About us

pharmadocs GmbH & Co. KG is an international service provider for the pharmaceutical industry that specialises in the registration of medicinal products for human use.
We take on your projects from planning, through production and submission of licensing documentation, to complete life cycle management.
Only work results of impeccable quality leave our house. We cooperate closely with the relevant authorities and always work in accordance with the nationally and internationally applicable laws, regulations and directives.
It is our main target not only to authorise your products, but to optimise your documents and processes in a way that makes it easy to deal with them in the future.

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pharmadocs

Drug Regulatory Affairs

Regulatory Writing and Artwork

- Information officer according to § 74a AMG
- Creation and revision of the labelling, package leaflet and expert information
- Review and approval of artworks
- Revision and review of advertising material
- Product information texts
- Company Core Data Sheets (CCDS)

Maintenance

- Assessment of the dossier
- Updating of the dossier
- CMC-Compliance Check
- Creation of administrative and country-specific documents (module 1)
- Product information texts
- Coordination of translations
- Communication with authorities
- Variations
- Renewals
- Periodic Safety Update Report (PSUR)
- Date and deadline monitoring

Marketing Authorisation

- Strategy development and planning of the marketing authorisation dossiers
- Communication with the authorities
- National, MR-, DC- and centralised procedures
- Regeneration of marketing authorisation dossiers
- Assessment and updating of existing marketing authorisation dossiers and creation of the necessary modules
- Product information texts
- Coordination of translations
- Creation of eCTD dossiers
- eSubmission

Regulatory Consulting

- Assessment of company´s internal and external processes
- Creation of a strategy of process optimisation
- SOP: development and implementation
- Assessment and classification of products
- Analysis of existing data as well as drafting and requirement of necessary documents
- Creation and development of a registration strategy
- Cost-benefit analysis
- Due Diligence
- Consulting meetings with drug authorities

eCTD Service

- Creation and validation of the marketing authorisation dossier and submission to the European authorities
- Reformatting to eCTD
- Creation of the eCTD Baseline
- Maintenance of the eCTD dossier
- Digitalisation of paper documents

Pharmacovigilance

- Periodic Safety Update Report (PSUR)
- Pharmacovigilance System Master File (PSMF)
- Risk Management Plan (RMP)
- EudraVigilance

Benefit from...

- ✓ our extense expertise in marketing authorisation.
- ✓ our transparent, structured and goal-oriented approach.
- ✓ us as a competent partner who proactively thinks for you and your products.
- ✓ a first-class support with us as the partner by your side.