Some of our Patient Safety & Compliance experts

NDA’s insight into pre- and post-marketing safety, and understanding of the needs of a quality management system, help you maintain and develop an in-depth understanding of your product’s safety profile.

In turn this will ensure proactive management of your product throughout its life on the market in a stable fashion, providing peace of mind and rapid response to any emerging concerns.

Patient Safety & Compliance

Working with NDA’s Patient Safety & Compliance experts you will:

• Reduce the risk of marketing authorisation application rejections and product withdrawals, saving time and money
• Increase efficiency by doing things right first time
• Achieve faster and less costly time to market through efficient processes, tools and decision making

Shelley Gandhi
Strategic Advisor, PV & Drug Safety

Helen Powell
Principal Consultant

Dr Julia Dunne
Medical Advisor

Dr Bill Richardson
Medical Advisor

Dr Brian Edwards
Principal Consultant

Dr Panos Tsintis
Medical Advisor

Dr Bridget King
Senior Consultant

Kath Denton
Senior Consultant

Helen Measures
Senior Consultant

Barbara Jones
Senior Consultant

NDA Germany
T +49 (0)89 3585 4000
E munich@ndareg.com

NDA Sweden
T +46 (0)8 590 778 00
E stockholm@ndareg.com

NDA Switzerland
T +41 (0)78 951 9929
E zurich@ndareg.com

NDA UK
T +44 (0)1372 860 610
E london@ndareg.com

NDA USA
T +1 609 583 1990
E usa@ndareg.com

www.ndareg.com
Why choose NDA?

At NDA we have in-depth understanding of global Pharmacovigilance and the tools required for system oversight, to direct and control a company’s quality across the lifecycle. Our skilled team will help you implement your systems as effectively as possible.

We understand exactly what international legislation demands, the meaning of quality and how you should efficiently comply to meet regulatory expectations both for routine maintenance and when faced with safety referrals.

We have worked with a great variety of companies, in the US, Europe, Japan, Korea and other territories concerning different medicinal products across all major therapeutic areas.

NDAs integrated Safety Services gives comprehensive support and an expert view about the safety of your product including Risk Management strategies and requirements of your quality system through the entire lifecycle. The team provides assurance as to the compliance status through bespoke risk based auditing approaches and supporting the QA function to strengthen your system of compliance.

Different competencies, processes, systems and tools are required throughout a product’s lifecycle to place treatments on the market and keep them there. We have the skills and resources on hand to address any need.

Managing risk ensures product survival in a competitive market.

How can NDA support you?

We provide practical and up-to-date advice about all your requirements for safety to help you establish and strengthen pharmacovigilance and risk management and mitigation strategies within a quality management system to promote effectiveness and compliance.

NDA can assist with consulting, training or operational support and project management. Examples of safety support provided:

- EU/EEA Qualified person for pharmacovigilance services including back up arrangements
- Advising companies on the development of your global PV system through your PSMF
- Developing and Advising on Risk Management / Minimisation strategies (RMP/REMS) and contingencies including input at regulatory milestones and into post authorisation commitments
- Other medical writing services include DSURs, PBRERS, SOPs
- Building global signal management systems and conducting safety signal generation and analyses as well as conducting ad-hoc safety assessments following requests from regulators.
- Audit strategy and support including developing risk-based audit strategies, audit plans and the conduct of Pharmacovigilance and GCP Audits, Inspection readiness, support during inspections, and support with development of responses/CAPAs.
- Management of regulatory interactions concerning:
  - Pre-submission meetings
  - Management of questions during the approval procedure
  - Safety referrals at PRAC and CHMP
  - Negotiations about Safety studies and commitments
  - FDA Advisory Committees