4 things to think about when preparing a Pharmacovigilance System Master File (PSMF) for a product in the EU

1. Plan ahead

When you are busy preparing your first marketing authorisation application (MAA) it is easy to leave the PSMF until later. The PSMF does not form part of the MAA, however it is expected that the PSMF document and the system behind it are established when the initial MAA is submitted.

2. Start early

Don’t underestimate how long you need to complete a PSMF. It is a complex, lengthy document which should provide a comprehensive description of the pharmacovigilance system for a marketing authorisation holder (MAH). It takes time to prepare, even if you have the luxury of a dedicated author start well ahead of your target submission date.

3. Be concise but comprehensive

A PSMF should be concise but needs to provide a full description of how each activity is performed, not just references to relevant standard operating procedures (SOPs). The scope should be global, even though it is an EU requirement. Remember that a PSMF is sometimes referred to as a ‘Potential Source of Major Findings’.

Common issues noted in inspections include:
- Insufficient detail e.g. ‘sources of safety data’, limited to EU only
- Lack of detail on how audits are planned
- Restriction of data regarding clinical trials or patient support programmes to those in the EU only
- Insufficient information about contractors and/or partners
- No inclusion of open critical or major audit findings in the body of the document.

4. Keep up to date

A PSMF cannot be written and then filed away. Regulatory authorities can request to view a PSMF at any time, with only seven days of notice. Inspectors and auditors will want to refer to the PSMF and will audit you against its contents. Keeping your document, including all annexes up to date is therefore crucial. The PSMF will also act as a current and accurate source of information for the EU QPPV.

And finally … Remember that you need procedures to describe how your PSMF is produced and maintained.