Navigating European medicines regulations

Health Inspired,
Quality Driven.

SGS

Navigating European medicines regulations

At SGS, you can trust our deep understanding of the ever-changing European regulatory landscape and the intricate journey toward successful drug development.

Our experienced consulting team specializes in European Medicines Agency (EMA) regulatory solutions, so we can help you navigate complex processes and systems to streamline your path to market.

Through our comprehensive approach, we blend boutique regulatory expertise with the advantages of a full-service CRO to provide you with seamless clinical trial support in the EMA territory.

Our expertise and approach

Experienced teams

Our experts collaborate closely with European regulatory agencies to offer you operational support for diverse medicinal products, including small molecules, biologicals, generics, biosimilars, and orphan drugs.

Strategic regulatory guidance

With our help you can navigate the regulatory maze with confidence. Accelerate your study and drug approval with strategic advice from our dedicated team of consultants.

Effortless company and product registration

EMA/OMS, XEVMPD and CTIS registration

Finding it difficult to work with European regulations and systems? The EMA landscape is evolving constantly including the expected updates in the coming years of the SPOR system. Our team is following up on the latest and future requirements and has the certifications to ensure your registrations are compliant with the latest EMA updates.

Rely on us, whether it is for your company registration in OMS your investigational medicinal product registration in XEVMPD / PMS your individual registration in EMA or your registration in CTIS. We will ensure smooth study start and interactions with health authorities.

Full-scope support

Delegate responsibilities confidently. Our skilled team can handle clinical trial applications in CTIS and requests through the IRIS platform – from scientific advice to orphan drug designation.

Streamlined clinical trial submission

Clinical Trial Application (CTA)

Rely on SGS to optimize your CTA process and facilitate individual study submissions in CTIS. Thanks to our consistent compilation of information and study documents and completion of the CTIS system, your submissions will be aligned with authority standards – greatly speeding up approvals.

Study maintenance

Gained approval for your study? We can provide timely updates to the CTIS on the study's status and follow up closely on authorities' requests for information. So potential issues or concerns can be immediately shared, escalated and managed for faster resolutions.

Robust IBs and IMPDs

Our regulatory team creates and reviews Investigator's Brochures (IBs) and Investigational Medicinal Product Dossiers (IMPDs) to meet stringent European standards.

Specialized Health authority interactions

Our experts will be there to guide you every step of the way, from helping you select the appropriate authorities to preparing briefing books.

Scientific advice for accelerated approvals

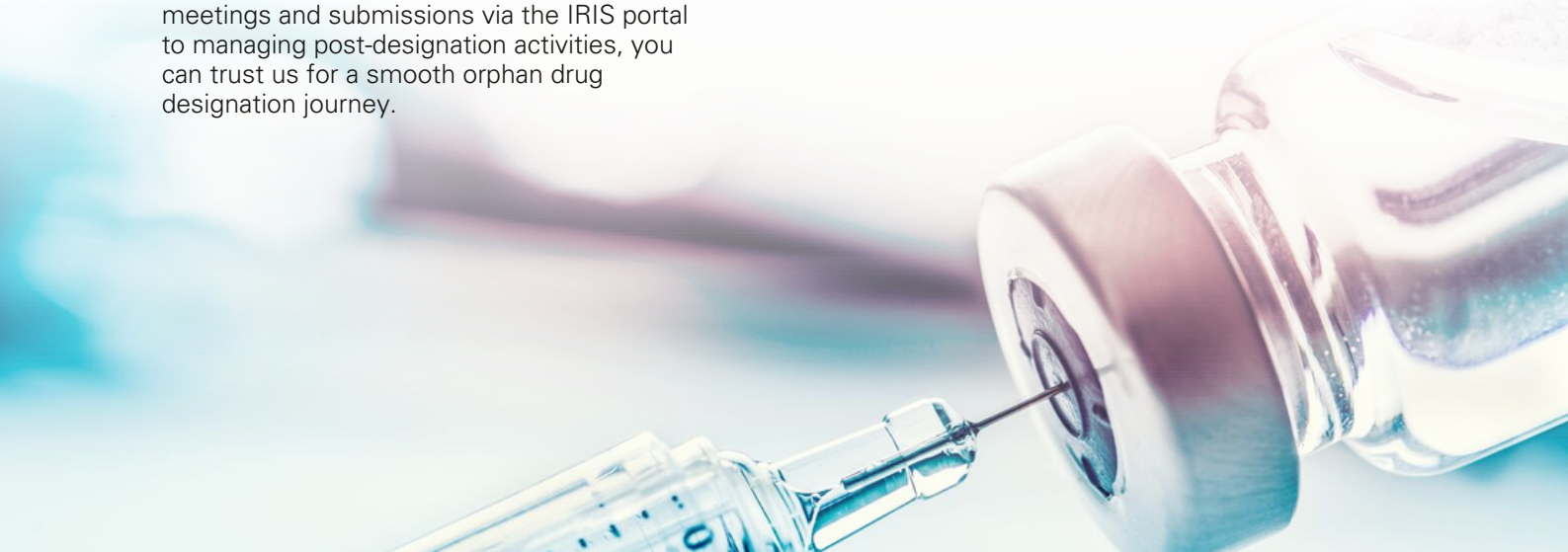
This helps you to make informed decisions and speed up the approval process. We handle submissions via the IRIS portal, participate in scientific advice meetings and work diligently to ensure a conclusive outcome, ultimately fast-tracking your study approval and/ or drug's path to market.

Orphan drug designation made easy

Secure orphan drug designation and its benefits. We can help you gain a competitive edge, so you can enjoy incentives such as 10-year market exclusivity for Investigational Medicinal Products (IMPs) for rare diseases. From pre-submission meetings and submissions via the IRIS portal to managing post-designation activities, you can trust us for a smooth orphan drug designation journey.

PIP excellence

To help you manage pediatric studies effortlessly, we develop initial Pediatric Investigation Plans (PIPs), manage modifications, waivers, and deferrals, and ensure seamless submission via the IRIS portal.



SME office support

Easily access for Small and Medium-sized Enterprises (SME) incentives with help from our experts. We can help you obtain SME status through the electronic declaration form, unlocking fee reductions and protocol assistance.

ATMP classification

For Advanced Therapy Medicinal Products (ATMPs), we guide you through every step of the classification process. We also submit requests and packages for scientific recommendations to EMA's Committee for Advanced Therapies (CAT) on your behalf.

SGS - your partner in European regulatory excellence

Tailored approach

Experience personalized boutique regulatory service with the added strength of a full-service CRO, delivering unmatched support throughout your drug development journey.

Supreme efficiency

Effortlessly navigate EMA's systems and requirements. Our experts help you ensure compliant, accelerate approvals and speed up your market access.

Seamless collaboration

Partner with us to transform complexities into opportunities. We can provide a helpful middle ground between you and the regulatory agencies, simplifying your path to European success.

Health Science

Health Inspired,
Quality Driven.

Contact us

healthscience@sgs.com

sgs.com/healthscience

sgs.com/healthcommunity

WHEN YOU NEED TO BE SURE

SGS

© SGS Société Générale de Surveillance SA. (2023)