

## Executive Summary

**Munich, July 2008. FGK Representative Service GmbH** announces that it has passed successfully the first inspection of a Legal Representative in the European Union by authorities.

Early in 2008, FGK Representative Service was, to their knowledge, selected for the first routine inspection of an EU company offering legal representation of clinical trial sponsors. This inspection did not reveal any critical or serious findings. The list of deficiencies submitted was used by FGK to improve compliance with requirements formulated by the authorities.

### **Nature and extent of inspection**

The GCP inspection was conducted pursuant to German Drug Law section 64 subsection 1 and German GCP Ordinance section 15 subsection 1.

The following topics were covered:

- Quality assurance system
- Documentation
- Trial protocol
- Investigational medicinal products
- Notification and reporting obligations
- Monitoring and audit system
- Personnel
- Study site selection

### **Summary and conclusions:**

Critical deficiencies: None

Serious deficiencies: None

Other deficiencies: 16

Based on the inspection conducted at FGK Representative Service GmbH, the net conclusion is that GCP requirements can be met to a large extent, provided deficiencies are suitably eliminated.

**About FGK Representative Service GmbH:** FGK Representative Service GmbH was founded in order to meet legal requirements of sponsor companies which do not have a subsidiary within the European Union, for the purpose of performing clinical research projects in the European Union. Such a representative, known as a “legal representative” for clinical drug trials and “authorized representative” for medical device trials, fulfils the obligation that the drug and the medical device companies must be established or represented in the European Union. FGK can represent drug and medical device companies as “legal representative” in all member states of the European Union for all drug and medical device trials to enable submission of the regulatory applications to the European authorities and ethics committees.

For further information please contact:

Ina Ott, Director Business Development  
FGK Representative Service GmbH  
Heimeranstr. 35  
D-80339 München  
Phone: +49-89-893 119-44  
e-mail: [ina.ott@fgk-rs.com](mailto:ina.ott@fgk-rs.com)