



Pharma Services

**INNOVATIVE SOLUTIONS,
EXPERT SUPPORT,
YOUR PARTNER
IN PHARMACEUTICAL SUCCESS**



KS pharma services

Your partner to bring you and your products to the market from A to Z!

KS pharma services is an **independent consultancy office** providing support and advice in **regulatory affairs, quality assurance, vigilance, market access**, for medicinal products, medical devices, food supplements, cosmetics, biocides within the EU.

Our know-how, based on more than **20 years of experience**, guarantees the accurate and timely realization of your projects.

We are committed to deliver **value and quality** through objective and effective customized advice to clients on all matters related to obtaining and maintaining access to market.

We provide **professional expertise** on a remote basis, on site or a combination of both, as desired. We can temporarily fulfil the role of industrial pharmacist-regulatory-quality expert over a predetermined period of time, e.g. in case of temporarily absence of the colleague or an exceptional workload (due to new projects, launch of new product, headcount freeze, etc.). We work together with you to analyse, strategize and implement value added solutions.

Through our EU-**network**, we work with **leading experts** in strategically important fields.



Regulatory
Affairs



Quality
Assurance



Vigilance



Market Access



Software





WHO ARE WE?

- ▶ Katrien Coppens – General Manager
- ▶ ° 17/03/1978
- ▶ Industrial Pharmacist
- ▶ Radiopharmacist
- ▶ RIP - FAMHP Responsible for Information: n° 1007
- ▶ QP - FAMHP Qualified Person: n°2570
- ▶ GDP Responsible Person



WHO ARE WE?

- ▶ Sacha Masson – General Manager
- ▶ ° 06/08/1995
- ▶ Master in Drug Development
- ▶ Industrial Pharmacist
- ▶ RIP - FAMHP Responsible for Information: n° 1122
- ▶ GDP Responsible Person

REGULATORY AFFAIRS



Regulatory affairs encompass a multifaceted field that revolves around the complex network of laws, guidelines, and policies governing the development, manufacturing or distribution of medicinal products, medical devices, food supplements, cosmetics or biocides.

All these regulations exist to **safeguard public health, maintain product quality, and foster innovation while minimizing risks.**

KS pharma services specializes in providing **comprehensive regulatory affairs services tailored to your pharmaceutical endeavors.** Our team of **dedicated experts** possesses an in-depth understanding of global regulatory requirements for each type of pharmaceutical product, ensuring your products meet the highest standards of safety and efficacy whilst being compliant with the local authorities.

Person Responsible for Information: A Belgian Requirement

The pharmaceutical industry is subject to stringent regulations. Transparency and communication play a pivotal role in maintaining public trust and ensuring the responsible use of pharmaceutical products.

As a pharmaceutical company operating in Belgium, it is an obligation to designate a Person Responsible for Information (PRI) who is responsible for ensuring compliance with local requirements related to the dissemination of information and publicity about pharmaceutical products and services.

Although it is not an obligation in other countries to designate a PRI, it is also important in these countries to ensure compliance with local requirements.

We at KS Pharma Services have the **necessary licenses and experience to support you as PRI towards the competent authorities or to support you to ensure compliance.**





QUALITY ASSURANCE

Quality Assurance is the systematic approach to proactively preventing defects and enhancing overall performance by implementing rigorous processes, best practices, and quality standards. At KS Pharma Services, **we specialize in providing comprehensive QA solutions tailored to meet the unique needs of your organization.**

With our extensive experience across diverse types of pharmaceutical organizations, we offer a wide range of services to optimize your company's quality management practices. Our experts meticulously analyse your existing processes, identify potential areas of improvement, and develop customized strategies to enhance quality throughout your operations.

Quality Assurance is not just a function; it's a commitment to upholding the trust of patients, healthcare providers, and regulatory authorities.



Good Manufacturing Practices (GMP) – Qualified Person (QP)

A QP is a legally designated role responsible for certifying that each batch of medicinal product meets the required quality standards before it can be released to the market.

With our team of experienced QPs, we provide comprehensive support throughout the entire product lifecycle. Our QPs work closely with your team to review and assess your quality systems, ensuring they align with current GMP requirements.



Good Distribution Practices (GDP) – Responsible Person (RP)

To ensure the Good Distribution Practices (GDP) of your pharmaceutical activities, you rely on a Responsible Person (RP).

By entrusting us as your RP, you can focus on your core business activities with confidence, knowing that your wholesale distribution operations are in expert hands.





VIGILANCE

Pharmacovigilance

At KS pharma services, we take our responsibility for pharmacovigilance seriously. Our team is at the forefront of these efforts, ensuring that our clients can have confidence in the safety and integrity of their pharmaceutical products.

We can **support you to fulfill the necessary EU and local requirements**. We understand that navigating the complex world of pharmacovigilance can be challenging. Our team of experts includes seasoned **QPPVs** (qualified person for pharmacovigilance – EU) and **LPPVs** (local person for pharmacovigilance) who can guide you through the intricacies of safety monitoring, regulatory compliance, and risk management. We are dedicated to supporting your mission of delivering safe and effective pharmaceutical products to patients worldwide.

Materiovigilance

Proper vigilance back-up system for medical devices

available 24/7.
by phone and email

Cosmetovigilance

Proper vigilance back-up system for cosmetic products

available 24/7.
by phone and email

Nutrivigilance

Proper vigilance back-up system for food supplements

available 24/7.
by phone and email



MARKET ACCESS

KS pharma services is dedicated to empowering pharmaceutical companies to overcome the challenges posed by market access. Our team of seasoned experts possesses a deep understanding of global healthcare systems, regulations, and payer landscapes. We offer comprehensive solutions tailored to your unique needs, including:

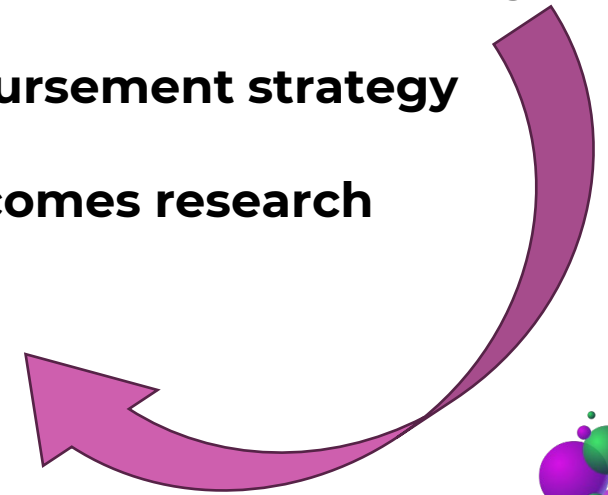
Strategic market access planning

Pricing and reimbursement strategy

Health economics and outcomes research

Stakeholder engagement

Patient access advocacy





SOFTWARE

Electronic Quality Management System (eQMS)

We are thrilled to announce our brand-new **partnership with an eQMS supplier company**, a leading provider of cutting-edge electronic quality management system (eQMS) solutions.

This strategic partnership represents a significant milestone in our commitment to delivering comprehensive and streamlined solutions to our clients in the pharmaceutical sector. Our collaboration empowers us to offer an even more robust suite of QA services that address the evolving needs of the industry.

Electronic Common Technical Document (eCTD)

We assist you in compiling and submitting the necessary documentation, to gain regulatory approval for your medicinal products, medical devices, cosmetics, food supplements and biocides in different regions and markets. We have the necessary softwares available to assemble your dossiers according to the current requirements and guidelines.

Why choose KS Pharma Services?



Our commitment to excellence sets us apart. We pride ourselves on our ability to:

- Provide tailored solutions that address the unique needs of each client.
- Stay up-to-date on the latest regulatory developments to offer proactive guidance.
- Execute the approval process efficiently, saving you time and resources.
- Minimize compliance risks, safeguarding your brand reputation and product integrity.
- Gaining a trusted ally dedicated to enhancing your company's reputation, customer satisfaction, and overall success.
- Ensuring that you can have confidence in the safety and integrity of your pharmaceutical products.
- We can support you to fulfill the necessary EU and local requirements.
- Empowering pharmaceutical companies to overcome the challenges posed by market access.
- We offer comprehensive solutions tailored to your unique needs.

With KS Pharma Services as your partner, you can focus on what you do best – innovating and delivering pharmaceutical solutions that improve lives. Leave it up to us, and together, we'll navigate the intricate path to success in the pharmaceutical industry.



CONTACT

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