Clinical Trial & Drug Safety

Expertise

- ADR Case Processing (Medical Review, Causality and Medical Assessment)
- Periodic Reporting (PSUR, PADER, Annual Safety Reports)
- Clinical Trials Safety Management (SAEs, SUSARs, AEs)
- Clinical Trials Project Management (Trials, Data Safety Monitoring Boards)
- Development of Trial Documents (Protocols, Investigators Brochures, Study Reports)
- Medical Monitoring

Information about Dr Viola Schultze

Viola Schultze, MD, PhD, qualified in Medicine in Germany, at Free University Berlin and became an Expert in General Medicine (Clinical background: gastroenterology, infectious diseases).

She was employed in pharmaceutical industry for 15 years - Chiron Vaccines, Novartis Vaccines & Diagnostics - and held various global managerial positions in Clinical Research, Clinical Trials Management and Pharmacovigilance in the field of vaccine development.

She is a member of DIA, DGPharMed, DGPI, ISID.

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Dr Schultze Consultancy

Clinical Development
Clinical Safety
Drug Safety
Medical Affairs
SUPPORT

Your Needs—My Passion!

Key Advantages

Expertise
Flexibility
Smooth collaboration

Details Services offered

The services I offer include the whole range of topics which come under the general heading of clinical research, Pharmacovigilance, and medical affairs, with particular emphasis on the medical aspects:

Pharmacovigilance

- ADR Case Processing (Medical Review, Causality and Medical Assessment)
- Periodic Reporting (PSUR, PADER, Annual Safety Reports)
- Clinical Trials Safety Management (SAEs, SUSARs, AEs)
- Ad hoc reports for internal for regulatory purposes

Clinical Research

- Clinical Trials Project Management (Conduct of trials, Collaboration with CROs, Data Safety Monitoring Boards)
- Development of trial documents (Protocols, Investigators Brochures)
- Medical monitoring
- Study reports
- Training of trial staff

Medical Affairs

- Congress preparation and support
- Product related documents (e.g., monographs)
- Publication support

In short,

if it's to do with Clinical Research Pharmacovigilance, and Medical Affairs most likely I have done it before and I am pleased to offer it as a service to you and your company

Enquiries in respect of any Clinical Research, Pharmacovigilance, and Medical Affairs services are always welcome

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