TEMPERATURE CONTROLLED LOGISTICS: STRATEGIES FOR THE FUTURE

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16TH ANNUAL COOL CHAIN
TEMPERATURE CONTROLLED LOGISTICS

FOREWORD

The future of the pharma cold chain logistics industry is in good shape, with sturdy growth being forecasted for the $12 billion market [1]. Similar to the pharma industry it can, at times, be sluggish to evolve. Despite this, many experts are of the opinion that a range of trends are due to take hold in the industry. The rise of cell and gene therapies and the logistics paths they require (patient to manufacturer to patient, for instance) and the inherent sensitivity of the biomaterials will place new demands on the industry.

Gary Hutchinson noted that we are due to see **packaging and network designs become more tailored for specific drugs.** We are seeing a trend in pharmaceutical manufacturers beginning to design their cold chain networks specifically to the drug platform or modality based on therapeutical area. The ability to tackle a whole range of chronic diseases and illnesses with exciting new technologies has driven more and more specialization in not only the cold chain but the entire logistics network. For example, stable and better characterized drugs with an exemplary safety record are using deferred shipping lanes, new transport modes including ocean freight, and an increased allowable range in shipping temperatures. However, more fragile platforms like a monoclonal antibodies require greater characterization of the drug product not only for temperature hazards, but a full range of environmental hazards including shock, vibration, temperature and humidity. The characterization of these synthesized human proteins in solution has shown a fragility that requires complex and specialized logistics networks supported by cushioning thermal packaging with tight control on temperature ranges. Coupled with the controlled temperature requirements for small molecule drugs, the depth and complexity of modern pharmaceutical supply chains will grow exponentially.

There are also new strategies appearing in terms of packaging conduct, payload volumetric efficiencies in packaging to leverage innovative techniques and metric calculations to maximise container utilisation. Also, some have been experimenting with the use of multi-cell trailers—refrigerated trailers with insulated curtains hung at intervals to create different temperature zones. Some peer pharma firms in the industry have noted the value in cross-firm collaboration on shipments and lanes to improve efficiency instead of having vacant space shipped due to packaging size constraints. The global insulated packaging marked is due to mature at a rate of 5.68% CAGR to 2020, driven by demand from the pharma industry. [2]

Experts are contemplating the impact that will be incurred on the cold chain by 3D Printed pharmaceuticals and the use of drones for delivery.

Pharma Logistics IQ presents the findings of its 2016 Temperature Controlled Logistics Future Trend Report, which examines the oncoming strategies likely to blossom in the cold chain industry.

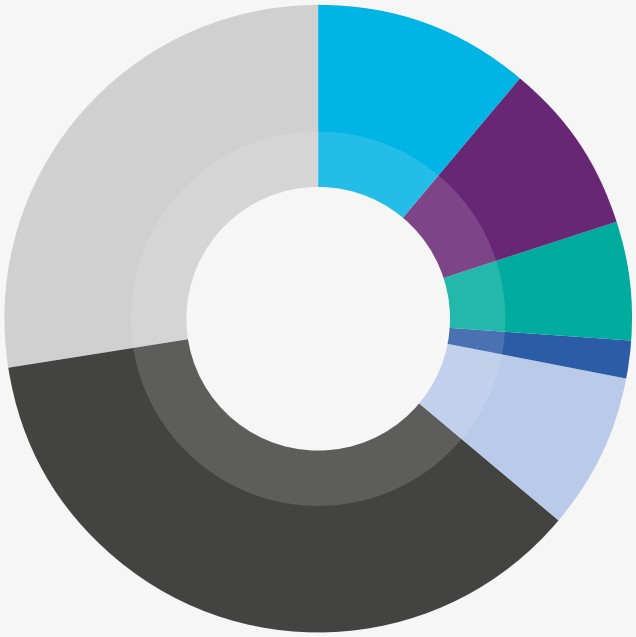
ABOUT THIS SURVEY

In Q3 of 2016, Pharma Logistics IQ hosted an online survey to assess current perceptions on how the cold chain industry is likely to evolve over the next few years. The survey gathered the responses of the many stakeholders in the international cold chain community.

Companies featuring in our respondent base include the likes of:

- **Eli Lilly and Company, Korea**
- **Astellas Pharma Inc.**
- **Ministry of Health - Morocco**
- **Ghana Health Service**
- **Novartis**
- **Marketsandmarkets**
- **Genentech**

WHAT CATEGORY DOES YOUR COMPANY FALL IN TO?



Large pharma/bio manufacturer	**11.4%**
Small-to-mid size pharma / manufacturer	**9.1%**
Medical device manufacturer	**5.7%**
Generics	**2.3%**
Government	**8.0%**
Solution provider	**36.4%**
Other (please specify)	**27.3%**

Pharmacy Products Distribution
logistics provider
Consulting
Wholesale and distribution to the maritime sector
Chilled Food Distributor
Freight forwarder
Market research
Contract Research Organization
API Manufacturer
consultancy on cold chain warehouses

RESULTS

FUTURE PROOFING

Pharma Logi IQ:
It's encouraging here to see that being future proof is a priority for the majority of our respondents. Although just under 20% of those who responded noted that there needs to be an improvement in regards to the focus applied on this area.

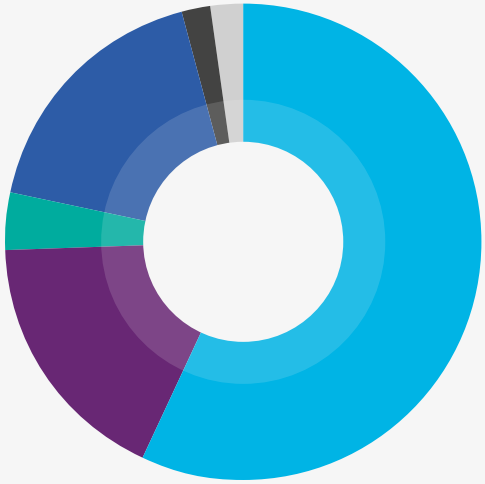
Heather Bogle, Supply Chain Solutions Manager at Almac Group:
"Temperature services is a growing industry that many pharmaceutical companies are increasingly embracing as a key priority in the business and this is reflected with over 50% of companies listing this area as prime priority. Within the past 5 years, Almac has seen a 40% increase globally in temperature shipments and it is becoming a trend that companies recognize is important to be an industry frontrunner. Many companies are taking a proactive approach to the realm of temperature controlled logistics rather than a reactive response to an inspection and audit findings. I find it surprising to see that there is still over a third of companies responding that this area needs more focus or that not many within their business champion this aspect. I suspect that with details of inspection results and further clarification of the regulators expectations throughout the next year we will begin to see a decrease."

HOW IMPORTANT IS IT TO STRIVE TOWARDS BEING FUTURE PROOF AS A TEMPERATURE CONTROLLED LOGISTICS ORGANISATION ?

- It is a prime priority for the business end-to-end **56.8%**
- There are a few members in the business who champion this aspect **17.0%**
- We have the right balance **4.5%**
- It requires more focus **17.0%**
- We are dangerously oblivious to its importance **2.3%**
- Other (please specify) **2.3%**

It will work for us as partners

We provide the services in order to enable temperature controlled logistics

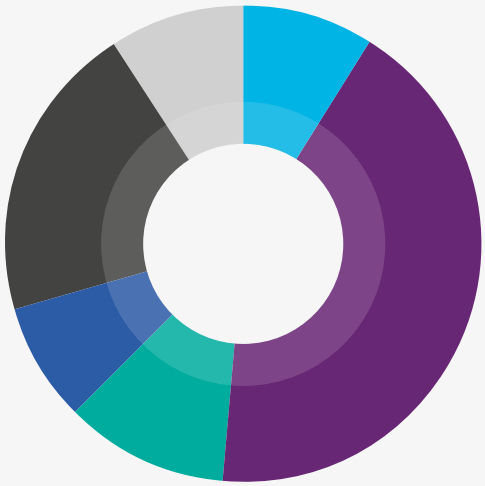


Pharma Logi IQ:
Here quality and risk management take the lead ahead of cost management. This is a positive trend as it indicates, that even though the industry has a focus on cost management this does not supersede the importance of protecting quality levels and mitigating risk.

Heather Bogle, Supply Chain Solutions Manager at Almac Group:
"Patient Safety is the core focus of managing temperature compliance. It is not surprising to see Quality rated as the area that could be most damaged and impacted if there is no adaptation within the temperature services industry. Regulatory requirements change and the healthcare industry is constantly growing; without continuous innovation to develop compliant offerings, there will be great risk to patients as services and software will not evolve fast enough to meet the industry's changes."

WHAT AREA WILL BE THE MOST DAMAGING TO YOUR FIRM IF YOU DON'T ADAPT AND INNOVATE QUICKLY?

- Compliance strategies **9.1%**
- Quality & risk management **42.0%**
- Product offering **11.4%**
- Creating a leaner the supply chain **8.0%**
- Cost management **20.5%**
- Accessing new markets **9.1%**



RESULTS

FUTURE PROOFING

Pharma Logi IQ: Entering emerging markets is seen as a top investment plan over the next 12 months which is to be expected due to the forecasted rapid growth. However, as noted in research reports a key challenge faced by cold chains operating through emerging markets is the high cost of real estate and energy.

WHAT ARE YOUR INVESTMENT PLANS OVER THE NEXT 12 MONTHS FOR OPTIMISING TEMPERATURE CONTROLLED LOGISTICS?

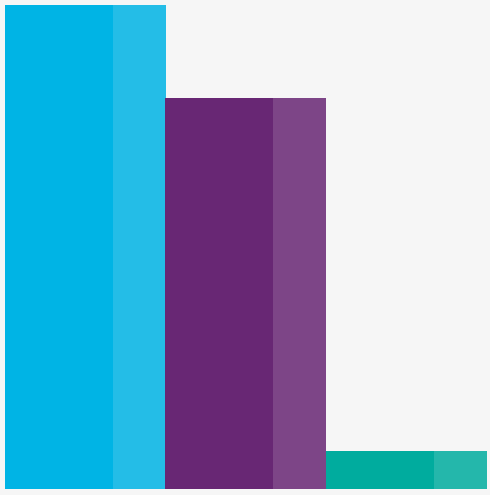
- Finding more efficient packaging suppliers **14.8%**
- Finding more innovative 3pls **20.5%**
- Locating more proficient data logging devices **14.8%**
- Partnering with more advanced freight forwarders **17.0%**
- Exploring for more developed airlines **9.1%**
- Searching for innovative sea freight providers **4.5%**
- Entering new emerging markets **19.3%**

Heather Bogle, Supply Chain Solutions Manager at Almac Group:

"Data capture and data integrity is what proves the quality, integrity and safety of a product. Ongoing temperature monitoring during the transportation of shipments is the only way to ensure the integrity of an IMP. Utilizing a fully validated central system that captures and retains temperature data, planned excursions, all linked to the product shipped, allows pharmaceutical companies to adjudicate excursions efficiently and accurately to determine the safety of the product for dispensation to patients. Accurate, accessible data ensures patient safety."

HOW IMPORTANT IS DATA FOR THE FUTURE OF YOUR FIRM'S PROGRESSION?

- Vital **52.9%**
- Important **42.9%**
- Somewhat of interest **4.3%**



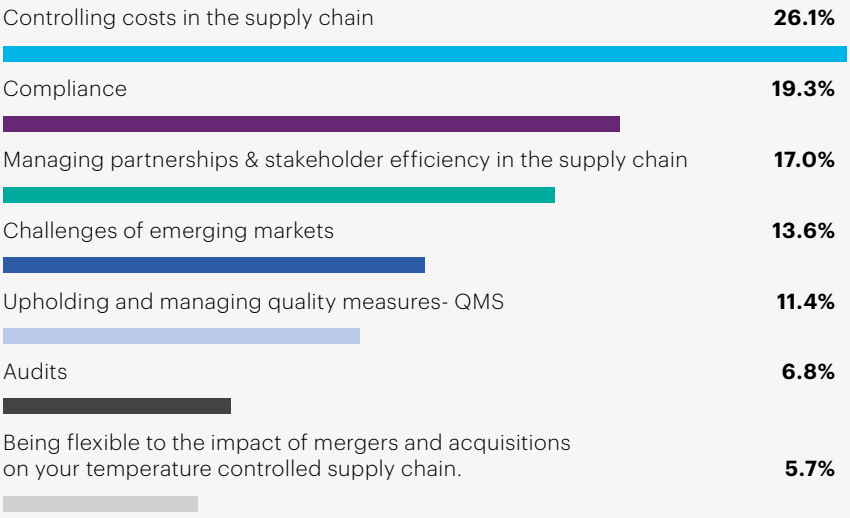
RESULTS

THE FUTURE & ITS PAIN POINTS

Pharma Logi IQ: Unsurprisingly, compliance ranks in the top 3 dominant pain points for temperature controlled logistics, interestingly though; it is rated below controlling cost. This signals that the industry is confident in the regulatory requirements expected of them. This is evidenced by the fact that a vast minority see audits as the main pain point in their corporations.

Heather Bogle, Supply Chain Solutions Manager at Almac Group: "There is a general consensus to the pain experienced by companies when they try to remain compliant with regulations but also mitigate costs. The challenge is always whether this is a necessity to ensure patient safety or are we tracking and documenting data just to prove compliance for a low risk situation. The response highlights that it is not easy, efficient or cheap to collect secure and sound data from multiple vendors and sources. There is a complicated balance to achieve between cost effectiveness with minimal resources and regulations that are not clear and constantly change. Keeping on the cutting edge with innovation, in line with regulatory compliance is the key. A flexible, evolving platform that allows multiple shipping vendors and different brands of monitors is the only solution that doesn't break the bank."

WHAT AREA WILL BE YOUR BIGGEST PAIN POINT OVER THE 12 MONTHS?



TOP 3 BLOCKS TO CHANGING PROCESSES OR OPTIMISING THEM QUICKLY

Complexity of business operations
29.5%

Lack of resources
26.1%

Lack of methodologies that enable rapid change
12.5%

RESULTS

THE FUTURE & ITS PAIN POINTS

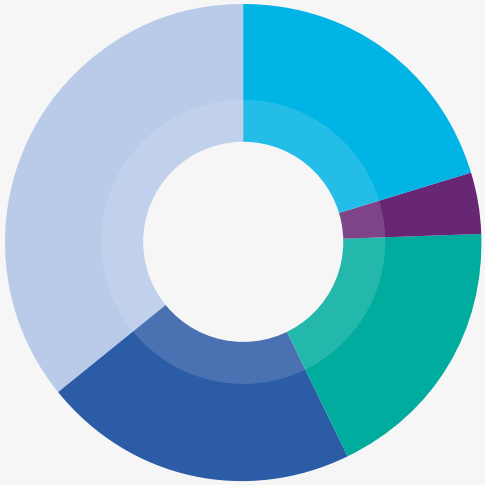
Pharma Logi IQ:
Cost control appears as the dominant pain point to navigate. Improving vaccine distribution in general is seen as a significant hurdle that will increase in the next few years, likely due to the increasing use of biotech and therapeutic biologics.

Heather Bogle, Supply Chain Solutions Manager at Almac Group:

"Keeping up with the changing regulations that are different for each country and each region across the globe continues to plague all of us. We are seeing slow changes within the industry and global groups pushing to the forefront to pull the different regions together and attempt to work towards a consensus. This is encouraging however the jury is still out as it is too early to tell whether or not it will be possible to achieve."

WHAT WILL BE THE DOMINANT CHALLENGE FOR THE FUTURE OF SUPPLY CHAIN LOGISTICS?

- Improving vaccine distribution in emerging markets as well as more established markets **20.0%**
- Seafreight and meeting weight declaration regulations **4.3%**
- Products spoiling due to being left on the tarmac for extended periods in airports **18.6%**
- The pressure to drive down outgoings in the supply chain **21.4%**
- Compliance and quality management **35.7%**



Pharma Logi IQ: The dominant challenge on validation aligns to the quality and risk focuses mentioned earlier in the data. Interestingly one participant notes the focus of tailor-making packing and distribution lanes to products as mentioned by some thought leaders in the industry.

WHAT WILL BE THE DOMINANT CHALLENGE FOR THE FUTURE OF TEMPERATURE CONTROLLED PACKAGING?

PCM liquid leakage	**4.3%**
Data loggers and temp controlled monitors malfunctioning	**22.9%**
Validation testing not being representative to real world use.	**37.1%**
Reducing the amount of 'air-shipped' in a container	**15.7%**
Abiding by the tight margins with CRT products	**14.3%**
Other (please specify)	**5.7%**

Thermal insulation
Designing flexible packaging and distribution planning for each product group

RESULTS

THE FUTURE & ITS PAIN POINTS

Pharma Logi IQ:
Considering that the majority of our participants noted that data is vital to the progression of their organisation, it remains a slight concern that the biggest challenge in data management is the process of using the data effectively.

WHAT ARE YOUR MAIN DATA CHALLENGES?

Organization not using data effectively	**22.9%**
Data is incomplete or incorrect	**18.6%**
Difficult to access data at point of process execution	**21.4%**
Data is kept in information siloes	**7.1%**
Inconsistent data definitions	**10.0%**
Returning of data loggers	**5.7%**
Malfunctioning data loggers	**4.3%**
Losing data loggers	**5.7%**
Other (please specify)	**4.3%**

Need more data sharing between providers and users
Defining the correct and effective positioning of monitors.

Heather Bogle, Supply Chain Solutions Manager at Almac Group:

"It is clear from these results that determining what to do with data is still something being tackled by the industry. We have given in to the fact that collecting data is the only real way to show evidence of compliance. However by the responses in the survey, we have not mastered organizing this into something that is useful within our companies. An opportunity is slipping through our fingertips as there are key performance metrics for our suppliers and internal business process improvement suggestions hiding within the multitudes of numbers.

Another point highlighted is that unless you make it easy for the sites, you are fighting a losing battle. It is well known across the industry that sites do not always comply with protocol in uploading data to applicable repositories and this results in companies turning into stalking the recipient to make a collection. Ensuring an easy site user experience to upload is vital, however there is still the human element factor to keep in mind. Additional email reminders that only occur after proof of delivery have shown to be successful. These notifications can include additional contacts, for example CRA's, which means the issue can be addressed during the next monitoring visit."

IN REGARDS TO THE EU UPDATE TO CLINICAL TRIAL REGULATION, DUE TO COME INTO FORCE IN 2017-2018, WHAT WILL BE THE BIGGEST HURDLE?

Labelling requirements	**5.7%**
Reporting requirements	**10.0%**
Meeting transparency requirements	**25.7%**
Adapting to the single electronic entry point for applications – the EU portal	**17.1%**
Co-operation between manufacturers and sponsors	**34.3%**
Other (please specify)	**7.1%**

Compliance
It will have some effect

NATURE'S GREAT JOURNEYS

#1 | THE SNOWFLAKE

Unique. Delicate. Magical. A snowflake requires precise circumstances to enable its creation and preservation. Temperature, pressure and humidity all need to be maintained within tight parameters for the snowflake to reach the ground.

Just like a snowflake, the manufacture of pharmaceuticals is only the start of their journey. Safeguarding the quality and integrity of these intricate and fragile materials requires care and attention every step of the way. But unlike the snowflake, we can't rely on Mother Nature to keep these forms intact all the way to their final destination.

TempEZ™, the latest next generation innovation from Almac, gives life science's companies and their supply chain partners a platform to document the temperature journey of their pharmaceutical products. This groundbreaking software provides access to temperature data for your product from API manufacture through to patient administration. TempEZ™ is designed to collect data from any stakeholder or monitor brand in your commercial or clinical supply chain, building a complete temperature history of your pharmaceutical products.

"All your temperature data, for all your products, in one place". **With you for the journey.**

VISIT ALMAC AT BOOTH NO. 67

TempEZ™

ALMAC

Partnering to Advance Human Health

almacgroup.com/journey

RESULTS

FUTURE TRENDS

WHAT DO YOU PREDICT WILL BE THE MOST DISRUPTIVE TECHNOLOGY FOR THE TEMPERATURE CONTROLLED SUPPLY CHAIN OVER THE NEXT DECADE?

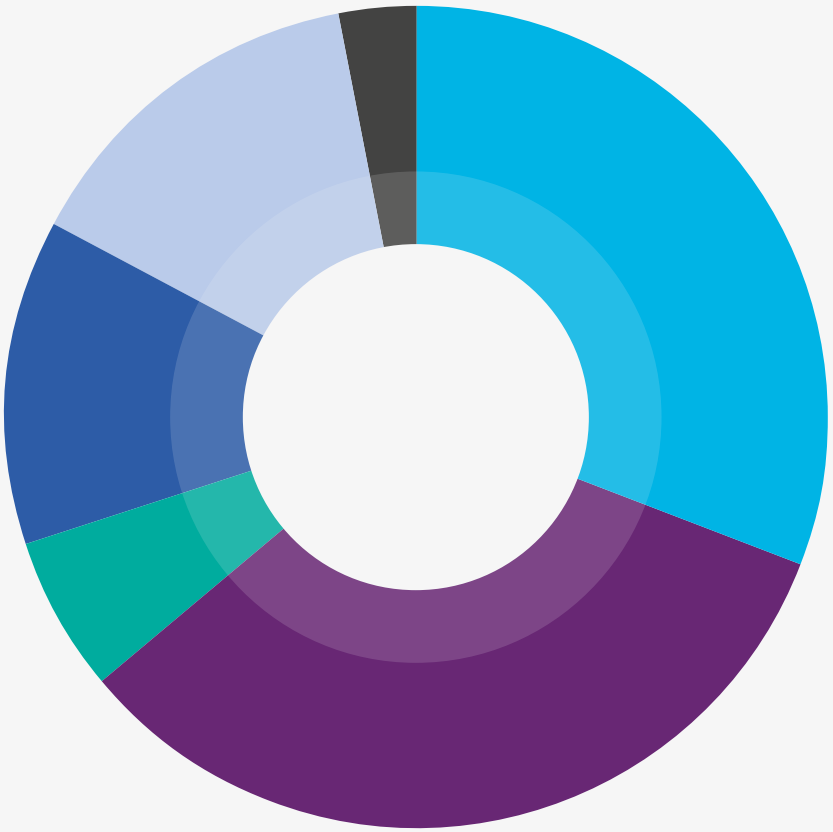
DRONES | 3D PRINTING | PRECISION MEDICINE | BIOPHARMACEUTICALS | HYBRID PACKAGING | DISPOSABLE DATA LOGGERS

WHAT WILL BE A KEY SUPPLY CHAIN LOGISTICS TREND TO CAPITALISE ON OVER THE NEXT FEW YEARS?

- Added visibility from serialisation and track and trace programmes **31.4%**
- Unlocking emerging markets via innovative strategies **32.9%**
- Performance-based financing **5.7%**
- Driving toward greener solutions **12.9%**
- Cutting costs **14.3%**
- Other (please specify) **2.9%**

Digital Logistics

Merger of cold chain technologies with serialization technologies



RESULTS

FUTURE TRENDS

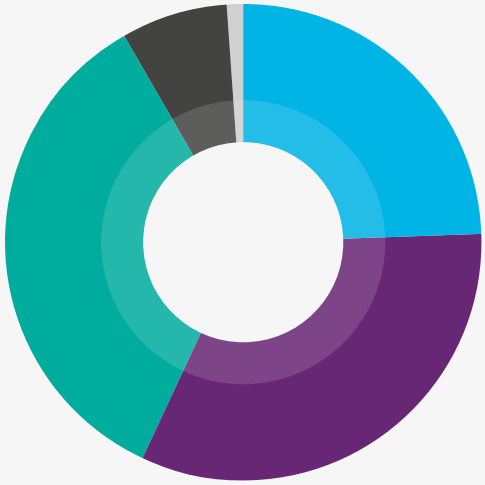
Pharma Logi IQ:
The application of stability budgets to better strategize temperature control lanes is a discussion that we have seen come to the fore recently, with some maintaining that the Time Out of Storage acquired from the stablility budget should be left for the section after the last mile as the product reaches consumption.

Heather Bogle, Supply Chain Solutions Manager at Almac Group:
"Three key areas are seen to carry similar importance. Having a centralized temperature database that can collect information from various vendors, various monitors and provides a link to the stability profile of the product is the key. This allows for the analysis of concepts, such as shipping lanes against excursion results, trends of excursions in geographic areas and even trends in site compliance by country or protocol. In addition, the flexibility of using any shipping vendor and any monitor ensure you are not restricted to making a commitment to one partner and limiting your options."

A KEY FUTURE TREND TO CAPITALISE ON IN TEMPERATURE MONITORING?

- Combining and integrating devices from various vendors **24.3%**
- Visualising data via information dashboards powered by cloud solutions **32.9%**
- Use of stability data to direct supply chain strategies **34.3%**
- Disposable Data loggers **7.1%**
- Other (please specify) **1.4%**

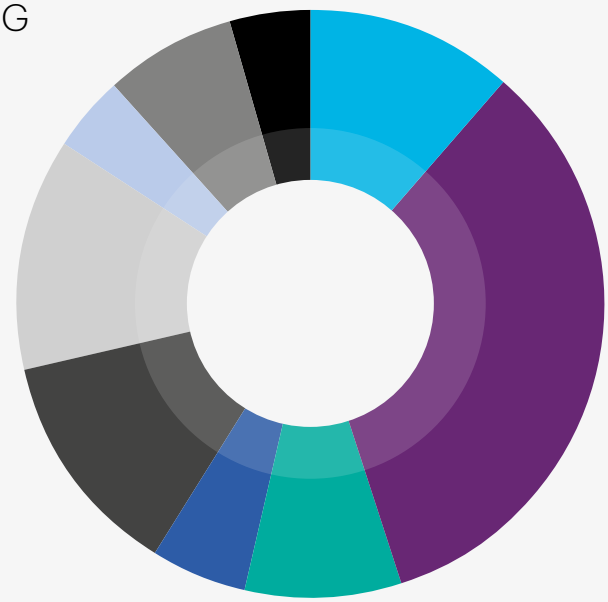
Wireless Based Product Condition Monitoring



NAME A KEY TREND WHICH IS LIKELY TO EMERGE OVER THE NEXT FEW YEARS IN REGARDS TO TEMPERATURE CONTROLLED PACKAGING

- Use of bulk passive units **11.4%**
- Custom packaging solutions **32.9%**
- Volumetric efficiency analysis **8.6%**
- Multi-cell trailers **5.7%**
- Peer collaborations during shipments **12.9%**
- Hybrid packaging containers **12.9%**
- SKU Congruency within passive units **4.3%**
- Use of numerical models to adapt packaging **7.1%**
- Other (please specify) **4.3%**

Internet of Things



INDUSTRY COMMENTARY: DRUGS VIA DRONE DELIVERY – A VIABLE SOLUTION?

Cathy Roberson

Drones are constantly in the news with the likes of Amazon, Wal-Mart, Facebook, Google and more testing them as delivery options. Imagine receiving a book you ordered via Amazon's drone delivery service or perhaps a hard to find part for your classic car by way of Facebook's drone delivery service. Depending on one's location and need as well as lobbying efforts such as Amazon's rumored spend to educate US government officials on a range of topics including this mode of travel; the future for drone deliveries is a reality.

For healthcare professionals, the use of drones has huge benefits in particular the ability to reach remote areas that lack proper infrastructure to deliver lifesaving drugs and other necessities. Many tests are underway to determine its viability but as one can imagine, it is under much government scrutiny and regulators in many countries are working with the industry to develop requirements for the delivery and flying of drones.

Last year's devastating earthquake in Nepal saw drones in action. Global Medic, a Canadian charity that provides disaster response in the form of medical assistance, flew drones over the affected areas to study and 3D map the worst hit zones. The information was then passed to rescue workers on the ground to show them exactly where to go.

In Africa, medical deliveries by drone are already underway. US-based startup Matternet has partnered with the government of Malawi and with UNICEF to deliver infant H.I.V. tests within the country and in Rwanda, another start-up, Zipline, is delivering blood and pharmaceuticals to remote locations in hours rather than weeks or months. According to Zipline, its system's speed makes it possible to maintain a "cold chain" and when it reaches hospitals, they will not land but will drop small packages from very low altitudes. The supplies will fall suspended by simple paper parachutes. The drones will then return to a home base, where they will be prepared for a new mission by swapping in a new battery and snapping in a new flight plan stored in a SIM card.

Drone deliveries are not only in emerging markets. Within the US, NASA partnered with drone startup business, Flirtey to deliver medicines and other medical supplies to an annual free clinic in Virginia. The entire operation took about two hours as Flirtey separated the medical supplies into 24 small packages which were then transported by the drone. The pharmaceuticals were lowered to the ground via tether and health care professionals at the scene received them.

In Europe, DHL is utilizing drones to deliver drugs and other urgent supplies to a remote island in the North Sea. The island, Juist, is only accessible by a once daily ferry service and regular passenger flights. According to a press statement from a DHL Parcel spokesperson back in 2014, deliveries are secured and all types of drugs can be carried except those which are dependent on refrigeration, as a refrigeration unit may be too weighty for the 'parcelcopter' to carry.

Also in Europe, a very interesting product has recently been introduced by Flash, a logistics provider that focuses on premium freight delivery

services. Flash's drone is one of the more unique in the market. Each drone is equipped with biologistic isothermal packaging for temperature control and monitoring and travels on a predefined and programmed flight path directed by longitude and latitude coordinates. Testing is expected to take place this year at the University Hospital Center of Bordeaux, a partner of Drones for Life which is a group of healthcare, technology and development experts trained to route and test drones safely and one in which Flash is a member. The delivery service itself will be marketable in Europe by 2017.

Is drone delivery viable? According to various market research companies, the estimated market size of the commercial drone market was about $609 million in 2014 and is expected to grow roughly to $4.8 to $6.4 billion by 2021. The market faces numerous challenges, most importantly how to share air space with larger airplanes as well as privacy and security concerns. However, its benefits in delivering life-saving pharmaceuticals to remote areas cannot be denied and perhaps this is 'secret sauce' within supply chains. But, like many other great innovations, its use will evolve and expand over time to perhaps delivering to the elderly and shut-ins to delivery within 'smart cities'. The possibilities are endless.

Final Remarks

A clear trend that is pinpointed by our participants is the personalisation of the cold chain. This stretches to encompass the technologies used and the networks being sculpted specifically for the products at hand. A labour intensive task but likely to produce a higher quality of work. Cost control is, unsurprisingly, expected to stand at the front of focus in the future alongside the project to crack the challenging but potentially rewarding emerging markets of the world.

Some progression needs to be made in regards to data management, as even though this tool is seen as vital to the future of the industry, many of our participants noted that the main issues lie within the organisations not using the data to its full capacity.

Acknowledgements

Pharma Logistics IQ thanks all the participants who responded to this survey and reminds those who entered the prize draw to look out for notification on whether you won the competition.

Resources

1. http://pharmaceuticalcommerce.com/supply-chain-logistics/pharmaceutical-cold-chain-logistics-is-a-12-6-billion-global-industry/
2. http://www.prnewswire.com/news-releases/global-insulated-packaging-market-to grow-568-by-2020---increased-demand-from-pharmaceutical-industry---research and-markets-300317680.html
3. http://www.coldchainiq.com/transportation-logistics/columns/drugs-via-drone delivery-%E2%80%93-a-viable-solution