AR 2i

Regulatory Affairs

OUR EXPERTISE

The AR2i REGULATORY AFFAIRS Division is here to help you with your regulatory applications in extensive range of subjects.
We have a solid expertise in preparing CMC dossiers and experience in working on a wide variety of active substances and pharmaceutical forms.

TECHNICAL-REGULATORY ADVICE

- Regulatory intelligence
- Registration strategy
- Contact/meetings with the authorities

COORDINATION OF PHARMACEUTICAL STUDIES : Analytic and pharmaceutical studies, Site Transfer

- Regulatory advice
- Study implementation
- Follow-up and analysis of data

AUDIT

- Regulatory portfolio
- Module 3
- Gap analysis
- Action plan proposals
- Risk analysis

DRAFTING OF MARKETING AUTHORISATION APPLICATION DOSSIERS

- Module 3
- Full applications
- Variation applications
- Responses to questions from the authorities
- Quality Overall Summary
- Baseline eCTDs

PRODUCT INFORMATION : SmPC, Leaflet and Labelling

- Product information variation dossiers
- Template formatting
- Comparison and alignment
- Checking of press proof document
- User testing of leaflets

SUBMISSION OF REGULATORY APPLICATIONS TO THE AUTHORITIES

- e-CTD submission (EnnoV software)

MORE INFORMATION

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