

A Colder Climate

Herbert Ernst at Sensitech talks to *PMPS* about the impact of the recession on the company, as well as on the cold chain industry as a whole

Q How do you believe the financial downturn has affected the pharmaceutical industry as a whole over the last few months?

A Business analysts suggest that the current situation of the worldwide economy is likely to prompt the pharmaceutical and biotech industries to enter an intense phase of mergers and acquisitions. The driving force behind this will be related to drug development activities and the associated funding possibilities. While it is to be expected that private equity funds will be more reluctant than previously to invest in high risk product development, especially in the biotech arena, the major pharmaceutical companies must be expected to do the exact opposite. The pharmaceutical and biotech industries understand the importance of the development of new and increasingly effective substances to ensure their own future, and simply cannot afford to neglect product development. Various leading analysts suggest that the lack of private equity funding possibilities will allow the big pharmaceutical players to use their advantage and profit on licensing and acquisition deals.

For smaller pharmaceutical and biotech companies, this will be a serious problem; the funding of late stage clinical trials may force them into the hands of bigger players. Biotech interest groups in the UK have gone so far as to suggest that the government should help compensate for the lack of available venture capital by providing a joint fund, while in Germany, tax breaks are requested from the government for development-related activities.

The product development efforts are stronger than ever before. Cost cuts are attempted in the overhead, particularly in sales, marketing, and management, to help fund these activities. Further attempts to reduce costs and increase efficiency, which experts claim have been put off or neglected for too long, are also to be expected. At the same time, the industry is careful not to compromise on quality-related issues.

Signs from healthcare insurers, public healthcare organisations, and the upcoming US Government strongly indicate that these organisations will be looking more carefully for proof of potency of pharmaceutical substances in the future, not least to cut down on 'ineffective' spending. Consequently, this will require more detailed clinical data from trials in the development phase, resulting in more complex and costly clinical trials, further enforcing consolidation.

Q What specific implications have there been for those involved in the cold chain sector?

A Since robust cold chains are directly connected to the product quality and are subject to regulatory requirements, there has been no immediate effect of the global economic crisis on the used procedures and best practices. Nevertheless, the ongoing activities to consolidate and standardise the cold chain management are pushed with increased urgency to consolidate the current Good Cold Chain Management Practices (cGCCMP). This includes a complete revision of USP 1079, a summary of current good cold chain

practices, a revision of chapter 17 of the IATA Perishable Cargo Regulations, as well as the approaches by the International Conference on Harmonization (ICH), which are all ongoing. A more significant effect of the financial situation may have to be expected in the field of third party logistics providers, who play an important role in the cold chain. Although the current relatively low oil prices, prompted by the financial crisis and subsequently reduced oil demand, are in their favour, an increase in oil prices is to be expected in the future. This will undoubtedly affect costs significantly. With this in mind, it is important to note that cold chain qualifications serve not only the purpose of risk evaluation, but also cost evaluation and optimisation. I find that in the majority of qualification projects, Sensitech's involvement in this aspect is not always sufficiently acknowledged by our clients, who rightfully rank quality aspects highest. The use of cold chain data for the improvement of long term business processes is yet to be discovered by the pharmaceutical industry. Other industries, such as the food industry, have set examples of what can be achieved in a more financially rigid, driven market.

Q How has Sensitech in particular reacted to the new economic reality?

A We are constantly working on improving the quality and efficiency of our products and services. At the same time we are, of course, in constant discussion with interest groups and industry forums to help consolidate and standardise cold chain related processes with the goal of optimising cold chain management practices, reducing the

related risks to the product and consequently the end user. We see it as our task not only to help our clients in the cold chain related risk assessment, but also to help them understand and evaluate the related costs.

Q What lasting impact do you see the recession having on cold chain operations within the industry?

A Under the given financial conditions, the pressure to consolidate cold chain management approaches in order to increase their efficiency is probably higher than ever before. This, in combination with the likelihood of mergers and acquisitions mentioned earlier may lead to more centralised and standardised approaches to cold chain management. If and when this will actually happen is yet to be seen.

We see today that some pharmaceutical players are considering taking high risk approaches on the transport leg of their cold chains, particularly during the shipping phase, by fully relying on packaging



About the author



Dr Herbert Ernst studied Engineering at the University of Braunschweig and Microsystems Technology at the

University of Freiburg, Germany, where he received his PhD for his study on high resolution thermal measurement methods. He has been working in the research and development of the medical device industry for over 11 years, and is also highly experienced in temperature monitoring and related sensor technologies. In 2007, Herbert joined the Professional Services group at Sensitech, where he is responsible for the pharmaceutical sector within Europe, the Middle East and Africa, focusing on the consultancy of the pharmaceutical industry on cold chain management-related issues.

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validation to indicate adherence to transport temperature specifications, rather than monitoring actual temperatures on individual shipments. This may help save costs in the short term, but neglects the fact that packaging validation is carried out under fixed assumptions that may not always be met under actual conditions. This approach is not only questionable for its increased risk to the end user but, equally importantly, it neglects current good cold chain practices, such as the recommendations by USP 1079, or the trends seen on the regulatory side. Certain European countries, such as Austria or Italy, are in favour of making temperature monitoring on all pharmaceutical shipments mandatory. It is likely that the result of this approach could be far more costly in the end.

This trend can be anticipated by defining and following clearer

procedures and industry standards, in particular for the development of validation specifications. What is required does, in principle, come down to good practices for system validation. Although we are all aware of what validation entails, the approaches that are being followed are still very widespread and, in some cases, inconsistent with the specified technical objectives.

Industry-driven interest groups such as PCCIG and PDA are working very hard on defining new best practices. We at Sensitech are following these approaches with great interest and believe that they show great potential.