



Unifusion_{B.S.C}

THE UNIQUE PARTNERSHIP

Unifusion B.S.C

A leading regulatory consulting companies approved by the Saudi Food and Drug Authority (SFDA), to act as an authorized representative (AR), dealing on behalf of the medical device, IVDs, Cosmetics, Pharmaceutical manufacturers, with its headquarters in Riyadh, Kingdom of Saudi Arabia.

At Unifusion B.S.C, we turn your vision into reality with our regulatory expertise in medical devices, pharmaceuticals, and cosmetics across the MENA region, focusing on Saudi Arabia.

With over a decade of experience and strong regulatory alliances, we ensure compliance and offer training to keep your teams ahead.



Vision

To be one of the leading global providers of innovative regulatory solutions, recognized for our commitment to excellence, integrity, and customer satisfaction.

We envision a future where our services enable businesses to effortlessly navigate regulatory landscapes, driving forward a new era of innovation and growth.


Mission

We efficiently streamline the regulatory journey for businesses worldwide, ensuring products meet stringent standards and regulatory requirements accurately.

As trusted partners, we simplify complex regulatory requirements, mitigate risks, and empower clients to focus on innovation and growth. Beyond compliance, we are committed to excellence, integrity, and client satisfaction, delivering tailored solutions to address specific challenges.

What we offer

Our comprehensive regulatory services ensure that your innovative products meet all required standards, paving the way for market success. Focus on innovation while we handle compliance.



**COMPREHENSIVE
REGULATORY SERVICES**



**STRATEGIC
DISTRIBUTION SOLUTION**



**LOCALIZATION
SUPPORT**



**EXPERT
CONSULTING**



■ Regularity Services



- **Authorized Representative (AR):**
Acting as authorized representative, ensuring products meet the necessary legal and regulatory requirements in Saudi market.
- **Marketing Authorization:**
Obtaining Marketing Authorization, for Medical devices, IVDs and Cosmetics from the SFDA on behalf of the manufacturer.
- **UDI Submission:**
Assisting manufacturers with the submission of Unique Device Identification (UDI).
- **Post-Marketing Support:**
Supporting manufacturers in post-market surveillance and vigilance reporting.

- **Product Classification:**
Submitting product classification with the SFDA.
- **Local Company Registration:**
Helping local companies obtain Medical Device National Registration (MDNR) with the SFDA.
- **Manufacturing Site Registration:**
Assisting in registering the manufacturer's site for a Medical Device Establishment License (MDEL) with the SFDA.
- **ISO 13485 Compliance:**
Achieving and maintaining the highest standards in medical device quality management systems.



Strategic Distribution Solutions

- **Medical Devices and IVDs:**
Delivering innovative medical devices and in vitro diagnostics to healthcare providers around the world.
- **Health Products and Supplements:**
Bringing health-enhancing products to consumers, supporting well-being globally.



- **Cosmetics:**
Distributing beauty and personal care products that meet stringent safety and quality standards.
- **Innovative Products:**
Introducing advanced healthcare innovations to the market, revolutionizing patient care and outcomes. Your focus on innovation will change lives, and we're here to ensure regulatory compliance every step of the way.

Localization Support

- **Local Manufacturing and Tech Transfer Support:**
Facilitating the transition of your products into new markets with local manufacturing and technology transfer expertise.
- **New Product Development:**
Supporting the development of products tailored to the specific needs of local markets, ensuring regulatory compliance and market success.

Expert Consulting Services

- **Registration Strategy:**
Developing comprehensive strategies to streamline the registration process, reducing time to market and ensuring compliance.
- **Market Entry Consulting:**
Expert advice on entering new markets, from regulatory requirements to market positioning.
- **Localization Strategy Consulting:**
Customized strategies to ensure your products thrive in the KSA market. Let us help you adapt and succeed.

From our Partners

In the world of Unifusion B.S.C, every client is a priority. We don't just offer services; we deliver tailor-made solutions that are crafted to fit the precise needs of your business. Our approach is personal, detailed, and centered entirely on helping you achieve your aspirations.




















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At Unifusion B.S.C, we measure our success by your success, and we will stop at nothing to see your business flourish.

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