ELPRO

WHITE PAPER

How to Implement a Temperature Excursion Allowance Model Using Multi-Level Data Loggers

we prove it.

Allowing Excursions Reduces QA Resources and Product Release Time

The other day someone asked, «can you *allow* excursions?». Yes, you can.
Temperature monitoring can be seen as yet another process to get under control for pharmaceutical shipments, and at times some companies want the easiest solution. Pick a high/low data logger off the shelf and throw it in the box.

But, what if you could save hundreds of hours in processing excursions and release products much quicker? It's possible, by implementing a temperature excursion allowance model.

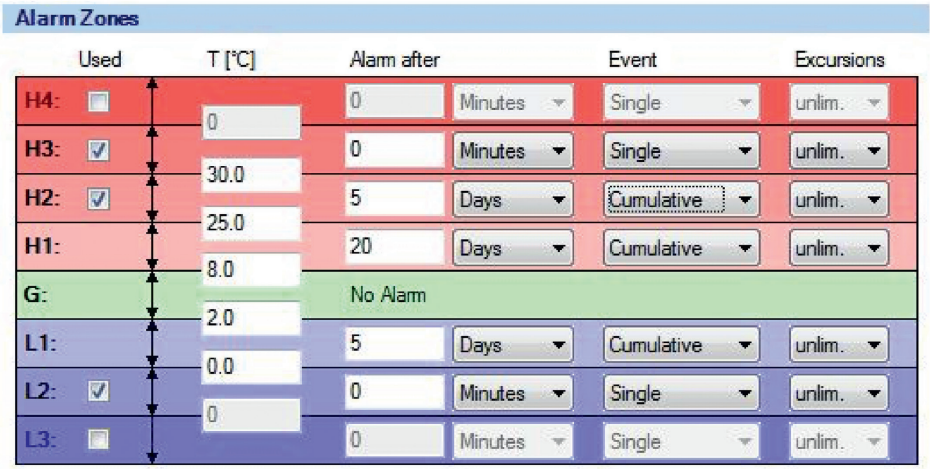
Step 1
Do you have stability data of your products? If not, this becomes the biggest challenge. If you ship clinical products, there is unlikely much stability data available yet. It's also common that a manufacturing site or the development teams haven't supplied the data. In any case, start asking where and how you can find stability study data that helps you decide on quality control processes.

In a 2015 benchmarking study with 5 globally acting pharmaceutical manufacturers, the responses varied when asked «What type of stability data do you ‹own›?». Several of the companies indicated for +2 °C..+8 °C products, they follow a «zero risk» policy and ship strict +2 °C..+8 °C. However, at times will use stability data at receiving sites to «cure» excursions. Whereas for CRT or «warmer» products, stability data is assigned to each leg of the supply chain using a stability budget, programmed into the data loggers or used at shipment receipt to «cure» excursions. There was one of the five companies interviewed that uses 100 % stability budget approach for their entire supply chain. So overall, companies are using more risk-based approaches for CRT products, or as the benchmarking study further describes, for lower value products.

Step 2
Make your business case. Identify products that have stability data, group them if possible, and write a protocol that explains the product efficacy remains intact if the product goes out of specification for certain time periods.

Step 3
Use multi-level data loggers. Based on your protocol justifying product stability outside strict storage limits, then take the stability data to program loggers to allow for certain number of minutes/hours outside of range. See Table 1 on page 3, this +2 °C..+8 °C product's stability data allows for the product to go up to +25 °C for up to 120 minutes. Once it exceeds +25 °C for more than 120 minutes in a single event (consecutively), then, and only then will it alarm. It will not alarm above +8 °C otherwise. On the cold side, this product is not allowed to go below +2 °C, and will alarm immediately below +2 °C.

Table 1



Is this a regulatory compliant practice?

Absolutely. As long as you have the data to justify your protocol outlining the wider shipping ranges.

At the recent Leading Minds Seminar in Princeton New Jersey www.elpro.com/elproseminar/ a group of 65 logistics and quality practitioners discussed how to prepare for regulatory auditor's questions on «showing data that supports certain shipping ranges». The group agreed the evidence you could provide to an auditor could be:

- Results of Operational Qualification (OQ) for specific product or mode
- Risk mapping – technical assessment, FMEAs, Risk Assessments
- Live data of actual shipments

To read the seminar post event report, please find it here http://www.elpro.com/en/support-center/knowledge-center/pharmaceutical-logistics-distribution/

How many hours do you spend processing alarms?

10,000 hours a year? 20,000? It can be frustrating and extremely time consuming to have every single excursion go through a QA investigation. By implementing an Excursion Allowance Model, you can reduce the sheer volume of products requiring an investigation, therefore releasing products quicker and reducing workload on the quality team.

At the Leading Minds Princeton Seminar, Wim Vangoidsenhoven spoke about a recent implementation of a global data monitoring system and Excursion Allowance Model at a global pharmaceutical company. Before they implemented, 56 % of their +15 °C..+25 °C shipments resulted in excursions, whereas after they used their stability data to program data loggers, the total number of excursions for CRT products went down to 18 % of total shipments. Similarly, for their +2 °C..+8 °C shipments, they reduced excursions by 77 %! The reduction of workload equated to 11,000 hours / year and reduction of lost sales was a staggering $61M USD / year.

These are very compelling business outcomes to implement an Excursion Allowance Model.

Please contact ELPRO with any questions on this topic. usa@elpro.com or swiss@elpro.com

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