FORUM

Medical Writing in Drug Safety

Update your PV writing skills

Dr Tiziana von Bruchhausen

Dear Reader

We are pleased that you are interested in our whitepaper and in enhancing your pharmacovigilance (PV) writing skills. In the following, you will find a concise overview of key pharmacovigilance safety documents, such as Development Safety Update Reports (DSUR), Periodic Safety Update Reports (PSUR), and Risk Management Plans (RMP).

These insights are designed to provide you with a clear understanding of these critical documents and give you a taste of our online training course, led by Dr Tiziana von Bruchhausen.

We hope you find this whitepaper informative and enjoyable.

About the author

Dr Tiziana von Bruchhausen
Principal Pharmacovigilance Writer, Boehringer Ingelheim International, Ingelheim, Germany

Dr Tiziana von Bruchhausen began her career in pharmacovigilance in 2008. Over the years, she has worked as a pharmacovigilance writer for mid-sized and large pharmaceutical companies, held various roles in contract research organisations, and worked as a freelance safety writer.

Currently serving as Principal Pharmacovigilance Writer at Boehringer Ingelheim, her responsibilities encompass both pre- and post-submission activities. These include global strategic planning and the preparation of key PV documents such as RMPs, PSURs, or DSURs.

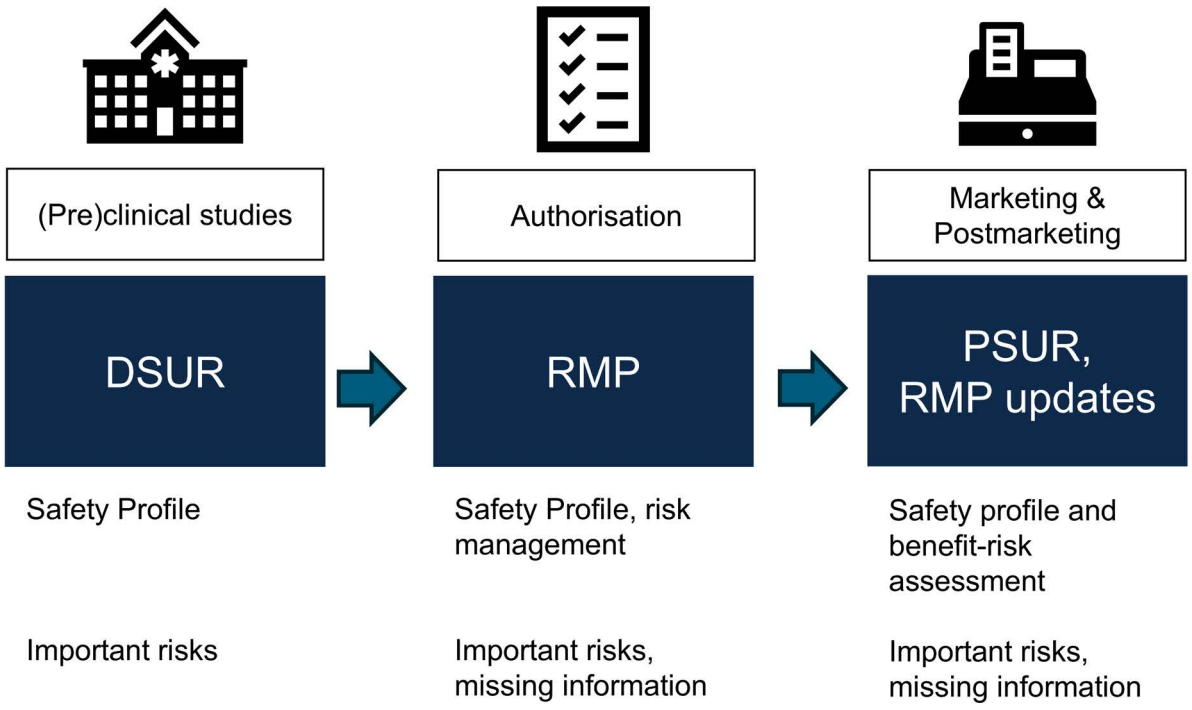
Dr von Bruchhausen is also an active member of the European Medical Writers Association (EMWA). Since 2017, she has chaired the Pharmacovigilance Special Interest Group Committee. Additionally, she served as EMWA's President elect from 2017 to 2019.

Medical Writing in Pharmacovigilance

The core principles of medical writing also apply to pharmacovigilance documents. A systematic and professional approach is critical to producing clear, accurate, and compliant safety documentation. Below is a checklist that can significantly reduce errors and improve the quality of PV documents:

- **Expert knowledge** of pharmacovigilance processes and requirements
- **Clear data presentation** using tables where possible for readability
- **Accuracy and consistency** across sections, modules, and documents
- **Avoidance of redundancy**
- **Appropriate language and style** for the intended audience
- **High-quality documentation** that meets regulatory standards
- **Effective management of timelines** to ensure deadlines are met

These success factors are essential for creating Development Safety Update Reports (DSUR), Risk Management Plans (RMP), and Periodic Safety Update Reports (PSUR), which are required throughout a product‘s lifecycle. These key pharmacovigilance documents are needed from the development stage through to post-marketing. DSUR focuses on monitoring safety during development, RMP outlines the plan to manage of risk, and PSUR evaluates the product’s benefit-risk balance in the post-approval phase. A critical aspect is meeting the growing regulatory demands, from the initial characterisation of the safety profile to the benefit-risk assessment at the time of application for marketing authorisation and in post-marketing phase. This ultimately determines the marketability of medicinal products.



Key Pharmacovigilance Documents

Development Safety Update Report (DSUR)

The DSUR is required annually during the development phase of a medicinal product and focuses on safety monitoring. Its key purpose is to analyse safety data gathered during clinical trials and provide updates on the safety profile, including newly identified risks that could impact patient safety. The DSUR includes:

- Monitoring and reviewing the product's safety profile
- Reporting regulatory actions and changes to the investigator's brochure due to safety reasons
- Defining for the first time the important risks of a medicinal product
- Benefit-risk considerations during the development phase

Risk Management Plan (RMP)

The RMP is a dynamic document that is regularly updated throughout the lifecycle of a medicinal product. It is used for risk planning and focuses on identifying, characterising, and minimising risks. Key elements of the RMP include:

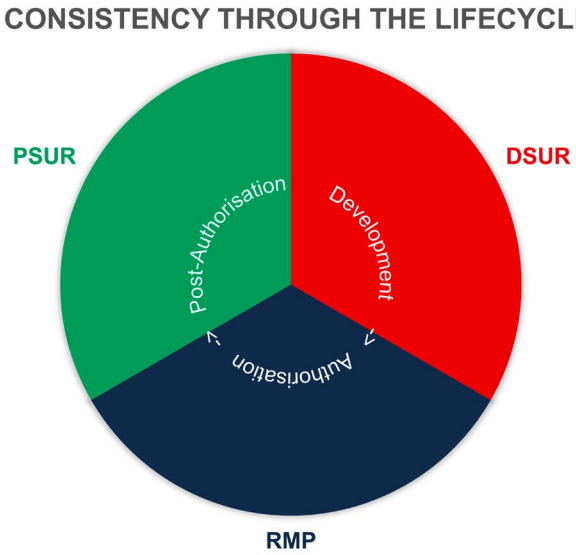
- The characterisation of the safety profile of a medicine (safety concerns)
- How risks will be prevented or minimised
- Plans for studies to gain further knowledge of a product's safety and efficacy
- How the effectiveness of additional risk minimisation measures will be assessed
- As outlined by the EMA, the RMP aims to ensure that the benefits of a product exceed its risks by the greatest margin possible.

Periodic Safety Update Report (PSUR)

The PSUR, also referred to as the Periodic Benefit-Risk Evaluation Report (PBRER), is crucial in the post-marketing phase. It focuses on safety evaluation by providing a comprehensive assessment of the evolving benefit-risk balance of a product. The PSUR includes:

- Characterisation and evaluation of new risks and benefits that arise post-authorisation
- Evaluation of signals that were closed during the reporting period
- Reporting regulatory actions and updates to product labelling due to safety reasons
- A comprehensive benefit-risk assessment

PSURs are submitted at defined intervals and serve as a tool for post-authorisation pharmacovigilance.



Best Practices in PV Writing

Writing pharmacovigilance documents requires consistency, clarity, and a strong understanding of regulatory standards. To achieve excellence in PV writing, consider the following best practices:

- **Consistency:** Ensure that data, key messages, wording, and list of safety concerns are consistent throughout a document and across different documents as applicable
- **Clarity:** Present data clearly, concisely, with an appropriate logical flow and ensure good readability of complex documents.
- **Accuracy:** Ensure that the required information is accurately summarised and presented at the appropriate level of detail and with the appropriate focus.
- **Regulatory Compliance:** Adhere to global guidelines, such as ICH E2F (for DSURs) and GVP (Module V for RMP and Module VII for PSUR).

These best practices are essential for producing high-quality PV documents that meet global regulatory expectations. Especially if English is not your first language, good understanding of grammar and syntax, as well as the principles of plain language and good writing practices can help you review and improve your documents.

Become a proficient „Pharmacovigilance Writer“

Effective writing is at the core of successful pharmacovigilance. This whitepaper has provided you with an overview of the key documents required throughout the product lifecycle and best practices to enhance your writing skills. By mastering these techniques, you can ensure the production of clear, accurate, and compliant pharmacovigilance documents that protect patient safety and meet regulatory requirements.

Update your English writing skills and become a proficient „Pharmacovigilance Writer“!

For more in-depth training on these topics, join our **online course “Medical Writing in Pharmacovigilance”,** where you can learn from Dr Tiziana von Bruchhausen and gain hands-on experience in creating DSURs, PSURs, and RMPs.

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