The complete package

Sometimes it makes sense to ask for a helping hand from a clinical trial management expert. Mark Paiz from **Sherpa Clinical Packaging** discusses the benefits of outsourcing some aspects of a business, so that one can better manage internal resources and concentrate on core competences.

Can you provide some background about your company?

Mark Paiz: Sherpa Clinical Packaging started doing business in clinical packaging in mid-2011 in the heart of the San Diego biotech community. Sherpa was founded by a former medical products industry executive and a packaging entrepreneur.

The organisation provides clinical trial material management services for clinical studies phases I–IV, including packaging, labelling, distribution and returns/reconciliation, for pharmaceutical, biotechnology, medical device and dietary supplement companies.

Sherpa specialises in labelling and packaging biologics and cold-chain logistics, but also handles solid-dose bottling. Our capabilities will soon also include cold-form and thermoform blistering. We believe that there is a need for our services on the West Coast, where many biotech companies are developing new drugs, especially biologicals. So, with this in mind, we built our facility adjacent to a contract manufacturing organisation (CMO) that manufactures biologics and performs fill finish to give clients the option to work with both companies for their clinical trial material needs. In the past three years since start up, Sherpa has served over 60 clients.

What challenges do smaller pharma and biotech firms face compared with their larger counterparts?

Small and virtual pharma companies sometimes need more help and guidance than larger companies with wider experience and resources. Small firms also tend to be very passionate about their project because it may be the only product being developed and one that will completely determine the fate of the company. As such, they may ask for added attention and may have many special requests.

How can these hurdles be overcome?

These needs can be met when pharma companies select suppliers that are a 'good fit', which is to say that they should have some similar characteristics. Passion, entrepreneurial spirit, personal commitment and other related traits often differentiate small vs large companies.

How can CMOs get the most out of collaborations with packagers?

After a clinical drug product is manufactured by a CMO, it is usually bulk packaged and often sent to a clinical packager for labelling and packaging into patient kits suited to the design of the study. Some large CMOs may offer clinical packaging and distribution services, which give them the advantage of having a 'one-stop shop'. Other CMOs can add value to their services by partnering with a clinical packager to offer a more comprehensive solution. Sherpa has trademarked The Complete Package™ to market its collaborations with CMOs. Sherpa currently has several relationships that result in win-win results for the client, the CMO and Sherpa.

As the clinical trials outsourcing market becomes more global, how is Sherpa responding to this trend?

Sherpa is responding to the increase in global clinical trials by partnering with clinical packagers in the EU (that can provide qualified person (QP) services) and the Far East (that can act as a depot), as well as working with speciality couriers and depot networks in countries around the world. Often, the in-country contract research organisation (CRO) has depot relationships that are leveraged to meet study logistics needs. A clinical packager does not need to replicate a global depot network in order to effectively and efficiently support clinical trials around the world.

What sets Sherpa apart from its competitors?

Sherpa prides itself on its high level of customer service. All of its employees must perform their jobs with the customer in mind and take this responsibility as seriously as any customer would. Sherpa can be flexible and creative without sacrificing quality or compliance, because it engages its clients to discuss the best options and solutions for their projects. Also, Sherpa is very adept at handling complex studies and cold-chain materials. Many of its customers use pre-filled syringes or vials with strict temperature control requirements. Sherpa's facilities were built with this in mind and it regularly performs packaging and labelling at 2–8°C and even at -20°C (yes, inside the freezer).

What are your future plans?

Our future plans include continued collaboration with CMOs and CROs to offer The Complete Package. We will soon have blister packaging capability for syringes and solid dose products. We also intend to significantly expand our controlled temperature storage capabilities to support the growing need for large molecule and biological products. ■

Further information
Sherpa Clinical Packaging
www.sherpaclinical.com