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Emerging Field Has Fast Become a Vital Component in The Medical Discovery Process

Medical research has enabled healthcare professionals to successfully treat and prevent diseases, and the establishment of a reliable cold chain for the safe storage and transport of samples is essential for the continuation of such activities. Here, Luc Provost, CEO of B Medical Systems, talks about the support of scientific and clinical research through a reliable cold chain and the importance of temperature-controlled shipments.

Medical research has enabled medical professionals to create therapeutics that can treat and even prevent a vast range of diseases and conditions that have before plagued communities the world over. The development of the first smallpox vaccine in 1796,[1] the discovery of insulin in 1921[2] and DNA in 1953[3] are examples of events that have had a profound impact not only in medical research, but on the everyday life of billions of people worldwide.

Biomedical discoveries have increased our knowledge of the world and with that, created new therapeutics to fight off infections and other diseases. This in turn enabled communities themselves to develop and flourish, leading to economic and social development.[4]

To this day, new technologies such as gene editing through techniques like CRISPR-Cas9 and AI applications in fields such as proteomics, are helping scientists create more advanced remedies for diseases and conditions.

Throughout the development of modern medicine, a new specific field has emerged which has fast become a vital component during the various stages of the medical discovery process – the medical refrigeration industry.

The medical refrigeration industry has for decades been one of the catalysts that has enabled the discovery of new biomedical technologies. Indeed, major laboratories around the world utilise some sort of refrigeration solution for their samples – whether it's a refrigerator, a freezer, an ultra-low freezer, or a combination of all three. Recently, because of the COVID-19 pandemic, the need for medical refrigeration has been brought to the attention of the public, specifically the various temperature and storage requirements of vaccines.

The Medical Refrigeration Cold Chain

The importance of a reliable, medical cold chain that guarantees the safety of samples and compounds and the role of refrigerators and freezers in biomedical research cannot be overlooked. Many laboratory compounds are thermosensitive, which requires them to be kept at a certain temperature else they degrade. As temperatures rise, molecules can become unstable and give rise to chemical reactions. This can irreparably change the nature of the samples or compounds. The same can also happen to specimens but in this case, entire biological systems may break down irreversibly. Moreover, bacteria and fungi may find ideal growth conditions under high temperatures which can contaminate samples. Flammable or explosive chemicals also need to be stored at the correct temperature in a reliable and safe refrigeration environment to mitigate the risk of ignition. This is why medical refrigerators, freezers, and even ultra-low freezers are utilised so extensively in laboratories around the world.

Laboratory refrigeration equipment is required to meet very high standards and are built specifically to safely store fragile biologicals.

Refrigeration needs for laboratories can vary widely depending on the biologicals that need cold storage, which typically is divided in three main ranges:

- The regular cold chain which provides storage in the range of +2°C to +8°C usually provided by refrigerators
- Laboratory freezers or plasma freezers that offer temperature ranges reaching as low as -41°C
- Ultra-low freezers that can reach -86°C (cryogenic freezers offering freezing storage environment with temperatures as low as -150°C also exist, although these products aren't used as frequently as their counterparts)

Specimens that require refrigerated temperatures (+2°C to +8°C) are the simplest thermosensitive ones to store.

In these temperature ranges, medical refrigerators provide the necessary cold chain infrastructure. This type of equipment is especially designed to maintain a set temperature in the range from +2°C and +8°C, depending on the biological requiring storage, along with its temperature requirement.

Laboratory refrigerators provide a uniform and stable temperature, usually via a forced or a controlled air-cooling system which allow them to perform well. Other features, such as gaskets, insulations and thermostats, ensure that temperature is maintained inside the cabinet while alarm systems alert associated stakeholders in the event of a change in the cabinet's storage conditions. Remote monitoring solutions – which send automatic alarms via SMS and email directly to laboratory professionals/technicians in case of issues – are being used at a growing rate.

Thermosensitive compounds and samples, such as blood plasma or tissues and cells that are suspended in appropriate stabilising solutions, require freezing temperatures ranging from -41°C to -20°C. At ambient temperatures, these biologicals would spoil very quickly, therefore impeding research and clinical efforts.

Medical freezers are the ideal cold chain solution for this temperature range. They deliver a uniform and stable temperature

distribution and a fast recovery time in case of door opening. A reliable model should also feature advanced defrosting technology, enabling a stable cabinet temperature even during the defrosting cycles, a system to reduce heat transfer during door openings (such as automatic switch-offs of evaporator fans) and an extended autonomy in case of possible power failures.

Alarm systems need to be highly sophisticated as in most cases they will store expensive and complex biologicals. Alarms should be audio-visual and ideally, connected to a remote transmission system which, in an emergency, can forward an alert via SMS or email.

There are many energy efficient models on the market which boast eco-friendly performance ratings with features such as insulated inner doors, sealed gaskets and other structural features to minimise cold air loss and heat conduction. These, combined with the use of natural refrigerants, ensure freezers are more sustainable to run compared to other refrigeration equipment. Laboratory refrigerators that use natural refrigerants and conform with the US SNAP and EU F-Gas regulations are not only kinder to the environment but allow research institutes to save on operating costs.

The most energy intensive laboratory refrigeration appliance is the Ultra-Low Freezer (also referred to as ULT), which is typically used for the long-term storage of samples with temperatures reaching as low as -86°C. However, advanced units will usually be able to reach less severe temperatures (as high as -20°C). Biologicals stored within these devices ranges from genetic material, such as DNA and RNA, to cell and tissue samples. This makes ULTs extremely important for advanced medical research and for scientists who need to preserve important specimens for extended periods of time. New advances in vaccines research related to COVID-19 have expanded the use of these products to include the storage of thermosensitive mRNA vaccines, as well.

ULTs are the epitome of advanced cooling systems that allow even and constant temperature distribution. Coupled with insulated inner doors and strong gasket seals, they ensure a reliable storage environment for optimal sample safety. Furthermore, the best ULTs provide a rapid pull down and strong door opening recovery and holdover times, which assist in maintaining a stable interior temperature during openings or even adverse events such as power outages.

Because of the extreme temperatures they need to reach, ultra-low freezers can consume as much energy as an average family household and, because of this high energy consumption, the CO_2 emission potential is high – typically, an ultra-low freezer and related HVAC can produce up to 100 tons of CO_2 in their life span.

To reduce the carbon footprint of its products, manufacturers need to invest in creating products that use green refrigerants with low Ozone Depletion Potential (ODP) and Global Warming Potential (GWP). Obtaining certifications such as Energy Star and abiding by the US SNAP and EU F-Gas regulations would be a great start towards energy efficiency for a lot of manufacturers regarding their ultra-low freezers. Training customers on how they can efficiently run a ULT is also recommended. B Medical Systems calculated that

simply switching a product's setpoint from -80°C to -70°C, could ultimately save customers 6.13 kWh/day.[5]

Transport of Biologicals via the Cold Chain

Although biomedical research is carried out in laboratories around the globe, compounds, samples, and other materials need to be safely shipped to and from each setting to ensure discoveries can be applied to the clinical world.

Pharmaceutical companies require the use of temperature-controlled shipments to ensure their products reach their target destination without having degraded during transport. In many cases, such as for medicines and vaccines, this is a complex operation that requires all necessary precautions to be considered to ensure products remain at the intended temperatures. Many vaccines are spoiled during transportation due to cold chain failures. To address this, medical transport boxes and temperature-controlled containers are widely used around the world. Transport boxes cater to the small sized shipments while temperature-controlled containers cater to the large-scale transportation requirements.

Medical grade transport boxes are necessary during the transportation of thermosensitive specimens, compounds, or vaccines. Typically, there are two types of transport boxes. Passive products maintain certain temperatures due to their insulating properties while those in the active category utilise a compressor to maintain the intended temperature. These products are far superior to non-medical boxes as they are designed to maintain precise temperatures for extended periods of time. They offer reliable protection from temperature excursions and physical shocks during transport, long-term durability, and tend to have user friendly designs, ensuring the usability is always front of mind.

Phase Change Materials (PCMs) or dry ice keep shipped samples at the correct temperature for the duration of the journey. Generally, dry ice is utilised to reach temperatures as low as -80°C, while PCMs can support a wide range of temperatures, including -32°C, +4°C, +22°C and +37°C.

It's noteworthy to highlight the use of temperature boxes during clinical trials is dependent on regulations which can vary widely between countries.

Conclusion

It is extremely important that biomedical research institutes and laboratories provide their researchers with reliable medical refrigeration products for the safe storage and transport of thermosensitive medicines, vaccines, samples, and compounds. The uniformity and stability can't be matched by household equivalents.

Moreover, when choosing the right medical refrigeration solution, it is important to not only consider what biologicals require storage, but also the reliability, convenience and energy efficiency these cold chain products offer.

B Medical Systems S.à r.l (formely Dometic/Electrolux) is a global manufacturer and distributor of medical cold chain solutions. Across the three major business portfolios of Vaccine Cold Chain, Medical Refrigeration, and Blood Management solutions, the company currently offers 100+ models including Laboratory Refrigerators, Laboratory Freezers, Pharmacy Refrigerators, Ultra-Low Freezers, and Transport Boxes. Throughout its over 40 years of experience, the company provided equipment to support its partners in vaccinating more than 350 million children in developing countries, and to enable clinical and biomedical research in tens of thousands of universities and research institutes worldwide.

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Luc Provost

Mr. Luc Provost believes in a vision that fosters innovation and customer-centricity. He is a hands-on leader who focuses on perfecting every customer interaction with efficiency and effectiveness. He has a proven executive management track record and over 20 years of experience in driving sales growth. He is passionate about helping save lives by providing solutions in the remotest areas and is also a prominent speaker and thought leader in the field of medical refrigeration. Mr. Luc Provost, CEO of B Medical Systems, a global medical refrigeration device manufacturer has been with the company for more than 20 years. He possesses a wealth of knowledge in business ownership, technology, operations, and sales and is at the core of the company's reputation as an end-to-end medical cold chain provider. Since joining the company, he has played a pivotal role in the company's revenue growth, geographical expansions and has signed various global commercial agreements for the company including with major corporations like Toyota. He was also instrumental in the launch of 50+ new products, many of which even created new WHO PQS standards. In his official capacity as CEO, he has travelled to 100+ countries and has worked closely with several central governments, ministries of health, international humanitarian and procurement organizations like UNICEF, WHO etc. Luc Provost holds a degree in Business and Management from University of Louvain in Belgium and has studied International Marketing at Laval University in Quebec. He is a Belgian citizen and has also worked for the Belgian Army. He speaks English, French, German, Dutch and Spanish.