

Cool heads, smart chains

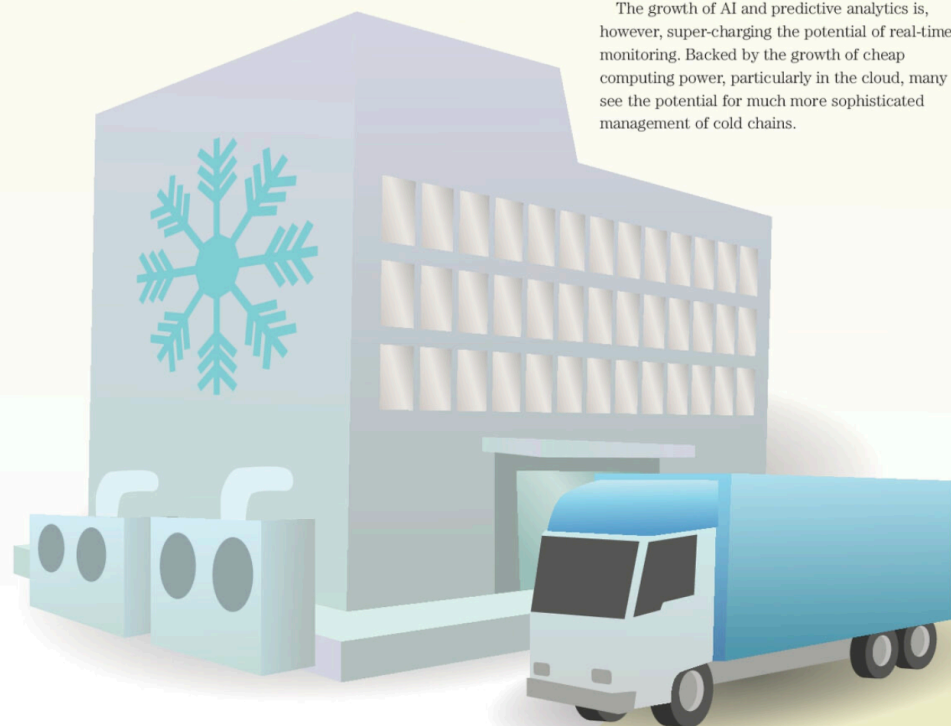
Biopharma companies are harnessing AI and predictive analytics to transform temperature-controlled logistics, with new entrants and innovations bringing advanced monitoring-and-control solutions. Claire Read speaks to **Jim Bacon**, president of Stay Cool Logistics Consulting, and **Phil Pluck**, chief executive of the Cold Chain Federation, about why building internal expertise and infrastructure is vital to support data-driven decision-making.

Jim Bacon has seen many developments in temperature control technologies during his two decades working in the pharmaceutical cold chain, but as he surveys the current horizon, he feels particular excitement.

"The biggest potential that I can see is in analytics; projecting and viewing in real time what's happening on shipments," says Bacon, the president and founder of Stay Cool Logistics Consulting.

In and of itself, the idea of real-time monitoring of shipment temperature is not a new one. Sensor technology has been around for some time, keeping a check on the conditions in which a drug is being stored. Increasingly, such devices assess factors such as humidity and air pressure as well as temperature, helping generate a deeper understanding of the situation across a drug's journey from the warehouse to the final destination.

The growth of AI and predictive analytics is, however, super-charging the potential of real-time monitoring. Backed by the growth of cheap computing power, particularly in the cloud, many see the potential for much more sophisticated management of cold chains.



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Real-time data allows for real-time actions that could stop pharmaceutical waste.

Bacon, who worked for several pharmaceutical companies before setting up his own firm last year, sees the technology as supporting a growing shift "from insurance to assurance".

"The earlier devices provided some insurance that at the end of the trip everything was fine," he explains. "You could easily see if there had been a temperature excursion, the gravity of that excursion, [the] length of time that excursion occurred, and so be able to ascertain whether the excursion was detrimental to the product or not."

Now the idea is to get ahead of any such excursion happening. "The technology transition is to assurance, where you're trying to predict what could potentially happen," he says.

"You're doing some lane risk analysis, where you might gather historical data over a period of time for particular lanes [by which drugs are being transported], and then you can determine what the incidents [with temperature excursions] might be, were they to happen. Where that leads is that you can then develop contingency plans."

In other words, real-time temperature monitoring technology is no longer simply focused on ensuring that the correct mark on the thermometer is being hit – and alerting when it's not. The next frontier is to use that data to make predictions about when problems are likely to occur, enabling early intervention.

"The technology that is going to take us to the next step is the technology where that sort of logic is built into the devices and software," says Bacon.

He cites a real-life scenario as an example of the difference that could make. It happened a few years ago, when a drug delivery was passing through an airport before connecting to another flight. A sensor showed that it had been put in a storage facility at the wrong temperature.

"We were able to see that in real time and

contact the airline," Bacon remembers. "They swore it was in the right facility, but we convinced them to go and look [because we had the real-time data]. They came back and confirmed it was in the wrong place. So, these real-time devices have really helped save product."

With AI-powered technology, however, the hope is "you get this predictive concept". Perhaps software will alert that there was a previous issue with that specific airport at that particular time of day and during that particular month, and flag that additional checks are needed. "It'll say: 'Hey, I've seen this happen before, and here are some of the contingencies you might be able to do right away to get things back on track'," says Bacon.

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Jim Bacon

Climate change to labour shortages: challenges shaping the cold chain

The potential causes of a temperature going off course are complex. Phil Pluck is chief executive of the Cold Chain Federation, a UK-based body representing the businesses that run the temperature-controlled supply chain, and cites numerous factors the industry now needs to manage. Some are centred on the sector itself, but others speak to issues that are worldwide challenges.

"If we look at the global issues that affect storage and distribution, we have climate change," Pluck begins. "We have an ever-increasing resistance to some drugs and therefore an ever-increasing production of other drugs. We have fluctuating energy prices. We have the drive towards a net-zero

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50%

Vaccines are wasted globally due to a lack of temperature control, logistics and shipment issues.

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future. And we have a recruitment crisis – can we get enough operatives in our warehouses, and enough drivers to drive the refrigerated temperature-controlled trucks that exist in the cold chain?”

He says progress is already being made in each of these spheres but believes that AI and other sophisticated technologies have the potential to accelerate that further. “When you look at these issues, it makes complete sense to look at how we can become much more efficient in the supply chain itself, and that’s where AI, new technology and predictive analytics all comes into play. I think times are very, very exciting.”

Indeed, he says data is already making a difference by making it easier to understand which temperature-controlled drugs are needed where. “Looking at our analytics, both historical and current, and taking into account seasons, the climate of the surroundings, we have enough analytics to understand what drugs need to be where and in what quantity. What that means is that we will have a hugely efficient distribution network and storage network moving forward, because we can feed in those analytics,” he suggests.

“It’s not unusual for a pharmaceutical delivery vehicle to operate today at 5°C, but then it picks up another order tomorrow, and it will then be operating at -15°C.”

Phil Pluck

And in an age of increasingly extreme temperatures, there is the potential to identify refrigeration failures before they happen.

“If we’re storing drugs at, let’s say, -25°C then there will normally be an enormous warehouse roof,” says Pluck. “It’s got solar panels on it, but if the temperature outside goes to 40°C, what that means really is the temperature of that roof is really sitting at about 51°C or 52°C in the sun. In order to keep -25°C underneath that roof, what’s going to happen is your refrigeration unit is going to have to work harder and harder.

“What we’re now introducing is predictive technology into large-scale refrigeration units. That means it predicts when something is likely to break down under certain circumstances and it predicts when we need to do maintenance.”

Protecting products – and patients – through smarter cold chains

It is not only storage units for which this is useful; it equally applies to vehicles being used to transport drugs. Pluck says this is important for pharmaceuticals because while refrigerated food deliveries involve keeping a consistent temperature between jobs, the same is not true for drugs.

“It’s not unusual for a pharmaceutical delivery vehicle to operate today at 5°C, but then it picks up another order tomorrow, and it will then be operating at -15°C. And then the next day it’s operating at -30°C.

“Those variations in temperature are not unusual and what that means is it’s more stress on the refrigeration units; more stress means more breakdown, which means that actually those drugs are not getting where they need to go. So those predictive elements of AI can drive down the costs by predicting those maintenance issues and understanding precisely when that point of failure is likely to happen. And for critical temperature-control drugs, that is a bit of a game-changer in terms of how we distribute those drugs.”

Certainly, there is a growing number of products for which such insight is likely to be useful. The growth in biologics, derived from living organisms, brings with it more drugs that require temperature control. And vaccines provide a continuous demand for an effective cold chain. Notably, it is a demand that is frequently not met. In the past, the World Health Organisation has estimated that up to ~50% of vaccines are wasted globally, largely due to lack of temperature control, logistics and shipment issues.

Such failures have a human price but also affect the financial bottom line for companies. That is particularly the case as drugs become more complex and thus more expensive to develop.

“Over the past 25 years, the cost of these products – to develop them, and then the products themselves – is such that they have become invaluable,” argues Bacon.

“The costs are so tremendous that you can be shipping millions of dollars in a small box. And many of these products are life-saving drugs. If they don’t get to where they need to be at the right temperature and the right time, it could be a very negative outcome for the patient.”

It is a point he says he always emphasises to colleagues within pharmaceutical cold chains. Indeed, asked what companies need to do if they are to capitalise on the latest technological developments, he says they need to build an understanding of this theme.

“You need very tight and compliant procedures in a cold chain, and then what follows is training [to help people understand why temperature regulation and compliance is so important]. This is where a lot of companies fail, because they take things for granted. The companies that do best are the companies that keep those things top of mind.”

Ultimately, he says that companies reviewing investment in temperature-control technologies need to consider the stakes. “It’s not just a package,” he stresses. “It’s a patient.” ●