newsflash

PHARMACEUTICAL SYSTEMS

SCHOTT
glass made of ideas

ISSUE 23 | April 2015

NEWS

Our shared responsibility

100% responsibility
GMP saves lives

Quality assurance plays a crucial role in the pharma industry – and this also applies to the production of pharmaceutical packaging. To help raise quality awareness, SCHOTT has launched a new campaign named '100 % responsibility.' This internal drive is encouraging all employees to adhere to Good Manufacturing Practice (GMP) guidelines everyday.

In recent years, GMP has become a fundamental base for pharmaceutical manufacturing. It brings together guidelines to ensure the quality of critical production processes. These guidelines comprise a series of general principles that must be observed during manufacturing, with patient safety being the overall goal. No wonder then that more and more countries are specifying GMP as a statutory requirement. This applies primarily to drug makers, but these guideline must also be met by suppliers of quality-related components.

SCHOTT manufactures roughly nine billion syringes, vials, ampoules and cartridges per year, and has more than 600 state-of-the-art production lines to create these high-quality pharmaceutical containers. Checks are performed throughout the entire production process to make sure the strict tolerance limits placed on pharma packaging are met. These are best technical conditions to ensure an optimal production process. The real challenge, however, is establishing a 'GMP mindset' among the employees to ensure that the guidelines are met every day.

Intrinsic Motivation

At SCHOTT, a core idea of '100 % responsibility' has been introduced to appeal to the sense of responsibility of the employees and to make each individual aware of their personal contribution. The credo 'Packaging is an integral part of the drug' drives home the message that the employees are not only responsible for the packaging, but also the safety of patients. This is particularly hard-hitting when one considers that, with a production volume of nine billion units annually, it is very likely that each employee will know someone who will be receiving medication packaged in a SCHOTT container.

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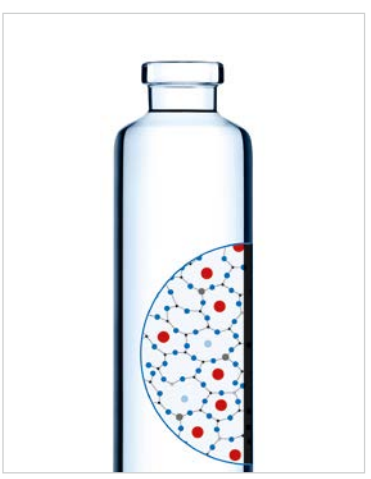
PREVIEW

Innovation – SCHOTT Vials DC are now also available in 6R and 8R ISO formats. Read more on page 3.



Innovation – SCHOTT Cartridges BR help pharma companies to avoid breakage. Read more on page 3.

Know-How – Glass quality plays a crucial role for the containers used to store highly sensitive formulations. More on page 4.

Market Portrait – Brazil destined to become the fourth largest pharma market in 2017. Read more on page 4.

EDITORIAL

Dear Reader,

As a supplier to the pharmaceutical and biopharmaceutical industries, SCHOTT shoulders the responsibility of delivering high-quality glass containers for advanced injectables. This is how we contribute in turning your research into health.

Whether innovative packaging solutions like break resistant cartridges and vials that are delamination-controlled, or 'just' standard ISO containers: Good Manufacturing Practice (GMP) is always our guiding principle. In fact, SCHOTT has elevated GMP adherence to a new level by launching a training and awareness campaign – for good reason this became the title story of our latest edition of 'newsflash'.

Sharing the same mindset is one aspect of customer proximity. Supporting our customers locally whilst ensuring global standards in supply chain management is another one. You will read more about our approach of 'being your global neighbor' on page 4.

I hope you enjoy this issue of newsflash.

Andreas Reisse
Executive Vice President
Pharmaceutical Systems

NEWS

Our shared responsibility

Continued from page 1

Ten key rules to follow

Every employee of SCHOTT Pharmaceutical Systems is constantly reminded of the ten key GMP rules:

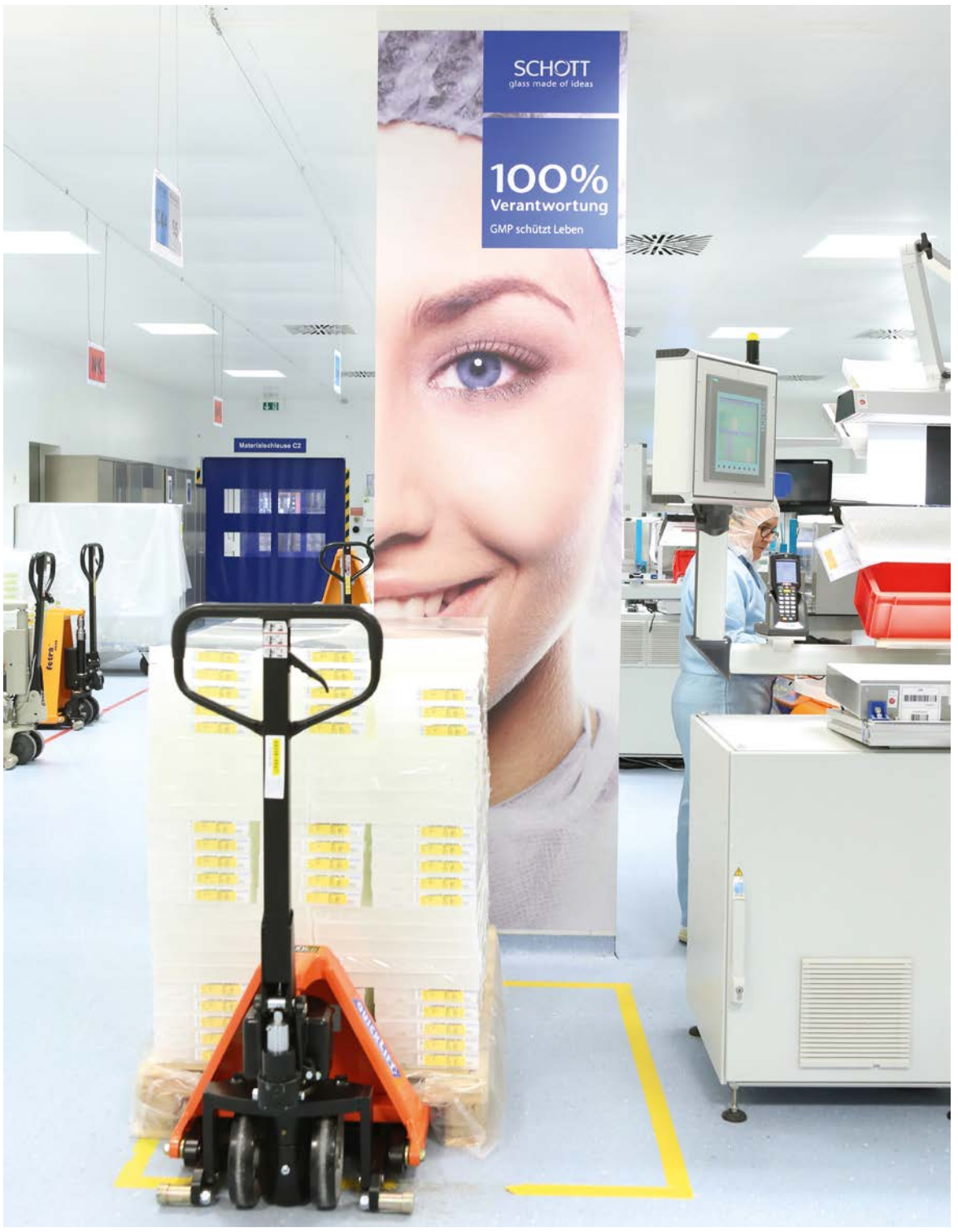
1. Take responsibility: Utmost care is required at all times.
2. Follow operating instructions.
3. Do what you were trained to do.
4. All procedures must be documented clearly so that in an emergency when errors are discovered, it is possible to limit the damage and to initiate targeted countermeasures.
5. Signatures must be readable so that it is possible to trace back documentation to the signatory.
6. Avoid contamination, for example by hair or fingerprints.
7. Do not mix products.
8. Four-eyes principle – all quality-critical process steps must be checked by at least two persons independently.
9. Do not give approval without checking.
10. Promptly report deviations, so that corrective action can be taken immediately.

In order to reinforce these strict guidelines, all employees, even those who don't work in production, enjoy regular trainings. To back this up, the '100 % responsibility' campaign deliberately uses emotional imagery at various points in the production line.

Quality is indifferent to hierarchy

GMP requires that team members continuously prompt each other, regardless of position, in order to adhere to guidelines. To lead the shift to this mindset, senior management at the manufacturing sites carried out a whole day event to kick off the campaign. Personal presentations and company videos underscored the message that everyone must work together to achieve compliance. A range of activities involving all team members also took place. For example, a team photo shoot demonstrated the correct wearing of clean room garments.

SCHOTT has now rolled out the campaign at more than half of its facilities and received lots of positive feedback from the teams and customers in the process. All sites will be working with the program by end of this year. Customers and suppliers who visit the production facilities are immediately aware that compliance with GMP rules is a top priority. As a result, the SCHOTT campaign will not only have an effect internally, but also enhance the existing image of the company as a trusted brand in the pharmaceutical industry.



More than 3,000 pharma professionals trained through SCHOTT FIOLAX Academy

SCHOTT has reached the landmark of training more than 3,000 professionals at its FIOLAX Academy. Started in 2010, FIOLAX Academy events share the latest information on the composition, properties and production of high quality pharma glass. This knowledge helps the industry to manufacture and use even better vials, syringes, ampoules, and cartridges for the optimal storage of medicines – supporting pharma companies in their efforts to minimize risks and ensure patient safety.

Participants have come from within specialist companies that are converting glass tubes to primary glass packaging, and from pharmaceutical businesses. The academy takes its name from SCHOTT FIOLAX® glass tubing, which has grown to become the gold standard 'raw material' for glass containers in the pharma industry. SCHOTT hosts FIOLAX Academy events in many of the world's leading and emerging pharmaceutical markets.

Since 2010 there have been more than 150 FIOLAX Academies in countries throughout the world, from Europe and US to South and Central America, India, Japan, and China. Dr. Bettine Boltres, Product Manager Pharmaceutical Tubing and responsible for this training program, explains: "At SCHOTT we are thrilled to have already trained so many people in the FIOLAX Academy. We are continually expanding the program to offer a complete training experience, covering topics such as drug-container interactions, regulatory requirements and glass quality. Through these training events we help our partners to improve quality and to increase efficiency and in turn advance their position in both their domestic and international markets."

The FIOLAX Academy modular training programme has been designed in six parts. SCHOTT experts share the latest industry information on the use of glass in pharmaceutical ampoule, vial, cartridge and syringe manufacturing. Specialist insight is also provided for drug makers and contract fillers about the handling of glass in the filling processes to help decrease the risk of breakage during production.

INNOVATION

New sizes for SCHOTT Vials DC available

SCHOTT has extended its SCHOTT Vials DC (Delamination Controlled) product range. These new vials bring the advantages of reduced delamination propensity and decreased risk of product recalls to the pharma industry. Specifically, the company has expanded its portfolio of SCHOTT Vials DC. They are now available from stock as 2R, 4R, 6R and 8R formats, whereas 10R will follow soon.

Delamination is the detachment of glass flakes from the inner glass surface of a pharmaceutical vial as a result of interaction with its contents. In response to the delamination issues surrounding the storage of pharmaceutical products in glass vials, SCHOTT has combined high quality FIOLAX® glass tubing with an optimized hot forming process and a quantitative chemical glass surface test routine to develop SCHOTT Vials DC. The improved manufacturing processes help to ensure the glass surface is more homogeneous and therefore less susceptible to delamination. Importantly, conventional tubular type I glass vials can simply be replaced by SCHOTT Vials DC for authorized drugs, without costly re-registration.

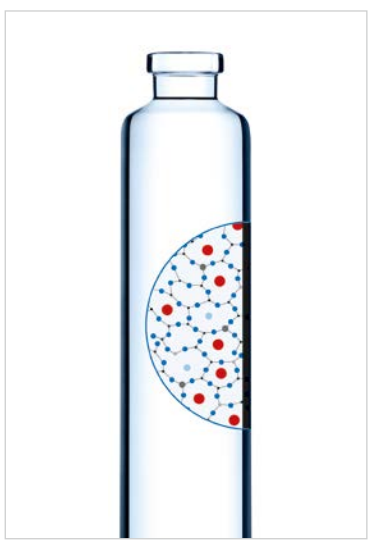
Dr. Bernhard Hladik of SCHOTT Pharmaceutical Systems explained that, "Minimizing the risk of delamination is a top priority for many pharmaceutical manufacturers due to the very costly drug recalls it can cause. The concept of SCHOTT Vials DC has therefore generated great interest within the industry. In order to offer maximum flexibility to our customers we are continuously extending our range of vial sizes and are also able to work on customized solutions."

The SCHOTT Delamination Quicktest

SCHOTT is the first manufacturer capable of determining the risk of delamination based on threshold values, and then monitoring these values over the course of manufacturing. To achieve this, the company developed a patented test method. In this SCHOTT Delamination Quicktest, a certain number of vials are removed from every batch. The random samples are then subjected to stress for four hours inside an autoclave to identify the delamination critical zone.

In a second step, the vials are filled with high purity water. Sodium is extracted inside an autoclave and the amount of sodium extracted correlates with the probability that the vials will experience delamination at a later point in time. By monitoring these values and adhering to certain threshold values, SCHOTT is able to control the risk of delamination.

Three times tougher: New chemically strengthened cartridges help drug makers avoid breakage



If a glass cartridge breaks on the filling line or during transportation, this can add significantly to operational costs. In order to meet this challenge SCHOTT has developed a chemically strengthened glass cartridge that is up to three times more resistant to mechanical stress.

The new product named SCHOTT Cartridges BR (Break Resistant) offer pharma companies a possibility to reduce breakage-related costs without having to compromise on the container geometry. It is designed specifically to offer utmost protection for very expensive or toxic drugs and for medications that need to be applied in hazardous environments where failure is just not an option. It is thus an interesting option for emergency or military applications as it can resist mechanical stress much better than conventional primary glass containers.

A traditional ion-exchange process which was optimized at SCHOTT's US Research and Development lab is used to achieve the desired glass strength. The cartridges are dipped into a potassium nitrate bath. During this process the sodium ions in the surface of the glass are exchanged with larger potassium ions. This introduces the compressive strength of the glass' surface layer without increasing the risk of extractables and leachables (E&L). The new product and its properties were subjected to a series of intensive tests whose results are made available on request.

SCHOTT Cartridges BR have the same dimensions as conventional cartridges and can be used with auto-injectors, needle-free injectors, insulin administrators, pen systems, and pump systems. Individual design options are also possible if requested by customers.

"SCHOTT Cartridges BR can stand up to the stresses that manufacturing, transportation, and application put on them," says Product Manager Andrea Wesp. "Its strength and durability offer a dependable solution to breakage problems without compromising the integrity of the drug, ensuring an optimal outcome for both manufacturers and patients."

Fight counterfeit drugs with new SCHOTT Ampoules AC

SCHOTT provides the pharmaceutical industry with a new tool in their fight against counterfeit drugs. SCHOTT Ampoules AC feature the coloured rings which are typically used for ampoule identification, but in the new product, the ink is doped with luminescent nanoparticles.

The rings cannot be distinguished with the naked eye from normal identification rings, which can be easily faked. A small detector, however, reveals the presence of the nanoparticles and confirms the authenticity of the product. In this way doctors and patients as well as retailers, pharmacies and customs authorities are able to quickly establish whether a drug is genuine.

The World Health Organization (WHO) defines counterfeiting of medicines as one of the most urgent problems prevalent in both developing and developed pharma markets. According to estimates about one in ten of all drugs sold worldwide are ineffective copies of the original product.

Counterfeiting can apply to both branded and generic products. This creates risks for patients as these drugs may contain no active pharmaceutical ingredient (API), an insufficient quantity of the same or the wrong ingredients altogether. At the same time, the manufacturer of the original drug loses a significant volume of sales due to the thriving trade in counterfeit drugs.

With safety and commercial drivers both playing a part, there is a constant need for pharma companies to stay ahead, and find new "anti-counterfeiting" (AC) solutions – an issue now addressed with the introduction of the new range of SCHOTT Ampoules AC.

Multitude of combinations

SCHOTT offers a wide range of ampoules that feature the anti-counterfeiting rings or dots. Available are B, C and D formats from 1 ml to 30 ml made of FIOLAX® clear or FIOLAX® amber glass. The luminescent particles are 5–20 microns in size and consist of an inorganic substance. They can be applied to the following HMF colours: white, yellow, green, blue, black, and red.

The multitude of combinations – ampoule shape and size, type of glass as well as colour, shape and number of identification rings or dots including luminescent particles – looks set to make it easier for manufacturers to protect their products against counterfeiting.

PROFILE

Supply Chain Management: Being the global neighbor

Modern client-supplier relationships impose enormous demands on the supply chain management (SCM). Pharma companies expect their packaging suppliers to show regional presence at least in the most important markets. At the same time, however, they should apply globally standardized processes. At SCHOTT this is achieved via a stringent global SCM management – and a credo that puts customer experience in the focus.

"If a packaging supplier has only four or five plants, implementing global standards is not so much of a challenge. But then the supplier can't offer the necessary proximity. And this proximity is absolutely essential to maximize customer service", says Silvia Gonzalvo, Director of Global Supply Chain Management at SCHOTT Pharmaceutical Systems.

With a global production network of 600 lines in 13 countries SCHOTT goes the more sophisticated way. Silvia and her team are responsible for managing the complete supply chain for 16 production sites, from customer inquiry right through to invoicing. "Our customers often buy from different plants, but still they want to receive a consistent high quality. Not only in terms of products, but also in terms of services", she explains her main task. In order to meet this challenge, highly organized supply chain processes are essential. "We want to make our customers feel truly confident in buying from us," Silvia states. "Being the global neighbor is our credo."

Cross-business experience

Her more than 20 years of experience in SCM help her achieving this goal. Also, the experience she gained at SCHOTT's pharmaceutical tubing business unit proves to be very beneficial. "In fact, understanding production processes and logistics in both business fields – tubing and packaging – helps us to secure lean processes and just in time delivery." Following time in the Business Services and Solutions group at SCHOTT Tubing in Mitterteich, Germany, she now leads the team that is responsible for supply chain process optimization and harmonization within the SCHOTT Pharmaceutical Systems organization.

One thing that Silvia, who is half Spanish, particularly enjoys about her job is the dialog and interaction with her divisional colleagues working at SCHOTT plants worldwide. And that's exactly why she can say with all certainty: "Customer satisfaction is paramount and everybody at SCHOTT is working together to make this vision a sustainable, long-term reality."

MARKET PORTRAIT

Brazil's complex pharma market experiences new dynamics

At first glance, IMS Health's recent summary report revealed a forecast that seemed astonishing: Brazil will be ranked fourth among the major pharma markets in the world in terms of drug spendings, displacing Germany. Not at some point in the distant future, but during 2017. For those, however, that have been following the development of South America's largest economy this prediction will not be a surprise.

Brazil has experienced political and economic stability for two decades, and despite a recent downswing this has had a sustained positive effect on the country's pharma industry. In their 2013 market report, PricewaterhouseCoopers (PWC) Brasil highlighted three reasons for the strong market growth. First, the country is "the only one in the world to have a universal and free public health care system, the Sistema Único de Saúde (SUS)". Secondly, disposable income has been rising and more and more Brazilians have joined private health plans. Finally, the third pillar highlighted by PWC was the country's shifting population demographics, with an aging population demanding more health care.

Based on this growth in health care expenditure the pharmaceutical industry in Brazil has made significant progress. "Today, the Brazilian market is certainly proving to be an attractive business proposition, with the unique mix of local companies and global players all being encouraged to increase capacity in their in-country manufacturing facilities," says Jürgen Buhr, Director of SCHOTT Pharmaceutical Systems in Brazil. "Furthermore, Brazil offers the perfect location to manage distribution throughout South America."

Importantly, working in a globally regulated market, Brazilian facilities are under the same pressures as businesses elsewhere in the world as they look to further increase quality as well as improving productivity and competitiveness.

SCHOTT has long been committed to the pharmaceutical market in Brazil: the company has a strong heritage in pharmaceutical packaging, something that began 80 years ago with local manufacturing facilities that were subsequently acquired and consolidated into SCHOTT Pharmaceutical Systems. "Supporting Brazil's market growth locally has been SCHOTT's ambition ever since. For sure, this will not change moving forward," resumes Buhr.

EXHIBITIONS & EVENTS

Come and see us at

CPhI Russia, Moscow
April 27–29, 2015

CPhI Turkey, Istanbul
June 3–5, 2015

55° Simposio AFI, Rimini
June 10–12, 2015

CPhI China, Shanghai
June 24–26, 2015

CPhI worldwide, Madrid
October 13–15, 2015

Upcoming Webinars

How to Bring Delamination Under Control
May 7, 2015

If Pharma Companies Knew What Cartridges Can Do
May 21, 2015

To register for a webinar visit
www.schott.com/pharma

MASTHEAD

NEWSFLASH
Issue 23 | April 2015

Layout: Knecht Digital- und Printmedien
Photos: SCHOTT AG

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KNOW-HOW

Glass material for containers for highly sensitive formulations

With the rise of expensive yet sensitive drugs, such as most biopharmaceuticals, containers guaranteeing the least possible interaction between drug and container have become a high priority topic for pharmaceutical companies. And packaging manufacturers are taking a multitude of measures to ensure that their containers are suited for highly sensitive formulations. An aspect, which cannot be overstated, is the crucial role the quality of the raw material (e.g. the glass tubing) plays.

Most biopharmaceuticals are quite sensitive towards any changes in their formulation like pH-shift, certain Extractables & Leachables or oxygen and/or water vapor. As glass is an inert material it does not allow any substances to pass into the drug solution. However, there are reactions with aqueous solutions causing elements from the glass to dissolve. These reactions and their intensity strongly depend on the nature of the solution, like the type of buffer, pH value, ionic strength etc., but also on the nature of the glass. According to the recognized pharmacopeia glasses are classified into type I and type III glasses with type I glasses being the ones of highest quality. In other words type I glasses like FIOLAX® show the least possible interactions with the drug solution.

Why geometry matters

Especially when small volumes are delivered in syringes and cartridges, geometrical precision is critical. Many of the geometrical requirements are already given or at least strongly influenced by the geometry of the glass tubing. Starting with the outer and inner diameter, these two are closely linked to the wall thickness and wall thickness distribution. These dimensions cannot be altered by the converter anymore. When forming e.g. the cone of a syringe the converter cannot remove or add any glass. He has to work with the glass amount given by the tubing. So the dimensional precision of the cone is among other factors influenced by the dimensional precision of the glass tubing. Another example is the filling volume. The more accurate the inner diameter and the wall thickness the more accuracy can also be reached with the filling volume. In the case of automated fill level inspection false rejects can thus be avoided. When using a syringe or a cartridge it is preferable to have break-loose and gliding forces as constant or low as possible. These forces are among other factors influenced by the dimensional quality of the glass tubing. SCHOTT pays close attention to these aspects and produces its type I FIOLAX® glass with the same high quality standards in Germany, Spain and Brasil.