WAINWRIGHT associates

Wainwright Associates Limited

Committed to excellence in regulatory affairs and pharmacovigilance

“Wainwright Associates has extensive regulatory experience and both regulatory strategy and regulatory operations capabilities for the EU. They are our “go to” folks when we have questions or concerns.”

Leading consultants in regulatory affairs and pharmacovigilance

Wainwright Associates provides a range of high quality consultancy services to companies of all sizes in the global pharmaceutical, medical devices and healthcare industries.

Technical and practical experience

We have a wealth of technical and practical experience in regulatory affairs, pharmacovigilance, licensing, medical information and strategic development, and can offer advice, guidance and hands-on support at every stage of the product lifecycle.

Depth and breadth of expertise

Our team of consultants offers a depth and breadth of collective and individual expertise that enables us to deliver consistently successful outcomes for our clients, achieved through a combination of innovative thinking, professional commitment and scientific rigour.

Flexible and approachable service

We provide a flexible and approachable service that can be tailored to the needs of the individual client and project, and we are particularly renowned for our lateral thinking and problem solving capabilities. As a result, the majority of our business comes from repeat business, referrals and personal recommendations.

Global network of advisors

There is no replacement for having detailed local knowledge. Understanding the complexities of country-specific legislation or knowing the most appropriate way to approach a project based on local medical guidance, is a key strength and helps us maintain our high success rate.

We are proud to be a member of EuDRAcon – an exclusive European network of regulatory affairs consultants, which has a partner member company in nearly all the EEA member states. In addition to our EuDRAcon partnership, we have built up an independent global network of local advisors who we can contact for country-specific intelligence on demand. This enables us to give you the best advice and support across a wide range of global territories. We have approximately 400 regulatory affairs, pharmacovigilance and licensing consultants located in over 70 countries worldwide, including emerging markets. All of our advisors are independent and speak the local language and can not only help with local regulations in their country but also advise on current attitudes. Their expertise covers human and veterinary medicines, medical devices, diagnostics, herbals, foods, cosmetics and toiletries.

Delivering successful outcomes

Whatever the scope, scale and duration of your project, Wainwright Associates are committed to delivering a successful outcome that exceeds your expectations.

A wide range of services

We can provide you with bespoke solutions to address any challenge. We have experience in a broad range of areas – from prescription medicines, OTCs, herbals and homeopathics (homœopathics), to biological and biotechnology projects and medical devices.

Using our wealth of experience we will help guide you through the complexities of the regulatory and pharmacovigilance landscape, allocating the best possible resources to ensure successful completion of your project.

Our priority is to ensure you successfully address your key regulatory challenges. Our high quality and diverse work enables us to provide you with a greater depth of experience and expertise. Regardless of whether we are acting as consultants or providing more hands-on support, it goes without saying that we are focused on outcomes. A positive result for you is a positive result for us.

So regardless of your challenge, we can help address it by finding the most appropriate solutions to assist you to achieve your desired outcome.

Our range of consultancy services includes:

- Regulatory affairs
  - Pre-authorisation
  - Submissions management
  - Post-authorisation
  - Training and seminars
  - Medical device services
  - Scientific consultancy
  - Technical support in healthcare litigation
  - Global regulatory intelligence
  - Audits and GxP
  - Promotional compliance
  - Product information and user consultation
  - Regulatory support for clinical trials
- Pharmacovigilance
  - Clinical study safety
  - Post-marketing pharmacovigilance
  - Medical device vigilance

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- Medical information
- Licensing
- Strategic development

We have experience of all therapeutic areas and novel product types, including biotechnology, are always a welcome challenge.

Industry knowledge

Having industry specific expertise available to support you through the local regulatory environment provides you with peace of mind and confidence that your project is being handled appropriately.

Our consultants have many years' experience working across the industry sectors and you can be confident that we have a multidisciplinary team of experts to provide you with that specialist knowledge and guidance.

The industry sectors we cover include:

- Medicines
- Medical devices
- Products on the borderline

In addition, we work in partnership with Contract Research Organisations (CROs), providing them with support for projects that require specialist knowledge and expertise.

Extensive client base

Our diverse range of clients means we have a wealth of technical and practical experience across many industries. Therefore no matter what your requirement, we can assign the most experienced regulatory or pharmacovigilance consultant to support your project.

Our clients are located across the world. They include multinational corporations, start-up biotech companies, private entrepreneurs, contract research organisations, management consultants, lawyers, patent and trade mark agents and all other groups requiring expertise in pharmaceutical or related matters.

As a result of the sensitivity of our industry, we take client confidentiality very seriously. We will never disclose details of the projects we work on or the names of the clients we engage with to third parties, unless express permission has been sought and/or a formal Confidentiality Agreement signed.

Free estimates

We always welcome enquiries for projects from companies both large and small and from all quarters of the globe. A briefing meeting is encouraged so that clients can meet our team of consultants and discuss their requirements face to face.

Estimates are provided entirely free and without obligation and can usually be sent out within 2-3 days of receiving the client's brief and copies of the documentation.

Work is undertaken either on a project basis, against a formal estimate, or on an hourly basis for general consultancy work. Estimates are fully inclusive of secretarial and administrative costs, but exclusive of VAT and expenses.

Once the project has started, we like to keep clients fully informed of progress with the project and with costs. We are happy to visit clients' offices as often and whenever required, both domestically and overseas.

For companies in the global pharmaceutical, medical devices and healthcare industries that require expert advice in regulatory affairs and pharmacovigilance, Wainwright Associates is a leading consultancy with a wealth of technical and practical experience and a reputation for innovative thinking. Our team of consultants use their collective and individual expertise to provide a flexible and approachable service that can be tailored to the needs of the client and consistently delivers successful outcomes and exceeds expectations.

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