



## Pharmacovigilance services – report writing

The Development Safety Update Report (DSUR), the Periodic Safety Update Report (PSUR), and the Risk Management Plan (RMP) are important documents given much attention by the Competent Authorities. A-consult has a long tradition of writing such reports.

### A-consult offers:

- DSUR
- PSUR
- RMP

With the introduction of the DSUR focus has shifted towards interpretation of new safety information and towards giving scientifically founded conclusions on the information. The report should assure Competent Authorities that the safety profile of the drug is adequately monitored and evaluated by the sponsor.

Once a medical product is registered in the EU, PSURs must be submitted, even if the product is not marketed. These PSURs are prepared at set intervals during the lifetime of the product. Preparation and reporting of DSURs and PSURs requires up-front planning and trained personnel.

Applications for marketing authorisations in the EU may require submission of a detailed and complex RMP. When the submission of the marketing authorisation application approaches we can assist with the development and writing of the RMP and advise you whether or not a Risk Minimisation Plan is needed.

Our experienced and trained personnel are ready to help you.

*Your challenges – we bring you to a safe landing*

LET US BRING YOU TO A SAFE LANDING

A-consult group is an European consultancy organisation founded in 1983, with a team of 40 highly educated and experienced employees in Denmark and France. A-consult a/s, situated in Denmark, has serviced more than 200 companies and handled regulatory tasks in more than 80 countries. A-consult a/s is offering professional regulatory affairs and product safety service to companies working with food, nutraceuticals, food supplements, cosmetics and pharmaceuticals.



For further information please contact us at:

A-consult a/s, Gladsaxevej 382 1  
DK-2860 Søborg, Denmark  
Tel: +45 3833 0080, [www.a-consult.com](http://www.a-consult.com)