

## Qualified Persons - The Key to Europe for North American Pharma

**THE** European Economic Area, consisting of 27 member states with a total population in excess of 500 million and a common regulatory framework, is a very attractive region for performing clinical studies. As a result, an increasing number of US and Canadian pharmaceutical and biotechnology companies are now looking to Europe as the primary or secondary location for more and more of their clinical trials.

However, in May 2004 the EU implemented Clinical Trials Directive 2001/20/EC, and companies wishing to undertake European clinical studies must comply with the regulations of this Directive. In summary, Investigational Medicinal Products (IMPs) manufactured outside of the European Economic Area (EEA) for use in European clinical studies must be imported into a European based licensed facility, released by a Qualified Person (QP) at the site and distributed to the clinic from the licensed facility.

For those larger companies with a presence in Europe and North America these regulations are reasonably easy to manage. However, for smaller pharmaceutical and biotechnology companies with no presence in Europe, these regulations can be quite daunting and off-putting. The regulatory framework is complex and all non-EU companies

who sponsor clinical trials must now use the specialised services of a QP in order to comply with the regulations. This can potentially be an expensive and protracted exercise because the QP has to perform a number of duties in order for the Clinical Trial Application to get the go ahead.

The QP must provide a statement to the effect that any non-EEA manufacturers which have been used, have cGMP standards which are at least equivalent to those specified within the EU. The QP must therefore carry out GMP audits of the supply chain (typically including drug substance manufacturers, drug product manufacturers and associated testing facilities) to determine that they are of the required standards before submitting the Clinical Trial Application.



Normally, there are very significant cost and time factors associated with getting European based QPs to perform the necessary audit of the supply chain in terms of international travel and availability.

To meet the needs of the smaller companies wishing to conduct clinical trials in Europe, Piramal Clinical Trial Services has now announced a new and unique offering which can dramatically reduce the cost of this process. Piramal have a dedicated, UK registered QP located in North America who is able to explain the process, perform the necessary GMP audits of your supply chain and review associated GMP batch documents and very much simplify the process. This is in addition to the three QPs that Piramal Clinical Trial Services currently have working from the UK who do the final QP release of the supplies.

Piramal work closely with sponsors to plan and organise the QP certification procedures, and the QP's GMP audits of your manufacturers.



Because this cuts down on the time and cost associated with the typical QP's transatlantic travel, Piramal can offer a very cost effective and responsive service. In addition to this, clients get the benefit of working with a QP with over 20 years experience in this field.

Piramal can also use its considerable resources to successfully and safely import the materials destined for clinical trials in the EU, and offer guidance on importation requirements for the countries participating in trials. Piramal also manage the onward shipments of patient kits to the clinical site through their GMP Global Distribution network. The company can prepare and manage the design, packaging and compilation of both open and randomised patient kits and offer translation services for non-English speaking countries.

For more information about this and all the other services that Piramal Clinical Trial Services can supply, please contact Chris Williams ([chris.williams@piramal.com](mailto:chris.williams@piramal.com)).

Piramal Clinical Trial Services

[www.piramalclinicaltrials.com](http://www.piramalclinicaltrials.com)

Tel: +44(0) 1670 562 400