SERVICE SHEET

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Regulatory Affairs

Global regulatory intelligence

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Global regulatory intelligence

No company can ever be aware of all the regulatory requirements worldwide for every type of product. Regulations and legislation are constantly being updated and new guidelines created. The international harmonisation process means that new procedures are always being developed and adopted by world regulatory authorities.

Wainwright Associates have developed a network of local advisors in all the major territories of the world. All are independent and speak the local language. They can advise not only on local regulations in their country, but also on current attitudes prevailing within their national regulatory body.

Our international regulatory desk research service is designed to provide up-to-date guidance on local regulatory requirements for products under development. It is particularly valuable for novel dosage forms and high tech products as well as for devices and borderline products.

Itemised reports are prepared detailing regulatory requirements on a country-by-country basis and providing appendices containing copies of specific legislation and guidelines.

Typical questions that desk research is designed to answer

- What are the latest registration requirements in specified countries?
- Where can I obtain copies of relevant legislation?
- Are there any relevant guidelines?
- What are the current application fees?
- What language requirements apply?
- How long does the registration process take?
- Who is the appropriate contact at the authorities?
- What is the prevailing attitude towards a particular product type?
- Will a particular country accept the Common Technical Document?
- What is the local procedure for obtaining reimbursement?
- What is the mechanism for pricing approval?
- What effect will local harmonisation efforts have on my marketing strategy?
- What are the requirements for making electronic submissions?
- Does my product need to be registered?
- Is my product a drug or a device?
- What special considerations apply to borderline products?
- Are there any similar products on the market?
- Is there a special procedure for herbal products?

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Our service is designed to provide up-to-date guidance on local regulatory requirements for products under development.

- Does my cosmetic label avoid medicinal claims?
- Is our clinical development strategy appropriate?
- Are there any patent restrictions?
- Can you find a local manufacturer or distributor?
- Where can we conduct local clinical trials?
- Do you have a local agent who can liaise with the authorities?
- Do you have translation capabilities?
- Can you source a raw material?
- What safety data are available on my product?
- Are there local differences in medical practice?
- What changes are expected in the coming years?

Network of local advisors

We have over 400 advisors in 70 countries; all are independent. Their expertise covers human and veterinary medicines, medical devices and *in vitro* diagnostics, herbal products and foods, cosmetics and toiletries.

Online literature searching

The amount of information published on the Internet is vast. Many companies and organisations now use virtual libraries instead of traditional paper ones. In many cases, the information is out there, but how do you gain access to it?

The key to obtaining the right information is a well-planned literature search of one or more of the on-line databases (e.g. Medline or Embase). Most databases are updated each day and provide archive material covering several decades.

Wainwright Associates can devise a literature search to meet your requirements, order references and prepare reports summarising the relevant information. Alternatively, we can provide regular updates on a particular topic, alerting you to new developments.

We can also advise on dates of first approval of specified products in various countries and provide copies of relevant product literature.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

www.wainwrightassociates.co.uk