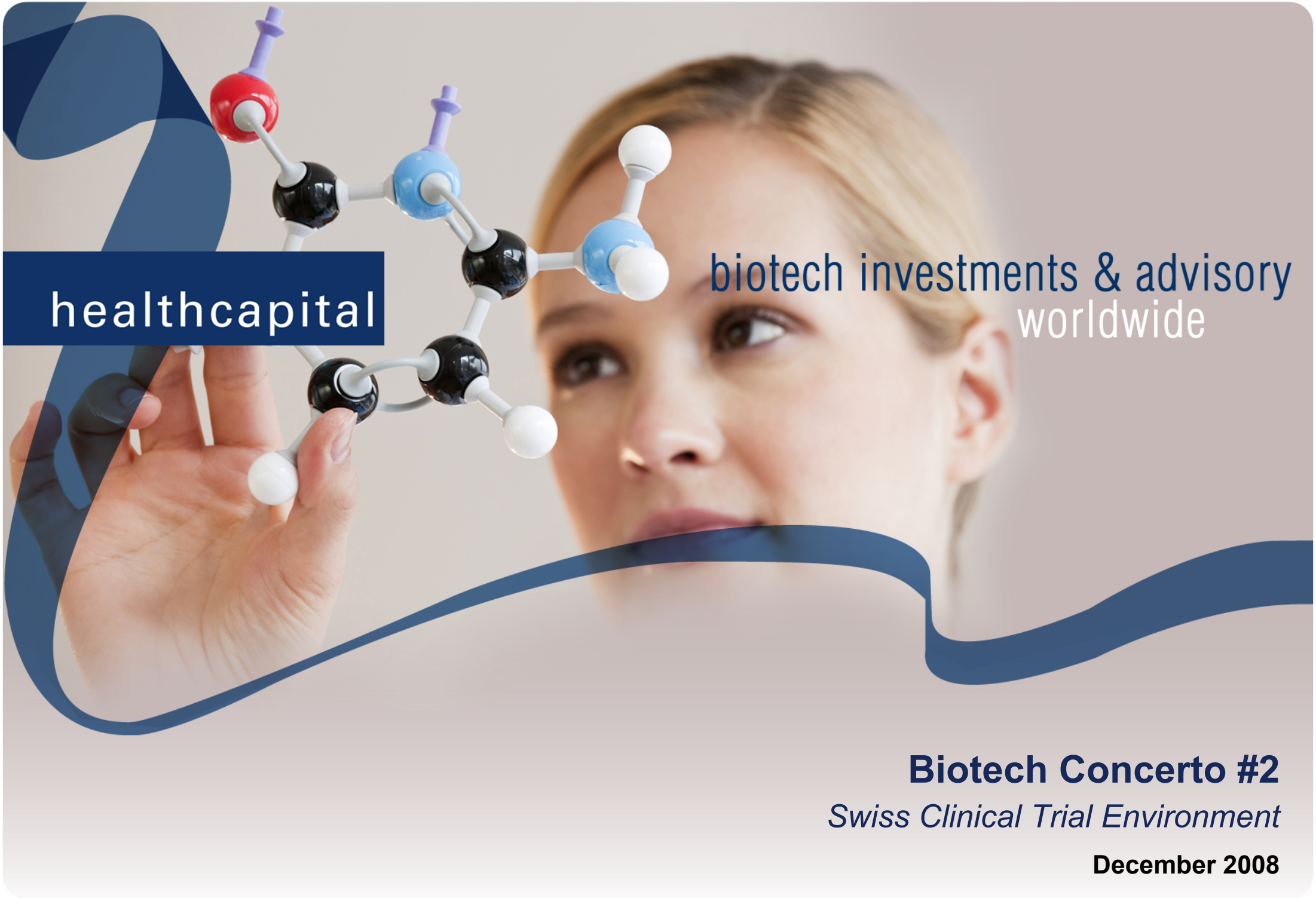

Biotech Concerto #2

Swiss Clinical Trial Environment

December 2008

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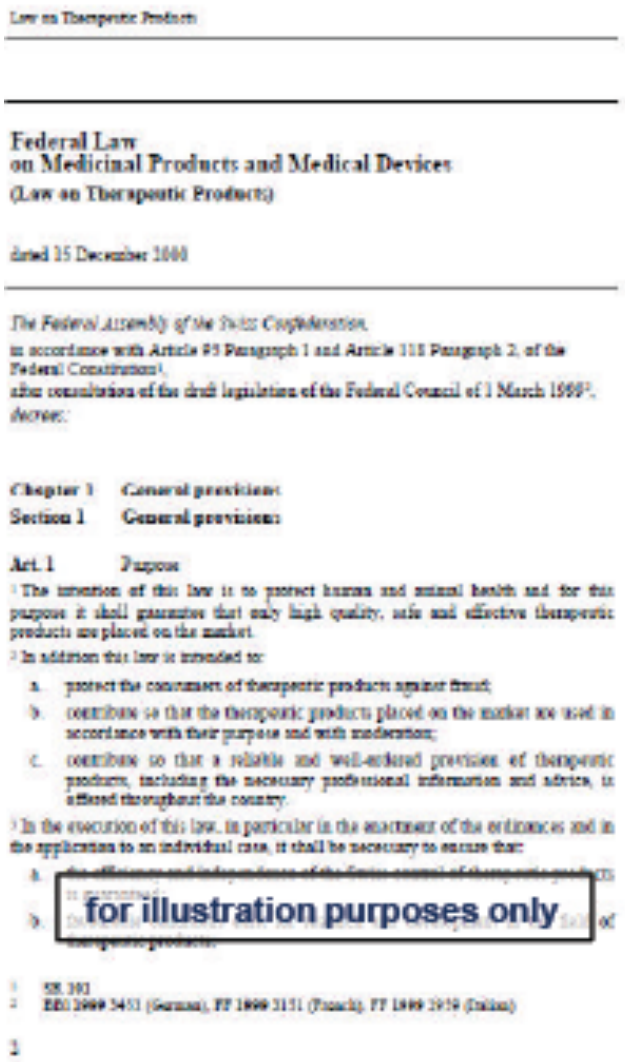
Federal Law on Therapeutic Products

Federal Law on Therapeutic Products

dated Dec 16, 2000

1. The intention of this law is to protect human and animal health and for this purpose it shall guarantee that only high quality, safe and effective therapeutic products are placed on the market.
2. In addition this law is intended to:
   a. protect the consumers of therapeutic products against fraud;
   b. contribute so that the therapeutic products placed on the market are used in accordance with their purpose and with moderation;
   c. contribute so that a reliable and well-ordered provision of therapeutic products, including the necessary professional information and advice, is offered throughout the country.
3. In the execution of this law, in particular in the enactment of the ordinances… (cont.)



Law on Therapeutic Products

Federal Law
on Medicinal Products and Medical Devices
(Law on Therapeutic Products)

dated 15 December 2000

The Federal Assembly of the Swiss Confederation,
in accordance with Article 95 Paragraph 1 and Article 118 Paragraph 2, of the Federal Constitution[1],
after consideration of the draft legislation of the Federal Council of 1 March 1999[2],
decrees:

Chapter 1 General provisions:
Section 1 General provisions:

Art. 1 Purpose

[1] The intention of this law is to protect human and animal health and for this purpose it shall guarantee that only high quality, safe and effective therapeutic products are placed on the market.
[2] In addition this law is intended to:
a. protect the consumers of therapeutic products against fraud;
b. contribute so that the therapeutic products placed on the market are used in accordance with their purpose and with moderation;
c. contribute so that a reliable and well-ordered provision of therapeutic products, including the necessary professional information and advice, is offered throughout the country.
[3] In the execution of this law, in particular in the enactment of the ordinances and in the application to an individual case, it shall be necessary to ensure that:

1 SR 101
2 BBl 2000 3451 (German), FF 1999 3151 (French), FF 1999 3919 (Italian)

1

Source: Swissmedic

National Ethics Commission

The National Ethics Commission is an independent advisory commission, established by the Federal Government on July 3, 2001.

The National Ethics Commission watches the scientific development on human health and diseases. With respect to social, scientific and legal questions, the National Ethics Commission takes position from an ethical point of view.

In consideration of new scientific insights and new technical opportunities, the National Ethics Commission aims to arrive at a careful, ethical judgment in order to contribute to a fair, argument-oriented public opinion and to contribute to the welfare of the society.

Source: translated from Bundesamt für Gesundheit BAG

Supervisory Authority: Swissmedic

Swissmedic is the central Swiss supervisory authority for therapeutic products. It is a public service organization of the federal government with headquarters in Bern.

Swissmedic is linked to the Federal Department of Home Affairs (FDHA). The Agency Council is its highest body and represents Swissmedic in contacts with the FDHA and the Federal Council (the Swiss government).

Swissmedic's wide variety of activities are adapted to the requirements of partners. These include patients, the therapeutic products industry, medical professionals, authorities and organizations in both Switzerland and in other countries, as well as the media.

Swissmedic's core competencies include licensing medicines, granting authorizations to manufacture/ distribute wholesale, inspecting facilities, monitoring medicines and medical devices already on the market, controlling the traffic of narcotics laboratory testing of medicine quality, and drafting laws and standards.

Source: Swissmedic

Institutional Review Board (IRB)

Institutional Review Boards (IRBs) are also known as an independent ethics committee or ethical review board.

The Ethics Committee, according to Directive 2001/20/EC, is an independent body in a Member State of the European Union, consisting of healthcare professionals and nonmedical members, whose responsibility it is to protect the rights, safety and well being of human subjects involved in a clinical trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

Similar approach in Switzerland,
with Ethics Committees in States/Cantons.

Source: Wikipedia, adapted

Swiss Ethics Committees

Ethical Committees in Switzerland are organized and managed on a State level, but coordinated by the Federal Government.

Ethical Committees are evaluating the conformity of proposed research protocols with the ethical and scientific standards as they are established in the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) and Ethical Committee(s) the WHO and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice.

Ethical Committees are responsible for the ethical approval of all clinical trials involving humans and its approbation is a legal prerequisite for the execution of any clinical trial. They provide comprehensive information and resources about ethical norms, submission procedures, and about the cantonal, federal, and international legal framework.

With ‘swiss ethics’, Swiss Ethical Committees have a joint web presence.

Documents (Excerpt)

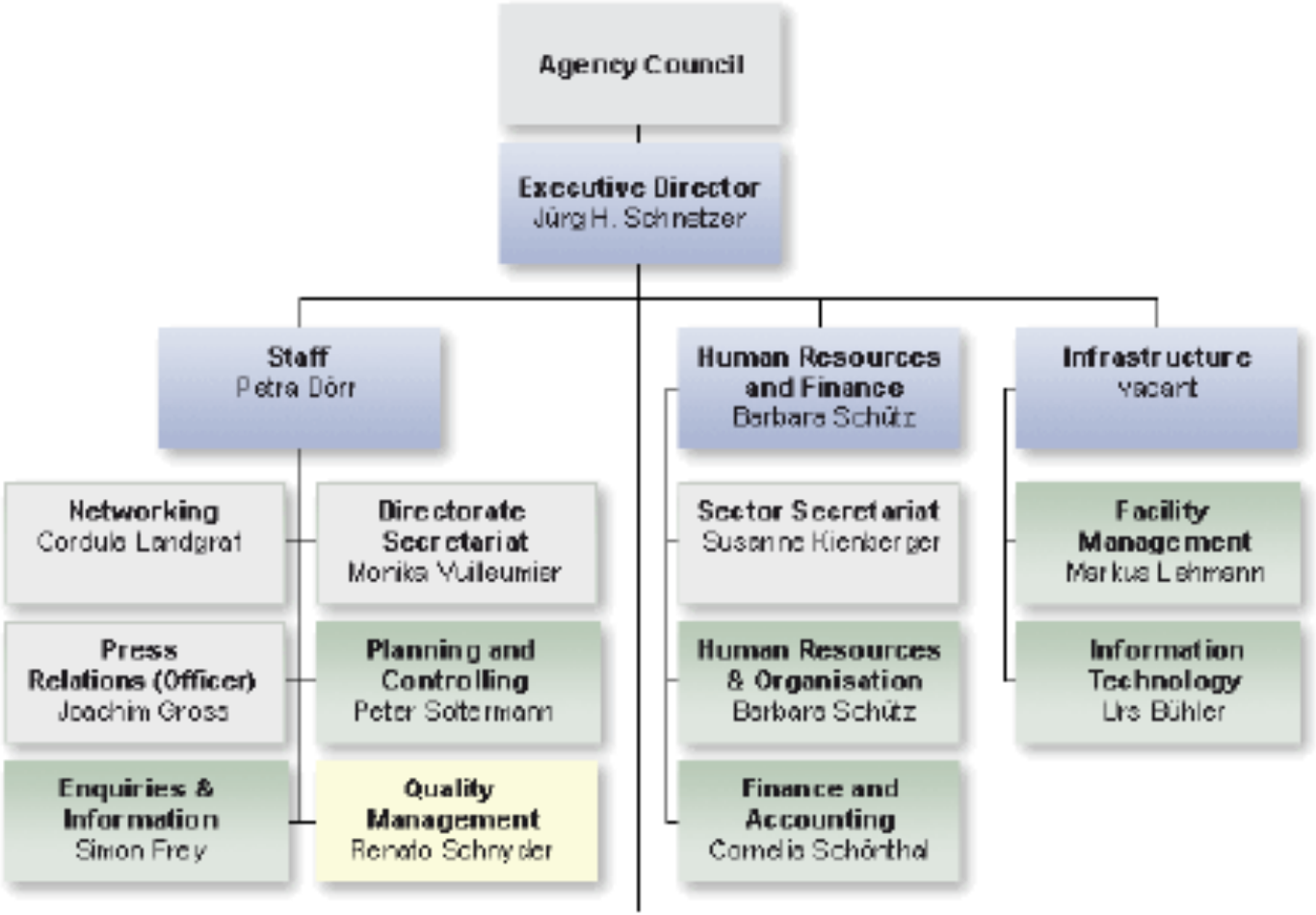
Legal Basis (Excerpt from repository)

- Federal Law on Therapeutic Products
- Ordinance on clinical trials of therapeutic products

Forms/Guidelines/Instructions (Excerpt from repository)

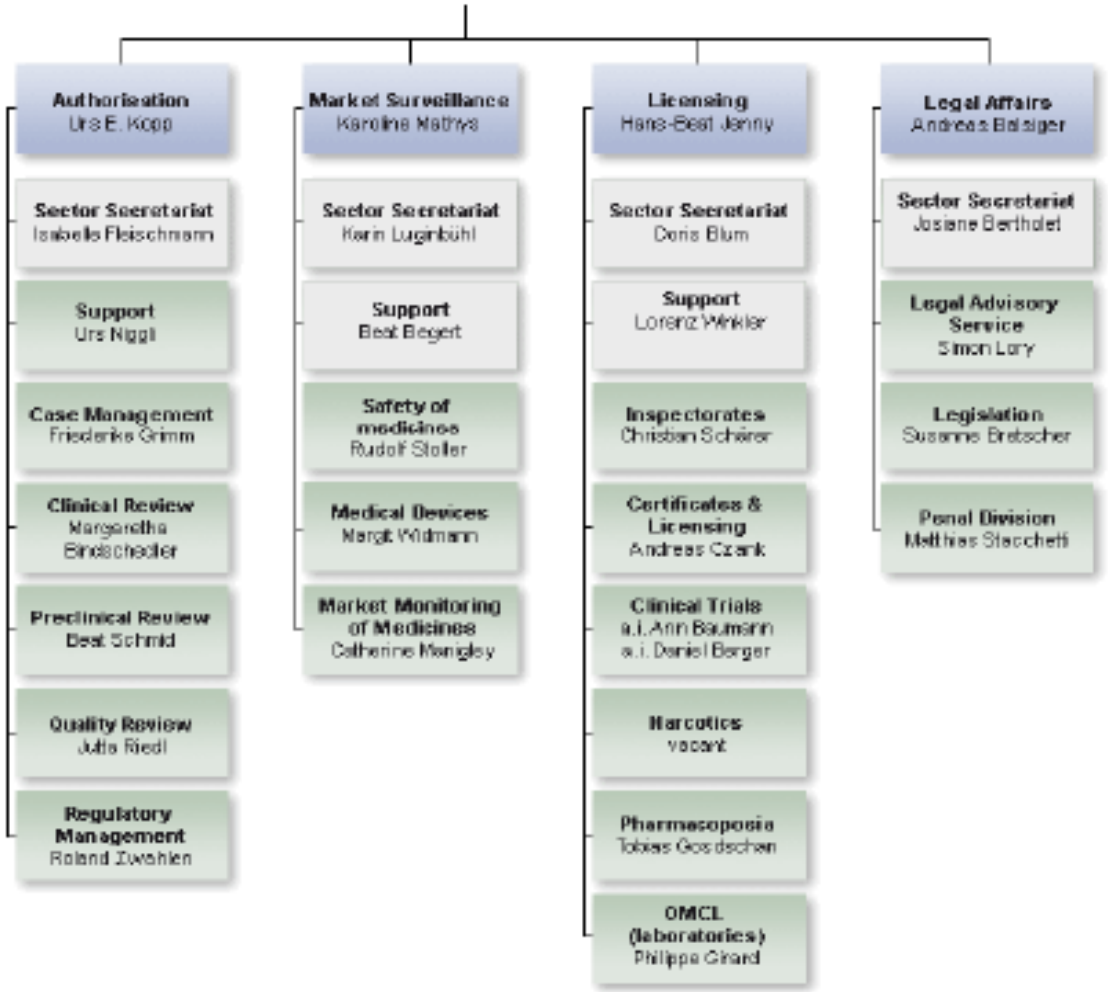
- Basic form for submitting a biomedical research project
- Drawing up information and the statement of informed consent for trial subjects
- Insurance certificate for the attention of the Swiss Ethics Commissions
- Form for the Decision announcement from the Ethics Committee
- Notification form clinical trials on medicinal products
- Documentation to be submitted for notification of a clinical trial on medicinal products
- Patient information model document and declaration of assent
- ICH Guideline for Good Clinical Practice
- Requirements for insurance policies for clinical trials on therapeutic products involving human subjects
- List of the Ethics Commissions appointed by the Cantons for clinical trials with therapeutic products

Corporate Functions



Source: Swissmedic

Line Functions



Source: Swissmedic

Stakeholders*

- Christine Beerli, Advocate, Vice President International Committee of the Red Cross, Geneva
- Prof. Michel Burnier, MD, Chief Medic Nephrology, Vaud University Hospital, Lausanne
- Carlo Conti, JD, Minister Public Health of the State of Basel-City, Basel
- Markus Duerr, VetD, Minister Public Health of the State of Luzern, Luzern
- Anne-Silvie Fontannaz, State Pharmacist of the State of Vaud, Lausanne
- Christiane Roth, MD, Managing Director Zurich University Hospital, Zurich
- Prof. Gerhard Schmid, JD, Advocate

* Agency Council Swissmedic, alphabetical order by last name

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