Geistlich
Pharma

Management-Handbook

1. Goal of the Management System

Geistlich Pharma AG is a medium-sized enterprise that sets itself long-term goals and is aligned to stability.

Geistlich Pharma AG is therefore making every effort to continually improve its market performance with a management system.

With the integrated process-oriented management system based on a strategic decision, Geistlich Pharma AG (hereafter referred to as *Geistlich*) aims to transparently describe and systematically implement the interlaced processes of the group of companies, and to produce products (articles) and services that meet the demands of quality and economy.

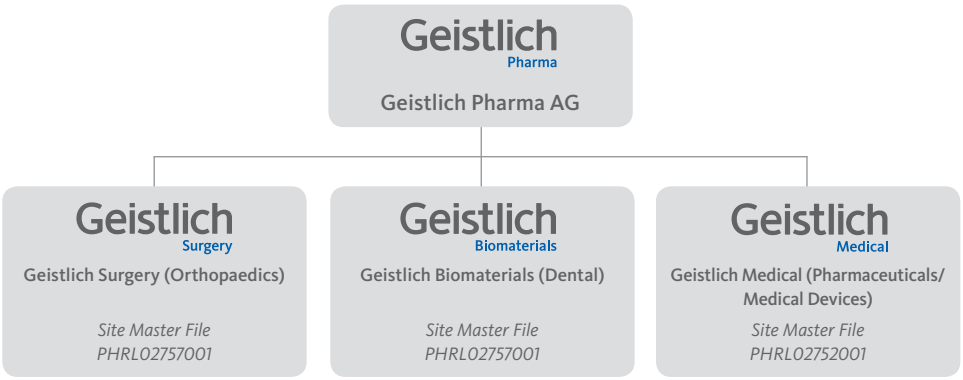
2. Company Portrait

Geistlich – domiciled in CH-6110 Wolhusen – is a subsidiary of Ed. Geistlich Söhne AG, a family-based public limited company which was founded in 1851 according to Swiss law, with registered offices in CH-8952 Schlieren, Switzerland. The aim of the corporation is the research, development, manufacture and sales & marketing of pharmaceuticals and medical devices.

3. Scope

The Management-Handbook applies for Geistlich Pharma AG located in Wolhusen and Root with their Business Unit Biomaterials, Surgery and Medical.

Geistlich Biomaterials und Geistlich Surgery:	Research and Development, Production and Distribution of Pharmaceuticals and Medical Devices (Notified body: SwissTS / TÜV for the Quality management for medical devices according to ISO9001 / ISO13485)
Geistlich Medical:	Design, development, manufacture and sales of Taurosept TM (Catheter lock solution for the prevention of catheter sepsis) and Taurocin TM (without sale) cavity filling material (Notified body: SGS for Quality Management of Medical Devices Taurosept TM and Taurocin TM according to ISO13485) as well as various medicinal products (supervised by Swissmedic / RHI)



4. Image

Our research supports projects aimed at the development of new, innovative products that can be transported, used and disposed of in a safe and environmentally friendly manner.

We want to continually adapt, and also further modernize and rationalize our order-based production through targeted investment in buildings, machinery and installations, whereby the safety and the protection of both people and the environment is our supreme priority.

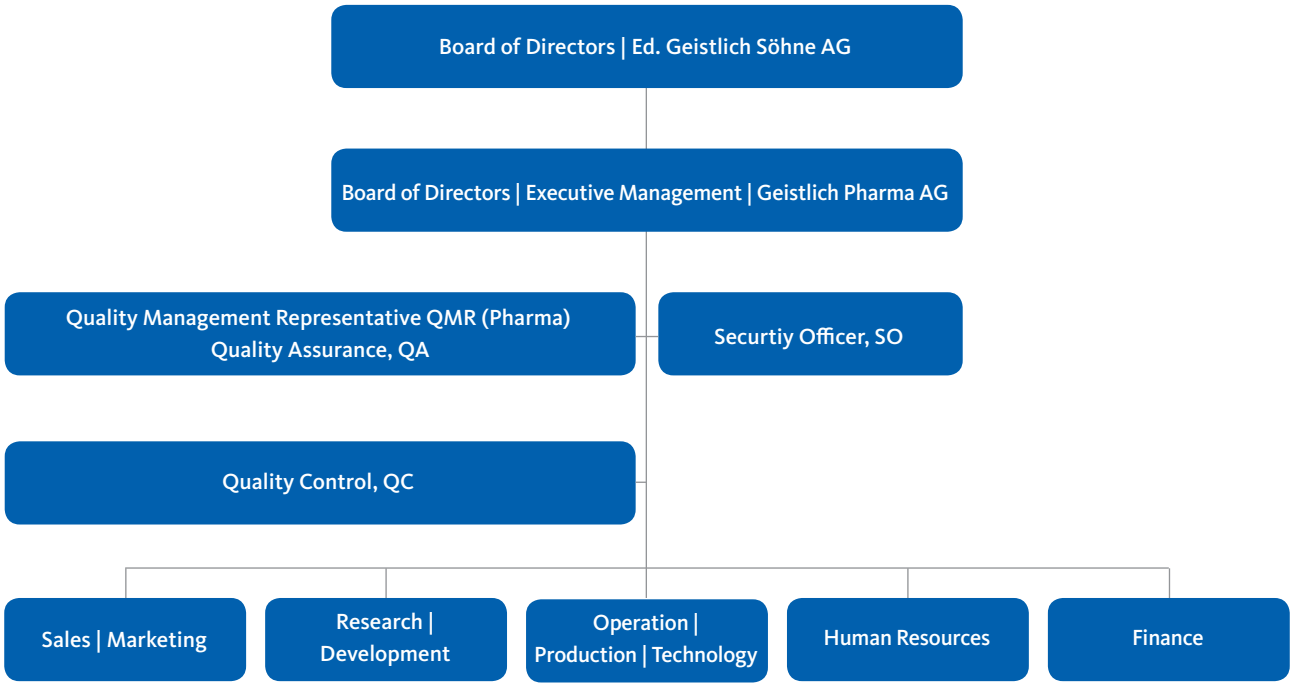
Through involving our suppliers and carefully selected partners in our processes, we want to satisfy the continually growing requirements of our customers and the market in the best possible way.

Thanks to the careful selection of our employees and their subsequent, targeted training and further education, we promote and support a high standard of technical competence at all levels.

We offer our personnel modern employment conditions and well-developed social benefits, and by taking appropriate measures, we guarantee working safety and the protection of health, as well as the avoidance of breakdowns and incidents.

Our entrepreneurial thought and action is characterized by our awareness of our responsibilities and transparency with regard to our employees, customers, suppliers and local authorities.

5. Organigram



6. Company policy

- By means of our targeted efforts in Research, Development and Application Technology, we continually strive to find new and innovative products and system solutions, to develop them and to bring them to market maturity.
- In existing business fields, we orientate ourselves to the needs of the markets and the customers as well as to the risks present in the environment, and, wherever possible, make use of our capabilities and the services we provide in market niches to satisfy the demands of our customers.
- We continually make every effort to satisfy customers requirements, and provide the best possible solutions for challenging problems. In addition, we continually further develop both our products and services.
- We pay continual attention to improving the profitability of our corporation and their activities in order to also be able to meet future requirements, and in this way, will be able to maintain our position in national and international markets.
- Our team-oriented and supportive management style creates the prerequisite for our employees to enjoy job satisfaction, and with targeted support of the company, can develop themselves further, both personally and professionally. In this way, the company will secure the extensive know-how of its employees.

7. Quality policy

- With the customer and process-oriented management system according to ISO 9001, ISO 13485, MDD 93/42 EEC, Commission Regulation (EU) Nr. 722/2012, 21 CFR Part 820, CMDR, PIC/S, EU-GMP-Guideline for medicinal products, PAL-QMS/MHLW Ministeral Ordinance No. 169, RDC#16, KGMP Regulation and ARGMD, each with the relevant national and international requirements, we want to continually increase our capabilities and to guarantee the highest possible quality of our articles and services.
- Our buildings, machinery and installations conform completely with the requirements of federal, cantonal, and communal laws. All permits necessary for their operation and maintenance have been obtained, and are strictly observed. The responsible authorities carry out periodical checks. The audit reports are worked through systematically, and any corrections of defects that become necessary are completed according to schedule.
- We continually monitor and develop our product quality with trained and qualified technical staff and with test and measurement tools that are free of errors. Quality assurance as a management obligation, is the permanent responsibility of every employee, and is written into all job descriptions / specifications.
- In the field of medical devices risk management shall be performed for the products in accordance with the applicable standards, whereby the management determines the criteria for risk acceptance.
- The services and deliveries of our suppliers must be in line with our Purchasing Requirements and are continually monitored by us.
- We ensure operational and work safety, as well as the protection of the health of the employees within the framework of the specifications of the local authorities and with the sector solutions of ECO SWISS.

8. Risk policy

No commercial success without risks
We want to actively exploit the opportunities available in the market. The risks inherent with this will only be taken if they have been thoroughly assessed beforehand. The risks must be commensurate with the resources and the financial situation and take account of statutory regulations and best practices. Risk-reducing measures are chosen such that the introduction of any additional risks is avoided. The risk assessment will highlight how they can be reduced, controlled and monitored. Risk assessments including the accepted residual risks must be documented in writing.

Use of risk management
The corporate strategy, strategic investment projects, product innovations as well as occupational and plant safety and IT security are supported by a systematic risk management process. Here the minimum standards set by risk management must be met.

Duty of the management
The management provides the necessary resources for the risk management, introduces the risk management system, monitors and improves it on a continual basis.

Responsibility and coooperation
Risk management is in principle the responsibility of the line management. Each line manager is a risk owner. The risk management officer supports the line management in the identifying, assessment and evaluation of the risks. The risk management officer must be notified of any risk assessments carried out. He will validate the risk assessments for forwarding to the competent management.

9. Process model

Main processes
The activities of *Geistlich* are organized into five main processes. Each main process forms an organizational unit, for which a process representative is appointed.

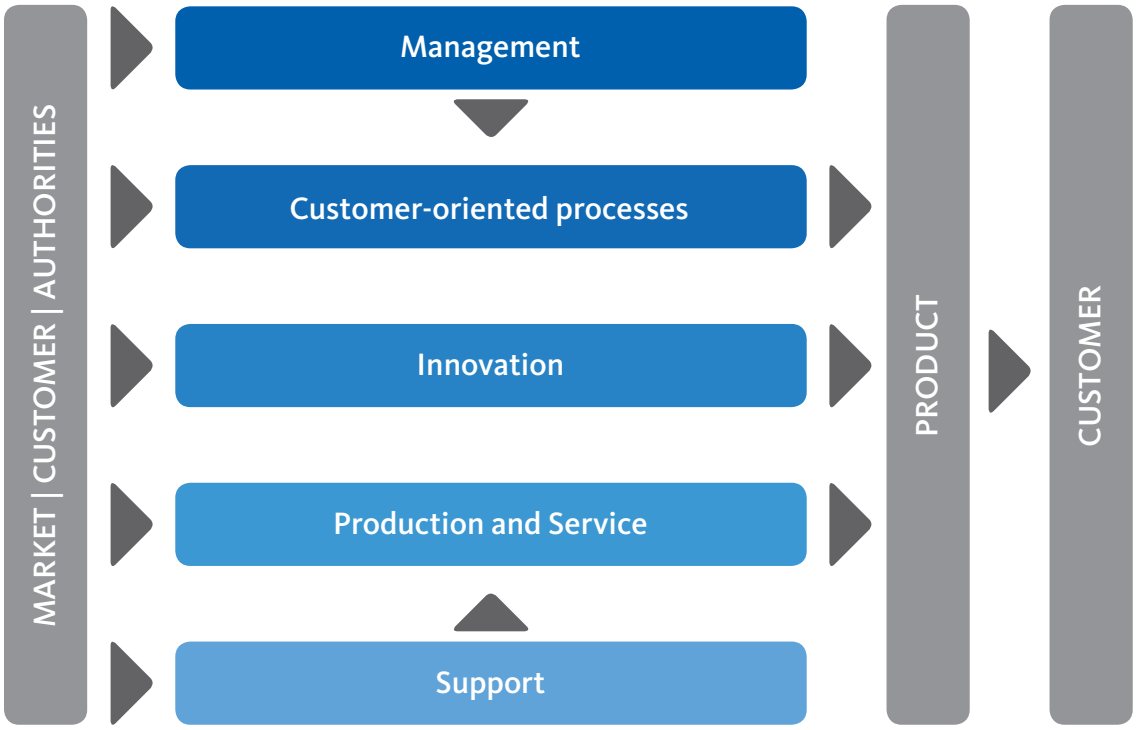
The main processes are divided into various sub-processes.

A sub-process always begins with a defined input, and the required and pre-defined goal will be achieved through various activities.

The processes include activities that are complete within themselves, and the interfaces between the individual processes are defined (interaction of the processes) and measurement dimensions and measurement values are also predefined.

The PDCA cycle (Plan-Do-Check-Act) is incorporated in all processes

Holding



10. Process definition

Management process

Executive management duties are stated in the management process.

These comprise: strategy, management review, corrective and preventative measures, process controlling, internal audits, human resources, finance, accounting, and Sales and Operations Planning (S&OP).

Strategic management, control and steering activities, and the continuous improvement of the management system are thereby all taken into account.

Customer-oriented processes

The main Customer-oriented processes process is divided into the sub-processes: Scientific support, marketing, sales and customer service.

In these sub-processes, analyses of the market and customer information for the expansion of our group of customers, and to promote customer satisfaction, stand at the center of our activities.

Innovation process

The main Innovation process is divided into the sub-processes: Research, Product Development, Process Development and Patents.

This main process defines the research, and ensures that it is carried out in a targeted and market oriented manner, and that market-conform products and processes are developed that fulfill all the required conditions and which, wherever possible, will be protected by patent.

Production / Service process

The main Production / Service process is divided into the sub-processes: PPS, Stores management, Production and Dispatch.

In this main process, all the operative measures necessary for the creation of the product are defined. Our products will be realized, tested and dispatched in this main process.

Non applicable from the ISO 9001 / 13485:
- Installation activities (7.5.1.2.2)
- Servicing activities (7.5.1.2.3)
- Customer property (7.5.4) (apply only to personal data of customers e.g. confidential patient data and study proposals and papers (Publications)).

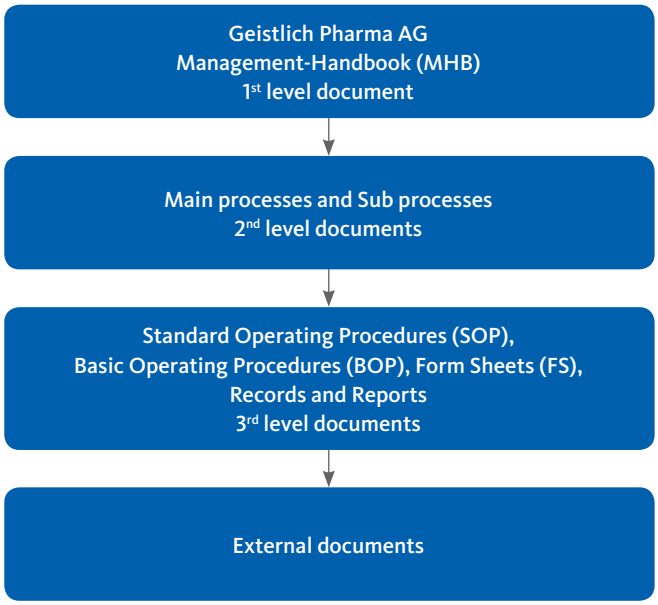
Non applicable only for the Business Unit Medical:
- Cleanliness of product and contamination control (7.5.1.2.1)
- Particular requirements for active implantable medical devices and implantable medical devices (7.5.3.2.2 and 8.2.4.2)

Support process

In the Support process, tasks and activities are described that have a supportive effect for the individual mainand sub-processes, or also for the subsidiaries at the Schlieren and Wolhusen locations.

These comprise the sub-processes: acquisition, monitoring of test equipment, document management and faulty products.

11. Document structure for Geistlich Pharma AG



12. Maintenance and further development

Geistlich sets itself management targets which are reviewed at least once a year.

In this way, the management system will be actively lived, be developed further, and be continually adapted to the latest and continually changing state of knowledge and requirements.

13. Coming into force

The Management-Handbook and all other valid documentation in their respective current forms are hereby declared valid and binding on all participants.

CH-6110 Wolhusen, April 2014

Geistlich Pharma AG

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