Roche Pharmaceuticals – Globalisation of the Pharmacovigilance System Master File (PSMF) Process

Louise Woodward, Roche Products Ltd, Welwyn Garden City UK - on behalf of the Local PSMF Project Team

With thanks to Erica Lye, Radoslaw Rysiewski, Amit Chourey, Zoe Conway, Maria Artolazabal and Helen Emery for review and preparation of material.

Introduction

A project, encompassing stakeholders from Business and IT, was initiated to enable compliant, consistent, efficient and cost-effective creation and maintenance of country/region specific PSMFs or Pharmacovigilance Sub-System Files (PSSF) to meet growing global requirements.

Objectives:

- Enable production of multiple country PSMF/PSSFs by adapting the existing EU PSMF collation process, using the same format and shared (global) PSMF components.
- Build on the existing processes for automated PSMF Annex generation, via the IT Tool “PSMF Generator” (original poster by Cloke et al, DIA Eurometing 2016), by adapting its connections to source systems to produce Annexes aligned to the existing EU PSMF format and content, but which fulfil legislation of other countries.
- Enable automated production of local PV metrics via the PV COMET tool
- Ability to rapidly translate new PSMF content, as required, in specific countries.

Development

A detailed review of global PV legislation was initially undertaken to determine suitability and feasibility for globalisation.

Concept:

- “Master” (global) data, taken from that provided for the EU PSMF Core Sections 2-7 and some EU PSMF annexes, which is applicable to the global PV system.
- Master data from source systems feeding into the PSMF Generator tool that is then filtered automatically to provide local annex information.
- Specific local (country/region) data (eg. QPPV details, local organisation details, local procedure details, metrics via PV COMET tool)

Figure 1. PSMF PRODUCTION

Figure 2. THE PSMF GENERATOR

Following review and sign-off, the tool allows automatic creation of locally relevant annexes by affiliates with a single click. The tool can be quickly and easily configured to:

- add a new country PSMF
- add/remove annexes to a country PSMF
- amend annex filtering to produce data filtered by country or product

To date the production of all suitable PSMF annexes has been automated and the ability to produce an automatic “history of changes” added. Changes to source systems and data may make additional annexes suitable for automation in the future

Results

Templates, based on the EU PSMF format, were created for both PSMF and PSSFs made available to affiliates. Master (global) data is created/updated according to a periodic schedule, aligned with the EU process.

- Manually produced Master data is made available to affiliates via a workspace.
- The PSMF Generator tool provides local annex data from Master data at the touch of a button.
- Local PV Comet provides local PV metric data.
- Additional local data required is collated by affiliates and added to the local PSMF/PSSF.

The estimated reduction in workload across the company with this approach is approximately 6.5FTE across the global functions and affiliates.

Conclusions

Regulatory requirements for PSMF/PSSF documents vary in their complexity globally. To meet the different requirements of global regulatory authorities, as well as the needs of Roche affiliates we created a single, scalable and efficient process for the production of quality PSMFs within Roche that:

- Enables automated production of complex data sets and ensures Roche can adapt quickly to new local regulations.
- Empowers affiliates to create local PSMF/PSSF documents according to local requirements, selecting only those elements that are needed per local legislation.
- Reduces time and effort taken to create local PSMF/PSSFs by the use of global elements already produced for the EU PSMF.
- Significantly reduces time and effort in producing complex local listings by the use of the PSMF Generator tool
- Provides a global standard for production of PSMF/PSSF documents