

Regulatory Affairs and Pharmacovigilance Consultancy



Wainwright Associates are consultants to the pharmaceutical, medical device and healthcare industries in product development, regulatory affairs and licensing. Successful approvals on behalf of many major multinational companies form the basis of the expertise which is now available under contract.

The objective is a professional and flexible service customised to clients' specific demands. Projects can be undertaken either at clients' offices or at our own premises in Buckinghamshire, UK.

Both short- and long-term appointments are welcomed and we are happy to provide additional resource for projects in-house as well as manage complete new programmes of work.

A full service, comprising advisory, technical, secretarial and administrative aspects is always available. Reports are prepared either in our own house style or according to the client's own template, as required. Documents can be provided electronically in Word for Windows format or other appropriate electronic medium.

Confidentiality and security of clients' data can be assured and, as an independent organisation there is no conflict of interest.

A Wide Range of Services

The regulatory affairs and licensing services provided by **Wainwright Associates** are applicable to many different product types, including human and veterinary medicinal products, medical devices and diagnostics, chemicals, biocides and pesticides, food supplements, cosmetics and herbal products. Specialists are available to advise on all these products and borderline substances are a particular area of expertise.

Our range of consultancy services includes:

- ✓ Planning and advice on regulatory strategy and applicable legislation
- ✓ Assessment of the scientific data in all disciplines
- ✓ Preparation and submission of dossiers for clinical and marketing approval, including eCTD
- ✓ Licence maintenance
- ✓ Readability Testing

Our speciality is in appeals and hearings and our success rate stands in excess of 90%.

Based in Europe we can advise on harmonised EU requirements for product types listed above.

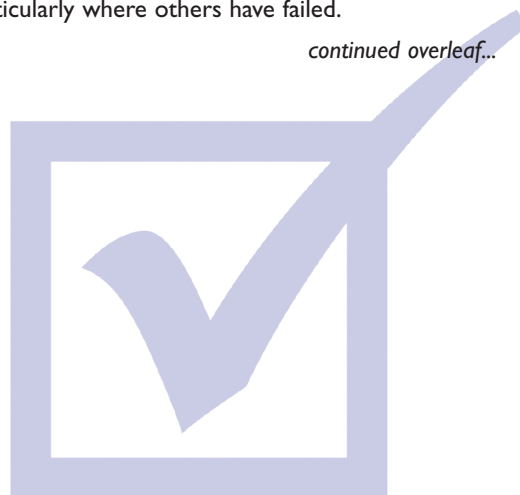
We also provide a search facility for new products, licensing partners and manufacturers.

Other services include GMP/quality audits, design of in-house seminars and technical support to the legal profession in litigation cases.

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

An innovative and creative approach to new projects is the hallmark of **Wainwright Associates'** style, particularly where others have failed.

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Services Offered

- ✓ Advice on EU medicines legislation
- ✓ Appeals, hearings and arbitration
- ✓ Applications for EU Scientific Advice
- ✓ Assessment of scientific documentation
- ✓ Audits for GMP, GLP, GCP and ISO 9000
- ✓ CE marking
- ✓ Centralised, Decentralised, Mutual Recognition and National Marketing Authorisation Applications
- ✓ Change of legal status
- ✓ Clinical Trial Authorisations
- ✓ Critical path analysis of R&D programmes
- ✓ Drug master files
- ✓ Electronic submissions (eCTD)
- ✓ Ethics Committee submissions
- ✓ Expert witness in healthcare litigation cases
- ✓ In-house regulatory support
- ✓ Labels, leaflets and Summaries of Product Characteristics
- ✓ Liaison with regulatory authorities
- ✓ Licence maintenance
- ✓ Licensing negotiations
- ✓ Literature searches
- ✓ Management advice on regulatory operations
- ✓ Mock appeals
- ✓ Orphan medicinal product designation
- ✓ Pharmacovigilance
- ✓ Pharmaceutical, preclinical and clinical consultancy
- ✓ Readability testing
- ✓ Regulatory desk research
- ✓ Regulatory strategy
- ✓ Scientific and regulatory due diligence
- ✓ Searches for contract manufacturers
- ✓ Searches for new products or licensing partners
- ✓ Seminars and lectures on regulatory topics
- ✓ Training of regulatory affairs staff

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.