



Pharmacovigilance services – system and support

Pharmacovigilance obligations are difficult to meet for small and medium sized companies. For many it is simply not economically attractive to employ people with the relevant experience.

A-consult has several years of pharmacovigilance expertise from working with small and large pharmaceutical companies. Together with continuous training and participation in national and international events, this forms the basis of our high quality pharmacovigilance counselling and services.

A-consult offers:

- Counselling
- QPPV
- Pharmacovigilance System Master File
- SOP writing
- PV Agreements

The Qualified Person for Pharmacovigilance must be continuously at the disposal of the MAH and shall be experienced in all aspects of pharmacovigilance. This is usually a challenge for small and medium sized companies – A-consult can provide your QPPV.

The Pharmacovigilance System Master File will gradually replace the Detailed Description of the Pharmacovigilance System and must be fully implemented in mid 2014. We will help you to stay compliant.

Do your SOPs need a reality check? We can review and adapt your existing SOPs for compliance with current legislation. We use our experience to advise how to build an efficient and compliant system.

A MAH rarely operates alone. It has partners and use service providers. Competent Authorities expect to see pharmacovigilance agreements between them that clearly describe the responsibilities for pharmacovigilance activities. Our staff has years of experience with writing and negotiation of pharmacovigilance agreements.

Our service concept is full-scale and flexible. We strive to match your needs whether it means full outsourcing or insourcing of A-consult staff in your organisation.

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.



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