QUALITY ASSURANCE MANUAL

INTRODUCTION

The Säntis Analytical AG, located in Teufen, Switzerland, was founded on April 1, 1999, and has evolved quickly into global leaders in the development, production and supply of analytical products.We see ourselves as partners; contributing our know–how and addressing the requests and wishes of our customers. At an international level, these are mainly distributors and manufactures of analytical instruments.

We feel the pulse of the market and are openly flexible so that we can react quickly and efficiently to the needs of the market.

We don't want to gamble with our flexibility due to unnecessary criteria and operational sequences of a certificate of quality. Of course we are nevertheless providing a very high quality standard that exceeds in a lot of areas the requirements of a standardized certificate of quality. And moreover, in our company the quality is "lived" by all our coworkers day by day! Irrespective of the certificate of quality…!!

Please find below an extract of our quality guidelines and processes!

QUALITY SYSTEM

Level 1: Quality Manual
This document details the corporate quality policy and structure of the Company and references appropriate Operating Procedures.

Level 2: Operating Procedures
These documents describe the actual process, and controls applied, to all activities concerned with the attainment of a quality assured contracting service.

Level 3: Quality Planning
As the Company operates a standard type and range of services, customer satisfaction and quality are achieved by operation in accordance with the documented quality system. Specific customer requirements are identified and documented during the contract review process, allowing these requirements to be communicated and achieved, ensuring satisfaction of all customer declared needs.

MANAGEMENT REVIEW and INTERNAL AUDIT

Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

a) To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customers needs and expectations, and functioning in accordance with the established Operating Procedures.

b) To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.

c) To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.

d) To review any complaints received, identify the cause and recommend corrective action if required.

e) To review the finding of internal/external audits and identify any areas of recurring problems or potential improvements.

f) To review the reports of nonconforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Programme is compiled at least a year in advance however, should particular needs be identified, the frequency of audit may be increased at the discretion of the Quality Manager.

CONTRACT REVIEW

The Company offers both standard products and specialist services to meet each customer's needs. Standard products are displayed in a catalogue. Specialist service requirements differ from one customer to another (and from one contract to another), therefore each tends to be quoted for the specific contract.

Once a proposal is accepted by the customer, or an order is placed, it is recorded and reviewed to establish that the requirements of the order are adequately defined and documented, any differences from the proposal are resolved, and the Company is capable of fully satisfying the customers requirements.

In addition to the original order/contract specification the customer may also request addition/ variation work to be undertaken by the Company. In these circumstances the work content is documented and agreed with the customer prior to execution to ensure that no ambiguity exists.

The Company operates on a computerized order processing system to ensure rapid fulfillment of customer orders.

DOCUMENTATION & CHANGE CONTROL

All documentation utilized within the Company related to the management system itself, or to the execution of individual customer contracts is controlled to ensure that it is issued to the appropriate personnel, under the correct level of authority, is revised and reissued as necessary, and all obsolete versions are removed from the point of use.

The Quality Assurance Manual, Procedures and Quality Plans are maintained by the Managing Director or Quality Manager who ensures that the appropriate items, at the correct revision levels, are issued to all who need them within the Company.

Each contract has a file which contains all relevant information. Information is also held on the company's computer system for ease of access and manipulation.

PURCHASING

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due consideration to the quality, statutory obligations, timescale and cost. A list of approved suppliers and sub-contractors is maintained which is compiled on the following criteria:

a) Previous performance in supplying to similar specifications and requirements.

b) Compliance with an approved third party product/quality registration scheme.

c) Recommendation by other similar purchasers or manufacturers of equipment.

d) A trial order and evaluation of performance.

All supplies and sub-contracts are subject to an authorized Purchase Order providing full clarification of the type and extent of supply.

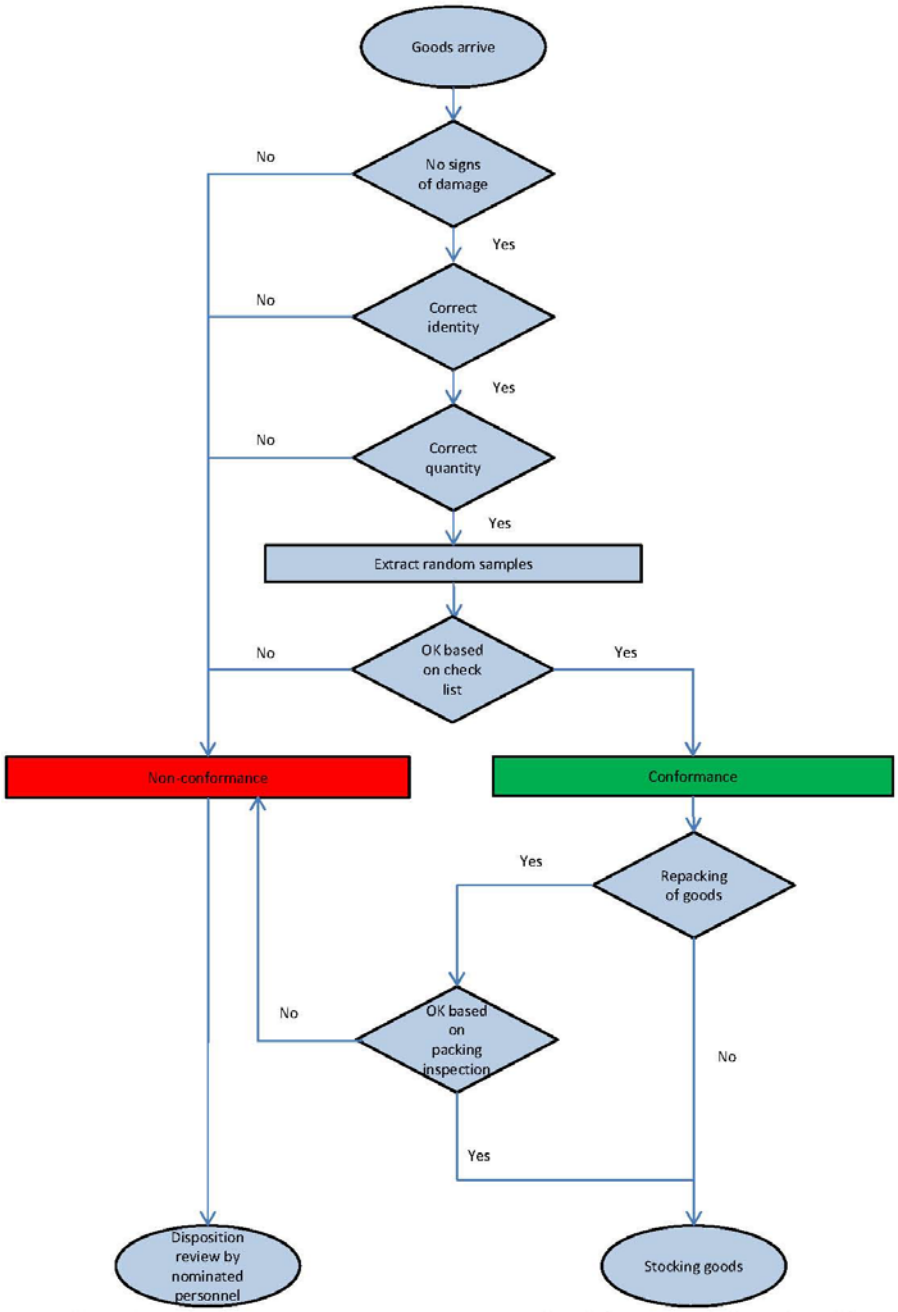
Should a supplier, not appearing on the Approved Suppliers List be proposed, they will be analysed by capability and subject to acceptance on the authority of a Director.

RECEIVING INSPECTION

All stores areas are maintained as secure as practical. All items received by the Company are identified and verified in accordance with the requirements of the Delivery Note and Purchase Order, and are inspected for correct identity, quantity and any signs of damage.

All goods received are documented and, in the event of non-conformance, the items are placed in a reject area or labelled to ensure identification. The extent of the non-conformance is noted and subject to disposition review by nominated personnel.

Process chart – Receiving inspection



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INSPECTION AND TESTING

Inspection and testing is carried out on completion of production, with results being documented. Should items not be acceptable against the agreed contract criteria they will be replaced.

Check list - receiving inspection

SÄNTIS analytical

Article number:	**SAN003125**
Description:	**Sn Kapseln, 0.012** **5 x 9 mm**
Supplier:	_____
Date:	_____
Batch Nr:	_____ **Quantity:** _____
random sampling:	After opening the box a coarse control of the caspules will be done 2 capsules a box (caspules from diffrent levels needed)

Control	What	Responsible	Initials
Packaging			
Dimensions	height (within tolerance)	QM	
	diameter (within tolerance)	QM	
	flat bottom	QM	
	no mustaches	QM	
	upper edge without notch	QM	
	no deformation	QM	
Weight	Weight of 10 capsules is 0.343g	QM	
Various			

Comments: _____

Date: _____ **Initials:** _____

Document created 24.01.2013, Matthias Burkhard Document changed 11.04.2013 G:\QS\Eingangskontrolle\Kontrollblatt _Englisch.xlsx

INDICATION OF INSPECTION STATUS

As goods are inspected, the status is defined by location in stores, with all non-conforming items being placed in a reject area or marked as reject for review. The status of work in progress is established by markings or associated documentation recording the inspections undertaken and their acceptability.

NON-CONFORMING ITEMS, PREVENTIVE & CORRECTIVE ACTION

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All employees are encouraged to suggest improvements in methods, materials, suppliers, and sub-contractors. The Company has established procedures for review of all activities in order to identify and evaluate all possible improvements in methods/materials and its procedures.

HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

The identification of materials/equipment, where it is not obvious, is confirmed by the presence of a manufacturers/suppliers part number or description label, or other marking for each item. The identification of the item may be on the packaging or on the item itself, and this identification remains in place for as long as possible, provided it does not hamper effective use of the item. Materials and consumables are not identified by the company where they are obvious to a trained/experienced employee, however, should a risk of misinterpretation exist between two or more types of material these will be marked in a suitable manner to ensure that no ambiguity exists.

Materials and goods received, whether the property of the company or others, will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer, or disposed of to a third party. The objective is to prevent deterioration and damage whilst in storage, or in the process of transportation, installation, commissioning or maintenance.

TRAINING

The policy of the company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The company generally procures and recruits employees capable of meeting the technical, skill, experience and educational requirements of the company's activities.

All employees are responsible for recommending the training needs of others, and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks. Once training needs are identified these are provided under the responsibility of the Directors.

Full records are maintained of all training undertaken by employees.

PRODUCTION & MEASURING EQUIPMENT

Production and measuring equipment held is maintained in good condition, and capable of safe and effective operation within a specified tolerance of accuracy. Test and measuring equipment is regularly inspected or calibrated to ensure that it is capable of accurate operation, by comparison with external sources traceable back to National Standards.

Contact

Adress: Säntis Analytical AG
Landhausstrasse 1
9053 Teufen AR
Switzerland

Phone: +41 71 330 07 10

e-mail: info@saentis-analytical.com