

TORSTEN MASCHKE, DATWYLER SEALING SOLUTIONS

Torsten Maschke has been Chief Executive of the Sealing Solutions division of Datwyler and a member of the group's Executive Board since October 2016. Before joining Datwyler Group, he was responsible for the worldwide distribution of sealing and damping solutions for the automotive industry at Freudenberg Group (Weinheim, Germany). Prior to this – having completed his education in 1996 – he was employed in various international management roles within the automotive business of the Freudenberg Group. Maschke earned degrees in Mechanical Engineering from Münster University of Applied Sciences (Münster, Germany) and Industrial Engineering from Bochum University of Applied Sciences (Bochum, Germany).

Interviewed here, Mr Maschke discusses some of the major trends and changes that are sweeping the healthcare and pharmaceutical industries, and highlights the significant role Datwyler's offering – in the area of parenteral primary packaging components – will play in the future as the industry evolves and new technologies emerge.



Q In your opinion, what are the biggest challenges for the pharma and healthcare sectors in a growing, global and competitive environment?

A The pharma and healthcare markets are continuously facing challenges and undergoing changes that are directly linked to the transforming needs of state-of-the-art healthcare. This applies not least around clean manufacturing. In a growing, global and competitive environment, pharma and healthcare companies need a deep understanding of the industry's current and upcoming requirements, and opportunities for future growth. Let me pick out three examples. Firstly, the increasing demands from the pharma industry's highly sensitive drugs, such as biologics and biosimilars. These require cleanliness in production, such as cleanroom manufacturing – especially with a view on the existing regulatory framework. We already have a zero-defect philosophy in place at Datwyler to ensure the highest product quality. Secondly, digital health is another hot topic for the healthcare sector with huge growth potential, as it is getting increasingly important for clinical, therapeutic and even individual purposes. Finally, it is important to combine global knowledge and local manufacturing expertise to leverage lean production processes and build on an optimised supply chain.

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Q How do pharma and medical manufacturers have to position themselves to keep up with international competition?

A First of all, it is essential to listen to your clients and to constantly observe market developments. In a competitive healthcare market, pharma and medical manufacturers rely on partners who can assist them in mastering the challenges of the global healthcare sector, enabling them to recognise their potential. This includes deep engineering competence regarding innovative technologies and, furthermore, technical knowledge transfer. Finally, manufacturers have to meet customers' business challenges with comprehensive industry expertise and lean production processes. That means providing reliable product solutions on a global scale throughout the entire product lifecycle.

Q Do you expect the pharma market to grow with the same speed in the next few years as it did in the last? Or will it slow down?

A It is difficult to provide precise forecasts, or even predictions, on market growth. For the pharma market, growth is estimated at 6-10% but always with regional differences that we as a globally acting company have to take into account. However, looking at the general population growth, and the correlating increased number of medical treatments needed, we can definitely expect more growth within the pharmaceutical market in the future.

Biologics and biosimilars are especially in the spotlight. The demand for biologic drugs still remains strong, and the biosimilars market is following in its footsteps. Growth here is likely to exceed expectations

and might well go into double figures. Therefore, requests for coated products, e.g. cartridge components, are rising. High value products will be an essential driving factor for growth because biologics and biosimilars in cartridge or pen packaging can under no circumstances be contaminated, e.g. with silicone oils.

Q Which trends and future topics do you expect to shape the pharma market in the next five years?

A As a globally acting company in the pharma industry we need to anticipate any upcoming trends. There are several developments that we see as important and interdependent trends in the pharma market right now. One important field is evolving around injectable drugs and their future forms of administration.

Other very important developments are happening in the treatment of diabetes patients, especially regarding the form and administration of their medication. The devices used to treat diabetes are changing and will continue to do so – both to facilitate drug administration and to provide more comfort for the patient.

Closely connected with diabetes are the developments in the digital health sector and wearables, which monitor and administer drugs. This also falls into the growing field of self-medication, particularly when we lay the focus on patients in emerging markets who may not yet have access to the facilities and infrastructure of the Western world. This leads us to the very important topic of patient safety. Safe and secure access to, and administration of, drugs will be even more essential in the future.

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As mentioned before, we expect the field of biologics and biosimilars to grow further. The requirements for drug packaging and elastomer components are always evolving and rapidly changing. Market trends indicate a growing demand for packaging solutions and components with the lowest possible risk related to drug stability and compatibility, minimised by providing extremely low particle levels and supported by a detailed lifecycle management strategy. With regard to patient safety, for a therapeutic protein the exact chemical make-up and three dimensional conformation can influence the efficacy of the drug product. Interactions with leachables, including silicone oil, can present a risk to the safety of therapeutic proteins and finally prevent the success of the drug product.

To summarise: there are several strong trends, especially if we consider the shift of some countries towards a more highly regulated market for the coming years. It is important to see their interdependencies and put them in the overall context of the development within the fast paced healthcare market.

Q Has the importance of R&D changed over the years? Has it increased?

A Investments in research and development are essential to stay ahead of shifting market dynamics and to always remain competitive. As innovative drugs emerge, there is also a need for the development of new and compliant packaging materials. As a supplier, we always need to be able to cater to these needs. This ensures not only that the market requirements are met, but that future-oriented solutions can, and will, be provided.

Co-operations and partnerships are very important to achieve these goals. For example, at Datwyler we entered into a partnership with the Interuniversity Microelectronics Center (IMEC) in Belgium to conduct research on wearable devices and sensors with focus on earbuds and brain

monitoring platforms. This partnership has been very beneficial for both sides.

Q Oncology and molecular therapies have been growth drivers for the pharmaceutical market in the past few years. Is this development going to continue?

A Particularly for molecular therapies, it will likely stay that way. There are more and more drugs being developed and registered for this field. At the moment, many drugs are in the clinical trial phase or in the process of being approved.

There are several factors which play into this. New drugs have to be developed for indications which had not been present in the market in the past, so innovative therapeutics are needed. Take diabetes for example, this disease is continuously growing more common – and so the demand for new types of drugs to battle the disease will also grow. Following closely are new methods for drug administration, including novel medical devices. New forms of therapy allow diabetes patients to monitor their blood sugar levels and health status themselves. The next step for patients is automatic drug administration via a wearable device, meaning that the patients themselves will not have to be hyper-aware of their disease at all times.

Q Will those new forms of diagnosis and therapy also create new business models?

A Most definitely. New, highly individualised ways of treatment will create new business opportunities and the potential for new products. This is a development that we are anticipating and preparing for. Wearables and body sensors are just a few examples of areas we are currently exploring.

We are constantly screening the market for new trends and business opportunities. As I emphasised just now, co-operations and partnerships are key. A lot of our customers have their own innovation centres, with

which we are in close contact. The issues they are working on are important in helping to identify new trends that we can explore together. Particularly as a global supplier, we can adjust or enhance our rubber components to support our customers, contribute to trends and benefit from them too. In the past few years, this has been especially important for digitally based and/or digitally supported methods of diagnosis and treatment.

Q So, is this a demand from your customers? They tell you as a company that they would like to involve you in the R&D process?

A Generally, yes, because the main objective is always to make the whole approval process as lean and efficient as possible. And naturally it is very important that all components come together as soon as possible, to further the development.

At the end, we always need to have a strong sense for future trends in order to advance global healthcare. Simultaneously, we have to provide tailor-made and smart solutions that meet current challenges and requirements.

Q How strongly will new technologies (such as imaging processes, new analytic methods, genetic research, predictive analysis, data exchange between patients and doctors, and electronic patient files) influence the market?

A I expect these technologies to be used for enabling patients to get a fast and comprehensive diagnosis and to introduce an effective therapy. Many of these new technologies can be used as preventative measures, for example, to diagnose or predict conditions even before the illness can break out. We want to

contribute an essential part in this process with our products.

Q Apps are already being used in the US to collect data for clinical studies. Are such developments in the best interest of the patients?

A The whole issue of digitisation and the collecting of individual data is not only a challenge for the pharmaceutical industry. For example, we have been following the discussions to what extent personal data can be stored and used in the automotive sector for quite some time now. I am sure that the ongoing legal discussion around it will provide us with clear guidelines and laws. The discussion is also pressing for the pharma industry, but in the end patients will have to decide for themselves if, and to what extent, they want to use these opportunities.

Of course, questions of data safety will come up if sensitive data on health statuses or conditions can be found online. In my opinion, this is not just a question of the legal framework in each country, but one that should ideally be aligned globally. It is also a question of how far each individual is willing to engage with and participate in the new digital health world. I expect that it is just a matter of time before our society will accept, and even embrace, the possibilities of digital health. And essentially it is already beginning. We have apps on our phones, or even watches, which already measure and monitor certain health factors. Theoretically, you could already monitor your blood pressure or your temperature with a smartwatch that helps to generate a shareable picture of your health status. Finally, it enables a better understanding of patients' conditions and the appropriate

therapies. This should be in my interest as a patient. Nevertheless, it is up to patients themselves how their data is dealt with. It is important to be aware of the advantages and disadvantages.

Q In summary, the pharma industry needs to look to the future, screen for trends, watch the markets, observe the legal situation and actively take part in all developments?

A Exactly. We certainly have several challenges we must take on. However, I think that the industry is well prepared and interested to invest in a safe and promising future in creating products, offering new services and generating sustainable, lasting results to improve the medical experience of patients. I am confident that the industry is on the right track to face the aforementioned challenges in order to offer the right solutions for the future.



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