

International Regulatory Affairs

- Marketing authorisation files and variations
- Expert reports, overviews and quality overall summaries
- Product development
- Registration strategy
- BA/BE studies: protocol and results evaluation
- Project management
- Marketing authorisation applications
- Appeals and hearings
- EU language translations
- European Drug Master Files
- Certification of Suitability EP
- Impurity profile evaluation
- PIL user testing
- Pharmacovigilance / post-marketing surveillance
- Health claim support (nutraceuticals, novel foods)
- Reimbursement applications
- EU batch release and QP service
- Parallel import
- QA/QC advice
- eCTD



What do we do ... in Pharmacovigilance

DADA knows, shows and leads the way in Pharmacovigilance as well. We are familiar with all pharmacovigilance requirements. We have an audited and accepted system with QPPV service and handle all aspects of case or periodic reporting. Whether complete or partial outsourcing, or auditing and advising your own system, each assignment gets the same high standard of attention to ensure complete compliance.

Pharmacovigilance

What do we do ... in Pharmaceutical Development

Pharmaceutical development is a multifactorial exercise: active ingredient has to match product development, while keeping a close eye on market, patent situation and current regulations. We have been involved in over 50 product developments and over 100 bioequivalence studies, and generics have no intricacies for us. This expertise is at your service when we evaluate drug master files or impurity profiles, audit API or finished product manufacturers, or act as Qualified Person.

And finally we support due diligence and in and out licensing.

Pharmaceutical



Final Remarks

DADA Consultancy is a highly specialised and independent consultancy agency in international regulatory affairs of human and veterinary medicinal products. This overview of its services demonstrates that DADA can provide tailor-made services completely in line with your needs. DADA can find optimal solutions for your requirements and is therefore an ideal partner for supporting and managing your European regulatory activities.

Consultancy



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