

Sanico

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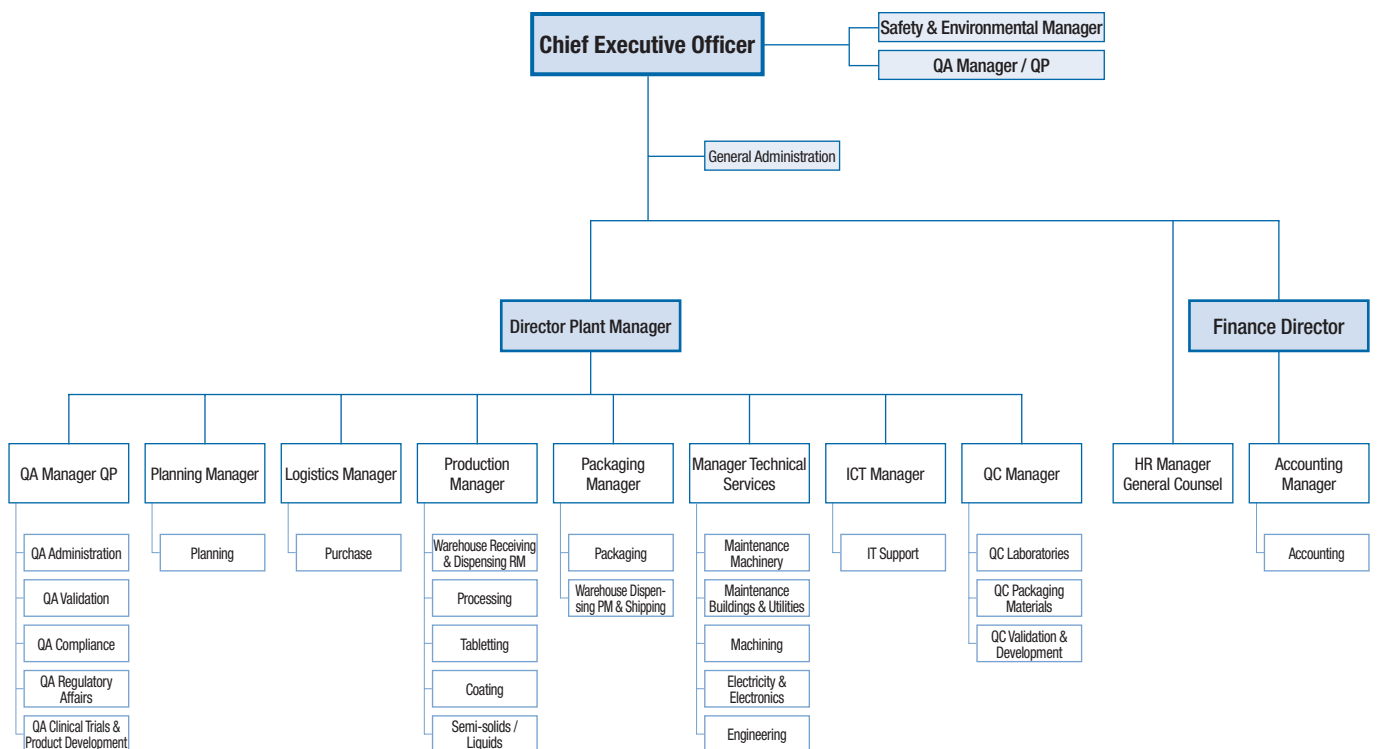
HISTORY

Sanico was established in 1932 by Mr. Marcel Flerackers Senior. Due to its constant growth and expansion Sanico was forced to leave its location at the center of Turnhout and to move to an industrial estate in 1979. From the start in 1932 until the early '70s Sanico produced and marketed mainly its own pharmaceutical brand specialties. Over the years, Sanico focused more and more on contract manufacturing resulting in a 100 % contract manufacturing company for both the home and export market.

Sanico's staff consists of 250 employees. With their specific training, expertise and high commitment, they contribute significantly to Sanico's longstanding success since they are responsible for managing the complex business processes. Our product range includes the production and packaging of all non-sterile galenic forms of ethical drugs, OTC and food supplements. All pharmaceutical products are registered at the Belgian Ministry of Health. The manufacturing license number is 616.



ORGANIGRAM





MISSION & VISION

Mission

We aim to fulfill our mission to be an independent European leader in contract manufacturing contract packaging and clinical trial services of non-sterile products by

- Maintaining a high degree of innovation
- Delivering superior quality
- Delivering excellent service and flexibility

Vision

We will

- Commit ourselves to the highest current quality standards
- Focus on 100% contract manufacturing
- Try to be the most effective contract manufacturing company at managing product flow and product quality
- Invest in the best available technology to build a strong and flexible organization
- Train our people to support them in their duties and skills
- Invest in high SHE-standards to keep our people and environment healthy



Corresponding to our mission statement, the QA-division assures a constant high level of quality.

Our Quality Management System is maintained by the Quality Assurance Department, which is independent from other operational departments of Sanico and consists of the following sub-divisions: QA Validation & Documentation, QA Compliance, QA Regulatory Affairs and QA Administration.

The system includes the following parts:

- Maintaining general cGMP-compliance
- Cleaning-, process- and equipmentvalidation
- Execution and follow-up of internal and external audits
- Equipment calibration
- Complaint handling
- Training follow-up
- Change control management
- Product quality review
- Batch release
- Master and executed batch record generation
- Deviation handling
- Regulatory affairs
- SOP review
- Stability follow-up

The Quality System is designed to comply with the Rules Governing Medicinal Products in the European Union of the European Commission. Sanico is subject to FDA inspections and has therefore also to comply with the US CFR Title 21 'Food and Drugs' and with specific requirements as agreed with the individual customers.



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SERVICES

Sanico offers the following services:

Production and packaging of non-sterile products:

- 1 Liquid dosage forms.
- 2 Semi-solid dosage forms.
- 3 Unit dose form (tablets, capsules, suppositories, powders, granules).
- 4 Multi dose form (powders, granules).

See below for a detailed equipment list.

Clinical Trials: production and packaging of clinical trial material.

Characterization Services

Formulation Development

Analytical Method Development and Validation:

Analytical methods can be developed and validated according to ICH or other parameters for drug substance and finished product.

Stability Studies (ICH), Storage and Testing:

Our stability chambers have extensive storage capacity for ICH conditions as well as custom storage conditions. All our chambers are continuously monitored by the CMS and are on full generator back up.

Quality Control/Compendial Analysis:

We perform API and excipient testing according to compendial methods for global release purposes (USP, PhEur, ...). We also have extensive experience for finished product analyses, in-process support, cleaning and process validations.



SITE

Short description of the site:

The factory is located on a large industrial area in Turnhout. Direct access is available to the European Highway E34 Antwerp-Eindhoven (exit 23).

The QC-laboratories (physico-chemical and microbiology) and storage areas (documents, reference and retention samples, documents) are located in building D (see site access plan). Both labs are equipped with state of the art equipment and controlled environments are monitored by the CMS.

The company made large investments in order to expand and keep facilities up to date to the current state of the art and all operations are performed under full cGMP-conditions. The plant is subject to continuous improvement and reengineering to optimize material and personnel flows and to incorporate a full hygiene zone concept.

The lay-out of the production facility is based on an integrated vertical material flow and complete segregation between technical and clean areas. The same principle was used to construct the packaging department with a complete separation between primary and secondary packaging activities.

15 packaging lines are installed following this principle. All "open" product (environmental contact) is handled in a class 100.000 environment.





EQUIPMENT

Summary of available equipment:

Manufacturing

- Mixing, granulating equipment
2 x Gral 300 ; 1x Gral 600 ; 3 x conical blender/vacuum dryer 1200 liter
- Drying equipment
Glatt WSG pro 300 (capacity 650 kg),
Vector (capacity 90 kg)
Both fluid beds equipped for fluid bed granulation (WSG) or in combination with high shear granulator;
Lytzen tray dryer (capacity 180 kg)
- Dry and wet mills
KEK; Quadro; Fitzmill; Frewitt
- Final blending
2 x Tumbler for IBC's 1500 l or drums 100 or 200l
- Tablet presses
3 x Fette 2090; 2 x Fette 1200; 1 x Fette 2100; 2 x Fette 3100; 1x Kilian RX67 (tooling EU B, BB, BBB, D)
Courtroy Performa P (extended dwell time capacity)
- Capsule-filling machine for hard gelatin-capsules
Bosch 1x GKF 2500; 1x GKF 1500; 1x GKF 1200
- Film- and sugar-coating equipment
1x Accela Cota 350 (non ex); 1x Accela Cota 150 (ex proof);
1x Accela Cota 150 (non ex)

- Semisolid preparation vessels
Ahlborn 400 l for crèmes, ointments, suppositories; Unimix 15 l pilot plant.
- Liquid vessels
Packo 5000 l (non ex); 2000 l (non ex); 1000 l (ex proof) ; 500 l (ex proof)

Packaging

- Blister lines: blistering, packing and wrapping machines
1X Uhlmann B1880MTI (capacity = 1300 blister / min) +
Cartonner C2404 (capacity = 400 boxes / min), 5x Uhlmann 1030 MTI (capacity = 400 blisters / min)+ C2155 cartonner (capacity = 120 boxes / min), 1x Klöckner Hänsel CP10 + C2155, 1x Klöckner Hänsel CP8 + C130. All lines have online (unitdose) printing and are able to run all thermoforming and cold forming foils with (cross) perforation; wrappers Skinetta, Pester; checkweighers OCS, Bosch.
- Liquid filling lines: filling, labeling, packing
Gröninger DFK 6001 / MCS for bottles 5 ml up to 300 ml (up to 7200 bottles/hr),
Farmomac F57 for bottles 5 ml up to 500 ml (up to 4000 bottles/hr)
- Tablet/capsule counting equipment
Gordic tube filler (dia 16, 20, 25 mm), Cremer container filler
- Powder filling equipment (bottles, containers)
Optima screw dosing powder filler (2 gr up to ...)
- Sachet filling equipment
Klöckner Hänsel LA160 for powders (0.5 till 5 gr), tablets, liquids and semi solids (1.0 up to 100.0 ml) able to run paper and multiplex foils.
- Labeling equipment syringes and vials
Rota, Baush & Ströbel, Neri, Herma
- Semisolid filling line
Kalix Dupuis KX80 2ml up to 100 ml metal tubes (up to 4000 tubes /hr), Crespi suppository filler (up to 10000 suppo/hr) in PVC (PE) preformed (and printed) moulds



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Laboratories

- ❑ liquid chromatography: 10 HPLC systems (UV, RI and DAD detectors) with CDS software, TLC
- ❑ gas chromatography: 2 GC systems (FID and TCD detectors), head-space sampler
- ❑ spectroscopy: UV/VIS spectrophotometer, IR-spectrophotometer with ATR
- ❑ dissolution testing: 4 dissolution apparatus with baskets and paddles, 2 fraction collectors
- ❑ titrations: Karl Fischer volumetric titrator, potentiometric titrator, manual titrations
- ❑ other physical and physico-chemical methods: density, refractive index, optical rotation, viscosity, melting point, loss on drying, conductivity, ...
- ❑ compendial methods of analysis for identification, limit tests, assays and pharmaceutical technical procedures
- ❑ microbiology: total viable count, tests for specified micro-organisms, preservative efficacy tests (PET), growth promotion tests, identification of micro-organisms
- ❑ microbiological and chemical monitoring of purified water systems
- ❑ environmental monitoring
- ❑ stability storage rooms: long term condition at 25°C/60%RH or other settings, intermediate condition at 30°C/65%RH, accelerated condition at 40°C/75%RH

IT-systems

- ❑ Manufacturing Execution System (MES).
- ❑ Warehouse Management System (WMS).
- ❑ Material Requirements Planning System (SAP R/3)
- ❑ Quality Management System (CATSWEB)
- ❑ Central Monitoring System (CMS)
- ❑ Chromatography Data System (CDS)
- ❑ Training Management System (SQTS / SQAS)
- ❑ Laboratory Information Management System (LIMS)
- ❑ Stand alone applications for controlling and managing specific manufacturing equipment (Fette, Kraemer, Vector, Accela-Cota, Glatt ...).



HVAC-CONCEPT

To avoid cross contamination and to protect our people and products Sanico has a full zone concept in place with a state of the art HVAC-system. Pressure differentials of at least 5pa between the different zones will avoid contamination from a zone with lower cleanliness gradation to a zone with a higher gradation. A central air-handling unit supplies the total volume of fresh air. Each individual cubicle has its own air circulation group resulting in a complete segregation of the air supply for each cubicle. This concept also gives the possibility to put each cubicle under particular conditions for e.g. relative humidity (it is possible to maintain humidity below 20% while feeding 100% fresh air to the cubicles). Differential pressures, temperature and relative humidity of each cubicle are monitored by the CMS. Visual and acoustic alarms are created when values are going out of limit.





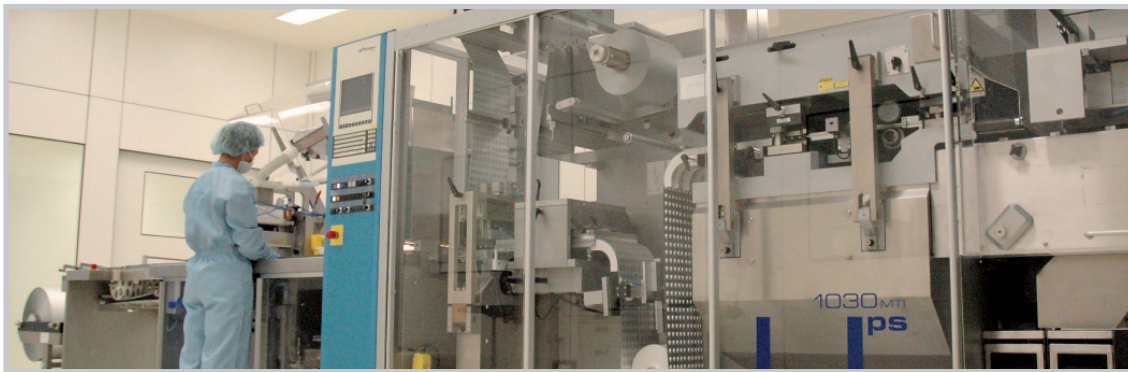
PURIFIED WATER SYSTEM

Sanico has installed 2 separated purified water loops to serve all the PW-users.

The first loop is serving the Solid Forms production. This installation consists of a demineralisation unit using filtered potable water. After filtration at 0.2 μ the water is stored in a 5000 l storage tank and distributed by the PW-loop. Sterilizing filters are installed in the loop. The conductivity, PH, flow and temperature are continuous monitored by the Central

Monitoring System. The user points are automated and they will be blocked when the water is out of specification. The loop is sanitised on a regular basis by heat.

The second loop is serving the Liquids and Semi Solids Production. A state of the art RO-installation is providing purified water directly into the 5000 l storage tank. The conductivity, flow and temperature are continuous monitored by the Central Monitoring System. The user points are automated and will be blocked when the water is out of specification. The loop is sanitised on a regular basis by ozone. No filters are installed in the loop.



IT APPLICATIONS

