

A SIMPLE ANSWER TO COLD CHAIN CHAOS

Pharmaceutical manufacturers and distributors are coming under a barrage of stringent regulations when faced with the challenges of cold chain distribution. While the pharma industry is well regulated, there is some confusion when it comes to the shipment of goods worldwide. Fortunately, Rafik Bishara is working towards a standardised set of global guidelines.



Profile

Rafik H Bishara, PhD, is the chair of the Pharmaceutical Cold Chain Discussion Group, Parenteral Drug Association. Bishara retired from his position as director, quality knowledge management and technical support for Eli Lilly and Co after a 35-year career. He frequently chairs industry conferences, has authored numerous articles and technically advised on good cold chain and temperature-controlled management practices.

As world attention increasingly focuses on strict cold chain practices, legislation and guidelines for different countries are proliferating. The result is a myriad of issues that pharmaceutical companies must put in practice when shipping goods internationally. But there has been a marked increase in the number of guidelines being published globally, as well as within regions in each country.

To rein in this confusing situation, the recently formed Temperature Control Pharmaceutical Group (TPG), which brings together cold chain experts from around the world, is working on a new global standard. The TPG is chaired by renowned cold chain expert Dr Rafik Bishara, who spent 35 years with pharmaceutical company Eli Lilly and is now a technical adviser for several organisations.

‘From mid-2005 to the end of 2006 we have seen about a dozen new regulations from around the world,’ he says. ‘Some are from Europe, some from Latin American countries such as Brazil

and Venezuela, while others have come from the Far East. We’re also finding that several countries within the EU are starting to indicate individual requirements. For example, there’s an Austrian or Italian requirement that may well be different to requirements from other countries. The good thing is that this shows that global regulators and governments are all interested in the proper handling of temperature control and sensitive pharmaceuticals, vaccines and biopharmaceutical products.’

The amount and variety of guidelines are likely to result in major opportunities for supply chain partners. ‘It is certainly a challenge for manufacturers and everyone involved in the supply chain,’ says Bishara. ‘All the people involved in the distribution chain need to pay attention to regulations, especially now there are more requirements that they have to meet and standards that they have to pay attention to.’

For example, shippers will need to know the requirements of the receiving region or country. But in general, these are all good business practice, according to Bishara.

‘As a patient, I would like it if the medicine coming to the US, Europe or wherever, has been properly handled to ensure the quality and integrity of the supply chain so that when I receive it, it has not been compromised,’ he says.

TPG Discussion Group

The risks of not heeding guidelines cannot be overestimated, as global regulators are now giving citations if these standards are not met. Over the last three years, Bishara has been working with

TPG members to produce a comprehensive global standard that will bring much-needed clarification and simplicity to the cold chain distribution process.

In developing this standard, there has been significant harmonisation operating between Europe and the US within the TPG's Discussion Group. The first meeting – the PDA Pharmaceutical Cold Chain Management Conference, sponsored by the Parenteral Drug Association – was held in Berlin, Germany, in October 2006. Here, European representatives from both the Cold Chain Committee and the Pharma Logistics Forum participated in the Pharmaceutical Cold Chain Discussion Group. Industry members shared examples to enable a clear understanding of problems in the world of temperature control and discussed ways to move forward as a collective group.

‘Although we are not a regulatory body we are looking at industry best practice’ says Bishara. ‘This will help us promote the best products and from there, we will offer opportunities to communicate with regulators and with pharmacopeias.’

WHAT IS THE PDA?

The Parenteral Drug Association (PDA) is a global association for the advancement of the science and technology of pharmaceutical, biopharmaceutical and related products. Its community of more than 10,000 individual member scientists represent large and small companies, regulatory agencies and academia.

The PDA works in the science and technology of manufacturing pharmaceutical, biopharmaceutical and related products, and in development, quality assurance, quality control and regulatory affairs. It is dedicated to:

- Advancing pharmaceutical and biopharmaceutical science and technology
- Global sharing of knowledge and innovation
- Creating a healthier tomorrow

Best practice

So what can we expect from the results of this harmonisation programme? Will the standard USP <1079>¹ be amalgamated with the PDA's best practice document, Technical Report 39²?

‘The USP <1079> is an official standard because by US law they are empowered to develop these public standards,’ says Bishara. ‘By contrast, the Technical Report 39 (TR39) represents industry best practices, and we are now revising it with European colleagues with the aim of publishing it in the second quarter of 2007. Although it represents industry best practice, it does not have any power of regulation under EU or British law, or by the FDA. Since we've established a good dialogue with representatives from these agencies, we hope that it will be adopted and that we will continue to work with pharmacopeias and regulators.’

Not only is the TR39 gathering momentum in the US and Europe, but the work of the TPG has won the support of Australian colleagues who are interested in joining them and working together, which will bring another continent into the mix – and represent another step on the route to a global guideline on the cold chain. According to Bishara, the Australians will bring interesting issues to the table because they have to tackle such extremes of cold and heat due to the vastness of the country.

EXAMPLES OF EXISTING COLD CHAIN GUIDELINES

USP <1079> offers guidance for manufacturers, distributors, wholesalers, repackagers and transport logistics providers handling pharmaceutical products. The document gives advice for ensuring a product's identity, strength, quality and purity across the entire distribution channel – from manufacturer to pharmacy. USP <1079> covers requirements for the handling and storage of products in:

- Warehouses
- Pharmacies
- Trucks
- Shipping docks
- Other locations

The Technical Report 39 provides guidance to both the pharmaceutical industry regarding shipment of products that require controlled temperatures during transit. It also offers a design approach to the development of specialised packages and systems, which will protect temperature-sensitive products during transportation.

Global credibility

While great progress is being made, it will inevitably bring even more challenges as more people get involved in the development of this global document. ‘It's taken three years to get everybody together to agree that to change anything for the better, we must stand united,’ says Bishara. ‘I don't envisage there being as many challenges ahead as there were in the past. Now we are bonding and we are building synergy. Timing is very important. Because of the continuous flow of regulation, people are realising that the more we discuss, the more we understand, and so the better all of us will be. We will invite regulators to join us so we can exchange ideas and make sure we are aware of all the challenges.’

The anticipated result of all this discussion, Bishara hopes, is a harmonised document that includes input from the major regions around the world, in particular Europe and the US. ‘The discussions will show that people in the global industry are working together,’ he says. ‘Hopefully that will help in getting more credibility with the regulators. The exciting point for me is that both sides of the Atlantic understand the challenges and are working on solutions. We will involve pharmaceutical companies, and send it to some of our supply chain partners and service providers so that they understand and will be able to provide good cold chain solutions. It's an area of importance to make sure that temperature controlled – and that includes controlled room temperature, refrigerated and frozen products – need to be handled properly and we are doing our best to provide the guidance to help us to achieve this goal.’

As more attention is focused on ensuring the highest standards for temperature-controlled products, the work of the TPG will be keenly watched in the coming years. Bishara's dream of a global standard on cold chain looks not only likely to succeed in the near future, but it will also be an outstanding legacy. **END**

References

- 1 General Chapter <1079> Good Storage and Shipping Practices, USP 29/NF24; USP 30/NF25 becomes official on 1 May 2007.
- 2 Technical Report 39, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment: PDA; 2005.