

Korea & Germany - One Common Spirit

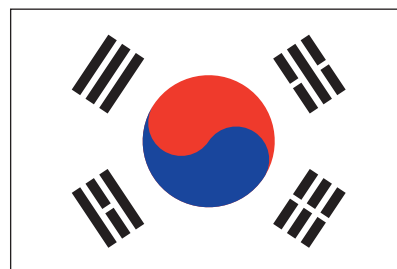
한국과 독일 - 동일한 관점

Similar History & Market Insights

In 1883, Korea and Germany started their diplomatic relationship by signing the Friendship, Commerce and Navigation Treaty and have continuously advanced their friendly, bilateral relations to this day.

Both nations are connected through similar historic experiences, such as the separation of their countries and their tremendous economic growth over the last 60 years. Comparable economic strategies have shown that both countries share one common mindset.

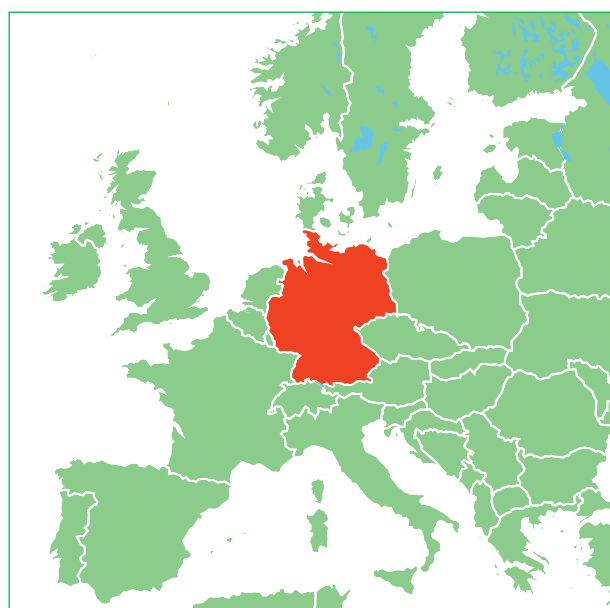
The pharmaceutical industry in Korea is one of the fastest-growing pharmaceutical markets in the world. The Korean government envisions Korea becoming one of the world's top global pharmaceutical producing countries. Thus, multiple governmental fundings have been established, dedicated to encourage the development of new global drugs and to ensure globe competitiveness in drug development. A key focus of this internationalisation program lies in expanding into the European pharmaceutical market.



Why CRS?

CRS is a European leading full-service Early Phase CRO with 6 CPUs and more than 250 beds located in Germany. CRS's excellent track record is based on 40 years of clinical research experience, accompanied by more than 2,000 completed trials and numerous authority inspections (e.g. FDA, EMA, BfArM). Our reputation - including capability, expertise, reliability, compatibility and quality - is demonstra-

ted by the CRO Leadership Awards 2016, that lists CRS as one of the Top Performers who exceeds customers' expectations (<http://www.crs-group.de/Info-Point>). Companies of all sizes decide to work with CRS as their CRO of choice. At present, CRS collaborates successfully with several Korean clients.



Locational Advantages - Germany

Germany is located in the heart of Europe and has an excellent reputation regarding quality „Made in Germany“. It is the second-largest pharma market in Europe with a long tradition in the development of pharmaceutical products. Germany is the No.1 sales market for herbal medicine in Europe and a key regulatory market for phytopharmaceuticals in the EU. The German regulatory environment is well-established, well-organised and highly transparent. Furthermore, based on yearly evaluations focusing on new registrations in „clinicaltrials.gov“, Germany is No.2 worldwide regarding initiation of clinical studies. In comparison to the US (No.1), Europe has a 5x greater population density, resulting in logistical advantages and shorter travel times.

Germany combines worldwide recognised, first-rate quality with competitive pricing. In addition, the Korean Won developed a 15% exchange rate profit in relation to the Euro over the last two years.

First-in-Human Case Study

임상1상시험



Full-Service Phase-I Package for a Phytopharmaceutical Product

CRS's high-valued Korean client, Green Cross WellBeing (GCWB), is clinically developing a phytopharmaceutical product and has decided to perform the FIH trial with CRS in Germany based on its reputation and expertise regarding herbal medicine.

At first, CRS supported GCWB with a study concept, which was discussed at a Scientific Advice Meeting with the German competent authority, the BfArM. In agreement with the BfArM, a complex umbrella protocol - including SAD, MAD and FDI - was developed and substantially amended once the PK samples of the SAD part were analysed and the dose ranges for the MAD part were determined. Regulatory aspects were evaluated by a qualified third party.

A full-service package was requested by GCWB and CRS provided Clinical Conduct, Medical Writing (protocol, amendment and report writing), Monitoring, Bioanalytics, Pharmacovigilance, Quality Assurance as well as services in Data Management and Statistics.

The FIH trial for the phytopharmaceutical product was funded by the Korean government, therefore adherence to the committed timeline was essential. CRS completed the FIH study in strict adherence to the timeline and GCWB was very satisfied with the outcome. The excellent cooperation is now planned to be continued and communications are assisted by our Korean representative, Dr. Eun-ha Shin, whose cultural roots and scientific expertise are the best basis to strengthen bridges. (Publication approved by GCWB)

CRS - Your Clinical Hub in Europe - 유럽 임상 허브는 CRS

New Chemical Entity (NCE): Currently, CRS realises approximately 5-7 FIH trials per year. Our expertise includes complex umbrella protocols, which cover several topics from FIH to POC in one trial protocol. Besides healthy volunteers, CRS also offers a broad range of special populations, such as patients of various therapeutic areas, postmenopausal women and the elderly.

Biologicals/Biosimilars: When the legal framework for approval of biologicals/biosimilars in the EU was established in 2003, CRS instantly implemented the regulation into the clinical trials. Our capabilities enable fast recruitment of large groups, e.g. healthy volunteers to test oncological products.

Generics: Germany holds the highest volume market share for generics in Europe and CRS originally started in the generic business in the early 70s. Our extensive expertise also covers special areas, including inhalative drugs and narcotics.

Phytopharmaceuticals: Herbal Medicine has a long, historical tradition in Europe, especially in Germany. Here, phytopharmaceuticals are recognised as effective drugs by law. Germany is the bridgehead for the clinical development and introduction of herbal drugs into the European market.

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