CITEMED

Building Your PMS Template for MDR

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Your PMS Template

The intention of this document is to cover a comprehensive framework for each of your individual products. Use it as a guide to direct your staff in the various parts of Post Market Surveillance for MDR compliance.

It is impossible to simply 'template' the entirety that is Post Market Surveillance, however in the reactive forms (PMCF, PSURs) we can help guide you to create reusable documents that are specific to your product lines.

Overview of the Regulation

MDR poses additional burdens of regulation on manufacturers in both time and resources. The most prominent of these being the Periodic Safety Update Report which is intertwined with the development of an appropriate Post Market Clinical Follow-up plan.

Demonstrating Competency

When discussing the details of specific regulations, it can be easy to get lost in the specifics of addressing the requirements with appropriate actions. The MDR has several very clear gaps in the interpretation of explicit instructions.

It's important to remember that the regulations are meant to be a guide and not a black and white work instruction (though many would argue it would help). In addition, a lot of interpretation is left up to the Notified Bodies to set the standards. However, despite the inherent flexibility, we need to always keep in mind the essence of such regulations. The EU MDR is just another important step towards ensuring manufacturers have greater oversight in all aspects of their product life-cycle, which needs to include safety awareness both within the manufacturing process and the end-user market effects.

At CiteMed we urge you to read the following document with the conscious intention of adhering to the regulation in doing the best possible job to keep your products safe in the hands of their users. Complying with EU MDR and reducing issues with Regulators and Notified Bodies will not be a matter of simply executing the bullet points below, but instead a matter of demonstrating responsibility as a manufacturer for the safety of your products.

How This Document Is Organized

Reactive Post Market Surveillance within MDR is broken down into several main categories. In this document we will go through each section, it's requirements, and our recommended means of implementation for the manufacturer.

EU MDR Post Market Surveillance

- Periodic Safety Update Reports
- Post Market Clinical Follow-Up
- How to Tackle PSURs

PSURs
Periodic Safety Update Reports

How to Tackle PSURs

The safety update reports outlined in the MDR are loosely defined and still slightly ambiguous to many interpreters of the regulation. However PSURs are standard in the Pharmaceutical Industry and we have drawn off extensive Pharma regulatory experience in order to bridge appropriate, and comprehensive templates.

One matter of discussion with our clients will be the status of their current documentation and compliance or gap analysis. During this process, any non-compliance with the MDR for their current products can lead to a remediation plan to demonstrate a good-faith effort to reclaim the lack of proper oversight. A realistic Post Market Clinical Followup plan will have to be created and submitted. It is this plan that will further allow our clients to define the exact structure/contents and cost of future PSURs activities.

It should also be noted that these types of clients typically have a team in place able to provide statistics and trending data on the number/severity of incident reports on their product lines. This will be an important point for any commitment of future oversight.

Specific Requirements

The following 3 categories mentioned in the PSUR must include data/findings referencing.

The Benefit-Risk Determination (Introspective Inspection)

The benefit-risk determination should be familiar as it is part of both your CER and Literature Search activities. We recommend using the same decision framework for creating your product Benefit-Risk conclusions including citing relevant (timely) clinical research from an updated Literature Search. *Literature Searches are discussed later on in this document.*

Findings from the PMCF

Concluding remarks and any relevant data obtained from your Post Market Clinical Follow-Up activities require summation and interpretation. *The details of the PMCF can be found in the following section.*

Volume of device sales, categorization of device users, frequency data (if applicable)

Summaries of your device usage in the market currently need to be accurately portrayed from marketing statistics. We recommend incorporating charts to track usage/ population over time as well as raw sales data.

PSUR Document Template

CiteMed's proposed PSUR template comprises the following detailed sections. This outline was derived from the requirements set forth in MDR 2017/745 as well as standard accepted practices in the Pharmacovigilance industry where PSURs are common practice.

Section	Description
Metadata Information	**Documents, product specifications, and versioning.**
Plan Implementation	**Consensus of PMCF plan and approach.**
Relevant Product Data	**Sales numbers, uses, population estimates.**
Overview of Data	**Summary of data including adverse events, recalls.**
Conclusions	**Statistically supported results; data and trend analyses.**
Actions Taken	**Overview of any actions taken by the Manufacturer.**
Benefit-Risk Update	**Updated based on revised information**
Conclusion	**Written summaries and concluding remarks**

Frequency of Updates

MDR cites specific requirements when it comes to the updating of your product PSUR. The following table outlines intervals referenced in article 86.

Device Classification	Frequency of PSUR Update
Metadata Information	**Documents, product specifications, and versioning.**
Plan Implementation	**Consensus of PMCF plan and approach.**
Relevant Product Data	**Sales numbers, uses, population estimates.**

PMCF
Post Market Clinical Followup

In the MDR, PMCF is defined as a set of processes a manufacturer implements in order to actively collect and evaluate clinical data in a meaningful way.

These processes can vary significantly by manufacturer and products making more explicit MDR requirements not feasible.

The following plan is based on an interpretation of the new MDR, which incorporates the “best practice” experience from MEDDEV 2.7.1 guidance documents on Clinical Evaluation. We feel strongly that your PMCF plan should contain not only realistic intentions of due diligence but provide robust and consistent processes that demonstrate a strong commitment to safety vigilance.

Building Your PMCF Template

For those attempting to build PMCF reports on their own, we recommend a similar format to those described in MEDDEV 2.7.1 for Literature Reviews. Capturing some of these initial sections can be used to highlight “new” information, impacts and benefit-risk conclusions.

Following this approach, some sections in your PMCF could be laid out in the following manner.

Search Protocol and Discussion

Clearly state your methodology of search and why it was chosen.

- Discuss specifics of search terms, databases, search method
- Provide and overview of the results (catalog and count every article)

Additional Changes and Justifications to Search Protocol

If any new information leads to changes in the search method/approach from your original CER Literature Review, it would be prudent to make reference to those changes and provide justifications.

Your Literature Review

Your team should already have an MDR compliant Literature Review process that is fully replicable. We recommend copying this process exactly for your updated Literature Review component.

Note If you do not have a Literature Review process or are uncertain of the level of quality required of your current documents, contact us at CiteMed today. We provide a standardized, modular Literature Review structure that could be utilized across all required documents including existing PMCF reports and CERs. We also have the capability to design Client specific structures to suit individual product needs.

Conclusions of Benefit-Risk and Comments on Updated Market Conditions

This section should be a rational summary that ties all the information together which has already been discussed in detail in your Literature Review Section. We recommend that you provide the following.

- Careful analysis of 'Current Events' that relate to your product
- If such events alter the overall benefit-risk, make that known.
- Conclusive remarks on the results of the Literature Search
- Were the results expected, why or why not?
- If any new or unique information surfaces during the PMCF, include plans to closely monitor the situation and describe how future projections may be influenced in terms of Safety Incidents etc.

Why Literature Searches Remain the “Primary Component” of Post Market Clinical Follow-up

Literature searches are by far the only, most comprehensive way to review the state of any product and it’s safety record in the market. By analyzing all published, relevant research (that have occurred since the previous filing) a manufacturer can satisfy its due diligence to manage the products continued safe and effective use. Over time this yields a robust process that will identify any potential indicators that may impact user saftey/efficacy and respond accordingly.

The issue as it stands today is that a proper “Literature Search”, outside of the CiteMed model is labor intensive, staff and cost prohibitive, and restricted by the number of products that can be managed simultaneously. Quite often these activities cannot achieve established timelines and overwhelm the hardworking, dedicated teams responsible for generating these reports (repeatedly) for large numbers of products.

This is why we recommend exploring exactly how using CiteMed technology can not only guarantee uniformity and consistency of these searches and reports, but can help clients achieve regulatory compliance for all its products in a timeframe that keeps them competitive in the world market.

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