



Webscout:

The world of drug development and approval

by Joeyn Flauaus

Regulatory writing includes, among other things, preparation of documents to be submitted for drug approval. In the course of drug development a broad spectrum of documents needs to be written, such as clinical study protocols, clinical study reports, investigator brochures, and 'Common Technical Document' (CTD) modules. Generally, the writing of submission dossiers (CTD modules) is the most challenging as all the data gathered in the course of drug development are summarized and discussed.

Because writing regulatory documents is a complex process, some insight into clinical development and regulatory requirements is useful. Medical writers have to make sure documents comply with regulatory or other guidelines for content, format and structure.

Below you will find a selection of links that provide you with detailed information, guidelines and templates that are required in drug development and for drug approval.

<http://www.fda.gov/oc/gcp/>

Good Clinical Practice (GCP) is a standard for the design, conduct, performance, monitoring, auditing, recording,

analysis, and reporting of clinical trials. This site provides information on Good Clinical Practice in FDA-Regulated Clinical Trials.

<http://www.ich.org/>

The regulatory authorities of Europe, Japan and the United States previously had their own processes and requirements for obtaining regulatory approval but a harmonization of these regulatory authorities was required to ensure a more economical use of human, animal and material resources, and reduce unnecessary delay in the global development and availability of new medicines. Hence, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was established to co-ordinate and harmonize international regulatory requirements.

<http://www.aboutctd.com/index.htm>

The CTD, a specification for applications for drug approval, was designed to be used across Europe, Japan and the USA. The CTD is maintained by ICH. This site provides comprehensive and detailed information about the CTD and the Electronic Common Technical Document (eCTD). In the download section, you can find the latest guidelines, templates, and FAQs for various modules.

<http://www.clinicaltrials.gov/>

This site, a service of the US National Institutes of Health, provides information about clinical studies in human volunteers sponsored by the National Institutes of Health, other federal agencies, and industry. Studies conducted in the US and in over 120 countries are listed in the database by diseases, treatments, locations, and names of researchers.

<http://www.wiley.co.uk/genetherapy/clinical/>

This site provides information on worldwide gene therapy clinical trials. The database allows a search by continents and countries where trials are being performed, indications addressed, vectors used, and gene types transferred.

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Please email me at joeyn@trilogywriting.com with any URLs comments or suggestions for the next issue.

Sensationalising science

The Social Market Foundation (SMF), an independent public policy think tank (www.smf.co.uk), has accused the UK media of sensationalising science. Pointing to the MMR vaccine shambles as an example, Claudia Wood of SMF said she thought the media should be cautious in how it gives over scientific evidence, and it should make sure that people understand that there are certain risks to some things but a lot of the time evidence isn't conclusive. The SMF have made several recommendations for improving scientific understanding among the public:

- Newspapers and broadcasters should employ more science graduates
- Scientists and science graduates should be encouraged to undertake media training
- Universities should offer multidisciplinary science degrees, which include issues of ethics
- Policymakers need a better understanding of public perceptions of risk

See: <http://news.bbc.co.uk/1/hi/sci/tech/4771154.stm>