5 Steps to Improving Pharmacovigilance System Master File (PSMF) Management

Christian Schmitz-Moormann, a senior consultant and pharmacovigilance (PV) expert, and partner of Generis, considers the role of this essential master resource in maximising opportunities to improve R&D processes and wider product lifecycle management.

Large pharmaceutical companies are often restricted by a lack of ability to exchange information and access data from other departments. Prompted by regulatory changes, they have largely transformed marketing authorisation (eCTD) submissions and pharmacovigilance (PV) reporting, so now the attention is turning to the management of the Pharmacovigilance System Master File (PSMF). That's because of its bearing on so many other aspects of research and development, wider product lifecycle management, and associated information management and reporting.

The PSMF is a core document describing the pharmacovigilance system used by the marketing authorisation holder (MAH) with respect to one or more authorised medicinal products. Bringing its management and data exchange capabilities up to scratch digitally makes sense now, given that its contents are so comprehensive and wide-reaching.

A Vital Master Resource

The PSMF's numerous sections and appendix require information and input from areas across the Quality, Safety, and Regulatory domains. Despite this, many organisations still use manual processes and tools such as Microsoft Word or Excel to maintain and track the master file. As well as exposing companies to non-compliance, inefficiency and delays, a manually-maintained PSMF limits visibility and transparency: characteristics which, if addressed, could be invaluable right across the business.

Part of the challenge around PSMF management is that so many different people are involved in providing contributory information. The file needs to be handy at all times, too – in a single, definitive location, and suppliable to an authority in the defined structure (also printable, or in an acceptable electronic format) within one week of a request being made, in the EU at least.

Although companies do have the option to lean on an external service provider to maintain and update the PSMF, the price tag for this can be hefty – running into the low six-digit range in the case of a very large pharma organisation with a great number of products, for each fresh version that is needed (not including the annual maintenance cost).

The alternative approach is to 'divide and conquer', allowing approved, live information to be pulled from individual, relevant departmental systems, and extracted and put together to form a comprehensive and accurate PSMF. This can be achieved with by integrating a PSMF management capability with existing functional systems across the pharma organisation, or by implementing a single open platform where all of the master information resides, already supporting any necessary integration and formatting standards.

Transforming Manufacturing Change Control

The impact of more fluid data interchange between systems, drawing on a common information core, would be widely felt.

Take the example of manufacturing and packaging, and the need to ensure that patient information leaflets reflect the current Summary of Product Characteristic (SmPC) – which outlines important information about medicines such as form, clinical parameters and pharmacological properties – plus the correct latest version of artwork. Ensuring that all of this up-to-date detail is reflected in the PSMF is crucial for all manufacturers. If teams have to trawl through 20 different SAP systems to find the correct batch information for products made across the world, this process could take up to 18 months and still be at risk of error or omission. Improved integration and data exchange between systems, supported by a common platform, can alleviate much of that time and effort.

Processes such as change control and deviation management also become much easier to manage once variations and deviations can simply be tagged for automatic inclusion in PSMF, as appropriate.

Enabling Seamless Data Sharing

Beyond compliance, the benefits of more dynamic PSMF creation and management, via shared and connected data, are to do with improved collaboration and communication across a national or international business group, keeping all teams singing from the same hymn sheet.

The better the state of the PSMF, the more powerful the lever to improve business processes. Strategically, that could include identification of PV risks or using the PSMF as a complete planning and tracking tool for the company's approach to PV.

This consistent rigour can help smooth PV compliance in other regions, too – even if the authorities concerned don't (yet) have a specific requirement for a PSMF. In the US, for instance, although the FDA doesn't demand a detailed PV master file, the authority can ask for evidence of the robustness of a company's PV provisions. Having standardised documentation on tap globally can be very reassuring here.

A standardised approach to PSMF management could also support new cooperation between companies to enhance pharmacovigilance and associated learning for the benefit of all.

Lessons from the Leading Edge: 5 Tips to Maximising PSMF Management

With all of this in mind, here are five specific ways a unified platform for Life Sciences processes can ease the management of the PSMF, with knock-on benefits across and beyond the enterprise:

1. Version Certainty

Using manual processes to collaborate and contribute to PSMF makes it difficult to maintain a single source of truth and know which version is current. With real-time collaboration and version control, you can be certain that you are working on the most up-to-date version, and any changes made are tracked on the master copy. Version control not only allows you to see what the correct version was at any point in the document

lifecycle, but also revert to previous versions when needed, and provides the ability to quickly pull up the most up-to-date version for audits, inspections, and regulatory submissions.

2. Granularity in Documentation Presentation & Access

The PSMF as a process does not operate in a vacuum, and often the supporting information is needed elsewhere in the company – for periodic safety update reports (PSURs), or a PSMF for another product for example.

With a data-first platform, the content of the PSMF can be separated into compartments, allowing for the flexibility of multiple data owners. Users can extract individual compartments from the PSMF for use as standalone documents, or for use in other items in the product development lifecycle, the compartments can either be presented as a "PSMF document view" or any other view, individually or in groups, giving the flexibility to use the same single data elements in multiple document views.

Simple tagging, searching, and filtering make it easy to retrieve content from the PSMF as a whole without wasting time going through folders file by file.

3. Risk Tracking

Risk management plans and associated documents need to be created and distributed to Affiliates, Distributors and Authorities. Traditionally those tools involve external systems for sharing content and a separate system for registering and reporting on implementation status. This can leave companies exposed to non-compliance if the process is not managed properly.

A platform designed specifically for pharma companies is likely to have security and compliance at its core, allowing for controlled access and granular user permissions. This means that users can only access the information or key parts of the PSMF that they need to do their work.

4. 'Submit & Go'

A single, centralised system can also help streamline the organisation and submission of the eCTD, during marketing authorisation applications.

Metadata makes it easy to create and pull together all the required components of the eCTD, such as the PSMF summary, with the ability to add cover pages and other finishing touches ready to submit to regulatory

authorities. Storing the information as components means that dossiers and submissions can be easily assembled and re-assembled as per the requirements of different regulatory authorities. Automations can ensure that submissions are not open to human error and reduce the stress of the risk of non-compliance.

5. 360-degree Oversight

Last but not least, a data-driven platform should provide a clear, 360-degree view of an entire organisation's content and information, and the relationships between them. With a single, structured information 'lake' that all linked apps can draw on, features such as 'where used' will make traceability and impact analysis simple.

With metadata relationships between different objects, it becomes easy to see where a change to one content item would impact items like the PSMF further down the line, for instance – all at the click of a button. Users should be able to easily access reporting and dashboards so that they can clearly visualise their processes.

By overcoming the technological, operational and financial drawbacks of a network of individual systems, via an open platform, the different functions of the pharma organisation can consolidate processes, data and content and harness their choice of apps for Regulatory, Quality, Safety and Clinical operations.

Meanwhile respective users can create, locate, and re-use information instantly in any process across the organisation drawing on a single, structured master data/information/content resource, enabling accelerated work with greater accuracy of information.

It's no coincidence that Life Sciences companies are moving towards PSMF transformation now. Taking what they've learned from eCTD and PV system optimisation, many see this as the next logical step in their digital process transformation efforts.

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