



## IS IGNORING PSMF AUTOMATION A BLISS? – A RELEVANCE PERSPECTIVE

## Background:

Pharmacovigilance System Master File (PSMF) is a document that contains detailed description of a Marketing Authorization Holder's (MAH) pharmacovigilance System<sup>1</sup>. A recent MHRA's Pharmacovigilance Inspection Report of Apr-19 – Mar-20 highlighted 34% of the total Quality Management System

(QMS) findings were on PSMF management of which 82% findings were major<sup>2</sup>.

Implications of non-compliance to PSMF management is manifold from regulatory warnings to penalties as needed and most important it might damage the reputation of MAH. With higher QMS findings, can

a robust technical solution address and minimize the findings? Infosys believes that the need of the hour to address major quality findings is process simplification with technology-based robust solution rather than following a conventional method of manual data collection and segregation.

## Inevitability and Significance of PSMF

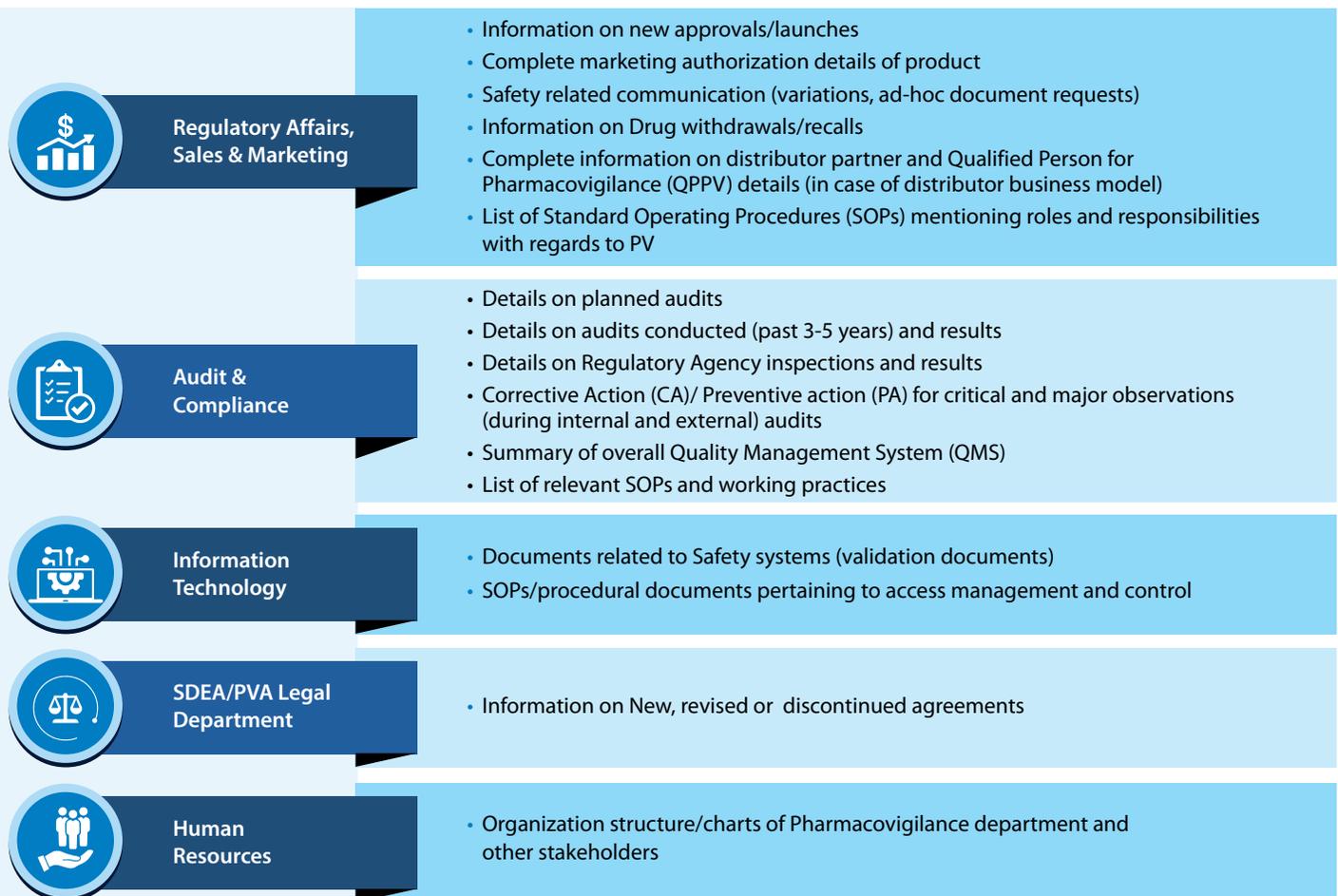
PSMF should be permanently available at MAH location for inspection and should be provided within 7 days to the Competent Authorities if requested. Certain processes where PSMF submission is mandatory are outlined below;

- New Registrations
- License Renewals
- Regulatory agency requests

PSMF can be of significance to both Regulatory Agency and MAH to understand the current PhV system and ways to improve it to achieve Quality, Compliance, and Transparency.

## Key Stakeholders and Data Collection:

PSMF not only contains data pertaining to Pharmacovigilance but also other allied departments. Below are some of the departments and information collected from them.



It is evident from the above depiction that how complex and tedious the task of coordination, compilation and/or segregation of data from these stakeholders.

## Current Industry Practices:

MAH do follow certain practices to avoid repetitive work and to minimize the overall time of data collection and segregation, which help them to a great extent. Few such practices are mentioned below.

- Common Global PSMF (Single main body of PSMF with regions-specific annexes)
- Use of Share-point or Document management systems
- Outsourcing of QPPV and related activities

## Leveraging Automation in Drafting and Maintaining PSMF:

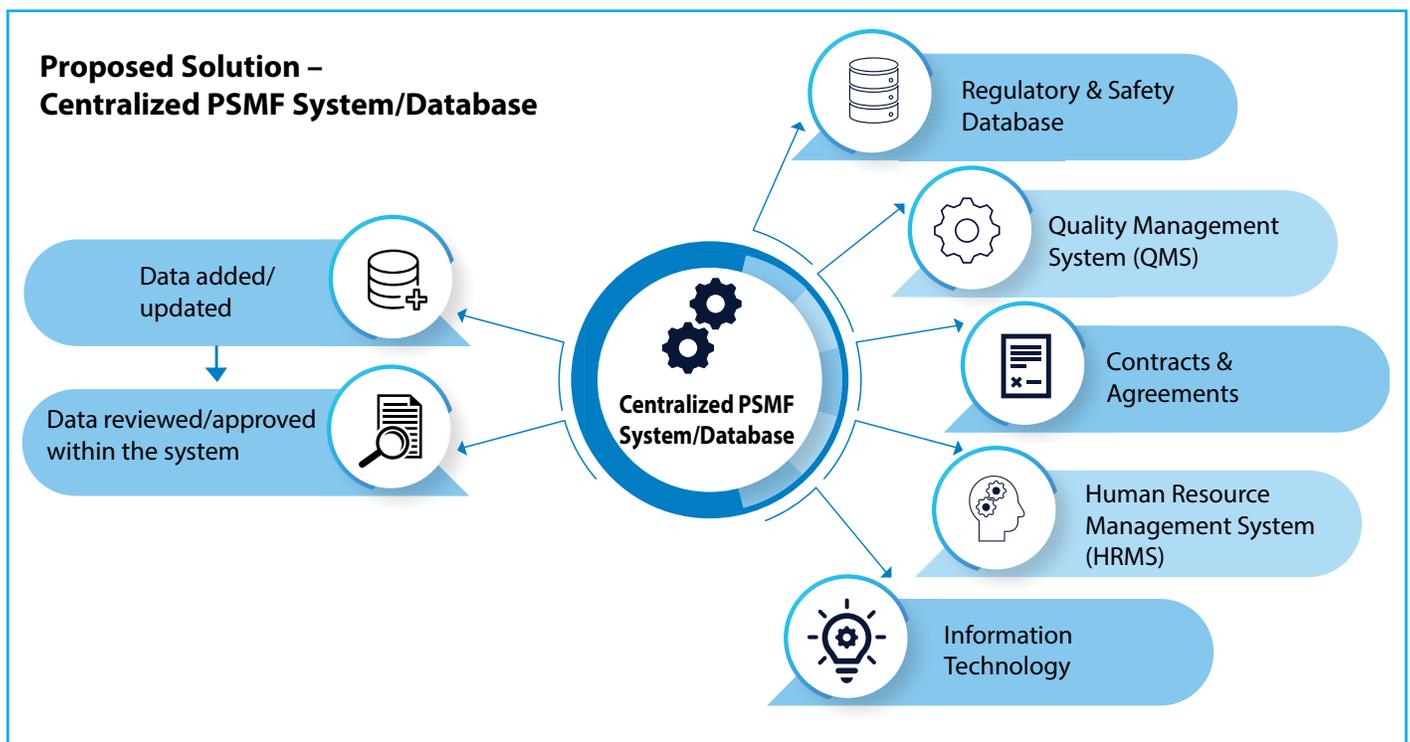
While activities such as ICSRs, aggregate reports, Signal management have gathered momentum from process simplification and automation, PSMF simplification and automation continues to be ignored and the reason would be gathering and segregation of complex data from multiple stakeholders on timely manner. Hence, a robust technical solution which can automate drafting and maintaining PSMF is an industry need.

**Framework 1:** A fully automated central database integrated with other allied department database:

1. Integration between the systems used by various departments with central database e.g. PhV database, regulatory database, etc.
2. This database will communicate with other systems using ETL (Extract, Transform and Load) process which will

help in flowing the data in continuous manner and allow proper versioning and better control.

3. E-mail notifications that can have direct impact on PSMF e.g. product approval/ withdrawal mails can be directed in the database (by having a dedicated mailbox within the database)
4. In-built templates for main body and annexes of PSMF for easy printing



Design Simulation of Centralized PSMF database

**Framework 2:** A central database with relevant tabs as per sections of PSMF embedded with template

1. No need to gather or segregate information from different stakeholders, rather other stakeholders will add/modify data related to their division
2. Access restrictions making sure that one department cannot access/modify other department's data
3. Availability of readymade templates. While printing main body or annexes of PSMF relevant data can be retrieved automatically.

## Key Benefits of Utilizing Central PSMF Database:

It is evident that investing in centralizing and automating PSMF management is beneficial to the functions which are managing multiple PSMFs at the same time. Such database will help not only to MAH which manages PSMF in-house but also for the vendors who provide these services to multiple MAHs. This will help PhV team to keep PSMF up to date and submit to auditors or regulatory inspectors without any delay.

## Centralized PSMF systems/database - Key Benefits

 Regulatory system requirements	 Integration	 Real-time Quick update	 Attachments & Output
<ul style="list-style-type: none"> <li>• Validation as per regulatory requirements</li> <li>• Audit trail</li> <li>• Access controlled</li> </ul>	<ul style="list-style-type: none"> <li>• Integration with other department database/system</li> <li>• Any update in other department database/system will be triggered as notification in PSMF database</li> <li>• Reduces human intervention and tracking</li> </ul>	<ul style="list-style-type: none"> <li>• No need to invest time on updating non-relevant data</li> <li>• Pre-defined (can be customized) templates for each section and annexes</li> <li>• Add/update only relevant data</li> <li>• In-built review and approval</li> </ul>	<ul style="list-style-type: none"> <li>• Various types of documents in word/excel can be attached</li> <li>• Chronology set-up of different sections</li> </ul>

## Conclusion

Even though MAHs have taken efforts to maintain PSMF by introducing concept of common PSMF, utilization of SharePoint or Document management systems and outsourcing PSMF management related activities, it's still an area where regulatory agencies find major deficiencies. This is because most of the activities associated with PSMF management are manual, there is a lack of data centralization and orchestration. To mitigate these challenges, MAHs should utilize data and process simplification followed by data centralization with robust automation to gain quality and compliance.

The adoption of technology will clearly outweigh the benefits of asynchronous manual methods. However, it is an

area which hasn't received the strategic attention from relevant functions and a topic of careful deliberation.



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## Sources

- 1 [Article 8\(3\) \(ia\) of Directive 2001/83/EC](#)
- 2 [MHRA GPvP Inspection metrics 2019-20 \(publishing.service.gov.uk\)](#)

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