SERVICE SHEET

WAINWRIGHT associates
Regulatory Affairs

Non-clinical consultancy

Our experienced consultants can help to design non-clinical development plans including strategic input into the non-clinical aspects of drug development.

Non-clinical consultancy

Substantial expertise in non-clinical regulatory strategy and supportive high quality submission documentation is available within our team.

We can provide specialist consultant input to help to design non-clinical development plans including strategic input into the non-clinical aspects of drug development, design of studies and preparation of protocols or we can conduct a gap analysis of non-clinical programmes already undertaken.

Specialist consultant advice is also available during the preparation of applications for Clinical Trial Authorisations, Paediatric Investigation Plans, Scientific Advice and Marketing Authorisations.

In addition to providing advice on the above, our specialists can draft the non-clinical content for the above submission types according to the format required, including eCTD format and provide expert signatures for Module 2.4 of Marketing Authorisation Applications.

Finally, we are also able to provide non-clinical support as expert witness in litigation cases.

Scientific advice

Obtaining ‘buy-in’ from regulatory agencies to company development plans can greatly facilitate the preparation of a feasible plan and subsequent approval of Marketing Authorisation Applications and Clinical Trial Authorisations.

Our team has a wealth of experience in leading clients through the Scientific Advice process both at the European and national levels. We can co-ordinate the process of applying for meetings, prepare questions and company justifications, write briefing documents and presentations and facilitate rehearsal meetings, as well as attend meetings with or on behalf of client companies to facilitate the process and capture minutes.

Paediatric Investigation Plans

All applications for new medicinal products in the European Economic Area are subject to the provisions of Regulation 1901/2006 (the ‘paediatric regulation’).

Our team is experienced in the preparation of Paediatric Investigation Plans (PIPs), and applications for product-specific waivers or deferrals. We can advise on the non-clinical strategy and development in support of the proposed clinical paediatric strategy, and write or review the non-clinical information within PIP/deferral/waiver applications.

WAINWRIGHT associates

We can liaise with the non-clinical departments to proactively identify potential regulatory questions and determine the response strategy to facilitate maximum efficiency.

Clinical Trial Authorisations

Under the 'Clinical Trial Directive' 2001/20, authorisation by a Competent Authority is required to conduct trials on human volunteers or patients in any EU member state.

We can advise on the requirements for and prepare the necessary non-clinical sections of the Investigational Medicinal Product Dossier (IMPD) in relation to the content of the clinical Investigators Brochure required as part of the application for Clinical Trial Authorisation to the Competent Authority of each member state where the trial will be conducted.

We can also liaise with your non-clinical departments to write or review responses to questions on the IMPD received from the Competent Authorities.

CTD non-clinical modules

As part of the preparation for Marketing Authorisation Applications, our team can advise on or write the Non-clinical Overview (Module 2.4) and Non-clinical Written and Tabulated Summaries (Module 2.6). This includes appropriate consideration of and cross reference to the information in the Quality Overall Summary (Module 2.3), Clinical Overview (Module 2.5) and Clinical Summary (Module 2.7).

We can liaise with the non-clinical departments to proactively identify potential regulatory questions and determine the response strategy to facilitate maximum efficiency and success in response to questions during the regulatory procedure. We are also able to provide non-clinical advocacy during appeals and hearings.

Environmental risk assessment

All applications for new medicinal products in the European Economic Area and some applications for type II variations require an Environmental Risk Assessment (ERA) to outline the risks arising from the use, storage, and disposal of the medicinal product (Module 1.6).

We can advise on or write this module in liaison with your non-clinical departments.

Non-clinical report writing

Once a study is completed, we can write the non-clinical study report by liaison with your non-clinical research and development departments or responsible CRO to provide study data. Once the report is in late draft, we will work with your non-clinical team and auditors to review and update it.

We can author reports according to our own in-house template or we are happy to utilise templates provided by your non-clinical department or that of the responsible CRO.

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