



HERBAL MEDICINAL PRODUCTS — MEDICAL DEVICES

CONSULTING AT THE HIGHEST PROFESSIONAL LEVEL

- Regulatory Affairs
 - Product Development
 - Safety & Quality Assessment
 - Scientific Consulting
- Expert Statements
 - Authority Meetings
 - Medical Writing

HERBAL MEDICINAL PRODUCTS

... health from nature



OUR EXPERIENCE:

a&r has been involved in the development and registration processes of over 300 herbal medicinal products for over 15 years, predominately in Europe, but in the US and Asia as well.

WHAT WE CAN DO FOR YOU:

Regulatory Affairs

- Complete handling of all regulatory procedures (national and international) in CTD format for:
 - New drug authorizations
 - "Well-established use" herbals
 - THMPs (Traditional Herbal Medicinal Products)
- Pharmacological-toxicological expert statements
- Expert reports proving traditional use
- Quality section of a CTD/eCTD
- Planning/organisation of meetings, and negotiations with the appropriate authorities

Pharmacovigilance

- PSURs (Periodic Safety Update Reports)

Product Development

- Development of new product ideas
- Scientific advice and product development support
- Market launch

a&r will support you in all the necessary development stages during the marketing authorization process for your product and beyond. We are your experts to assure a successful market entrance and the long-term marketability of your innovative and outstanding herbal product.

MEDICAL DEVICES

... new opportunities for natural ingredients



A medical device certification can be an interesting alternative to a drug application, as it is less time and cost intensive and opens new opportunities especially for herbals or natural ingredients. a&r has been involved in many medical device certification procedures for a broad range of different product groups and indications, such as:

- Transdermal patch (periodontitis)
- Wound dressing (atopic dermatitis)
- Nasal spray (rhinitis)
- Fat blocker (slimming)
- Carbohydrate blocker (slimming)

WHAT WE CAN DO FOR YOU:

- Development of new, innovative medical devices
- Assessment of feasibility, especially in the case of borderline products
- Preparation of the technical documentation for all risk classes
- Clinical evaluation
- Consultation procedure
- Scientific advice and support of product development
 - Organization of biological tests and clinical studies
 - Optimization of the production process
 - Support in the implementation of a quality management system
- Preparation and organization of meetings with notified bodies

Natural components offer a great potential as ingredients in medical devices. With the experience and knowledge of a&r, you can enter new market segments with confidence. a&r – the experts for your success!

MEDICAL WRITING

... go public



OUR EXPERIENCE:

We have successfully published scientific articles, reviews, meta-analyses, monographs, expert statements, product brochures, popular scientific manuscripts, books, and developed innovative marketing concepts for the last 20 years.

We are Authors/Co-Authors of

- PDR for Herbal Medicines
- Die grüne Apotheke
- Reports for Business Insights Ltd London
- Quickfinder Pflanzenheilkunde
- The Complete German Commission E Monographs
- Natural Standard Monographs
- etc.

Members of Editorial Boards

- Journal of Herbal Pharmacology
- Evidence Based Integrative Medicine
- Nutraceuticals World
- NUTRAfoods
- AGROfoods International
- etc.

WHAT WE CAN DO FOR YOU:

Customized preparation of various kinds of publications at a peer review or popular scientific level.

...Contact us for more information!



Company Information

analyze & realize ag is a leading contract research organization serving the food, supplement, herbal medicine, and medical device industries. We are an audited CRO and member of the German Association for Medical CROs. We have conducted over 190 clinical trials with herbal medicinal products, medical devices, functional foods and dietary supplements.

Our dedicated professionals in the fields of pharmacology, medicine, food science and regulatory affairs work in a client-orientated atmosphere and provide creative solutions to exceed our customer's expectations. We anticipate challenges by devising a flexible approach to a proactive strategy.