# European Market Entry Consultancy

Facilitating the development & launching of wound care products



# INTRODUCTION

Navigating the European market for wound care products can be daunting due to its complex regulatory, clinical, and commercial requirements. To succeed, you need precise, wound expert guidance. That's where the EWMA Innovation Alliance comes in. Our team, composed of seasoned wound care industry professionals and key opinion leaders (KOLs), offers expertise and assistance in several critical areas.



# PRODUCT DEVELOPMENT AND OPTIMIZATION

# **Product Design and Development:**

- Expertise in European standards.
- · Advice on materials, formulations, performance.
- · Early technology review on market relevance.

# Co-funded Consortia:

· Delivering any of the services mentioned.



# REGULATORY COMPLIANCE

# Regulatory Pathway Analysis:

- · Regulatory requirements in the Europe.
- Classification.
- Contacts to executing regulatory authorities.



#### CLINICAL TRIALS AND RESEARCH

#### Clinical Trial Design:

- · Regulatory requirements.
- Second opinions and GAP analysis.

#### Data Analysis and Reporting:

KOL opinions on Clinical Evaluation Reports.

#### Product Health Economy:

· KOL analysis.

#### Access to Trial Sites, Patients and CRO's:

- Trial site identification and lead investigator contact.
- Locate CROs with specific wounds expertice.



# STRATEGIC PARTNERSHIPS AND FINANCING

# Merger and Acquisition:

Matchmaking with established wound care companies

# Venture and Equity Financing:

- · Matchmaking with investors
- EIA Letter of Support on clinical relevance



#### MARKET ENTRY STRATEGY

# Market Intelligence and Strategy:

- Expert input on Intelligence.
- KOL opinions on clinical relevance.
- · Second opinions on strategy.



#### COMMERCIALIZATION AND MARKET ACCESS

# Reimbursement Strategy:

- Knowledge on reimbursement landscape.
- · Second opinions on reimbursement strategies.

#### Distribution:

· Matchmaking with distributors.

#### Marketing and Promotion:

- Strategies, trade shows, partnerships.
- · Materials and compliance with regulations.



# POST-MARKET SURVEILLANCE AND COMPLIANCE

## **Continuous Improvement:**

Second opinion, post-market clinical follow-up.



# TRAINING AND EDUCATION

#### Staff Training:

- · Regulatory, quality, clinical trials.
- Trends and innovations in wound care.
- Legal ICH investigator training.

# **Customer Education:**

- Educational materials HCPs and patients.
- · Training on product use and benefits.



EWMA is the world's largest wound management association reaching out to more than 100.000 health care professionals globally. EWMA is linking national wound management organisations, individuals and groups with an interest in wound care.

# Read more at www.ewma.org.

EWMA Innovation Alliance connects and supports wound care companies, regional authorities and hospitals, universities, and investors facilitating the development and uptake of new and better wound care solutions.

# Read more at www.ewmainnovationalliance.org



# CONTACT

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