Patient Safety & Compliance

Peace of mind and rapid response

www.ndareg.com
Patient Safety & Compliance Services

Drug development is a long and costly process. Ensuring that the right things are done the right way first time is critical to reach patients in need as quickly as possible, as well as ensuring that the right measures are taken to ensure patient safety throughout the development process.

NDA offers advice throughout the lifecycle of your product, from development and approval, to post development activities. This includes advice and hands-on support with your risk management, pharmacovigilance and patient safety strategy and organisational implementation. Our safety team comprising over 20 specialist auditors and quality management experts further supports the continual development of your practices and ensuring that these practices become embedded in your organisation. This way we are ideally placed to help you get the best drugs on the market – and keep them there.

Support through the lifecycle

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.
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

“Managing risk ensures product survival in a competitive market.”

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
- Strategically assess your emerging compliance needs & review your existing programmes
- Optimize your critical business processes by providing advice regarding best practices
NDA Advisory Board

If you are looking for answers to your drug development concerns, the top level advice from NDA's Advisory Board is unmatched in the market. This unique group is comprised of some of Europe's most distinguished regulatory and HTA experts - leaders in their fields.

Using our Advisory Board allows you to get competent, unbiased answers and input into your development program, reducing risks and improving your chances for success.

The aim of this is to facilitate a fast and positive outcome to your drug development program.