



For further information, advice or other questions, please visit our homepage www.ages.at - our FAQs (Frequently Asked Questions) may help.

Also please do not hesitate to contact us personally:

Contact:

Alexander Hönel

Head of Unit
Tel: +43 (0) 50555 36400
Fax: +43 (0) 50555 36407
E-Mail: alexander.hoenel@ages.at

Araxi Guiragossian

Assistant to Alexander Hönel
Tel: +43 (0) 50555 36401
Fax: +43 (0) 50555 36407
E-Mail: araxi.guiragossian@ages.at

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Health. Nutrition. Safety. Our Concern.



Agriculture

From healthy soil to safe food in Austria



Food

Safe food...
...and labels that tell the truth



Veterinary Medicine

Healthy animals - safe food, protection
against animal and zoonotic disease



Human Medicine

Fighting infectious diseases



PharmMed

Safe and effective medicines



Competence Centers

The lab labs rely on



Data, statistics and risk assessment

From data to knowledge



Inspections

Inspections



About AGES PharmMed:

On 2.1.2006 the new Austrian Medicines and Medical Devices Agency - AGES PharmMed - was founded. It is an organisation characterised by flexibility, competence and spirit of service. AGES PharmMed fulfills on behalf of the Republic of Austria, public service responsibilities related to the inspection and approval of medicinal products and medical devices. The Republic of Austria as owner of AGES PharmMed is the guarantor for objectivity and impartiality in all of the services provided. AGES PharmMed is made up of the following closely collaborating units: Pharmacovigilance, Science and Information, Medical Devices and Haemovigilance, Inspections, Marketing Authorisation and Life Cycle Management and finally the Official Medicines Control Laboratory.

About Inspections:

One of the units in the AGES PharmMed is "Inspections". The unit's goals are to reduce both the inspection lead time and the time it takes for reports and written decisions to be issued, and to position the unit as a competent partner.

The close interaction with internal and external networks guarantees the continuous exchange of knowledge and internationally harmonized inspections.

Further Information about AGES PharmMed: www.ages.at

The unit is made up of three departments:

Department for IT and Medical Devices Inspections

Focusing on inspections of computer-assisted systems and data management solutions, this department plays a pioneering role amongst European inspectorates. Furthermore the experts of the department are in charge of handling procedures related to drug import and free sales certificates.

Contact: Roland Bauer, Head of Department

E-Mail: inspektionen@ages.at

Department for GCP Inspections

The department performs inspections of clinical trials with investigational medicinal products or medical devices, ethics committees and pharmacovigilance systems. More and more the traditionally high number of routine inspections is replaced by ad-hoc inspections triggered by the Unit for Marketing Authorisation & Life Cycle Management, international authorities, WHO or other PharmMed Teams. The proportion of inspections of bioequivalence studies, a lot of them are carried out beyond Austrian borders, increased markedly.

Contact: Alexander Hönel, Head of Department & Unit

E-Mail: inspektionen@ages.at

Department for Pharmaceutical Inspections

This department is responsible for inspecting manufactures and distributors of human and veterinary medicines and control laboratories from office to logistic, wholesaling and manufacturing, from tablets to blood products and recombinant proteins. Furthermore the inspections in third countries make up a considerable share of the daily business, particularly inspections of plasma and blood donation centres in the USA, on which assessments of European Plasma Master Files are based. In the area of blood and plasma inspections, the Department for Pharmaceutical Inspections is one of Europe's leading competence centres.

Contact: Andreas Krassnigg, Head of Department

E-Mail: inspektionen@ages.at

Medical market surveillance

The purpose of Medical market surveillance is to record and process any incident related to medicinal products or medical devices which are in nonconformity with applicable rules and regulations. Doubtless one of the most important tasks of the Department for Medical market surveillance is to carefully analyse the potential health risks associated with any newly reported case of suspect non-compliance.

Contact: Alexander Hönel, Head of Department & Unit

E-Mail: inspektionen@ages.at