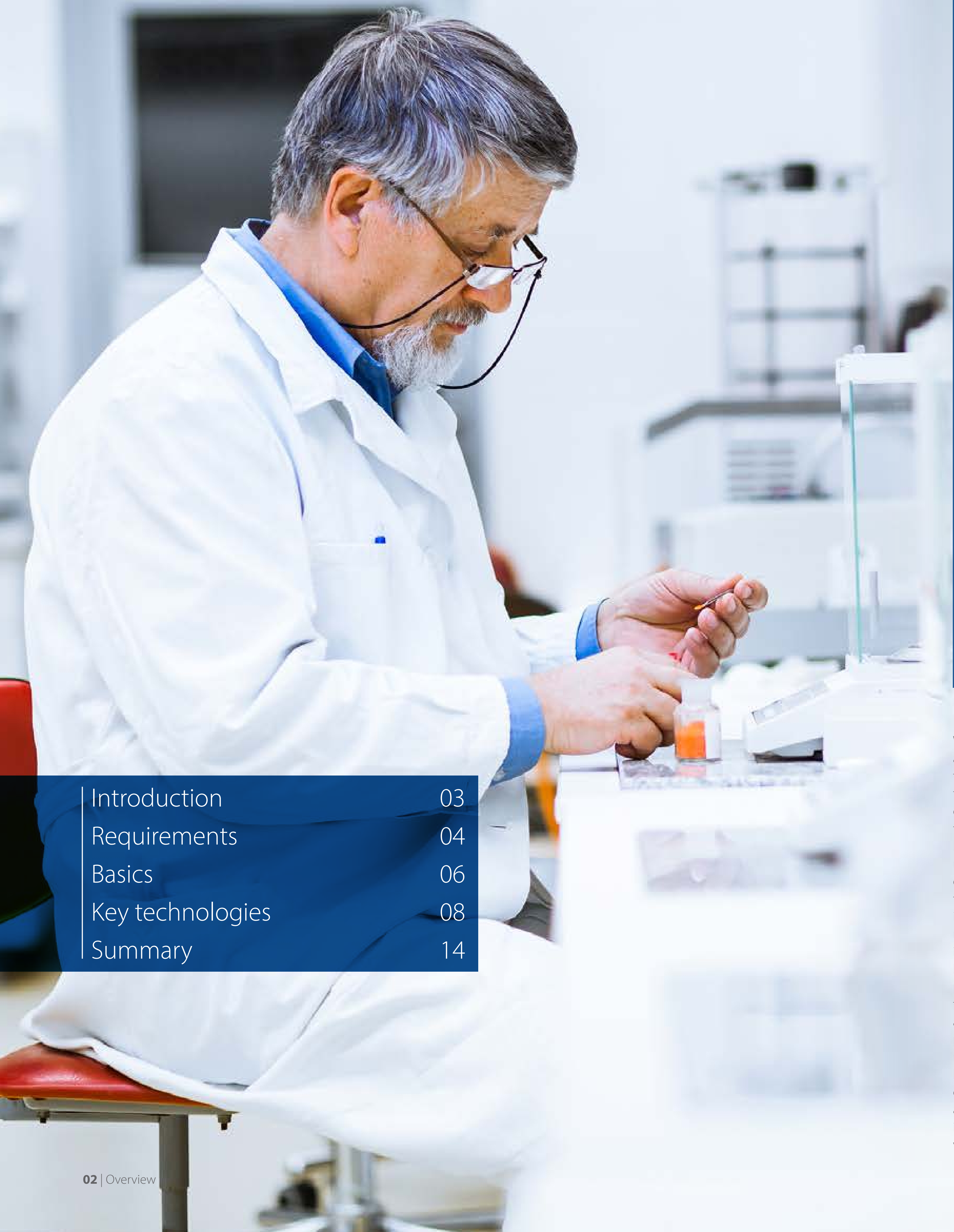
va-Q-tec

ALWAYS THE RIGHT TEMPERATURE

Drivers of Digital Transformation in the

TempChain



Temperature-controlled Transport Logistics

World-wide coordination of secure, reliable and temperature-controlled logistics is a major challenge. Discussion in the sector frequently revolves around the cold chain. We consciously employ the term TempChain rather than cold chain because, as we see it, a reliable temperature range must be ensured for every outdoor temperature. Depending on the temperature, this can require either cooling or warming. Findings from market research and expert workshops with international customers suggest that, besides the quality of passive thermal packing systems (containers and boxes), their availability is one of the most important criteria in determining the use of this product. Passive means in this case that no active components such as electric batteries, electronics, blowers or electrically operated heating or cooling systems are installed. The insulation performance is based on the physical principle of the vacuum. Passive systems require no maintenance. The thermal energy is stored exactly at the temperature at which it is used and needed. Containers and boxes are available as either single- or multiple-use solutions keeping the temperature constant for 4 to 5 days without external energy supply under extreme conditions - even 1 to 2 weeks under moderate conditions. This performance is achieved by insulation using vacuum insulation panels and highly efficient energy storage by PCMs (Phase Change Material). Based on need, this results in varying temperature ranges between -50 °C and + 50 °C.

Digital transformation is accompanied by a variety of efficient solutions to leverage enormous opportunities in logistics through passive thermal packing systems. The temperature-controlled supply chain is very complex. With the proper use of digital solutions, control and degree of automation can increase. To arrive at a fully functioning and digitalized TempChain 4.0, it is necessary to overcome several challenges, some of which can only be addressed through the use of technologies and the involvement of all participants in the supply chain. Beyond a certain point, isolated solutions are no longer helpful.

In this white paper, we begin by describing the requirements of a reliable TempChain, using the pharmaceutical industry as an example (Chapter 2). This is followed by a presentation of basic digital techniques (Chapter 3). It is only when the real world is also depicted virtually that digital key technologies like blockchain and artificial intelligence can be fully effective in transport chain logistics (Chapter 4). The paper concludes with a summary. We maintain that market participants can achieve enormous efficiency gains in the TempChain through cooperative behavior.

TempChain requirements: the example of the pharmaceutical industry

Due to the sensitive nature of their products, pharmaceutical companies frequently find themselves in need of a temperature-controlled transport chain. For this reason, they also represent the segment with the highest turnover rather valuable in the area of thermal packaging systems. As a result, the requirements of the pharmaceutical sector for TempChain 4.0 can be used as valid requirements for a general approach in thermal logistics.

Clinical study

Clinical studies are of great importance in research for modern pharmaceutical companies. New treatment options for patients whose recovery depends on the results of these studies are becoming increasingly important. Even the slightest variations in the temperature of highly sensitive active ingredients can completely falsify the results. Thermal and mechanical sustainability are indispensable in the area of clinical studies.

Commercial distribution

In addition, the number of temperature-sensitive pharmaceutical and biotechnological products is increasing. They permanently require a constant temperature range. More stringent good distribution practice (GDP) regulations now require these to be monitored and verified in all temperature ranges. Soon it will be necessary for more than half of the world's top 50 drugs to be stably stored and transported at precisely controlled temperatures under all climatic and environmental conditions. This is due to the trend to develop increasingly more complex – and thus more temperature-sensitive – biomolecules in the substances of ultra-modern medications. If there are even the smallest unscheduled temperature fluctuations during shipping or storage, the drug, for example a vaccine, may no longer be fully effective or even harmful.

Last mile

The so-called 'last mile" also plays a significant part in the shipping of pharmaceutical products. This refers to local delivery to the customer: to pharmacies, hospitals, laboratories or – with growing frequency – directly to the patient. The medication requires a temperature-controlled shipment even over the last mile. In Germany alone, there are almost 20 thousand pharmacies, that are subject to increasingly strict GDP regulations. At the same time, the last mile is characterized by short transportation times and a high frequency – thus generally resulting in relatively high costs.

va-Q-tec solutions

Passive thermal packaging systems are outstandingly well suited for deviation-free transportion of pharmaceutical products. They guarantee the TempChain's compliance and ensure long-lasting performance. va-Q-tec has developed boxes and containers to manage the risks of the slightest fluctuations in temperature for the transport of research medicines and pharmaceutical products.

Using innovative concepts for the leasing of temperature-stable packaging, pharmaceutical companies around the world can profit from optimized processes and customer individualized performance of thermal packaging solutions. The performance and quality of thermal packaging solutions are ensured through a patented va-Q-check testing system and internal special production of all key components.

Typical temperature ranges which are in demand by pharmaceutical companies:

- -40 °C to -20 °C
- -25 °C to -15 °C
- +2°C to +8 °C
- +15°C to +25 °C

Quality of service also plays a crucial role in the pharmaceutical sector. This applies both to the constant traceability of the shipment and fully guarantees the quality of each respective transport solution. Therefore, individualized pre-cooling (preconditioning) in a TempChain Service Center is the key. This step precisely characterizes how the traditional box and container production is systematized and digitalized.

From real to virtual: Basic digital transformation techniques

The first step to digital transformation is the conversion of real economic processes into a digital environment. The capability to track the complete TempChain is ensured by data loggers. Only in this way can the (disruptive) innovations described in the next Chapter succeed.

Software-controlled procedural steps

Each step in the process (release, receive, repair, …) of transporting a container or box is mapped in the software. At each step, the employees of the global TempChain Service Centers receive corresponding instructions. Problems are detected by the system because each incorrect entry immediately results in an error message. Primarily barcodes and scanners are used to generate entries. This technique minimizes human error frequencies and accounts for a high level of stability in each process. The resulting data serves to document the entire execution.

Asset management

In order to ensure the quality of a box or a container all components must be permanently monitored perfectly. In this case the quality means to permanently weld the performance of the first day and thus corresponds to the initial validation. The goal of asset management is to provide a digitally documented overview of the complete history of a container or box. This focuses on the state history of the thermal packaging solution. More specifically, this involves the container's initial configuration as well as ongoing servicing information – e.g., when and where a component has been replaced. In addition, the intended container modifications are documented at this point. The container represents a thermal packaging solution having individually components that can be optionally swapped. Lately, asset management can reproduce at any time the condition of a container or box as well as any servicing work carried out up to that point. This information remains up to date for the entire container fleet. The data regarding which shippings the container or box has already carried out are likewise available. These are not the focus of asset management, however.

Stock management

While asset management concerns itself with the life cycle of a container or box, stock management adopts the perspective of the current availability of a TempChain Service Center and/or the entire fleet. The fleet manager must have information at all times regarding the availability of the thermal packaging solution as well as which specific product stocks can be build up at a certain point in time. For this analysis, the fleet manager requieres not only the quantity of containers and boxes but also the number of PCMs, loggers and consumables. This function is technically comparable to a warehouse management system. By adding to an order and re-entering the explicitly recorded objects (entities) into the inventory across the processes in the software, the necessary information automatically appears in the database.

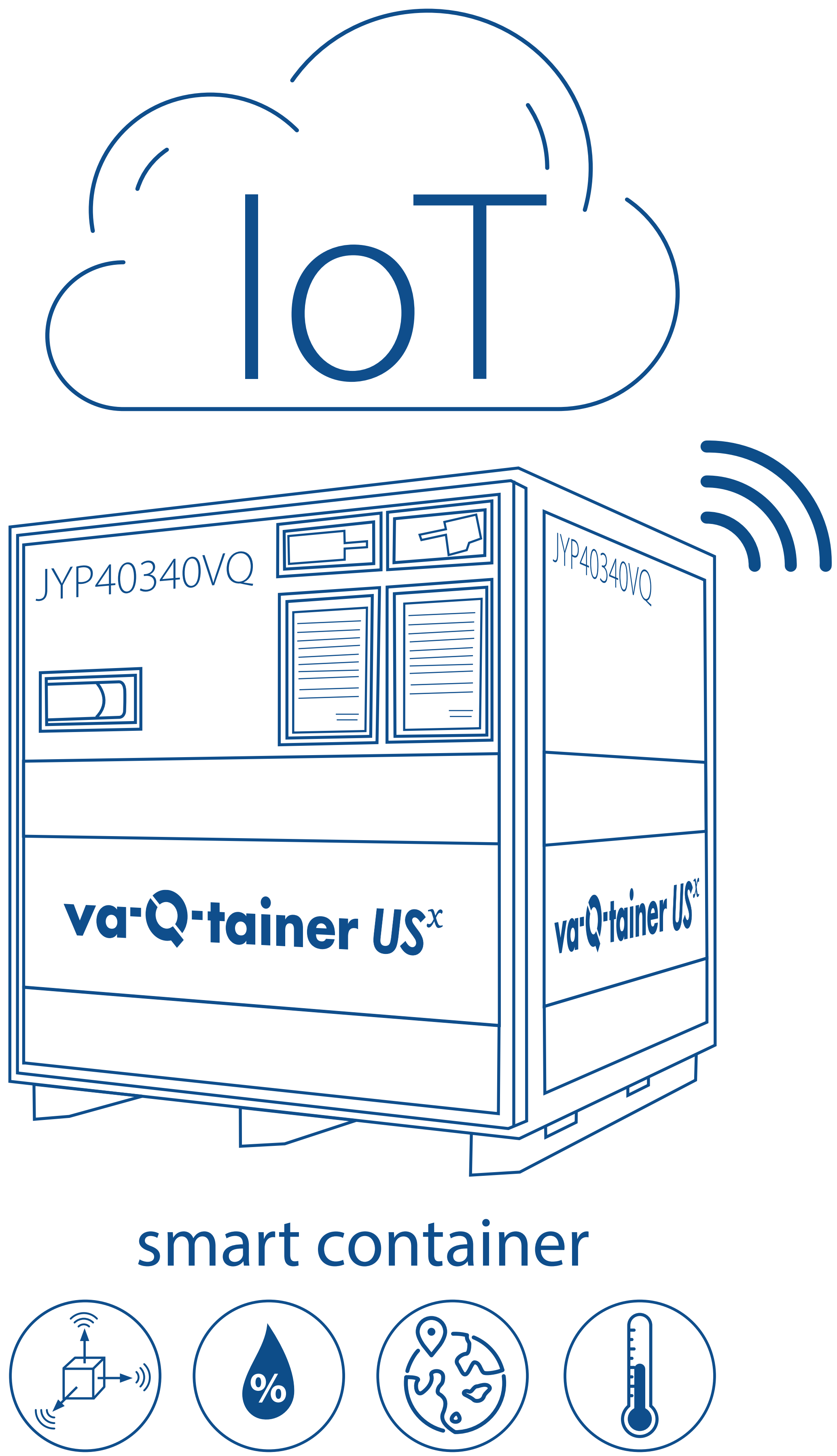
Reporting

Reliable reporting is essential for any company. All collected and analyzed data must be able to be displayed transparently. The primary purpose of the reports is to provide support to the company's decision-making process. There are reports on which the various roles (station fleet managers, management, financial accounting, etc.) can rely in their own areas. Based on these reports, key information such as container and box availability or fleet size can be determined. Statistical analyses and preparation of temperature curves can also be generated in these reports.

Interfaces/API

Another crucial point is the provision of interfaces/APIs (application program interfaces). External applications and databases can be integrated into a wide range of processes using these interfaces. Based on heterogeneous IT infrastructures, the holistic approach requires integration of the represented technological artifacts and components. Only in this way the full efficiency potential can be utilized. The guarantee of access to all information at any time prevents redundancy, keeping data from being collected and stored more than once. In the same way, functions would only be developed at a single point.

Interfaces offer even more benefits. They create the potential for all components to communicate and interact with one another. Additionally, they allow other external entities such as logistics partners and customers to be included. In this way, entire process chains can be digitized across company boundaries - including TempChain logistics.



How digital key technologies can achieve full effectiveness

The challenges of maintaining an up-to-date TempChain require the use of a variety of digital key technologies. Their application requires that the real world be depicted virtually through the basic techniques described above. In the following chapters, we present in detail the individual key technologies that, taken together, possess disruptive potential.

IoT – Internet of things: va-Q-tainers + tracking devices = smart container(s)!

Simply put, "Internet of things" (IoT) refers to the networking of objects capable of communicating digitally with one another. To make use of this approach, va-Q-tec equips its thermal containers and boxes with special transmitting sensor devices. These can be used to measure a variety of parameters – e.g., external and internal temperature, humidity, brightness, external shocks, pressure, position, movement and vibrations. The device has an implemented GPS sensor to enable it to be located anywhere in the world in real time. At the same time, a GSM/CDMA module is integrated into the container solution, which is available to upload the data to the global mobile network at any time.

The key benefit of IoT technology is proactive quality control. Threshold values are set for the individually measured parameters and their combinations. In this way, it becomes possible to determine early in the process whether, for example, the internal temperature of a container has reached a critical level. In such cases, the incorporated monitoring software quickly sends an alarm based on the sensor data. If possible, the central TempChain Control Tower automatically initiates the corresponding measures.

For example, if a logistics malfunction causes the container temperature to rise to 50 °C on the runway at Dubai Airport, the system reviews options for temporarily adding the stock to another temperature-controlled site as rapidly as possible. For this step to be successfully initiated by the system, prior human action is required to move the container from the runway.

For air freight transport, mandatory approvel for the devices and the entire thermal packaging solutions based on IATA regulations is required. The devices' transmission function is automatically deactivated when the aircraft takes off. During the flight, the aircraft's location is monitored. This allows the shipment to be constantly tracked in real time. Once the flight has landed, the transmission function is activated and the sensor data collected during the flight can be sent.

BLOCKCHAIN TECHNOLOGY

Blockchain: Trust and values are digitally represented

A blockchain can be most easily compared to a digital record comprised of a string of data blocks that stores information regarding all completed processes. The data are stored not on one main computer but on many decentralized servers. Each of these manages a complete copy of the data. All elements in the chain work together to form a decentralized network. Should one server fail, the entire information is retained on all other computers.

In the blockchain, only changes can be stored; however, the complete data history remains. This keeps the data safe against falsification and manipulation, especially since the encryption takes place asymmetrically. The blockchain is therefore an ideal technology for any type of transaction. This also explains the emergence of crypto-currencies based on blockchain.

In the pharmaceutical sector, significant blockchain applications are primarily found in logistics. In the TempChain, a special characteristic of an agile supply chain is that it generally involves many different participants. These include pharmaceutical companies, a wide variety of providers of logistics services, airlines and authorities such as customs – however, also companies like va-Q-tec, which provide preconditioned, passive packaging solutions.

If the entire global TempChain and its participants form a digital blockchain, each participant retains a complete, redundant map of the supply chain on its own computers. In principle, a decentralized, transparent design like the blockchain has many great advantages. It is unsurprising, therefore, many companies are currently attempting to develop their own blockchain to be able to assess the technology and their own options for using it. In fact, small and medium-sized companies will certainly not define blockchain implementation in the future.

In the supply chain area, since this technology relies heavily on the capacity for interoperability, it is necessary at this point to define precise standards. Both bottom-up and top-down approaches exist. The market leaders will of course play a key role in this development. For example, the Danish logistics group Maersk and the U.S. IT concern IBM have jointly developed a blockchain platform named TradeLens for the area of sea freight logistics. Other shipping companies have already joined the venture. With this as a model, blockchain platforms could also be developed for other logistics area.

Individual smart contracts in the blockchain provide a solution for implementing the negotiation mechanism. These involve algorithms that represent a participant and its interests.

From a data perspective, the primary entity is the container or box, which represents the digital twin supported by the basic technologies described in the previous chapter. Hidden behind the digital twin is a data object that accompanies the entire (logistical) process. Documentation (access, storage of additional data etc.) across the logistical process with respect to a container or box takes place continuously in the context of the digital twin. In principle, apart from the real one, there is

> A blockchain is a decentralized database. The data is mirrored to a large number of computers in the network in form of blocks. The authenticity of the data is ensured by a common consensus mechanism.

an identical virtual representation that can be accessed at any time. In this manner, authorized users from any of the companies and organizations participating in the provision of the transport service can enter the data related to the project at any time – and, should complications occure – as described in the previous chapter, they can directly arrange for necessary measures to be taken.

In the va-Q-tec AG business model, service quality together with the ability to demonstrate it plays a significant role. This quality corresponds to the transparent guarantee of a secure, reliable and unbroken TempChain. va-Q-tec is able to demonstrate to the customer at any time that the thermal packaging solution has been correctly preconditioned. The blockchain, in turn, is a useful technology for bringing this evidence.

A hash value can be calculated from the stored parameters of preconditioning and quality of service regarding the perfect condition of the container or box. This is an alphanumeric value produced by a special kind of hash function. It maps a character string of arbitrary length onto a fixed-length character string. The function can therefore only be solved in one direction. Applied to our case, this means that the originally calculated one-to-one hash value that has been stored in the blockchain must be able to be reproduced at any time from the individual source data.

The hash value is then stored in a blockchain and can never be modified. If the source data were to be falsified, this manipulation can be ascertained by calculating the hash value and comparing this with the value in the blockchain. Based on the data, this is the best possible proof that the guaranteed quality has been achieved – and implicitly, that it contributes in a significant way to a business relationship characterized by a high level of trust. This hash value incorporated into the blockchain is a practical application with low hurdles that is also easy for the customer to verify.

Artificial intelligence: Intelligent analysis of existing data

Artificial intelligence (AI), as a part of computer science, is currently extending its reach into ever growing interests. Along with basic research, companies' R&D divisions are working on the development of concrete AI applications. The pathway for the current potential in this area was prepared by advancements in research, the exponential growth of available data and the increasing availability of high computing power.

The AI concept encompasses the methods that place machines in a position to find solutions to problems through the use of human-like intelligence. Examples of this are machine learning and natural language processing. In contrast to humans, AI systems can process a far bigger quantity of information and in this way generate valid predictions. AI can recognize patterns, form associations and draw conclusions from data. Machines are permanently available and less prone to errors than humans.

> Artificial intelligence is a branch of computer science and deals with methods which allow computers to solve tasks with methods derived from human thinking structures and solution patterns.

In the context of TempChain services, we use AI options in three different areas.

Data-driven container inventory management and positioning

This approach aims to create a model for optimizing an existing container network. va-Q-tec currently has a container fleet comprising of around 2000 containers, which are efficiently distributed across 35 TempChain Service Centers (TSCs). Data-driven container inventory management and positioning takes place based on various parameters – such as data from CRM systems – combined with human experience.

The containers are originally sent via their own transport, for example by shipping a freight load from Europe to Asia, and the container is subsequently returned to a TSC in Asia. If more transports are gradually shifted from Europe to Asia than in the opposite direction, an imbalance occurs in the network. This results in the need to reposition the containers. Generally speaking, to ship an empty container involves costs that are as high as those for shipping a full container. This creates the possibility of enormous efficiency gains from optimal repositioning.

The purpose of the model currently being developed by va-Q-tec is to analyze the strategic alignment of the network and to provide recommendations for repositioning the containers. This involves analyzing historical data. In the further curse traditional time series models (ARIMA models) and machine learning processes such as random forests and neural networks will project demand.

Temperature management

Another practical application for artificial intelligence is in the area of temperature range analysis. Since 2011, va-Q-tec has used a temperature logger to record the complete temperature curve (internal and external temperature) of a leased container. Even though the relevant portion of the graph is the part of transport or customer use, the temperature logger records the entire course of a container's movements (pathway to customer, transport/customer use, pathway back to TSC). Therefore, the temperature records must be automatically segmented. This occurs through determination of change points such as the point where the door is opened to load the goods for transport. This process is assisted by the pruned exact linear time algorithm (PELT), a special algorithm for performing structural break analysis of time series. The process is limited, however, if internal and external temperatures are close to identical then no change points exist.

Based on these data, it is also possible to make statements regarding the need for phase change materials (PCMs). To determine the need for accu types, various machine learning approaches are compared with one another. The best results are currently provided by XGBoost (gradient boosting) and Facebook/Prophet (additive regression) models.

These data are likewise appropriate as an indicator of the state of the container. Certain measured variables in the container can also be used during transport to verify functionality. Here as well, the algorithms must relearn the pattern in a first step to be able to form conclusions for additional containers.

Prescriptive maintenance

In the course of the Fourth Industrial Revolution, companies throughout the world are modernizing their organizations through the use of new technologies to profit from ICT innovations. This has already led to the implementation of predictive maintenance approaches that significantly reduce downtimes and their associated costs by detecting the imminent failure of a machine and introducing preventive measures. "Prescriptive maintenance" is an AI-supported advancement. It offers an optimized decision-making system based on forecasts of a machine's remaining service life. This involves precise forward-looking calculation of maintenance intervals and necessary resources (personnel, replacement parts).

In the case of va-Q-tec's own containers and boxes, internal gas pressures measured on the panels over time with the help of the patented va-Q-check quality control system can be used to forecast whether the respective characteristic vacuum is still sound. This system is ideally intended to intervene in the planning of container fluids based on the container's predicted service life to ensure timely repair at a TSC.

For this purpose, container service lifetimes are subdivided into different phases and used as the basis for calculating a "health indicator". The health indicator estimation and the container's service life are produced using the XGBoost algorithm. Furthermore, the remaining service life of the container is forecasted based on the estimated "health indicator" under various conditions using Holt's linear trend method (double exponential smoothing). Finally, a decision-making support system is created.

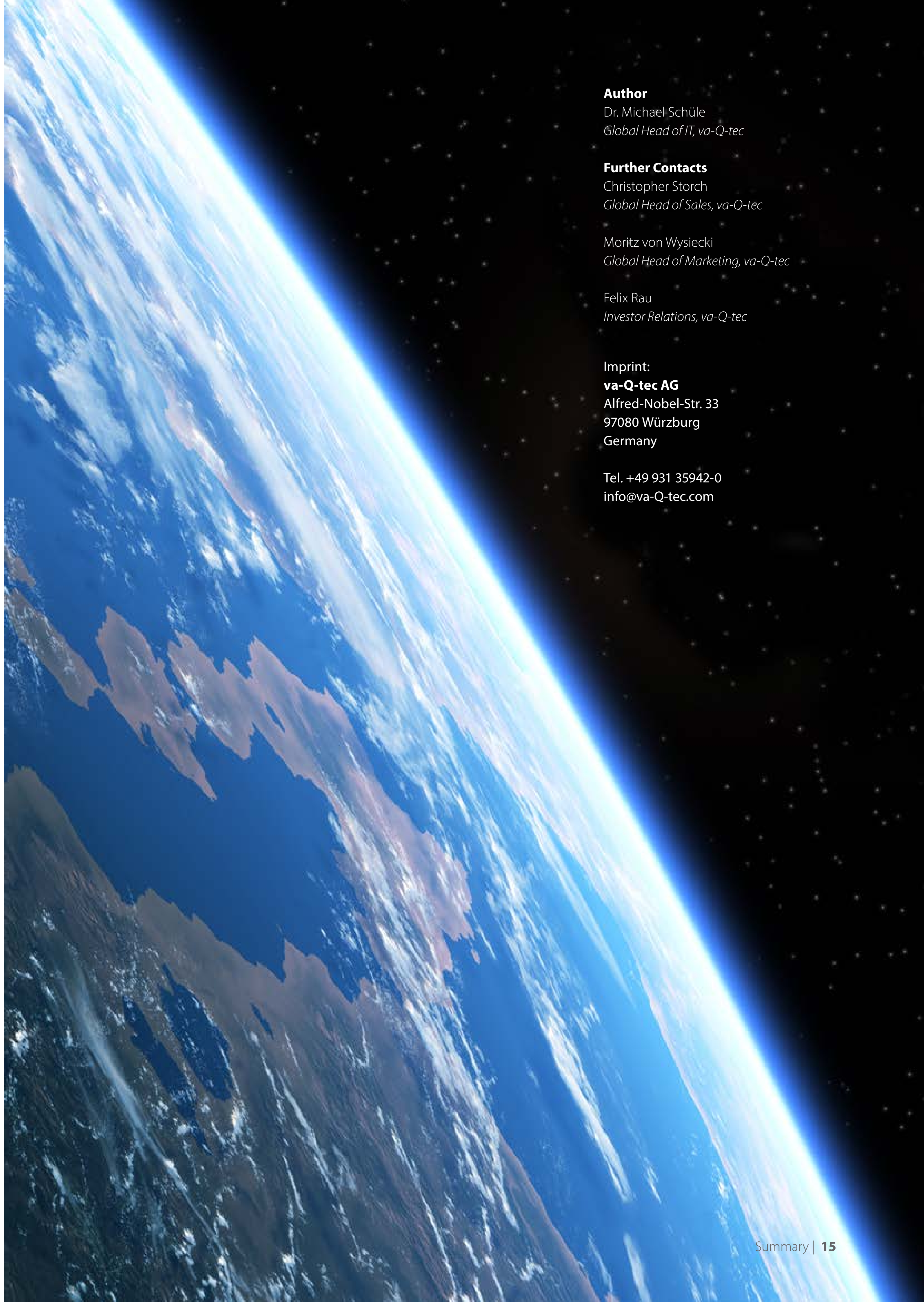
The results of the "health indicator" estimation indicate that 44% of the variance of the test set can be explained. The median absolute error percentage is 18.96 for the prediction over a one-period forecast range. The quality of the prediction and the decision-making support are strongly dependent on the manner in which the container was damaged. While slight damage can be predicted, it is not possible to predict "sudden death" scenarios.

The quality and service life of VIPs depends on the quality of the core material, the barrier foil, and most importantly, on the internal gas pressure. That is why va-Q-tec developed the globally patented quality control system va-Q-check. It allows for the precise measurement of the internal gas pressure of every individual VIP in seconds. Each va-Q-tec VIP comes equipped with a small sensor disc for measurements and a bar-code label. These two components allow va-Q-tec to store all information about the VIPs.

An external sensor measures the heat transfer between the two sides of the panel and within second the va-Q-check gives a precise indication of the internal gas pressure of the VIPs. The transparent inspection system checks every single box, panel or container before leaving production. Along with the high quality materials, the va-Q-check can thereby ensure the quality of the products for up to 50 years.

Summary

This white paper has demonstrated the following: Digital key technologies can become a powerful driver in the transport of temperature-sensitive products. There are already many promising applications. We are working every day to develop innovative thermal packaging solutions and to optimize fleet data management. If individual technologies are used in isolation from one another, they generally produce an appreciable improvement in the efficiency and effectiveness of the TempChain. In practice, however, it is only through implementation of integrated solutions that their full potential can be realized. The pathway to TempChain 4.0, fully integrating all technologies, is feasible. Because so many different participants are part of a temperature-controlled supply chain, their cooperation with one another certainly cannot be dispensed with beyond a certain point. Only in this way is it possible to develop comprehensive standards for interoperability. If more trust is created in the supply chain through the use of standards and certain key digital technologies, then our industry will have taken a major step forward on the path to TempChain 4.0. Moreover, such an achievement would also be the prerequisite to the announced full automation of the logistics chain.



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