

# Stay cool

As clinical trials become more global in nature, and outsourcing more common, pharmaceutical companies' logistics needs are changing. Mark Paiz, president of **Sherpa Clinical Packaging**, explains how a specialist in CTM management services can provide the support they require, particularly in the field of temperature control.

**C**linical trial materials (CTM) are becoming ever more complex to manage. As biologics-based products become more prevalent, temperature control is key, and pharma companies require logistics partners with well-developed cold chain capabilities.

This isn't simply a question of cranking down the heating. As these drugs are so sensitive, it's important to control the environmental conditions at every step of the way. This might mean cold storage, cold processing and cold packaging, sometimes in temperatures as low as -20°C.

"In some cases, there is no stability data on the product when we receive it, and we have to process it at cold temperatures as well as store it," says Mark Paiz, president of Sherpa Clinical Packaging. "So a clinical packager's systems and capabilities have to be carefully designed."

## Labelling and packaging

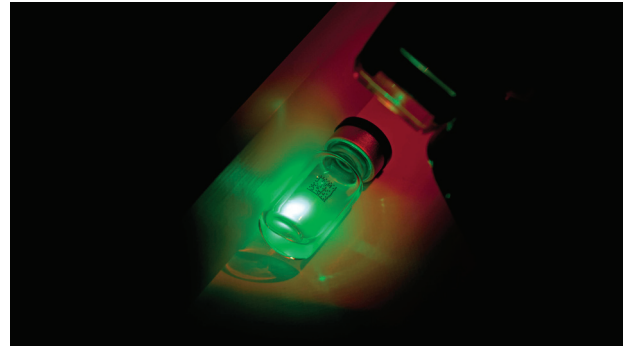
Sherpa Clinical Packaging is a leading provider of CTM management services, based in San Diego, US. It specialises in supporting small to medium pharma and biotech firms, especially virtual companies, which tend to require more collaboration than their larger equivalents and are increasingly counted upon for product development work.

Specifically, Sherpa provides primary and secondary labelling services, as well as packaging for phase I, II and III clinical trials. In the case of randomised blind clinical trials, it can also provide the randomisation if needed. Following storage, it will ship the material directly to the clinical site, and subsequently handle the returns (and destruction of the material) at the end of the trial.

"There are a lot of parenteral drugs being developed in our area, and so we knew we needed extensive refrigeration and freezers," says Paiz. "We have walk-in temperature-controlled storage areas at 2–8°C, -20°C and controlled room temperature. So, if a company wants to have the labelling performed at -20°C, it can be done."

Sherpa was founded in 2010, hence its facility is relatively new and all equipment is up to the minute. All of its walk-in cold rooms have redundant refrigeration systems to ensure back-up in the case of mechanical failure, and its key systems use emergency power. It goes without saying that the facility is fully monitored and alarmed.

"We're an expert in handling parenteral drug products – anything that's in a vial or pre-filled syringe that requires cold storage and cold processing – and we're an expert in working with companies that need collaboration," says Paiz. "We're also the only dedicated clinical packager on the West Coast in the US, so that makes it convenient for clients that are west of Mississippi from a time zone and access standpoint."



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## A global outlook

As the clinical trials outsourcing market becomes more global, Sherpa is responding accordingly. It is focusing on cultivating relationships with CMOs, CROs and non-US-based clinical packaging companies, which gives it the capacity to support the needs of international clinical trials.

"We're continuing to expand our alliances with other companies that can sell Sherpa services in a synergistic offering with their services," says Paiz. "Not only are US companies looking to other countries to conduct their clinical trials, but also companies in other countries may need to conduct some studies in the US to have their product commercialised here. That requires us to think globally, asking how we are going to play in this changing market."

Above all, Sherpa sets itself apart through its reliability and emphasis on customer service. Since its clients tend to be heavily involved in the details of their outsourced projects, their specific requirements are given top priority. The company can design, supply and assemble kit configurations as requested, with materials ranging from chipboard boxes to die-cut foam. Looking to the coming year, its list of services will expand further still.

"We're going to continue to expand our operational capabilities and cold-storage capacity – we'll continue to do that on an as-and-when basis – but we're also looking at bringing in more primary packaging capabilities such as blister packaging," says Paiz. "Generally, I think Sherpa will be well equipped to support clinical trials in 2014." ■

### Further information

Sherpa Clinical Packaging  
[www.clinical-packaging.com](http://www.clinical-packaging.com)

