

The background features a light gray hexagonal pattern. On the left side, there are two large, overlapping geometric shapes: a dark gray triangle and a teal triangle. The Unifusion B.S.C logo is positioned in the top right corner.

# Unifusion<sup>B.S.C</sup>

THE UNIQUE PARTNERSHIP

# COMPANY PROFILE

**EMAIL**

[info@unifusion-bsc.com](mailto:info@unifusion-bsc.com)

**WEBSITE**

[www.unifusion-bsc.com](http://www.unifusion-bsc.com)

**TELEPHONE**

+966 55 769 6888



## ABOUT US:

A leading regulatory consulting firm, certified by the Saudi Food and Drug Authority (SFDA), dedicated to providing comprehensive services as an authorized representative (AR) for various manufacturers.

With our headquarters strategically located in Riyadh, Kingdom of Saudi Arabia, we are specialized in managing regulatory affairs for medical devices, in vitro diagnostics (IVDs), cosmetics, and pharmaceutical products.

Our expertise lies in navigating the complex regulatory landscape, ensuring compliance, and facilitating market entry for manufacturers.



## OUR VISION:

Our goal is to be a top global provider of regulatory solutions, known for our dedication to excellence, integrity, and customer satisfaction. We aim to make it easy for businesses to navigate regulatory requirements, driving innovation and growth.



## OUR VISION:

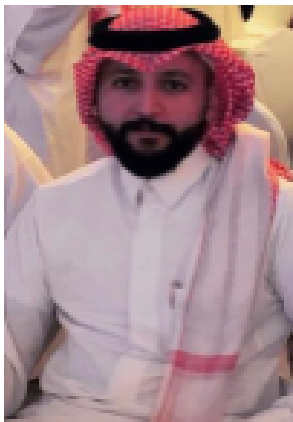
We make sure the regulatory process is handled as efficiently as possible to ensure manufacturers' satisfaction and success. Our dedicated team carefully manages every aspect of regulatory compliance, maintaining high standards throughout. By simplifying complex requirements and mitigating potential risks, we empower manufacturers to concentrate on their key innovations and growth.



# OUR TEAM



## LEAD STAFF

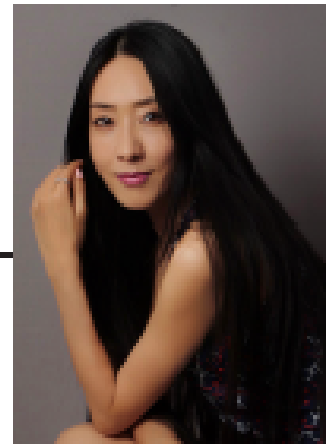


### ABDULRAHMAN ALSAEED

- 15 Years Experience in Medical Regulatory
- ISO 13485 Lead Auditor
- 9 Years MDMA Operation In SFDA.

### SOFIA PANG

- 6 years experience in Saudi medical market
- Supported more than 150 Chinese manufactures entering Saudi

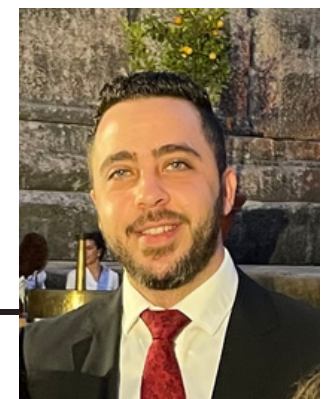


### MOHIDDIN FAROOQUI

- 15 years experience in Medical Regulatory
- Secured more than 350 MDMA approvals

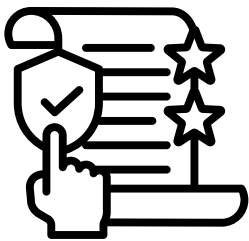
### KARIM KOULI

- 8 years experience in Medical Regulatory
- Secured more than 600 MDMA approvals for more than 200 manufacturers.

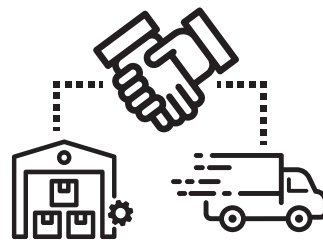




## OUR SERVICES



Comprehensive  
Regulatory Services



Strategic  
Distribution Solutions



Localization Support



Expert Consulting





## COMPREHENSIVE REGULATORY SERVICES:

- **Authorized Representative (AR):**

Acting as authorized representative, ensuring products meet the necessary legal and regulatory requirements in Saudi market.

- **Obtaining Marketing Authorization:**

Facilitating the acquisition of Medical Device Marketing Authorization (MDMA), 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:**

Bringing cutting-edge healthcare innovations to the market, transforming patient care and outcomes.

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## 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 cost and time to market and ensuring compliance.

- **Market Entry Consulting:**

Expert advice on entering new markets, from regulatory requirements to market positioning.

- **Localization Strategy Consulting:**

Tailored strategies to adapt your products for success in diverse global markets

**COMMITMENT, SUCCESS, PARTNERSHIP**





In the world of UniFusion B.S.C, every client is a priority. We don't just offer services; we deliver 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.

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

## FROM OUR CLIENTS

**mindray**<sup>TM</sup>

**SHINVA**

**Autobio**

**COMEN**

**HEALGEN**<sup>®</sup>

**LEPU MEDICAL**

**WEGO**

**heyder**

**Wondfo**

**WOODPECKER**<sup>®</sup>

**INTCO**

**SAIKANG** / Medical



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**WWW.UNIFUSION-BSC.COM**



**INFO@UNIFUSION-BSC.COM**

3RD FLOOR, BUILDING #6217, AL OLAYA STREET, AL OLAYA DISTRICT,  
RIYADH, KINGDOM OF SAUDI ARABIA

