Quality Management System
Sigma-Aldrich Buchs – Overview

This information sheet is an extract of the quality management system (MS) of the Sigma-Aldrich Group Switzerland at the site Buchs. It illustrates our MS structure and our main business processes. The complete and official MS is only available via the company’s intranet.

Main Pages

The main pages of the MS mirror the structure of the Sigma-Aldrich Group Switzerland at the site Buchs, which consists of three companies:

- Sigma-Aldrich (Switzerland) Holding AG
- Sigma-Aldrich Chemie GmbH
- Sigma-Aldrich Production GmbH

Certain business processes apply to the whole site, while others are only relevant for Sigma-Aldrich Production GmbH or Sigma-Aldrich Chemie GmbH.

Overview of the site Buchs and of the business processes which are relevant for the whole site (business process number starts with “S”):
Overview of the business processes which are relevant for Sigma-Aldrich Chemie GmbH (business process number starts with “C”):

Overview of the business processes which are relevant for Sigma-Aldrich Production GmbH (business process number starts with “P”):
Basic information

- Every business process has a business process owner.
- For every business process relevant KPIs have been defined.
- Details regarding the business processes are described on the following pages.
- The Sigma-Aldrich sites Buchs is certified according to the following norms and regulations, which are implemented in our MS:
  - ISO 9001:2008
  - ISO 17025:2005 and ISO Guide 34
  - ISO 13485:2012
  - GMP

Description of the business processes

S00: System description

Objective

The MS is the basis for the preservation and continuous improvement of the quality and management level at the Sigma-Aldrich site Buchs.

Scope

The MS is binding for all employees and all activities of the Sigma-Aldrich group at the site Buchs.

The process model – basis of the management system

Definition, application and continuous improvement of our processes form the basis of our management system. By “process” we mean an integrated network or a sequence of activities.
Management System Documentation

The structure of the system documentation follows the process idea. The document- and system-hierarchy is structured according to the following scheme:

**MS Documentation**

**MS**
- Process network
- Company Portrait
  - Introduction of Sigma-Aldrich Group Switzerland,
  - company policy, integration into corporation, structural
  - organisation, legal structure
- System Description
  - Basic description of the MS
- Overview of Business Process Owners
- Search function

**Business Processes**
- Overview: Main activities within the processes

**Work and Part Processes**
- More detailed description of activities, together with the
  - related responsibilities and applicable documents

**SOPs**
- Standard Operating Procedures, available as electronic
  - and/or paper documents

**Auxiliary Documents**
- Management Documents
- Checklists
- Forms

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**Operational Implementation**

**Order/product-specific documents and data**
- Order-specific or product-specific use of the MS
  - documents (e.g. audit plan, production orders,
  - manufacturing instructions, test specifications, project
  - specifications, databases, external requirements such as
  - laws, norms, etc.)

**Records**
- Evidence of accurate execution of orders or of a
  - functioning MS (e.g. audit reports, batch records,
  - inspection records, reports, inspection certificates, etc.)
Generation, Release and Publication of MS Documents

Business process owners are responsible for the contents of the MS, the creation of new documents and the update of existing documents. MS documents are reviewed by users and business process owners with regard to technical correctness. Quality Assurance reviews the norm conformity of the documents. In case of documents critical for the quality of products and services (e.g. documents specifically for GMP) an additional review and release by the Manager Quality Assurance is required. The administration of the MS as well as the publication of released documents and the archiving of outdated documents are within the responsibility of Quality Assurance.

As far as possible, MS documents are published electronically. Paper copies of documents are possible anytime, but copies of SOPs show a day stamp and are valid only on the day of printout.

Documents are reviewed regularly

- during audits,
- at management review meetings,
- by Quality Assurance.
### S05: Portrait of the Sigma-Aldrich Group Switzerland

<table>
<thead>
<tr>
<th>Topic</th>
<th>Details</th>
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</table>
| Founded                                         | 27 July 1950 in St. Gallen as Fluka Chemie AG  
1953 Relocation to Buchs SG  
1 July 2005 renaming of Fluka in Sigma-Aldrich                                                                 |
| Sigma-Aldrich Group Switzerland                 | Three companies are located at the site Buchs:  
- Sigma-Aldrich (Switzerland) Holding AG  
- Sigma-Aldrich Chemie GmbH  
- Sigma-Aldrich Production GmbH                                                                 |
| Shareholder of the Holding and the GmbHs        | 100% Sigma-Aldrich Corporation, St. Louis, USA                                                                             |
| Governing Board                                 | Dr. Dieter Hofner                                                                                                         |
| Management of all companies                     | Dennis Tschudin, Site Director  
Alexander Pirc  
Reto Salzgeber  
Heiko Diederichs                                                                 |
| Activities of Sigma-Aldrich Production GmbH     | Sigma-Aldrich Production GmbH deals with the manufacture of pharmaceutical ingredients, laboratory reagents, biochemicals, research chemicals, fine chemicals and intermediates as they are used in modern chemistry, biochemistry and pharmacology.  
Since 1 October 2012 these activities are conducted on behalf of Sigma-Aldrich International GmbH (St. Gallen) as so-called “toller” (contract manufacturer).  
Additionally, the following supporting functions for the whole site Buchs are part of Sigma-Aldrich Production GmbH:  
EHS, Quality Management, Compliance, Finance, IS, Human Resources, Facility Management                                                                 |
| Activities of Sigma-Aldrich Chemie GmbH         | Sigma-Aldrich Chemie GmbH is the sales organisation for Switzerland and as such responsible for the sales of products of Sigma-Aldrich International or other daughter companies of the Sigma-Aldrich Corporation to Swiss customers.  
Worldwide distribution is carried out primarily by distribution companies which are part of the Sigma-Aldrich Corporation, partly with own warehouses, or via Sigma-Aldrich International GmbH.  
Additionally, some departments which exercise activities under technical regional and corporate guidance, are part of Sigma-Aldrich Chemie GmbH:  
Innovation, Product Management, Marketing                                                                 |
Company Policy

The directives of the Sigma-Aldrich Corporation, its organisation and culture form the basis for the management system and for the objectives, culture and organisation of the Sigma-Aldrich Group Switzerland.

The following principles are applicable:

- **Our Vision:** To be the Trusted Global Partner of Choice for our Customers
- **Our Mission:** Enabling Science to Improve the Quality of Life
- **Our Values and Conduct:**
  - Employees, customers and shareholders are equal partners.
  - We treat our partners with respect and dignity.
  - We are role models in performance and conduct.
- **Legal Compliance:** Sigma-Aldrich is committed to adhering to legal requirements.
- **Quality:** Our basis for quality is described in our Quality Policy.
- **We create added value:**
  - Our activities are:
    - customer-oriented
    - process-oriented and integrated in the process network
    - characterised by simplicity, efficiency and self-responsibility
- **Continuous improvement:** We are passionately improving our processes and activities.
- **Safety, health- and environmental protection** are equal objectives to turnover and profit (EHS Policy).
- **Our service** is the basis for our success; we are continuously improving it with passion.
- **Innovation** is essential for future success.
- **Technology:**
  - We provide optimal infrastructure by directed investments.
  - We use our infrastructure in the best possible way by know-how, organisation and leadership.
- **We are a team:** The team is the basis for our success. We develop the potential of our individual employees.
- **We are part of the public:** We are part of the public and accept the corresponding responsibility (Sigma-Aldrich Statement of Corporate Responsibility).
S10: Site Management

**Input:**
- Vision & Mission of Sigma-Aldrich Corporation
- Strategic plan from corporation
- Tactical plan from EMEA region
- Laws (international / Swiss federal / cantonal)
- Corporate guidelines
- Corporate Business Code of Conduct
- Economic circumstances and market conditions

**Process:**
- Implement tactical plans of EMEA region on behalf of the Swiss Principal
- Manufacture and fill products as contract manufacturer (toler)
- Sell products on Swiss market
- Strategic marketing, product management and innovation for selected products
- Corresponding organisation
- Define and manage KPIs and objectives
- Rolling plans for site development and related investments
- Communication

**Output:**
- Directives for process owners
- Define responsibilities and competences
- Balanced scorecard for the site Buchs
- Communication plan
- Site development plan
- Organisation chart

![Diagram of S10: Site Management](image-url)
Objective

This process has the following objectives:

- Ensure safety for all employees, neighbours and customers
- Outstanding customer satisfaction through delivery of highest quality for all products and services
- Continuous enhancement of productivity by process improvements
- Long-term financial success for the corporation by successful implementation of the topics mentioned above

S20: EHS and Compliance

Legal and regulatory requirements
- Federal and cantonal laws and regulations
- Regulatory conditions (directives, licences, etc.)

Rules and standards
- guidelines
- consultative documents
- norms

Requirements of Sigma-Aldrich Corporation
- EHS Policies, Principles, Procedures
- EHS Objectives

This process describes the implementation of legal, regulatory and corporate requirements with regard to safety, health and environmental protection:

- Safety
  - Occupational safety and prevention of accidents
  - Plant safety

- Health Protection
  - Occupational hygiene
  - Ergonomics

- Environmental Protection
  - Waste
  - Waste air
  - Waste water
  - Soil

Compliance
- EHS Compliance
- Product & Trading Compliance

Security

Documents
- Standard Operating Procedures (SOPs)
- Management documents
- Forms
- Trainings

Operation and Management
- Waste water plant
- Waste disposal

KPIs
- Internal statistics
- Reports for authorities and corporation

Prevention of non-occupational accidents

S20-01 EHS Organisation
S20-02 EHS Principles
S20-04 EHS Audit System
S20-05 Incident and Emergency Management
S20-10 Safety
S20-20 Health Protection
S20-30 Environmental Protection
S20-40 Compliance
S20-50 Security
S20-60 Occupational Hazard Analysis
Objective

Safety and Health Protection for the benefit of employees, customers and the public as well as protection of the environment are important concerns of the Sigma-Aldrich Corporation.

Business decisions and activities must not contravene this principle.

We foster safety-, health- and environment-consciousness and a sense of responsibility of our employees in all areas of life. This is accomplished via information, training and instructions as well as by appropriate reviews. Corporate EHS principles are integrated into our processes.

The relevant legal requirements are binding for us. Further, we will meet or exceed generally accepted norms and standards.

For the day-to-day implementation of the EHS requirements we seek the support of every single employee.
S30: Quality Management

This process describes:

**QMS / Customer Service:**
- Administration of the MS (see also S00)
- Handling of
  - Quality complaints
  - Recalls and returns
  - Quality incidents
  - Audit requests
- Further quality-relevant customer service

**QA GMP:**
- Supervision of GMP products and GMP production runs
- Process validations

**GMP Compliance / Training / Validation / Qualification:**
- Method validations
- Computer validations
- Qualification of equipment and facilities
- Administration of training system
- GMP Compliance

- Fulfilled quality requirements from different norms
- Products manufactured in accordance with regulatory requirements
- Documentation of deviations, nonconformances and changes
- Investigation of quality complaints, definition and administration of CAPAs
- Handling of recalls and returns
- Documentation of quality incidents
- Audit reports and CAPAs
- Training documents and records
Objective

All employees of Sigma-Aldrich Buchs are responsible for the quality of products and services for internal and external customers.

This business process describes the competency, responsibility and organisation of quality assurance and further their tasks and activities to meet the requirements of the norms implemented at our site Buchs (please see above).

The MS is fundamental for meeting all these requirements. It describes all business processes and activities. GMP-relevant directives, guidelines and processes are integral part of the MS. The manager quality assurance is responsible for the administration of the MS as well as for the integration of GMP requirements.

Organisation and Responsibilities

General

The organisational structure at the site Buchs is defined in an organisation chart which is reviewed periodically by site management and adjusted as required. The tasks of all employees are defined in job descriptions. The process organisation and the process responsibilities are described in the MS.

The quality assurance department of the Sigma-Aldrich Group Switzerland at the site Buchs reports to the site director. The implementation of corporate and regional quality assurance directives is ensured by cooperation with corporate and regional quality assurance departments.

Responsibility of the Manager Quality Assurance

The quality assurance manager is responsible for all activities of the quality assurance department in Buchs and is also the qualified person as required by law.

Quality assurance and quality control are both independent from production, ie the manager quality assurance is independent from those departments which are directly involved in the manufacturing of products. The quality assurance manager reports directly to the site director.

The quality assurance manager has the competency and the duty to highlight quality problems and to propose and implement solutions to such problems. Further, the quality assurance manager is authorised by site management to interrupt deficient processes any time, to implement corrective actions and to monitor the effectiveness of such actions. Hence, with regard to quality issues, the quality assurance manager is authorised to issue instructions to all other departments and employees on site.

Verification activities such as testing and monitoring of procedures and products are mainly the responsibility of the business process owners and departments. For all GMP products, the responsibility lies with quality assurance, as defined in GMP guidelines.

The qualified person exerts direct technical supervision of the operational departments and ensures especially the correct handling of pharmaceutical products. The qualified person is responsible for the quality of the manufactured substances and intermediates and has to ensure that these meet their current specifications and are manufactured according to GMP guidelines.
**S40: Process Improvement**

- **Input:**
  - Suboptimal KPIs, processes or situations
  - New ideas for the reduction of costs, work time, cycletime or ideas for the enhancement of sales, safety and quality

- **Process:**
  - Continuous improvement
  - Systematic search for ideas, and evaluation of their effectivity
  - Preventive actions

- **Output:**
  - Profitability (cost reduction, increase of sales)
  - Speed (cycletime)
  - Readiness for delivery
  - Customer satisfaction
  - Quality
  - Safety and environment

**Objective**

This business process describes methods and procedures for process improvement (CIP, PDSA) which may also be utilized for corrective and preventive actions.

**S50: Information Services**

- **Input:**
  - User Requirements
  - Legal Requirements
  - Corporate Requirements

- **This process describes how:**
  - IT investments are planned and implemented
  - Hardware and software are purchased or leased
  - Data are protected
  - Access rights are assigned and monitored
  - Data security is ensured

- **Output:**
  - Provision of reliable systems (hardware and software)

**Objective**

This process describes and defines the main Information Services processes with regard to the site Buchs:

- Procurement of hardware and software
- Access authorisation / Data protection
- Data security
- User support
S60: Human Resources

Input:
- Corporate / EMEA Objectives
- Site Management
- Mission and Vision
- Organisational development
- Budget
- Guidelines, laws, directives
- Management decisions
- Principles of HR management
- Applications / hires
- Resignations / retirement

This process describes the recruitment and development of human resources from demand for open positions to resignation and retirement.

**Recruiting:**
- Describe demand (open positions)
- Search for suitable candidates
- Evaluation and hiring of new employees
- Planning of initial training, evaluation of probationary period

**Appraisal:**
- Appraisal interviews and discussion of qualifications

**Development:**
- Definition of development goals
- Evaluation of potential
- Local talent management
- Planning and implementation of trainings
- Monitoring of performance
- Wages (Comp. and Ben.)

**Resignation:**
- Interviews
- Administration

Output:
- Contract of employment
- Personnel administration
- Information for new hires
- Appraisal results
- Training courses
- Talent pool
- Resignation in due time

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**Market / Job candidates**

- **S60-10 Recruiting**
- **S60-20 Appraisal**
- **S60-30 Personnel Development**
- **S60-40 Resignation**

- **S60-31 Apprenticeship**
- **S60-32 Qualification**

- **S30-10 Training**

- **Market**
Objective

- Implementation of strategic directives of the Corporation and of EMEA Headquarters
- Participation in decision processes as HR Business Partner
- Support of management at the site Buchs as HR Business Partner
- Ensure a professional administration of human resources and personnel management by suitable means and tools
- Recruiting:
  - Acquisition of employees which meet the requirements, have the appropriate qualification and potential
- Human resources development:
  - Be prepared for future challenges and be able to meet them
  - To be able to replace key functions internally by talent management
S70: Engineering and Facility Management

Objective

Ensure full operability of existing buildings, facilities, and equipment.
P10: Planning

Objective
This business process describes the efficient implementation of the short-term plan while meeting timelines and costs.

P15: Project Management

Objective
This business process is to ensure that customers obtain customised products and solutions which meet timelines and costs by efficient project management.
Objective

Timely and cost-effective delivery of required goods and services in the correct amount and quality.
P25: Vendor Management

Objective

This business process ensures that all supplier invoices are filed and booked correctly and as required by law (including local law) and by directives of the corporation (US-GAAP, Sarbanes-Oxley) and the EMEA region.

P30: Goods Receipt

Objective

This business process ensures that the correct amounts of the correct materials are booked into our data systems. Further, it describes the preparation of incoming goods for safe storage or distribution while adhering to safety and quality guidelines.
P40: Production

**Input:**
- Production quantities
- Production schedules
- Specification requirements
- Proposals for the development of new products
- Customer requirements according to contracts
- Hourly wages and extra charges
- Storage and handling instructions
- Legal requirements and safety-relevant findings
- Changes in customer requirements
- Raw materials

**This process describes the:**
- Production Planning
- Management of orders
- Supply and execution of (Process) Development
- Chemical manufacturing
- (GMP) Filling
- Finishing of orders
- Quarantine and release
- Ensure suitability for storage
- Management of bulk warehouse
- Process monitoring (schedule, cost, quality)

**Output:**
- Information required for order confirmation
- Information regarding the status of a single order
- New manufacturing process
- Waste and waste-related information
- Changed specification
- Final specification of new product
- Certificate of analysis
- Information regarding storage conditions
- Information regarding changes in value of material
- Product

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**Standard Processes**
- P40-10 Production Planning & Administration
- P40-20 Management of Material
- P40-30 Safety Laboratory
- P40-40 Process Development
- P40-50 Bulk Production

**Special Processes**
- P40-60 Kits & Medical Devices
- P40-70 Elite & GMP Fillings
- P40-90 Certified Reference Materials

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**Swiss Principal**

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**P10 Planning**

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**P80 Distribution**

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**P15 Project Management**
Objective

Timely and cost-efficient manufacture of the required Sigma-Aldrich products in the correct amount and quality.

P50: Production Finished Goods

Input:
- Planned orders for prepack (long-term to medium-plan generated by Swiss Principal)
- Planned orders for SPEC (customer-specific orders)
- Process orders for Intercompany Bulk Transfers

Process:
The toller generates the short-term schedule and produces the required product in the correct amount and quality and in due time.

Output:
- Prepack
- SPEC
- Interco-Bulk
- Labels for external suppliers or warehouses

Objective

This business process describes the efficient handling of orders while observing timelines, cost-efficiency and the required level of quality.
P60: Quality Control

Input:
- Goods receipt (purchased materials)
- Goods receipt (inhouse manufactured materials)
- Transferred Material
- Multibulk
- Periodical Retests
- In Process Controls
- Samples from suppliers and customers
- Customer enquiries (analytical methods and results, requests for analyses)
- Customer complaints
- Enquiries regarding qualification/validation/transfer of analytical methods

Process:
- Support for the creation and administration of specifications
- Sampling at goods receipt (for purchased materials)
- Sampling and release of product (purchased or inhouse produced)
- Testing of samples required for the qualification of suppliers
- Retest of products to ensure the quality of stock material and to manage the data regarding shelf life and storage conditions
- Rejection of materials
- Processing of analyses for external and internal customers
- Preparation of analytical methods for external and internal customers
- Coordination of analyses with external contract laboratories
- Handling of in Process Controls
- Development and validation of analytical methods
- Maintenance, calibration and qualification of analytical equipment
- Support for Innovation, Sales and Marketing
- Processing of customer and vendor complaints
- Administration of data required for the creation of Certificates of Origin

Output:
- Analytical results
- Released bulk materials and finished goods
- Certificates of Analysis
- Certificates of Origin
- Methods of analysis
- Analytical results for external and internal customers
- Qualification and validation documents
- Operational procedures
- Retest and/or expiry dates
- Storage conditions

Diagram:

- P30 Goods Receipt
- P40-70 Elite-/GMP-Fillings
- P40-90 Certified Reference Materials
- P40-50 Manufacture of Bulk Material
- P40-40 Process Development
- P50 Production
- P60-10 Release Analytics
- P60-30 Reviewing Chemist Duties
- P60-30 Analytical Development
- P50 Production Finished Goods
- P20 Purchasing
- C40 Innovation / Promotion
- P40-60 Custom Synthesis
Objective

Quality Control supports the interests of Sigma-Aldrich in the following areas:

- Sales of Sigma-Aldrich products
- Generation of analytical data for customer projects
- Supply chain
- Innovation
- European Centre for Quality Control (support of other European sites)
- Investigation of customer complaints

P70: Warehouse

**Input:**
- Transfer of goods from goods receipt department
- Production Finished Goods or Manufacturing has open demand (process orders, material orders)
- Orders (Returns / Sales)

**Process:**
- Warehousing of chemical materials, auxiliary materials and packaging materials
- Provision of materials including decanting for Manufacturing
- Provision of materials and technical processing for Production Finished Goods
- Cycle counting

**Output:**
- Transfer of ordered materials to internal orderers
- Service provider for several internal departments

Objective

Timely provision of chemical materials, auxiliary materials and packaging materials for internal orderers.
P80: Distribution

Input:
- Production Finished Goods or Manufacturing fills materials ready for sale
- Purchasing orders materials ready for sale, filled by external suppliers
- A customer order or the stock requirements of another warehouse or planning lead to an open demand.

Process:
- Distribution stores materials ready for sale, commissions them or compiles materials. The materials are packaged, and the required shipping documents are created.

Output:
- Shipping documents and correctly packaged materials are handed over to carriers.

Objective

Handling of the materials to be shipped (chemicals, packagings, etc.) while adhering to timelines and legal requirements.
Objective

Smooth operation of all sales-relevant processes
**C20: Invoice Processing**

**Input:**
- Products ready for shipment according to customer order
- Billing according to customer order
- Legal Requirements
- Directives of Corporation / EMEA

**This process describes the:**
- Billing based on customer orders
- Accounting control

**Output:**
- Customer Invoice
- Internal/external reporting (to EMEA Management and Corporation)

**Objective**

This business process describes the correct processing of customer invoices, the related workflow and the correct calculation of value added tax for end customers.

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**C30: Accounts Receivable Management**

**Input:**
- Customer Invoices
- Outstanding payments from customers
- Legal Requirements
- Directives of Corporation/EMEA

**This process describes the:**
- Classification of (new) customers on creditworthiness
- Credit limits
- Accounting of payments received from customers
- Dunning
- Dealing with defaulting customers

**Output:**
- Receipt of payment
- Resulting internal and external reporting

**Objective**

This process ensures that customer invoices are managed according to legal requirements (local law) and as required by directives of the corporation and the EMEA region (US-GAAP).
C40: Innovation & Promotion

Input:
- Corporate / EMEA Strategy
- Customer enquiries
- Proposals from scientific consultants
- Input from sales department
- Product proposals from different initiators
- Customer complaints (product improvements)
- Projects
- Marketing plan
- Budget
- Objectives and directives

This process describes the:
- Definition of product groups and product design on brand level
- Generation of ideas, evaluation, and development of design specifications for new products / services
- Provision of guidelines for sourcing (Purchasing and Development)
- Development of manufacturing processes and application data
- Investigation and assignment of product data and product design
- Assignment of compliance data
- Continuous product improvement
- Means and channels of promotion

Output:
- Product groups
- Results of development
- Marketable product
- Product classification
- Product master data in different data systems
- Regulations for storage (storage classes)
- Data regarding chemical stability
- Label data
- Instructions for Procurement
- Packaging instructions
- Instructions for shipping documents
- Instructions for packaging materials
- Product Data Sheet
- Customer Intelligence

Diagram:

- C40-10 Generation and Evaluation of Ideas
- C40-30 New Product Introduction and Product Design
- C40-20 R&D Research Specialties
- C40-40 Product Enhancement / Changes
- C40-50 Promotion


Customer
Objective

This process ensures that

- the product strategy is adapted and implemented according to the development of the market and based on the strategy of the corporation
- products are introduced which are attractive and market-driven in terms of quality, preparation, additional information and price. This is precisely defined by processes, activities and responsibilities and includes adaptations and enhancements of existing products.
- the marketing objectives are achieved.