FORUM

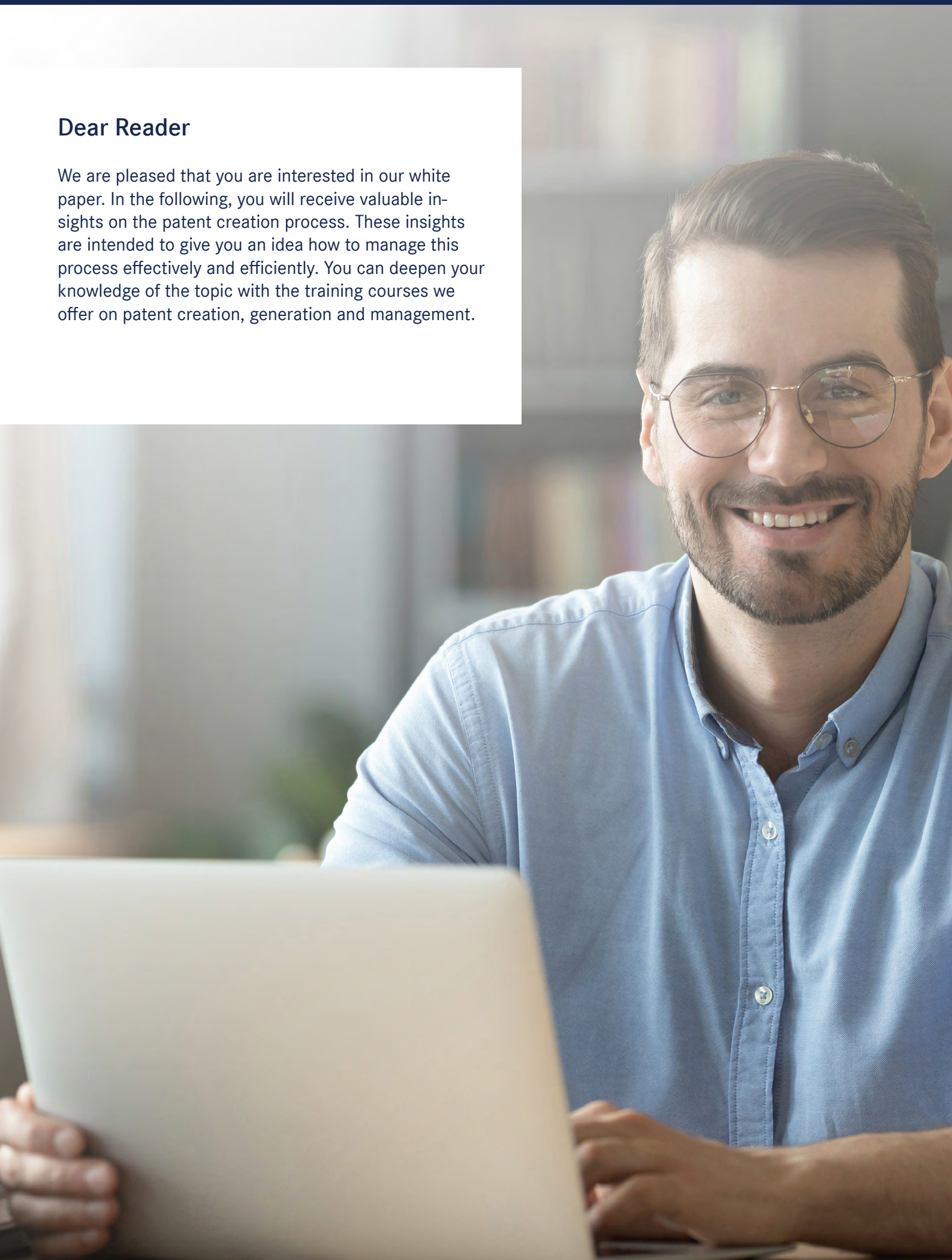
Medical Writing in Pharmacovigilance

Update your English writing skills

Dr. Tiziana von Bruchhausen

Dear Reader

We are pleased that you are interested in our white paper. In the following, you will receive valuable insights on the patent creation process. These insights are intended to give you an idea how to manage this process effectively and efficiently. You can deepen your knowledge of the topic with the training courses we offer on patent creation, generation and management.



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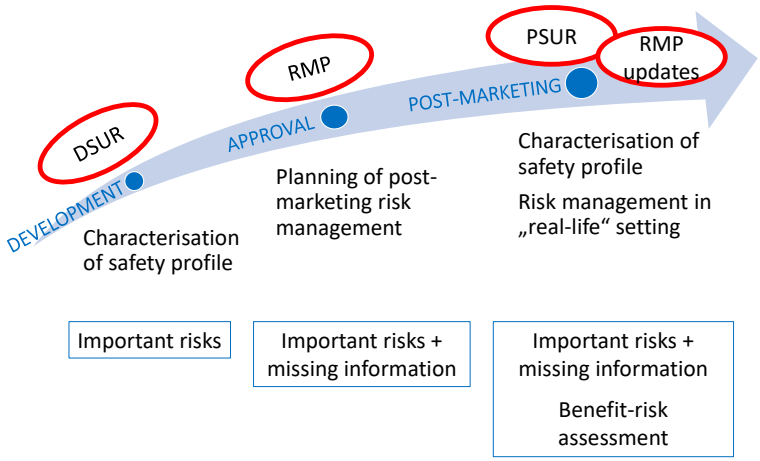
The main success factors for medical writing as a whole also apply to the requirements for writing PV documents. This checklist sounds banal at first - but it reduces the error and defect rate enormously!

PV Writing is Medical Writing

- ✓ Expert knowledge
- ✓ Clear data presentation
- ✓ Readability
- ✓ Tables often better than long text sections
- ✓ Correctness and accuracy
- ✓ Consistency across section/modules/documents
- ✓ Avoid redundancy
- ✓ Proper language and style
- ✓ Language appropriate to the audience
- ✓ Document quality
- ✓ Management of timelines

You need these PV documents and contents from development to post-marketing.
DSUR stands for Development Safety Update Reports.
RMP is the Risk Management Plan.
PSURs are Periodic Safety Update Reports.
Important here are the growing requirements for the work of pharmaco-vigilance from a first characterisation of safety profiles up to the be-nefit-risk assessment, which decides on the marketability of medicinal products.

PV and product life-cycle



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