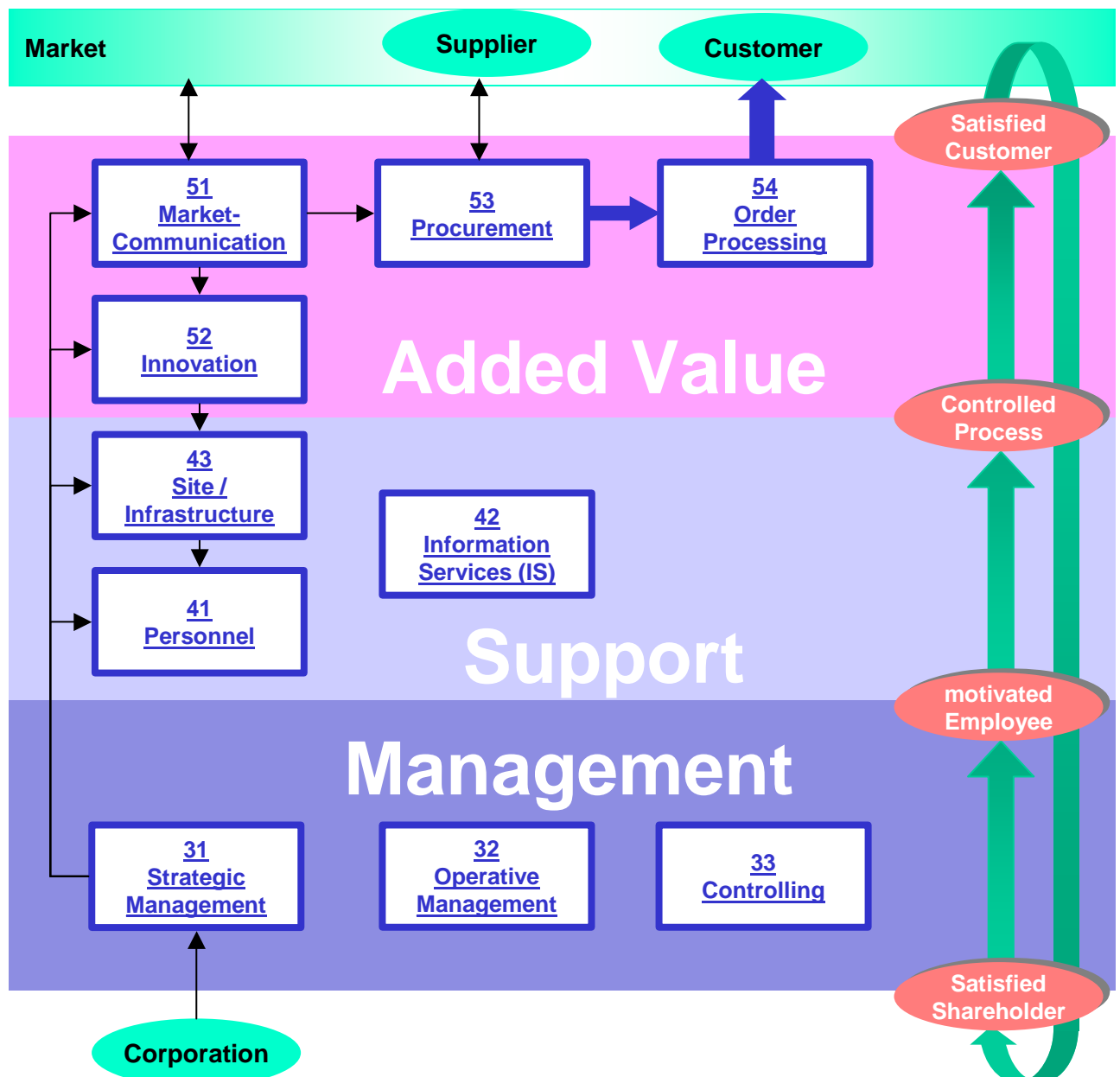


# Management System (MS) Overview

This information sheet is an extract of the integrated Management System of the Sigma-Aldrich Group Switzerland, which is certified according to ISO 9001:2008. It illustrates our MS structure and our main processes.

The complete and official MS is only available via the company's Intranet; hence the hyperlinks are not active.

## Process Network



## Portrait of the Sigma-Aldrich Group Switzerland

<b>Foundation</b>	27 July 1950 in St. Gallen as Fluka Chemie AG 1953 Transfer to Buchs SG 1st July 2005 Renaming of Fluka in Sigma-Aldrich
<b>Sigma-Aldrich- Group Switzerland</b>	Today, the group of companies is called Sigma-Aldrich Switzerland and consists of the following companies:  Sigma-Aldrich (Switzerland) Holding Ltd  Sigma-Aldrich Chemie LLC  Sigma-Aldrich Production LLC
<b>Shareholder of the Holding</b>	100% Sigma-Aldrich Corporation, St. Louis/USA
<b>Governing board</b>	Dr. Dieter Hofner, Grabs/SG
<b>Management of all companies.</b>	Trevor Jones, Country Manager Switzerland  Dennis Tschudin  Reto Salzgeber  Urs Wild
<b>Activities of the Sigma-Aldrich- Group Switzerland</b>	The Sigma-Aldrich Group Switzerland deals with the development as well as production of laboratory reagents, biochemicals, research chemicals, fine chemicals, and intermediate products as they are used in modern chemistry and biochemistry, mainly for the brands Fluka and SAFC.  The Group distributes the delivery programm of the Sigma-Aldrich Corporation in Switzerland, consisting of more than 100'000 chemicals and 30'000 accessories. The customers comprise mainly research laboratories (universities, industry) as well as development departments and producing chemistry firms.
<b>Distribution organization</b>	Ca. three quarters of all sales of chemicals produced in Switzerland (mainly brands Fluka and SAFC) are export sales.  Worldwide distribution is done primarily by company owned shipping plants of which some also have warehouses.

## Company policy (Q-policy)

The Sigma-Aldrich-Group Switzerland is part of the Sigma-Aldrich Corporation. The Sigma-Aldrich directives such as Q-Policy, organization and culture form the basis for the management system, the objectives, the culture and the organization 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 / our conduct:**

- Employees, customers and shareholders are equal partners.
- We treat our partners with respect and dignity.
- We are role models in performance and conduct.

**We create added value:**

- Our activities are:
  - customer-oriented
  - process-oriented and integrated in the process network
  - characterized by simplicity, efficiency and self-responsibility.
- Continuing improvement:  
We are passionately improving our processes and activities.
- Safety, health- and environmental protection is an equal goal to turnover and profit.
- Our service is the basis for our success; we are continuously improving it with obsession.
- Innovation is essential to be successful in the future.
- Technology:  
We provide optimal infrastructure by directed investments and use it in the best possible way with know-how, organization and leadership.

**We are a team**

The team is the basis for our success. We unleash the talents of each of our individual employees.

**We are part of the public:**

We are part of the public and accept the corresponding responsibility.

**Certified Reference Materials**

Sigma-Aldrich Switzerland manufactures certified reference materials for the analytical market. The production and certification of reference materials (CRM) are accomplished in accordance with the guidelines EN ISO/IEC 17025 + ISO Guides 30-35. The laboratory is accredited according to ISO/IEC 17025 and ISO Guide 34.

**Materials for the production of medicine products**

Sigma-Aldrich Switzerland manufactures components for Medical Devices on a subcontract basis under adherence to the ISO standard 13485:2003.

# **System description**

## **1. Objectives**

The management system forms the basis for the maintenance and continuing improvement of the quality and management standard.

## **2. Area of validity**

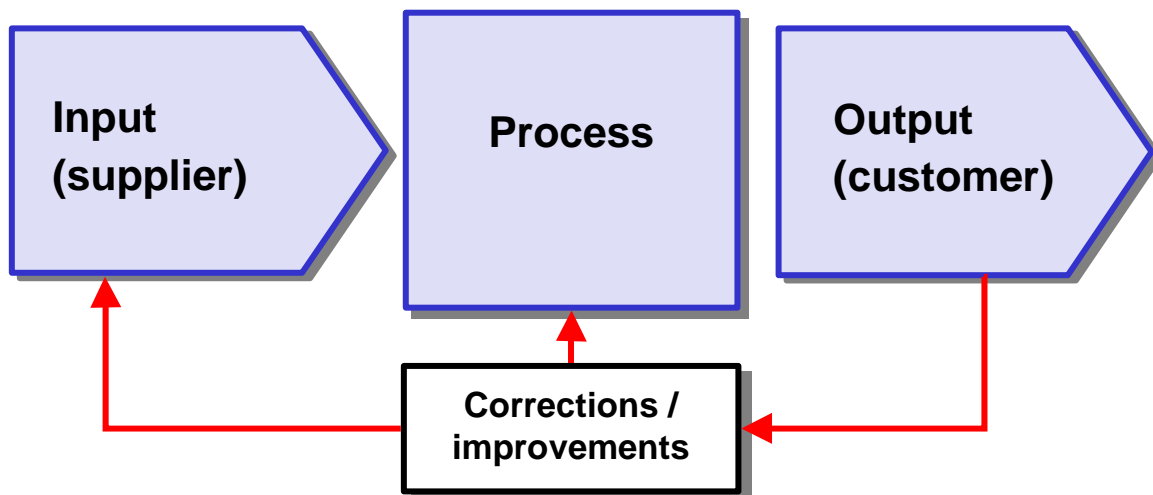
- For the legal units of the Sigma-Aldrich Group Switzerland: Sigma-Aldrich (Switzerland) Holding Ltd, Sigma-Aldrich Production LLC, Sigma-Aldrich LLC, Sigma-Aldrich Chemie LLC, this management manual is binding.
- The described management system is valid for all employees of Sigma-Aldrich Corporation at the locations of Buchs. Possible limitations are recorded in the business processes.
- The validity comprises all activities for the Sigma-Aldrich Group Switzerland.

## **3. Structural organization & Responsibilities**

The structural organization is laid down in Organigrams, which are checked periodically by Management and are adjusted where necessary. The process organization is displayed in the Process User Matrix.

## **4. The process model – basis of the management system**

Definition, application and continuing improvement of our processes form the basis of our management system. By process we mean an integrated network or a sequence of activities respectively.



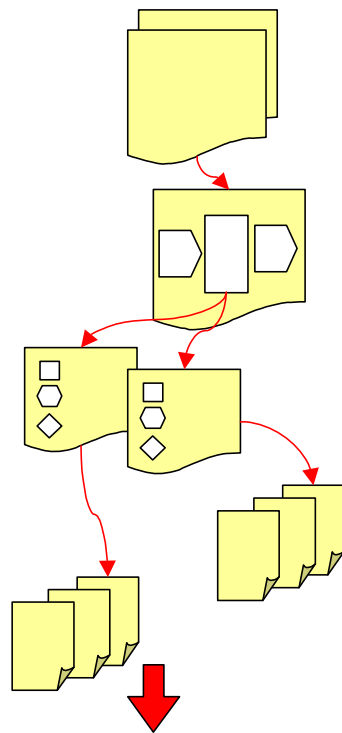
## **5. Structure of the management system**

The structure of our management system is illustrated in the Process network.

## 6. Management system documentation

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

### MS-Documentation



#### MS-Manual

##### Process Network Administration

(Abbreviations, Glossary)

##### Short Portrait Sigma-Aldrich

(Presentation of S-A, Policy, part of the S-A Corporation, Organisation, Legal structures)

##### System-Overview

(Basic description of the management system)

#### Business processes

(Overview of the essential activities within the process)

#### Work- and Partial processes

(Description of activity groups and the corresponding responsibilities, SOP's and aids.)

#### SOP's \* (Standard Operation Procedure)

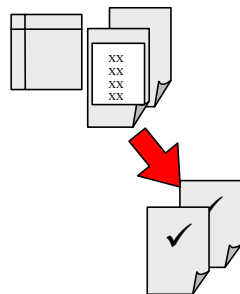
[Aktuelle SOP-Vorlage](#)

#### Aids \*

Management tools  
Checklists  
Forms

\* Available in electronic and / or paper form

### Realization



#### Order-/productspecific Documents / -data

Order or product-specific use of MS documentation content (eg. auditplan, productionplan, production order and -procedure, test procedures, project obligations, data bases, external directives, laws, norms, etc.)

#### Quality records and -data

Proof of the faultless order- and work execution and the functioning of the MS (eg. Q-reports, auditreports, batch- or lot protocols test protocols, reports and certificates etc.)

## 7. Quality planning

Q-planning takes place on three levels: Strategy / Process / Product

## 8. Validation methods, statistics and Q-improvement tools (PDSA)

## 9. Identification and traceability of products.

All products processed are labeled. The labels contain unique product identification. Information provided include at least: material number, lot or batch number and coded filling or processing date.

## 10. Laws/ regulations and general norms

The responsible job holders make sure that the company complies at all times with the current standards and regulations/laws. The compliance of our products is described in AP 52-60.

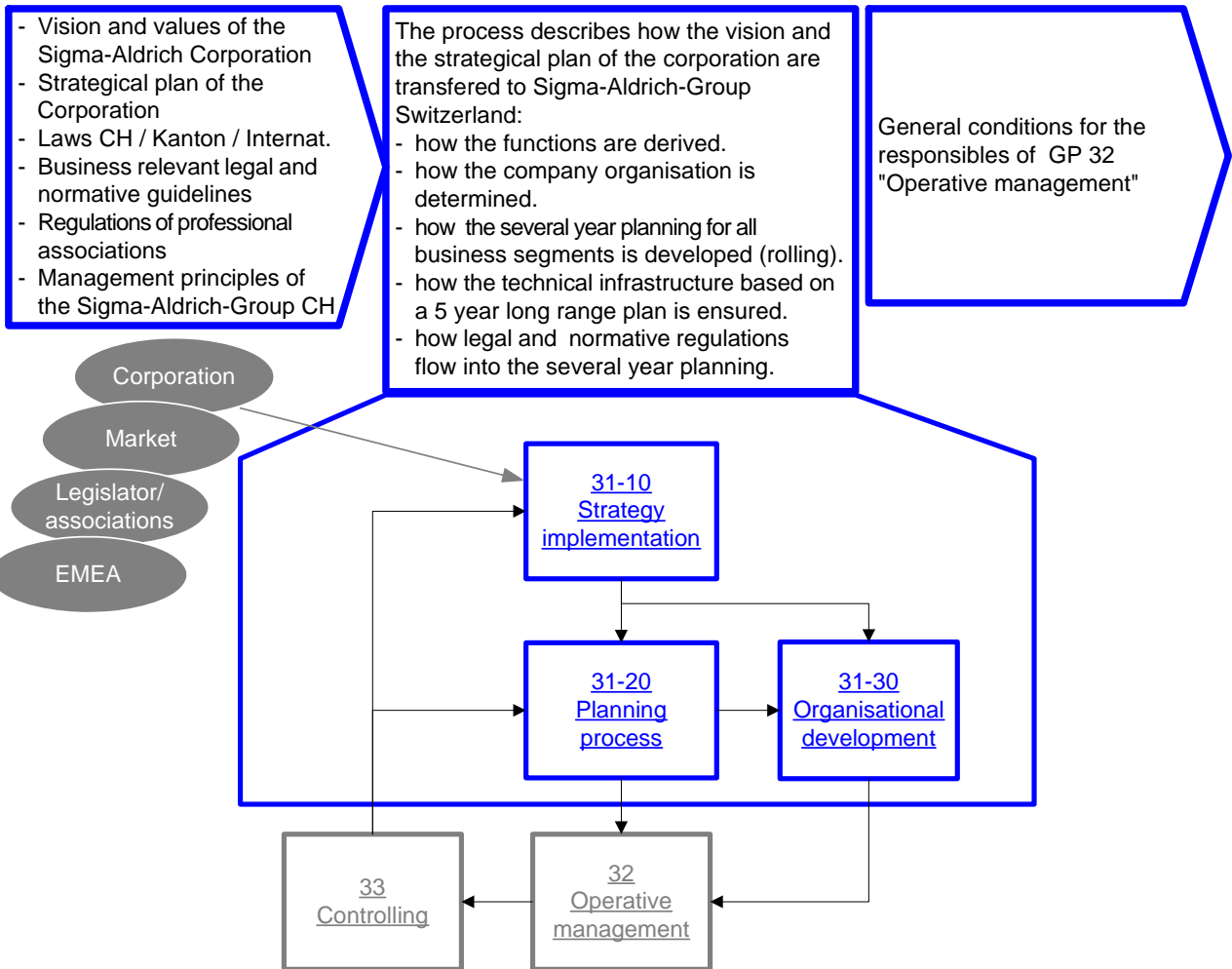
## 11. Valid documents

### Index:

<b>00</b>	<b>Administration</b>
<b>10</b>	<b>Short Portrait Sigma-Aldrich Group Switzerland</b>
<b>20</b>	<b>System</b>
<b>21</b>	<b>QM</b>
<b>22</b>	<b>GMP</b>
<b>23</b>	<b>SGU (Safety, Health and Environment)</b>
<b>00-01</b>	<b>Document Matrix</b>
<b>00-02</b>	<b>Glossary</b>
<b>20-01</b>	<b>Process User Matrix</b>
<b>31</b>	<b>Strategic Management</b>
<b>32</b>	<b>Operative Management</b>
<b>33</b>	<b>Controlling</b>
<b>41</b>	<b>HR (Human Resources)</b>
<b>42</b>	<b>Information Services (IS)</b>
<b>43</b>	<b>Site / Infrastructure</b>
<b>51</b>	<b>Market Communication</b>
<b>52</b>	<b>Innovation</b>
<b>53</b>	<b>Procurement</b>
<b>54</b>	<b>Order Processing</b>

With this logical document numbering system it is clear what type of document it is and to which process it belongs, e.g. 52-30-F003 is a form used in the work process Sourcing, which again is part of the business process Innovation.

# 31 Strategic Management



## Objective

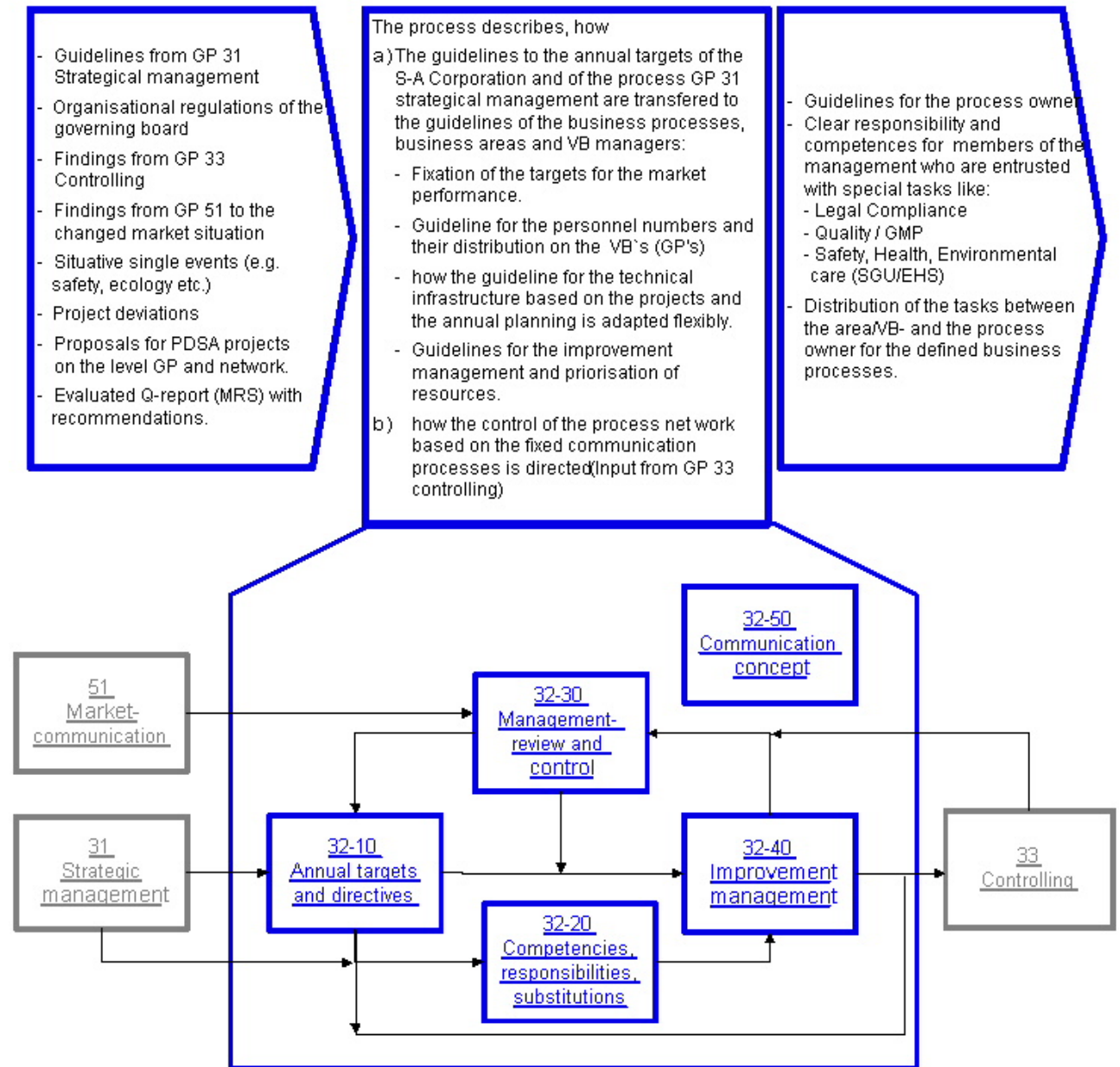
Long-term safeguard of the success (Business Excellence) of Sigma-Aldrich Group Switzerland for the increase and maintenance of the competitiveness on the world market and within the corporation.

## Field of application

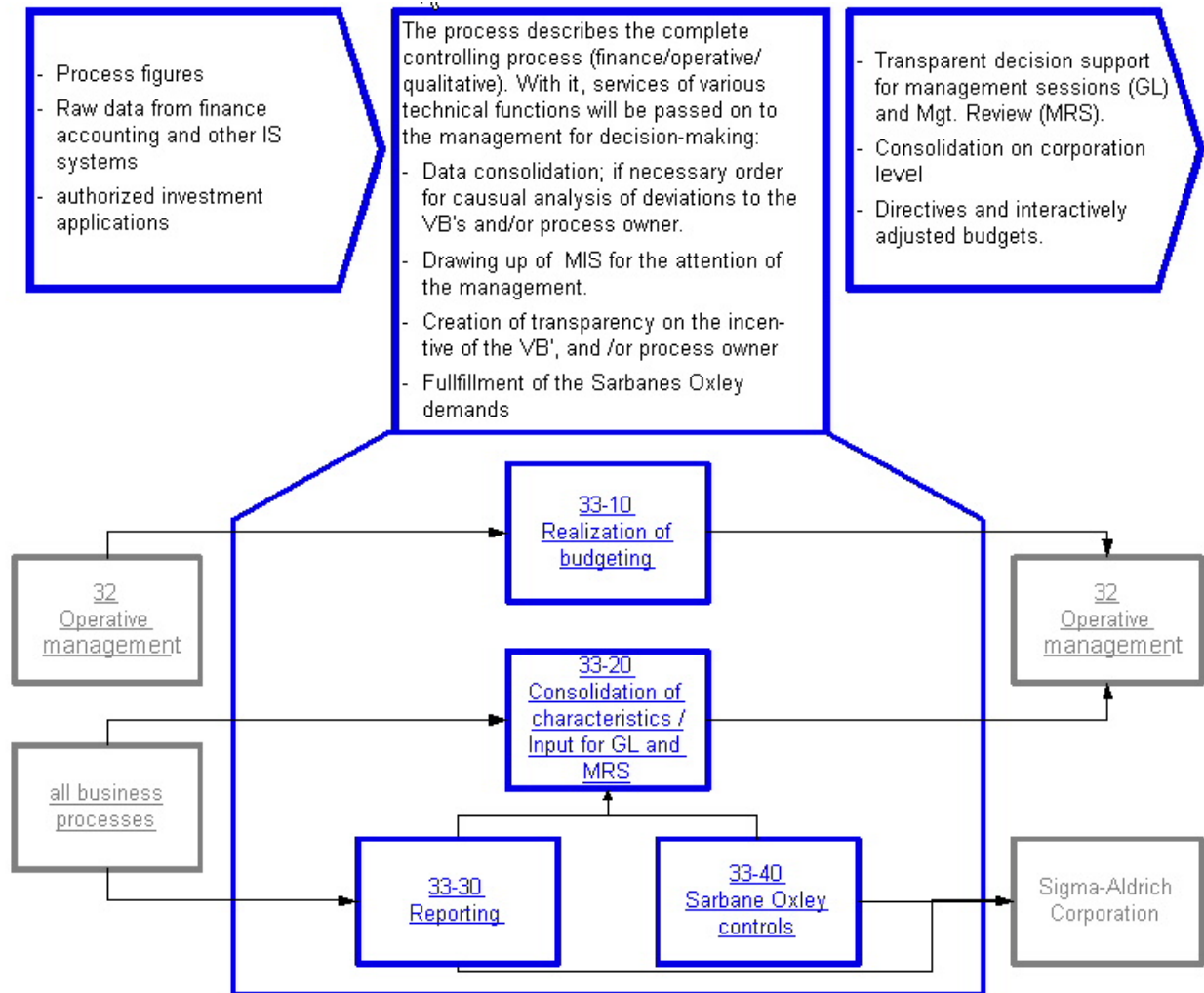
The process is valid for:

- The Sigma-Aldrich Group Switzerland consisting of Sigma-Aldrich (Switzerland) Holding Ltd, Sigma-Aldrich Production LLC, Sigma-Aldrich Chemie LLC, Sigma-Aldrich LLC.

# 32 Operative Management



# 33 Controlling



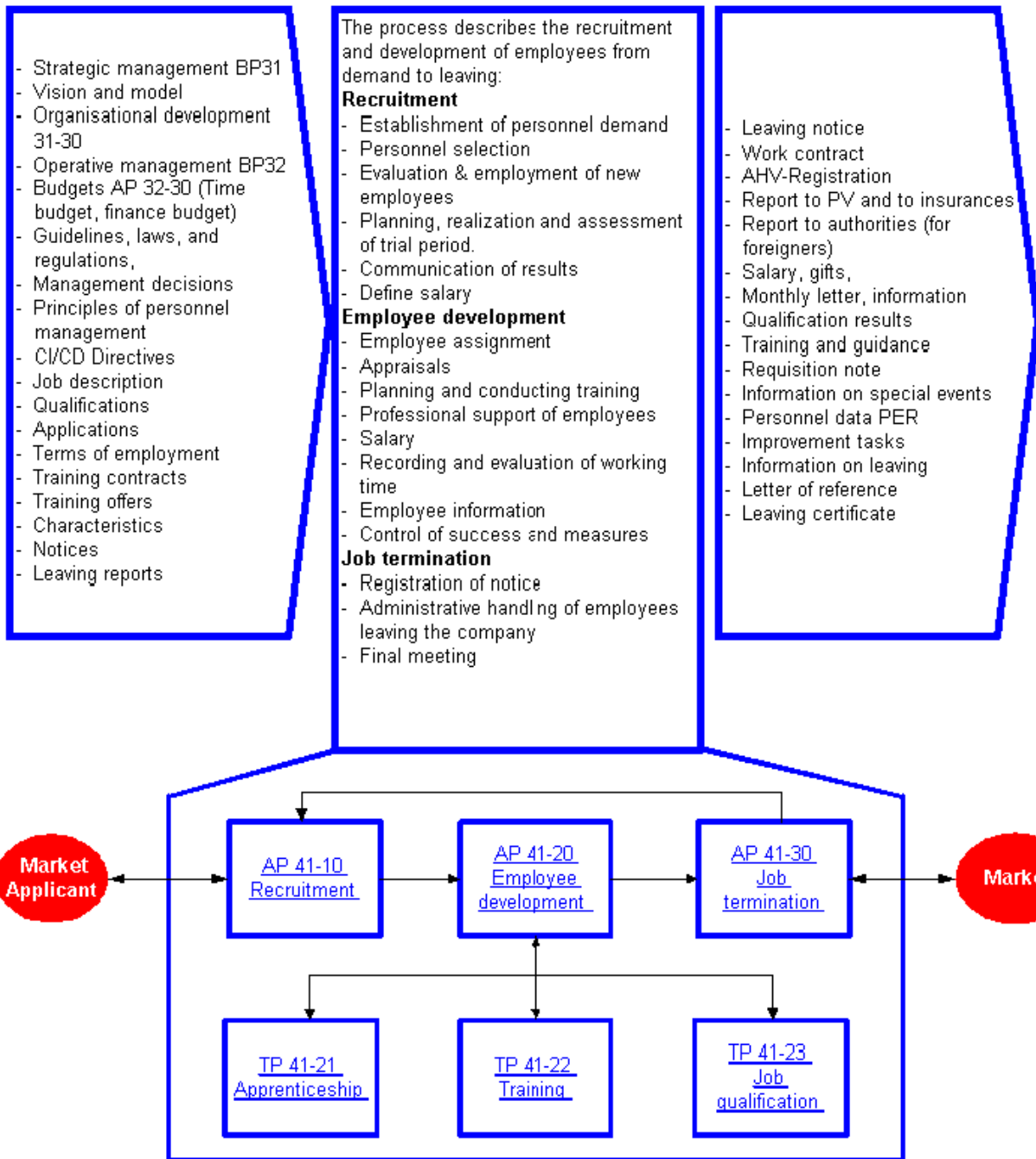
## Objective

- Provide basis for leadership and decision-making in a timely manner
- Financial and performance related reporting to the Sigma-Aldrich Corporation as a basis for consolidation on corporate level.
- Support the process owners and their employees in recognizing and dealing with non-standard situations.

## Field of application

The process is valid for the Sigma-Aldrich Group Switzerland

# 41 HR (Human Resources)



## Objective

Suitable instruments for a professional personnel management are provided for Sigma-Aldrich executives. Clearly defined processes prevent wrong decisions.

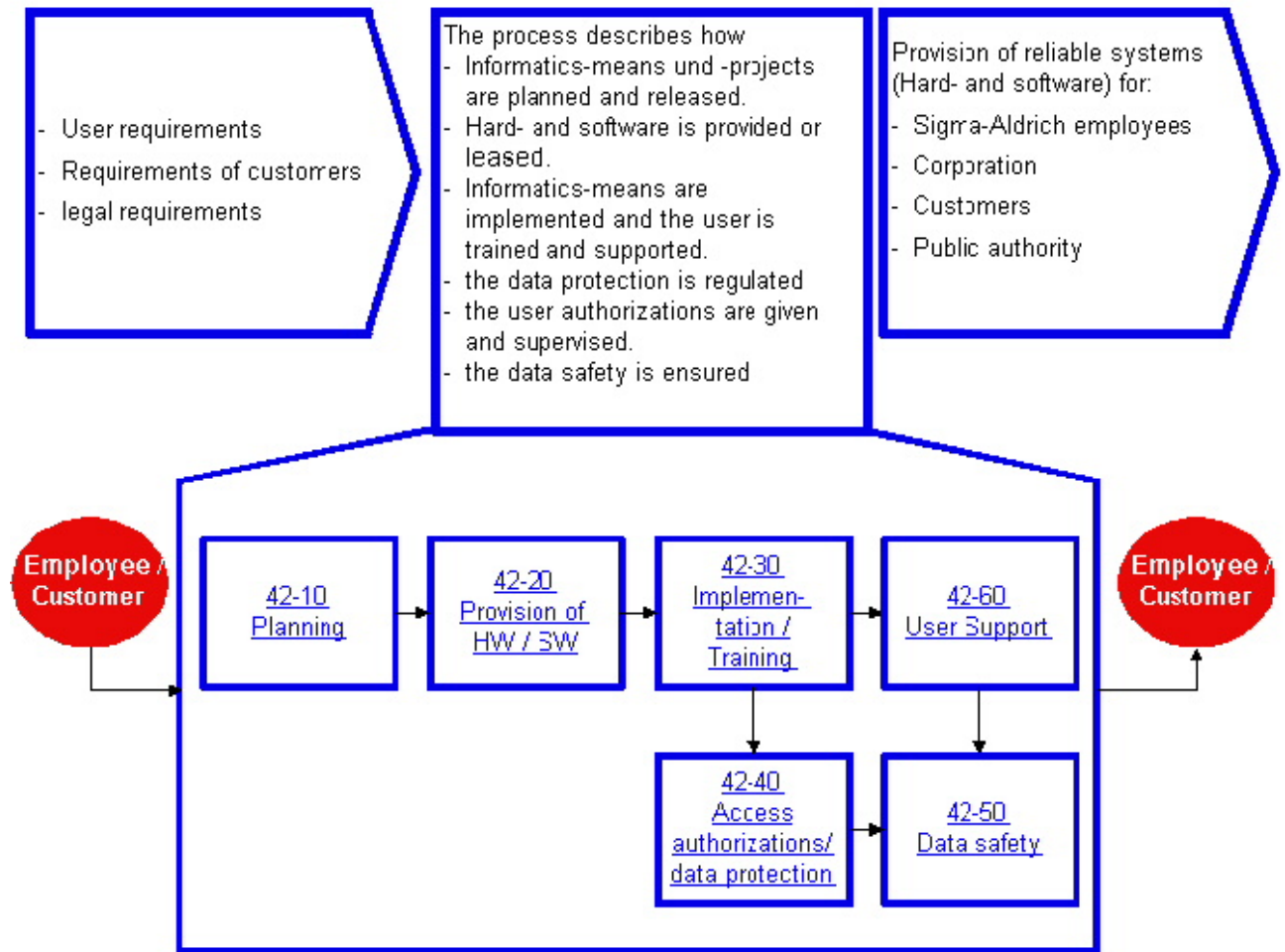
### Personnel provision

To enable a qualified person in the right position to contribute his/her best to the overall success of the company at a reasonable and adequate administrative cost.

### Personnel development

We enable our employees to broaden their expertise continuously with specific measures. We create a motivating environment.

# 42 Information Services (IS)



## Objective

Description and definition of the main processes of informatics at the Buchs site.

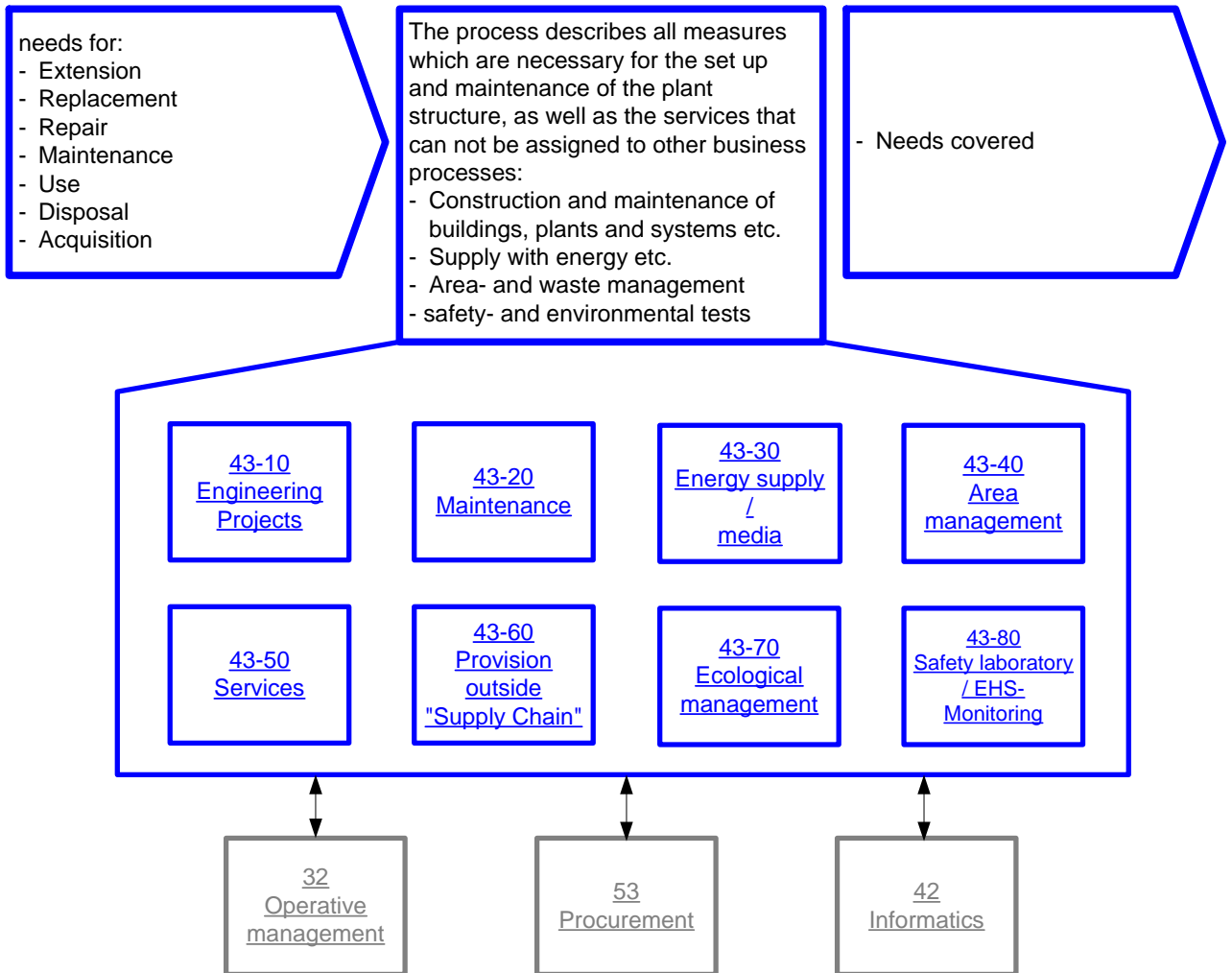
Since January 2007 the Corporate division information services is organized with world-wide responsibilities about systems and services. Details in addition are evident in the Intranet (directory, organization chart).

## Field of application

All computer systems which are relevant for the Buchs site are listed in 42-M002 with the system responsables.

A list of the GMP-relevant computer systems and computer-based systems is located in chapter 22 and is available at 22-M009.

# 43 Site / Infrastructure



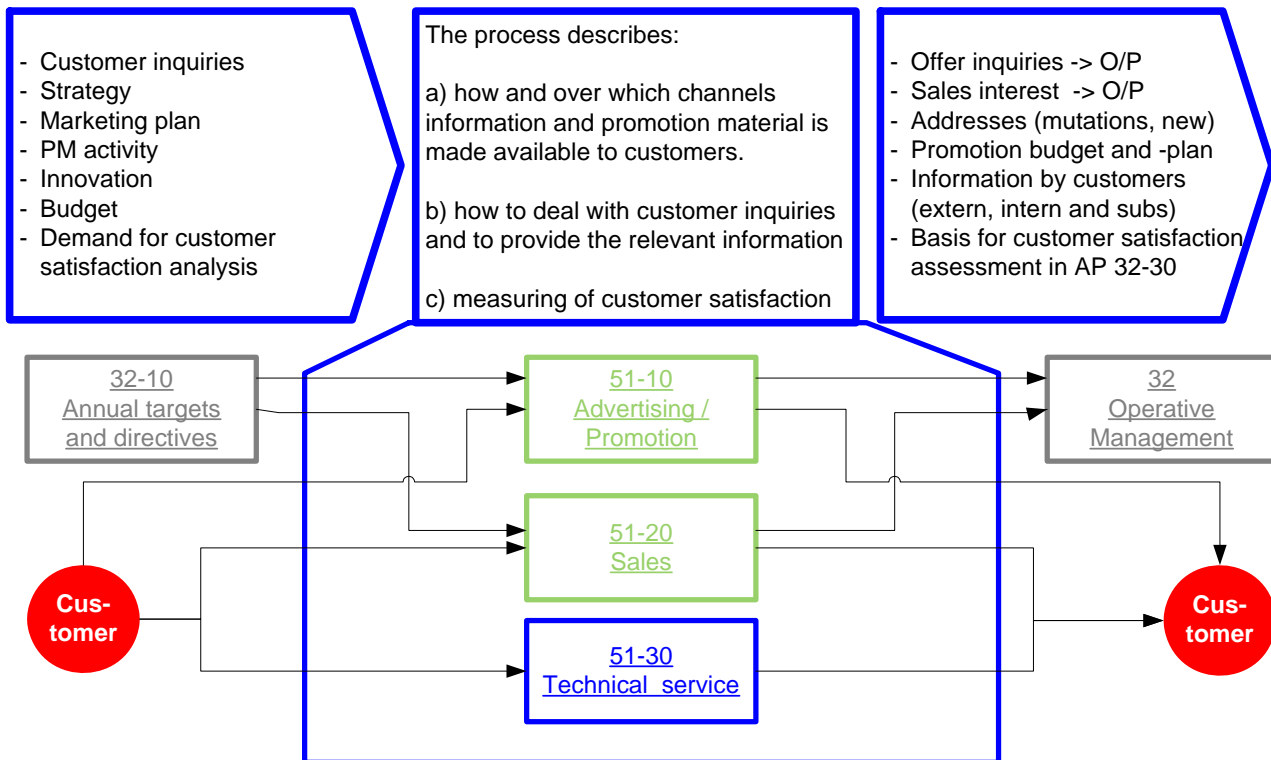
## Objective

Ensure full expedience of existing plants and facilities and set up of new buildings and facilities with optimal use of resources.

## Field of application

This process is principally valid for all buildings, plants and facilities of the Sigma-Aldrich Group in Buchs.

# 51 Market Communication



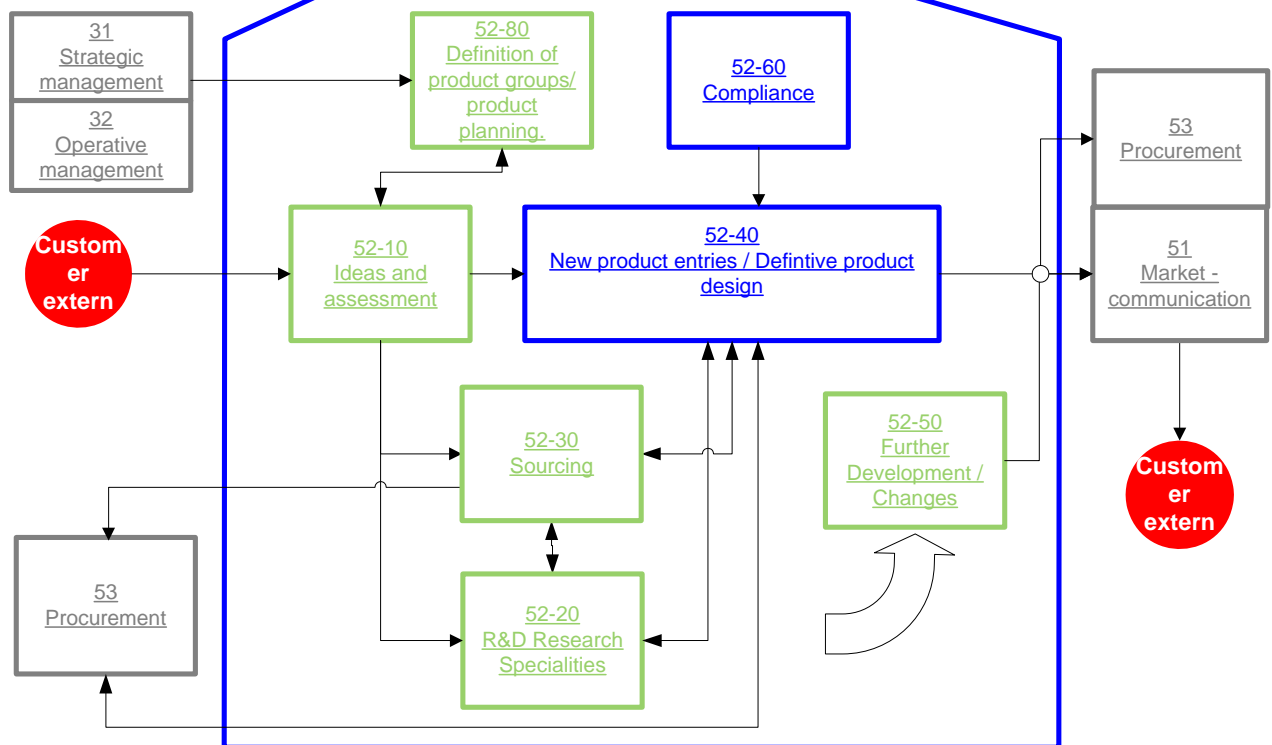
## Objective

Achieving the marketing goal according to AP 32-10.

## Field of application

The process is valid for Sigma-Aldrich Group Switzerland. In particular for the employees of marketing communications, sales force and technical service/customer support.

# 52 Innovation



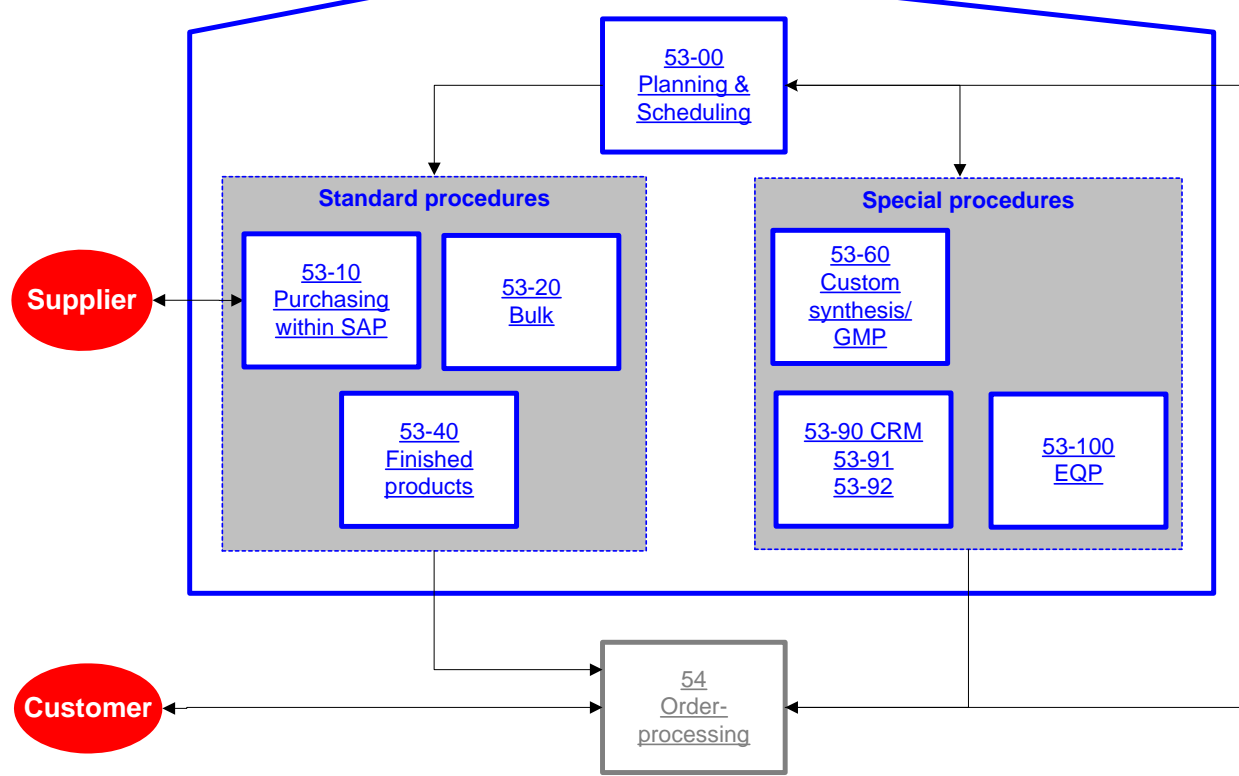
## Objective

The innovation process ensures that

- the product strategy in the scope of the corporation strategy is continuously adjusted to the essential developments on the market.
- with regard to quality, offer form, additional information and price an attractive and market conform product is created. It is clearly regulated by processes, activities and responsibilities and includes also adjustments and further development of existing products.

# 53 Procurement

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li>- Procurement decision</li> <li>- Completion deadline</li> <li>- Supply sources and conditions</li> <li>- Specifications-directives</li> <li>- Proposal for the development of new products</li> <li>- Customer guidelines according to contract.</li> <li>- Hourly wages and surcharges</li> <li>- Storage and handling regulations</li> <li>- legal guidelines and safety relevant findings</li> <li>- Changes of customer guidelines.</li> <li>- Invoice of the supplier</li> </ul> | <p>The process describes:</p> <ul style="list-style-type: none"> <li>- the use of sales forecasts for the demand planning.</li> <li>- the supply source decision</li> <li>- the order placing</li> <li>- the procurement in             <ul style="list-style-type: none"> <li>- Development (product/packaging)</li> <li>- Production (chemistry/filling)</li> <li>- External procurement</li> </ul> </li> <li>- the acceptance of products             <ul style="list-style-type: none"> <li>- Testing and release</li> <li>- Provision of storage suitability</li> </ul> </li> <li>- the warehouse management (bulk and prepack warehouse)</li> <li>- the process control (schedule, cost, quality)</li> </ul> | <ul style="list-style-type: none"> <li>- Info to order confirmation</li> <li>- Info to status of single order</li> <li>- new procedure</li> <li>- Waste and correspondig info</li> <li>- Workshop order (WA)</li> <li>- changed specification</li> <li>- definitive specification of new products</li> <li>- Certificate of Analysis (CoA)</li> <li>- Test results (out of LIMS)</li> <li>- Analysis methods for customers</li> <li>- validated methods</li> <li>- Info on storage conditions</li> <li>- Expiry data</li> <li>- Info on value change</li> <li>- Product</li> <li>- Paid invoice</li> </ul> |
|---|--|--|



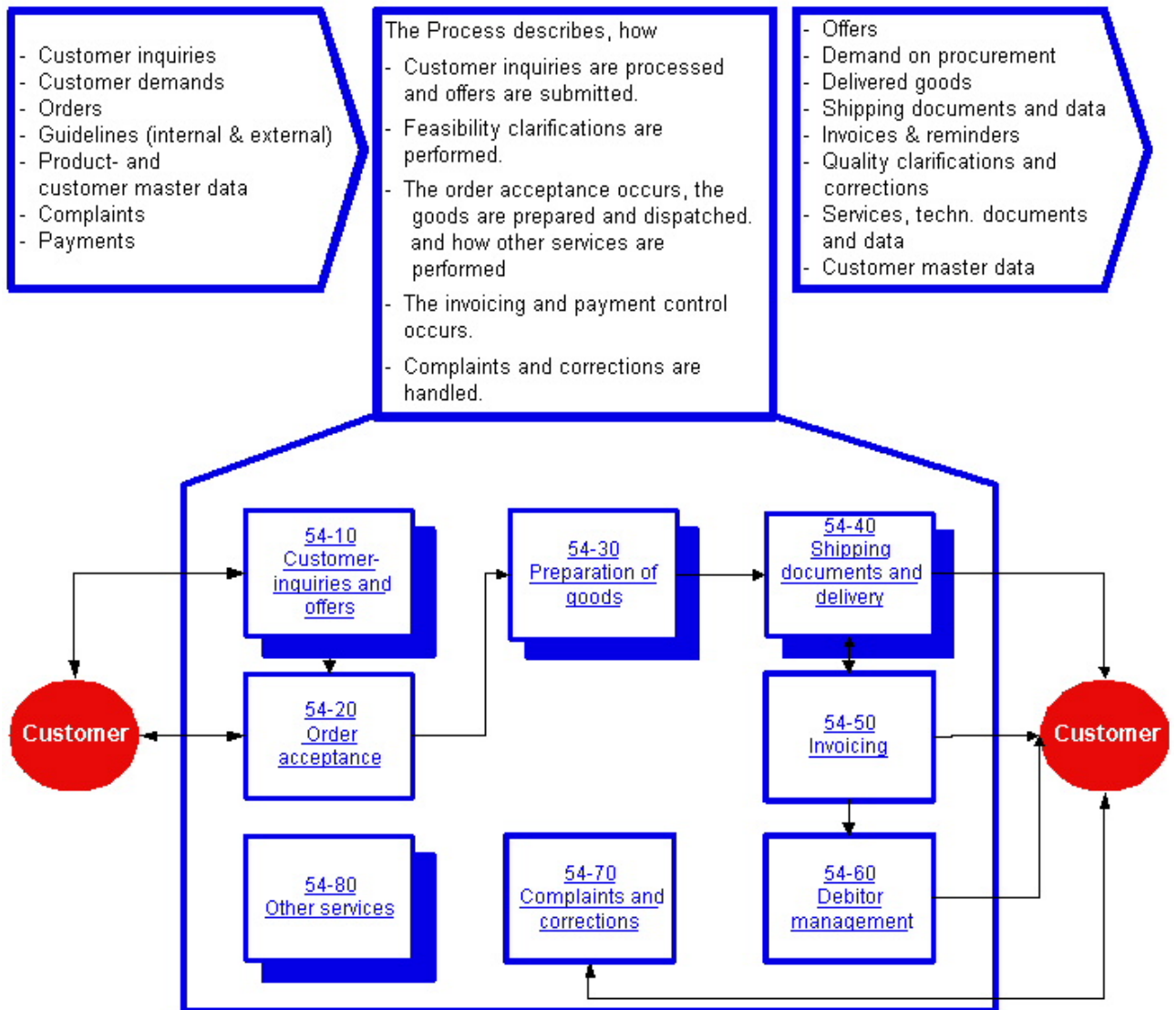
## Objective

Providing the required Sigma-Aldrich products in the proper quantity and quality in a timely and cost-effective manner.

## Field of application

This process applies for the Sigma-Aldrich Group in Switzerland, primarily the employees of Sigma-Aldrich Production GmbH.

# 54 Order Processing



## Objective

Reliable fulfillment of customer required services in terms of quality, delivery times and costs.

Clear understanding of workflows, networking and responsibilities of the work process.

## Field of application

The process is valid for Sigma-Aldrich Group Switzerland.