Marketing Authorisation Application Services

Securing approval in Europe

www.ndareg.com
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NDA is the world’s leading drug development consultancy.

Compiling your MAA application is a complex and intensive exercise. Much time and money is invested in getting it right. At NDA, we have a team of MAA experts on board to guide you through the process and help you achieve a positive outcome.

NDA offers advice and assistance throughout the lifecycle of your product, from development and approval, to post approval activities.

**DEVELOPMENT STAGE**

- Regulatory Development / PV Strategy
  - Gap Analysis
  - Scientific Advice
  - Presubmission Meetings

**APPROVAL STAGE**

- Full MAA Management
  - Centralised / Decentralised / Mutual Recognition
  - Submission / Application Process Management
  - Response Strategies & Oral Explanations

**POST-APPROVAL STAGE**

- All Variations and Renewals
- Line Extensions/ OTC Switches
  - Labelling Updates
  - Referral Procedures

“Thanks to the support of NDA Group, we achieved our first approval from the European Commission [...] A large part of our successful application and registration process can be attributed to the expertise, dedication and passion of the NDA team. Together we worked side-by-side to provide the EMA with a well written and comprehensive application.”

*Chief Regulatory and Drug Safety Officer, InterMune*
Why NDA for your MAA?

• We have the right people:
  NDA's team has in-depth knowledge and experience of the European Regulatory Procedures: Centralised procedure, Decentralised procedure, Mutual recognition procedure and National. Our unique NDA Advisory Board is also on hand to advise during critical points of the submission and approval process.

• We have a flexible approach:
  We can provide strategic insights, right through to operational delivery. We can advise on an entire application, or provide focussed support for individual components. We can be your independent sounding-board, or your day-to-day guiding hand.

• Our scope is broad and deep:
  - All product types including small molecules, biologics, ATMPs and devices
  - Medicines intended for well established or novel uses
  - Full applications for new active substances, orphan drugs, new indications/formulations, OTC switch, generics

• We deliver results:
  We've been involved in over 40% of all positive opinions under the EU Centralised Procedure since 2013.

How can we support you?

• Getting the strategy right first time:
  At NDA we can help by ensuring your development plan and regulatory strategy are fit for purpose. We can conduct a gap analysis of your development programme or submission dossier highlighting additional data required, or mitigation strategies for a rapid and successful approval. We can also prepare you to gain Agency Scientific Advice at an EU and national level.

• Ensuring optimal approval:
  Once strategic decisions on regulatory procedure (CP, DCP, MRP, National) and key data requirements are made, NDA can also assist in authoring all submission components (including PV).

We can support pre-submission meetings with the EMA, or national agencies, through to submitting the MAA and managing the approval process.

Once the application is in review, NDA can advise on response strategies to questions that arise, assist with Agency oral explanations and hearings.

We also have an experienced pharmacovigilance team on hand to advise on all aspects of safety requirements throughout the life cycle of your product.

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NDA has supported the varying regulatory development needs of more than 1000 clients for over 20 years.

Today NDA can support the regulatory needs of large as well as small pharma and biotech companies through a portfolio of services comprising:

• Study enabling submissions, such as CTAs/INDs
• Large scale submissions, such as MAAs/BLAs/NDAs
• Pediatric strategies and plans
• Orphan Drug Designations and local representation
• Risk Management through RMPs and REMS
• Life cycle management support incl. publishing
• OTC switch assessments
A selection of our Experts

Alex Meldrum
Senior Consultant
Expertise in regulatory submissions for companies of all sizes across Europe, US and Japan for all aspects of drug development and strategies throughout the product lifecycle.

Olga Björklund
Senior Consultant
Expertise in preparing and delivering regulatory operational and strategic plans, clinical trials start up, leading global multidisciplinary teams, scientific knowledge in Pharmacology and Investigative Toxicology.

Christian Redondo-Müller
Principal Consultant

Dr Stephanie Krumholz-Bahner
General Manager, Switzerland
Expertise in regulatory support of BLA and MAA submissions through to approval across several therapeutic areas.

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