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特別講演

Drug Research and Development Services in the United Kingdom

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Prior to 1968, there existed in the UK a purely voluntary scheme for the control of medicinal products under the Dunlop Committee, so called after its first chairman Sir Derrick Dunlop. This was set up in the aftermath of the thalidomide disaster which struck in the early 1960's. Later, new and far-reaching legislation for the control of drug development, clinical testing and marketing was introduced in the UK in the form of the Medicines Act 1968. As a result of these changes pharmaceutical companies had to restructure and expand their drug development and regulatory departments in order to meet the demands of the new laws. At the same time a few enterprising individuals recognised a potential market for independent contract organisations to provide comprehensive services with respect to drug research, development and testing for pharmaceutical manufacturers who either had no available in-house expertise or whose manpower resources were stretched to capacity.

Thus, in the early 1970's the first contract research organisations (CROs) were founded in the UK, a country which is internationally recognised as one of the foremost in the world for drug research. There are many examples of major drug discoveries originating in the UK including, to name a few, penicillin, β -blockers and H_2 receptor antagonists, which have had a significant impact on world healthcare. In parallel with this, the concept of controlled clinical trials with the application of appropriate statistical methods was developed and maintained alongside the introduction of a system of controls overseen by the national drugs licensing authority (Medicines Control Agency). A more recent, important development for the UK following the introduction of a central drug approval process for all member countries of the European Union, is the establishment of the offices of the European Medicines Evaluation Agency in London. Considering these factors, it is not surprising that Britain has the highest number of CROs in any

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country apart from the USA, and that drug companies from around the world seek to have clinical trials carried out in British universities, hospitals and other institutions. In many cases, foreign drug houses prefer to use CROs which have access to the leading investigators and are familiar with the drug registration processes in the UK and Europe.

The number of CROs in Britain has increased considerably in recent years particularly since the introduction of Good Clinical Practice (GCP) in 1990 and companies wishing to develop their drugs in the UK can choose from the large multinationals to smaller UK-based companies. These latter include individuals offering specific services such as study monitoring and companies offering a range of services such as pre-clinical testing, Phase I studies, Phase II/III clinical trials, regulatory submissions or other combinations of functions involved in drug development.

As pharmaceutical companies continue to downsize and outsource a greater proportion of their work and with the growth of young biotechnology companies with limited in-house facilities, it seems certain that the CRO sector will see continued growth over the next few years, together with strong competition resulting in an overall improvement in the standards and uniformity of services.