THE PROBLEM

Post-Market Clinical Feedback Service for Wound Care Dressing Companies

Background:

Under the new Medical Devices Regulation (MDR), specifically Annex XIV, Part B, manufacturers are required to implement a Post-Market Surveillance (PMS) system for each medical device. This system must be maintained and updated, with attention to the device's risk class and type.

MDR Guidance:

"Post-Market Clinical Follow-up (PMCF) is a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of Annex XIV. It must be included in the manufacturer's post-market surveillance plan."

— MDR Article 61, Part B, Annex XIV

The Challenge:

In the wound care industry, gathering clinical feedback is notably difficult. Wound care dressings are often sold through complex supply chains, making direct clinician engagement a challenge. Wounds can heal quickly, and by the time feedback is received, it's often because an issue has already arisen. Regulatory and quality assurance teams are frequently alerted only when problems emerge.

Our Solution:

To address these challenges, Med Dev Services (MDS) has partnered with Wound Care People, the wound care industry's leading med-education provider to create Post Market Insights™, a comprehensive Post-Market Clinical Feedback (PMCF) service. This service ensures clients have brand specific Post-market surveillance data to help maintain their compliance with MDR requirements, helping manufacturers meet their obligations related to post-market surveillance and clinical follow-up.

MDS has worked closely with Notified Body auditors to understand their specific audit checkpoints. Our services help wound care device manufacturers proactively gather post-market clinical feedback, ensuring compliance and reducing the risk of audit failures.

Post Market Insights™:

- ➔ Designed specifically to meet the regulatory demands of MDR audits.
- ➔ Helps collect, analyse, and report clinical data for regulatory submissions.
- ➔ Ensures manufacturers are audit-ready and compliant with PMS and PMCF requirements.

THE SOLUTION

Post Market Insight™

Features

- 10 question digital survey
- Combination of open and closed questions to provide both quantitative and qualitative data
- 6 standardised questions to meet the needs of auditors, as verified by current notified body auditors and MDR experts
- 4 Client specific questions to add specific value to each client
- GDPR compliant database of over 135,000 registered healthcare professionals
- 62,000 healthcare professionals who spend more than 50% of their time treating wounds
- Typical response rates exceed 500 completed surveys
- Ability to geographically target surveys to high density areas (e.g. Formulary & contract listings)
- Clearly presented reports ideal for audit assessment

Advantages

- Fast response, surveys open between 24-72 hours
- Option of an express service to fast-track your survey if deadlines are looming
- Proactive plan provides peace of mind in a market where feedback can be minimal

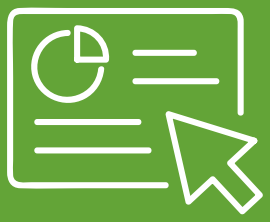
Benefits

- Access to Clinician Insights: Through WCP's vast clinician network, clients will gain invaluable, real-world feedback from users of their products.
- Regulatory Compliance; Post Market Insights will assist manufacturers with their MDR compliance providing high quality feedback for audit reviews.
- Analysis of the data will deliver actionable outcomes beyond the regulatory team, PMI Provides strategic insight into product issues and can steer new product development.

Our Process

INITIAL SCOPING:

MDS will consult with the client to understand their specific research objectives and scope the PMCF study accordingly.



SURVEY DEPLOYMENT:

WCP will utilise its established network of healthcare professionals to conduct surveys via Survey Monkey to opted-in relevant healthcare professionals

DATA ANALYSIS & INSIGHTS:

MDS will analyse the collected data and produce a comprehensive report, including actionable insights. These insights will be presented to the client in a workshop or presentation format.

Our credentials

Who we are....

MDS and WCP are collaborating to provide a highly effective PMCF service to medical device manufacturers. By combining WCP's extensive clinician network with MDS's expertise in product management and data analysis, we can deliver high-quality, actionable insights that meet the evolving needs of the medical device industry.

Med Dev Services

MDS is an independent consultancy with over 30 years experience in the wound care sector, much of that time spent managing wound care brands for some of the biggest names in the industry. We understand the challenges that organisations face in generating quality post market clinical feedback and we can work with each client to get the most out of every survey.

Wound Care People

Wound Care People are one of the UKs leading nursing publishing houses with titles such as the Journal of Community Nursing, Journal of General Practice Nursing, Wound Care Today and more. WCP have a vast digital audience of over 135,000 GDPR compliant highly engaged HCP subscribers as well as an unrivalled social media network and reach.

The ability to reach your desired audience demographic through geo-targeting, job function, areas of interest and more means a guarantee that you get the data and responses that you require from the correct people the first time.

Contact details

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References

MDR : Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices
Guidance document Medical devices – Market surveillance – Post Market Clinical Follow-up studies – MEDDEV 2.12/2 rev.2
MDCG 2020-13 Clinical evaluation assessment report template
ISO 14155:2020 – Clinical investigation of medical devices for human subjects – Good clinical practice
ICH guideline E6 on good clinical practice