OUR PROCESSES

Process map of the Federal Office for Safety in Health Care

strategy process
(incl. risk management)

framework of the product realisation process:
• Austrian Health and Food Safety Act,
• national legislation listed in §6a,
• respective European legislation

product realisation processes
types of product realisation processes:
• registration of clinical trials *
• scientific advice *
• marketing authorisations (incl. life-cycle) *
• laboratory analysis (incl. assessment of related documentation) *
• market surveillance and vigilance *Ø•V
• other procedures and answering queries *Ø•V

fields of activity:
• medicinal products *)
• medical devices Ø)
• blood *)
• tissues •)
• narcotics V)

controlling processes
output- und outcome-related controlling (financial and process controlling) & normative controlling (quality system)

output- und outcome-related controlling (financial and process controlling)

• budget
• qualified staff
• IT infrastructure
• IT systems
• other products and services
• legal expertise

normative controlling (quality system)

provision processes

customer requirements
stakeholders:
• patients
• physicians
• pharmacists
• industry and SME
• Ministry of Health
• European Regulatory Network
• society

products fulfilling customer requirements

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OUR PROCESSES
in the Life-Cycle of Medicinal Products

PRE-AUTHORISATION

PRIME
Scientific / Regulatory Advice
Manufacturing Authorisation (GMP-Inspections)
Assessment of Clinical Trials GLP- & GCP-Inspections

MARKETING AUTHORISATION

Market Surveillance OMCL Batch Release

POST-AUTHORISATION
Suspension of Marketing Authorisation
Variations / Renewals of Marketing Authorisation
Safety Signals & Risk Management periodic GMP-Inspections PV-Inspections

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OUR PROCESSES

concerning Blood & Tissues

Manufacturing Authorisation
(Inspections acc. to Medicinal Product Act or Tissue Safety Act)

Variations of Manufacturing Authorisation

Haemo- & Tissue Vigilance
periodic Re-Inspections

OrganTransplant-Register by GÖG
(www.goeg.at)
OUR PROCESSES concerning Medical Devices

Product development and conformity assessment by manufacturers (and Notified Bodies)

Authorisation & Inspections of Clinical Trials

Vigilance, Market Surveillance Inspections of e.g. Manufacturers, Distributors, Operators etc.

Conformity assessment by manufacturers (and Notified Bodies)

Manufacturer Register by GÖG (www.goeg.at)