WAINWRIGHT associates

Regulatory Affairs

Data assessment

A Technical Assessment Report identifies any weaknesses or omissions in the data and allows sufficient time to resolve the issues without delaying the approval process.

Assessment of scientific data

The success of regulatory approvals is highly dependent upon the quality of the data submitted. Preparing a registration submission should not be an administrative exercise intended simply to assemble the appropriate documents into the format laid down by the relevant guidelines. If a dossier is to be approved without raising concerns from the assessors, the task of preparing it is a highly technical one.

To assist companies in judging whether a dossier meets the appropriate standards for a particular purpose or authority, we can provide an independent Technical Assessment Report. Written by experts in each of the necessary disciplines, the purpose of the Technical Assessment Report is to identify all the weaknesses and omissions in the data at an early stage in the project, allowing time to resolve the issues without delaying the approval.

Technical Assessment Reports are written to be intelligible to non-technical personnel as well as scientists, with a star rating system to quantify the probability of success in addition to the expert commentaries.

Technical Assessment Reports

A Technical Assessment Report is a detailed report, prepared by discipline experts, following a thorough review of the client's data. Its purpose is to gauge the suitability of the documentation for registration purposes in a specified territory or territories and to quantify the probability of success. The objective is an assessment that mimics that of the authorities with a view to identifying all the points requiring attention before submission.

Laid out in a format that broadly follows the Common Technical Document (CTD) format, each item required for registration is evaluated by the appropriate specialist. The assessment is based on both scientific considerations and administrative aspects such as layout and presentation of the data, taking into account relevant current guidelines.

A checklist format is used to record the areas where additional data are required and make recommendations for resolving the issues. For each item a weight is applied according to its importance for registration purposes and a Score based on the quality of the data. This provides a presentation that is intelligible to non-technical as well as technical personnel. An executive summary completes the picture.

Technical Assessment Reports have proved popular with clients because they distil all the essential aspects of a product, including a list of the deficiencies and additional study requirements, into a single document. This allows an early start to be made in planning the work needed to finalise the registration package.

Technical Assessment Reports provide an unbiased, independent evaluation of the quality of product documentation.

Useful for every situation

Technical Assessment Reports are invaluable management tools in many situations. They provide an unbiased, independent evaluation of the quality of product documentation, identify the need for additional data or new studies, and make positive recommendations on how the package can be brought up to the standards required for successful registration.

During preclinical and early clinical phases, a review of the historical data is crucial to future strategic planning. Assessment of the raw data prior to compilation of a registration dossier can save a rejection by the authorities. This not only speeds up the approval but avoids the high cost of an appeal.

Independent assessment reports carry weight in licensing negotiations or in technical due diligence, ensuring agreement is only reached on products destined for an early launch.

We have even prepared assessment reports to support funding applications to banks and venture capitalists.

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**

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