WAINWRIGHT associates
Regulatory Affairs

Publishing and submissions management

Our consultancy services will help you through your regulatory submissions from pre-authorisation planning through Marketing Authorisation Applications to lifecycle maintenance.

Regulatory submissions

Our very experienced team is well-placed to provide advice on all aspects of the scientific disciplines required for successful EU Marketing Authorisation Applications, as well as registrations in other major territories, including emerging markets. We can help determine whether the Centralised, Decentralised or Mutual Recognition Procedure would best fit with a client's objectives or advise on a national procedure if applicable.

We make sure that the full range of pre-submission support is taken into account, so that the most can be made of Small and Medium-Sized Enterprise (SME) status, regulatory and scientific advice, as well as paediatric and orphan incentives, according to individual circumstances.

High quality, professionally published submissions are an expectation of all regulatory authorities and use of eCTD format is increasingly expected as standard. When it comes to submission and handling the procedure, your application will be in safe hands. We know how to present and justify data in ways to optimise likely success and our published outputs bear a high quality and user-friendly finish to facilitate review.

Our flexible service

Our service is flexible and geared to the needs of individual clients.

Publishing and submissions management is available as a service in its own right; we wcan handle all types and complexity of submission in any of the above formats. Alternatively, it can be a feature of a comprehensive package of regulatory support for a particular project.

Building publishing considerations into an overall regulatory project plan ensures efficient transition from preparation of submission components to compilation of a dossier; with a focus on achieving deadlines.

We can maintain a dossier from initial submission and supplementary information through to variations, renewals and/or submission of a PSUR. A dossier can be stored within our archive or transferred to a client's publishing team as required.

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High quality, professionally published submissions are now an expectation of all regulatory authorities and use of the eCTD is increasingly demanded.

Publishing and submissions management

We are committed to ensuring that all published outputs bear a high quality and user-friendly finish to create the right impression and facilitate review from validation, throughout assessment and on to approval.

Using our state-of-the-art publishing technology, we publish and manage submissions across a full spectrum of formats, including paper, non-eCTD electronic submissions (NeeS) and eCTD, ensuring that they are compliant with individual requirements of receiving regulatory authorities.

Our clients can specify whether we use our templates or theirs. Our use of Extedo software, which is widely used across the industry, includes validation tools that are used by competent authorities.

We handle all kinds of regulatory submission, including:

- Clinical Trial Applications (CTAs)
- Marketing Authorisation Applications (MAAs)
- Post-authorisation procedures including: Post-Authorisation Measures (PAMs), Periodic Safety Update Reports (PSURs), variations and renewals

We can also assist with conversion of existing dossiers into eCTD format.

Efficient dossier management

Step 1: Identify submission components for application type/legal basis

Step 2: Allocate ownership for each submission component, define interdependencies and plan a sequence for preparation

Step 3: Preparation and quality checks on submission components

Step 4: Publishing: hyperlinking, eCTD, NeeS

Step 5: Dossier despatch

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