

Regulatory Affairs



A-consult offers world wide Drug Regulatory Affairs services.

A-consult has a significant team of employees highly educated within the pharmaceutical sector. All are trained and experienced in regulatory affairs. Our specialists and senior consultants have up to 30 years of experience. This enables us to provide you with a broad range of regulatory services and know-how.

A-consult offers:

- Regulatory advice, including correspondence, negotiation, and follow-up with medicines agencies.
- Marketing authorisation applications and life-cycle management – preparation, review, submission of dossiers, and managing procedures.
- SPC, PIL, labels and other regulatory documents - Preparation, translation, and proof-reading. Uploading to the Danish Package Leaflet database.
- CTD format conversion and eCTD preparation.
- Clinical Trial Application – preparation and submission.

Our broad range of services enable us to supply the necessary expertise and suitable workforce for your regulatory tasks. Our high number of payroll employees makes it easy for A-consult to support you in urgent situations.

We support you in your regulatory strategic considerations. We provide a single access point for your regulatory tasks.

We are experienced in the European regulatory procedures and manage application procedures from our A-consult offices.

Our service concepts are flexible and we strive to match your needs. A-consult offers to be your partner in total outsourcing of your regulatory affairs tasks. We offer to join-in in your regulatory department or to solve your tasks from our offices.

LET US BRING YOU TO A SAFE LANDING

A-consult group is a European consultancy organisation founded in 1983, with a team of highly educated and experienced employees in Denmark and France. A-consult group has serviced more than 200 companies and handled regulatory tasks in more than 80 countries. A-consult is offering professional regulatory affairs service to companies working with pharmaceuticals, nutraceuticals, foods, food supplements, medical devices and cosmetics.



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