medibridge
Regulatory Affairs

# How can Medibridge help you in your regulatory projects in Europe?

***An experienced multidisciplinary team at your service: pharmacists, physicians and scientists***

***Over 20 years' experience with healthcare products***

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# Marketing Authorisation Applications: European and national procedures

- Strategic and operational regulatory consultancy
- Pre-submission data review and evaluation in the light of European requirements and national context/habits: chemical (DMF), pharmaceutical and clinical data
- Due diligence activities
- Organisation of meetings with Health Authorities and representation of the client company
- Compilation of the files in EU-CTD format:
  - Preparation of Module 1
  - Drafting pharmaceutical, preclinical and clinical overviews/summaries
  - Drafting and/or layout of the whole dossier
- Management of the submission
- Follow-up: checking the progress of the application, preparation of replies to any questions, assistance with correspondence, etc.

# Lifecycle management of medicinal products

- Updates
- Variations
- Renewals

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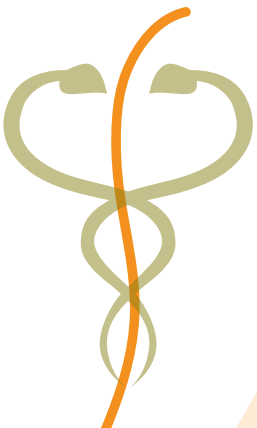
# Summary of product characteristics, leaflet and labelling

- Search for SmPCs of competitive products
- Comparison of European SmPCs in the context of MRP and DCP applications
- Comparison and update of national SmPCs with Company Core Date Sheet
- Reviewing, drafting in line with QRD templates, updating and translating

# User testing Patient information leaflet (PIL)

- Strategic advice and implementation (Full test, bridging/focused test)
- Harmonisation of PIL text (e.g. within a product range or across different countries)
- Amendment after medical and regulatory review
- Graphic design, production and amendment of mock-ups



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# Regulatory clinical trial support

- IMPD: quality, non-clinical and clinical documentation
- Investigator's brochure
- Ethics committee submission
- Clinical study report
- Notifications to Health Authorities and other official bodies

# Other activities

- Regulatory intelligence
- Determination of product status, formal or informal contacts with Health Authorities for all categories of healthcare products (medical devices, cosmetics, reagents, etc.)
- Viral safety dossier
- Preparation and follow-up of dossiers for the Transparency Commission in France

## The following have already trusted us:

*Almirall, AstraZeneca, Bayer, Boehringer Ingelheim, BMS, Cephalon, Chiesi, Colgate-Palmolive, Ferring, Gaba, GlaxoSmithKline, Hisamitsu, Leo Pharma, Merck Serono, Mylan, Novartis Pharma, Pierre Fabre, Ratiopharm, Roche, sanofi-aventis, Shire, The Medicines Company, Wyeth, Zambon, etc.*

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