: info@sigma.sial.hu

India
Tel: +91 80 6621 9400
Fax: +91 80 6621 9650
Email: india@sial.com

Ireland
Free Tel: +1 800 200 888
Free Fax: +1 800 600 222
Tel: +353 402 20370
Fax: +353 402 20375
Email: safcei@sial.com

Israel
Free Tel: +1 800 70 2222
Tel: +972 8 948 4100
Fax: +972 8 948 4200
Email: isrsafc@sial.com

Italy
Telefono: +39 02 3341 7350
Fax: +39 02 3341 7201
Email: itasafc@sial.com

Japan
Tel: +81 (0)3 5796 7340
Fax: +81 (0)3 5796 7345
Email: safcjp@sial.com

Malaysia
Tel: +60 3 5635 3321
Fax: +60 3 5635 4116
Email: sam@sial.com

Mexico
Free Tel: +01 800 007 5300
Free Fax: +01 800 712 9920
Email: mexico@sial.com

The Netherlands
Tel: +31 (0)78 620 5414
Fax: +31 (0)78 620 5424
Free Tel: +0800 022 9092
Free Fax: +0800 022 9093
Email: nldsaf@sial.com

New Zealand
Free Tel: +0800 936 666
Free Fax: +0800 937 777
Email: anzcs@sial.com

Norway
Tel: +47 (0)23 176 000
Fax: +47 (0)23 176 010
Email: nordicsafc@sial.com

Poland
Tel: +48 61 829 0100
Fax: +48 61 829 0120
Email: plorsafc@sial.com

Portugal
Tel: +351 21 924 25 55
Fax: +351 21 924 26 10
Free Tel: +800 20 21 80
Free Fax: +800 20 21 78
Email: espsafc@sial.com

Russia
Tel: +7 495 621 58 28
Fax: +7 495 621 59 23
Email: ruorder@sial.com

Singapore
Tel: +65 6779 1200
Fax: +65 6779 1822
Email: sapl@sial.com

South Africa
Free Tel: +0800 1100 75
Free Fax: +0800 1100 79
Tel: +27 11 979 1188
Fax: +27 11 979 1119
Email: rsa@sial.com

South Korea
Tel: +82 (0)31 329 9000
Fax: +82 (0)31 329 9090
Email: hcjoo@sial.com

Spain
Tel: +34 91 657 2073
Fax: +34 91 490 5785
Email: espsafc@sial.com

Sweden
Tel: +46 (0)8 742 4200
Fax: +46 (0)8 742 4243
Email: sweorder@sial.com

Switzerland
Swiss Free Call: +0800 80 00 80
Tel: +41 (0) 81 755 25 29
Fax: +41 (0) 81 755 27 70
Email: safcswitzerland@sial.com

United Kingdom
Tel: +44 (0) 1202 712 305
Fax: +44 (0) 1747 833 572
Email: safcuk@sial.com

United States
Toll Free: +1 800 244 1173
Call Collect: +1 314 534 4900
Toll Free Fax: +1 800 368 4661
Fax: +1 314 652 0000
Email: safcglobal@sial.com

SAFC®

ORO
78834-509886
1052