



SCHOTT  
glass made of ideas



The premium way  
to package health



FIOLAX® Glass Tubing



SCHOTT is a leading international technology group in the areas of specialty glass and glass-ceramics. With more than 130 years of outstanding development, materials and technology expertise we offer a broad portfolio of high-quality products and intelligent solutions that contribute to our customers' success.

With a production capacity of more than 140,000 tons and production sites in Europe, South America and Asia, SCHOTT's business unit Tubing is one of the world's leading manufacturers of glass tubes, rods and profiles. Approximately 60 glass types are produced in large external diameters and a variety of lengths based on site overlapping strategies in development, production and quality assurance.

SCHOTT Tubing provides customised products and services for international growth markets such as pharmaceuticals and electronics as well as industrial and environmental engineering.

## FIOLAX®

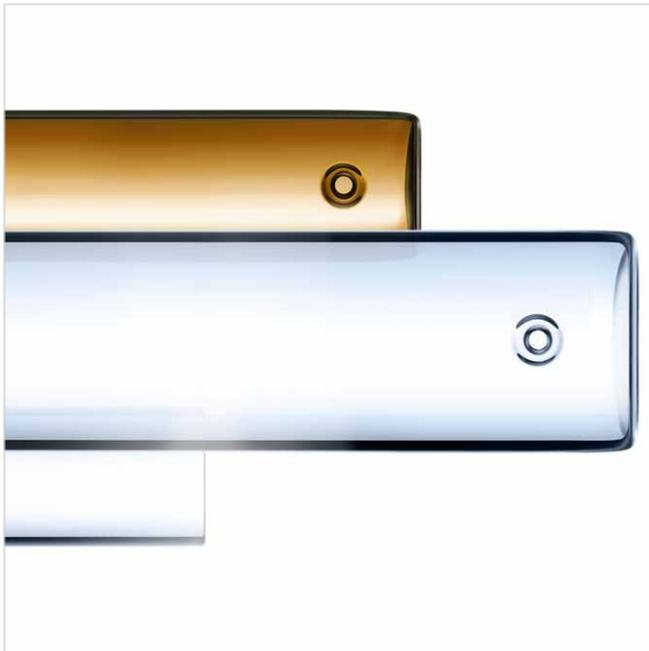
The premium way to package health - since 1911

### Patient, Product, Process

Patient safety is of top priority. Pharmaceutical companies and their partners along the value chain are therefore obliged to highest diligence and quality. This particularly applies to the primary pharmaceutical packaging.

Glass is the material of choice when it comes to packaging sensitive drugs. Glass can be sterilized very easily. It is impervious to gas, has a good temperature resistance, and withstands high inner pressure – especially when glass tubing such as FIOLAX® is used for packaging.

Discover the benefits of FIOLAX® on the following pages.



### FACTS ABOUT FIOLAX®

- Premium material to package sensitive pharmaceuticals and biomedical products
- Since 1911, FIOLAX® has been registered with thousands of drugs
- This high quality Type I glass tubing complies with all international pharmacopeia
- Its high hydrolytic resistance sets the world-wide standard
- Three production sites on three continents ensure the steady supply worldwide



## Quality right from the start

### Uncompromisingly safe

Manufacturers of premium pharmaceutical products make no compromises concerning the packaging. The same applies to SCHOTT. Our extensive product line of high-quality borosilicate glass tubing has been carefully designed to preserve active pharmaceutical ingredients and thus ensure their effectiveness.

FIOLAX® is a Type I glass tubing that is used around the world for the production of ampoules, vials, cartridges and syringes.

Due to its low alkali content, FIOLAX® provides an exceptionally low risk of drug container interaction. It offers superior hydrolytic resistance and optional UV protection and thus safely preserves the structure, state, and effectiveness of pharmaceutical products – even for long time in storage.

FIOLAX® glass tubing complies with all international pharmaceutical regulations. It provides the basis for superior quality in the packaging process as an important contribution to the reliability of a drug and the well-being of its users.

### FIOLAX® - BENEFITS AT A GLANCE

- Constant Type I glass composition of tubing and containers
- Hydrolytic resistance is certified for every tubing pallet
- Glass composition provides an exceptionally low risk of drug container interaction
- FIOLAX® amber: Reliable UV light protection
- FIOLAX® safely preserves the effectiveness of pharmaceutical products

### Chemical data

	FIOLAX® clear	FIOLAX® amber
Main components [approx. % by weight]		
SiO <sub>2</sub>	75	70
B <sub>2</sub> O <sub>3</sub>	10.5	7.5
Al <sub>2</sub> O <sub>3</sub>	5	6
Fe <sub>2</sub> O <sub>3</sub>	-	1
Na <sub>2</sub> O	7	6.5
K <sub>2</sub> O	-	1
BaO	-	2
CaO	1.5	<1
TiO <sub>2</sub>	-	5
Hydrolytic resistance acc. to ISO 719	Class HGB 1	Class HGB 1
Hydrolytic resistance acc. to current Ph. Eur., USP	Type I	Type I
Hydrolytic resistance acc. to current JP	fulfilled	fulfilled

perfeXion™ – The New Era of Quality Processing

100 % in-process measurement with line scan and area cameras, laser, optical and IR inspection systems

**Production Line**

Inspection over entire tube length **NEW**



**Dimensional Features**

- Outside Diameter
- Wall Thickness **NEW**
- Siding **NEW**
- Inside Diameter **NEW**

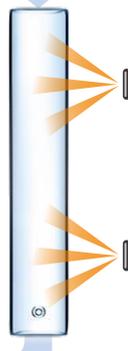
**Visual Features**

- Open Airlines **NEW**
- Closed Airlines
- Knots
- Stones

Sorting

**Every Single Tube** **NEW**

Specific Area Inspection



**Dimensional Features**

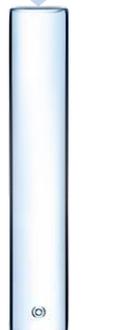
- Straightness
- Circularity
- Outside Diameter
- Square Cut

**Visual Features**

- Large particles
- Contamination
- Tube-ends

Sorting

**Final 100 % Inspected Single Tube**



All measured single tube data are used for certification **NEW**

**Packing**



Quality data per pallet are also available in SCHOTT'S e-commerce system

**Process Control and Integrated Data Management System** **NEW**



- Integrated network for real-time collection and evaluation of all dimensional and visual glass quality and process data
- Storing more than 100,000 real-time data tags per minute
- Operational intelligence: Control and improvement of production process through  $C_p$  and  $C_{pk}$  data
- PI database – proven and established in pharmaceutical industry. It is conform to FDA 21CFR Part 11 as well as with the most recently published ISO 15378 (GMP) standard



# perfeXion™ – The New Era of Quality Processing

Our aim: zero defect. Documented for every single FIOLAX® tube.

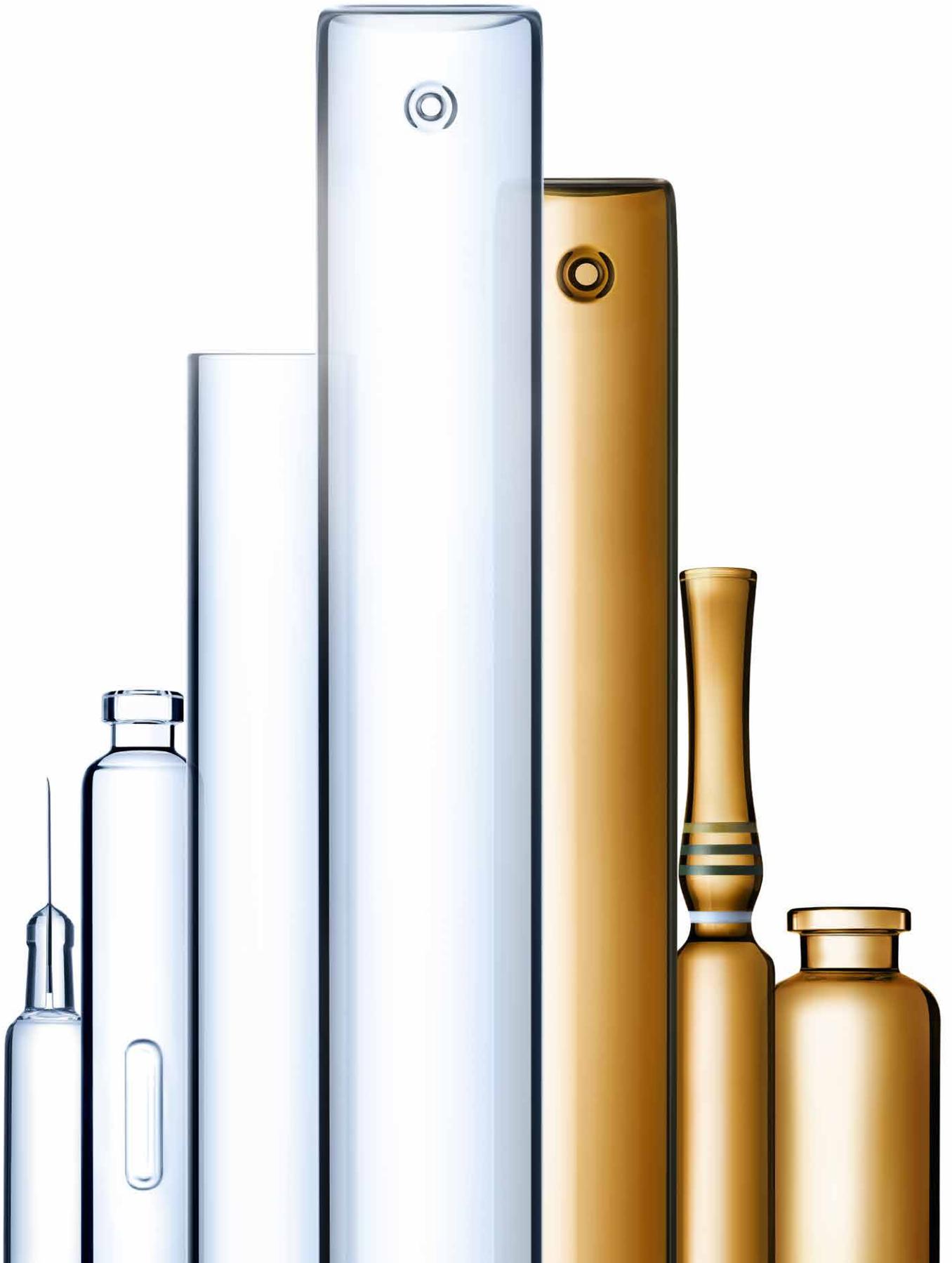
Seamlessly integrated data network.

perfeXion™ stands for the transition from statistical quality control to 100 % inspection of each individual FIOLAX® tube. Various interacting online inspection devices, in combination with integrated data collection and data analysis, allow quality parameters of the original tube to be adapted to the container format (syringe, cartridge, vial or ampoule) and customer specification.

## BENEFITS AT A GLANCE

- perfeXion™ enables more precise geometry:**  
 A more consistent wall thickness of the initial tube, for instance, facilitates a **more precise hot-forming process in geometrically critical container sections**, such as the crimp neck of vials or the cones and flanges of syringes. Tightly-toleranced inner diameters of the original tube not only ensure a **constant gliding force** but also enhance **dosing accuracy**, in particular for highly concentrated injectable substances in multi-dose devices.
- perfeXion™ facilitates superior cosmetic quality:**  
 The seamless cosmetic inspection of each individual glass tube over its entire length **reduces yield loss in camera-controlled primary packaging production** as well as at the end of the value chain at the visual inspection of the filled container. Furthermore, and in particular for cartridges and prefillable syringes, the detection and sorting-out of inner open airlines within the original tube contribute to **improved container closure integrity** by preventing bypass effects.
- perfeXion™ is based on figures, data and facts:**  
 During the tubing production process, online process- and product-quality data are collected in **real-time** and transmitted to an industry-standard **data management system** (PI database). This significantly increased data depth is now available to facilitate the calculation of the statistical certification data. For the first time, single tube data are used to control and stabilize the tubing production processes. This enables downstream post-processing steps to be efficiently aligned with the tubing quality.





# High quality tubing for high quality containers

## Pure and highly transparent

Glass is a preferred packaging material for pharmaceuticals because it consists of only few components. This allows for reliable information on the chemical resistance and preservation of the medicine.

From the glass composition and processing to the final packaging for shipment: We assure the quality of our products at each step. A non-stop opto-electronic monitoring process helps to avoid that FIO LAX® glass tubing is delivered to our customers with cosmetic defects like stones, knots or airlines.

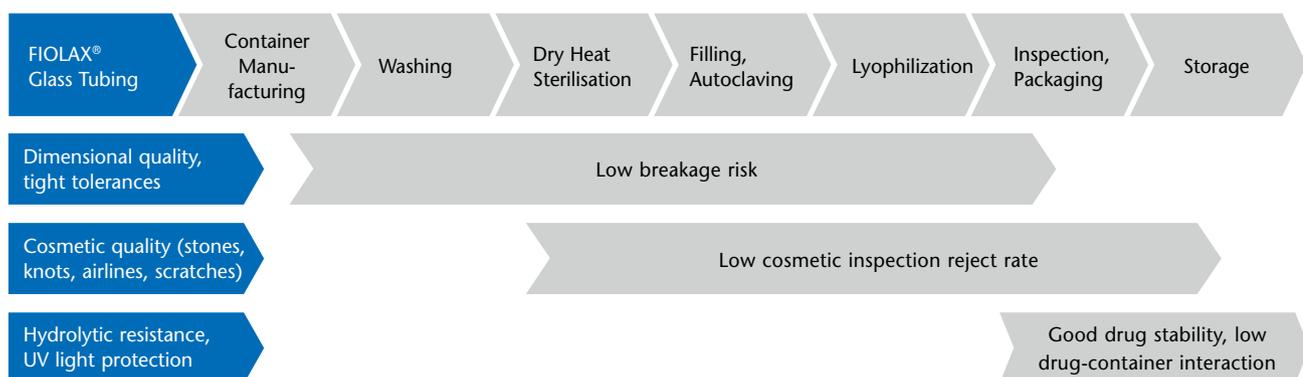
A scratch-resistant outside coating of the tubing and the sturdy DENSOPACK® packaging ensure the high cosmetic quality of our glass tubing during shipment. The dimensional accuracy enables converters to supply the pharmaceutical industry with packaging solutions that offer an excellent performance on high-speed lines by ensuring lowest possible breakage risk and constant filling levels.

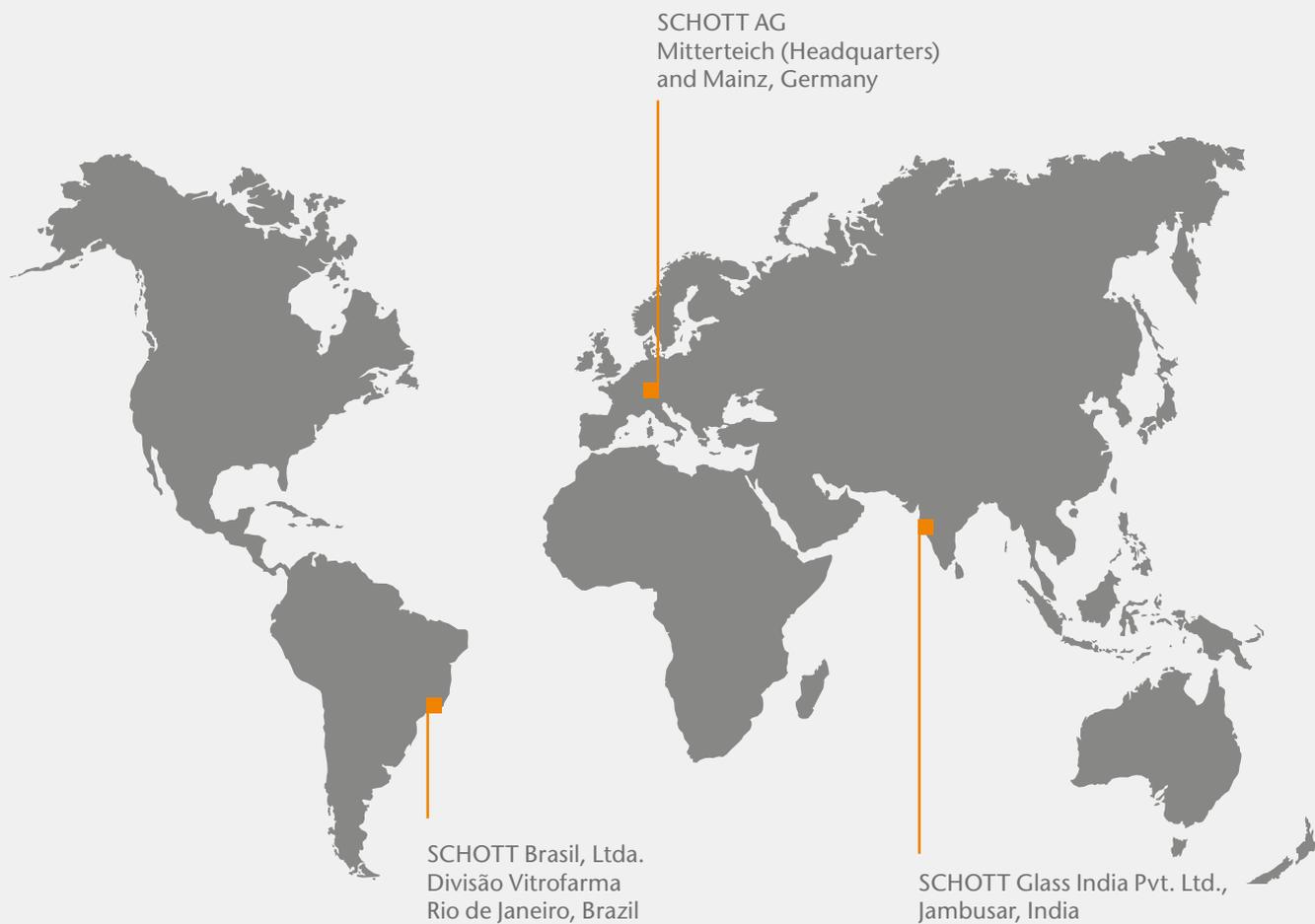
Due to their high cosmetic quality, containers made of FIO LAX® offer a high yield and low reject rate during the filling process. The clearness of the glass inspires confidence and underlines the quality of the pharmaceutical product.

## FIO LAX® - MORE ADVANTAGES

- FIO LAX® glass tubing is produced with very narrow dimensional tolerances
- Dimensional accuracy allows for constant filling levels and low breakage risk
- Nonstop opto-electric monitoring process ensures highest quality
- Scratch-resistant outside coating and sturdy packaging protect the tubing during shipment
- Cosmetic quality provides high yield and low reject rate during the filling process

## Advantages of FIO LAX® tubing e.g. for the filling process





■ Pharmaceutical Tubing Production Sites

# Dividing risks ensures maximized safe supply

## Three locations, three continents, one glass

A steady supply with glass tubing for pharmaceutical packaging solutions is the precondition for making drugs available whenever and wherever they are needed.

SCHOTT continuously deals with global risk management. By having decentralized the production of FIOLAX®, we can exclude shortages in supply. Our factories are sited at three locations, distributed on three continents. Should local occurrences ever affect one of our facilities, we can immediately shift to another.

## SCHOTT sets the standards in excellence

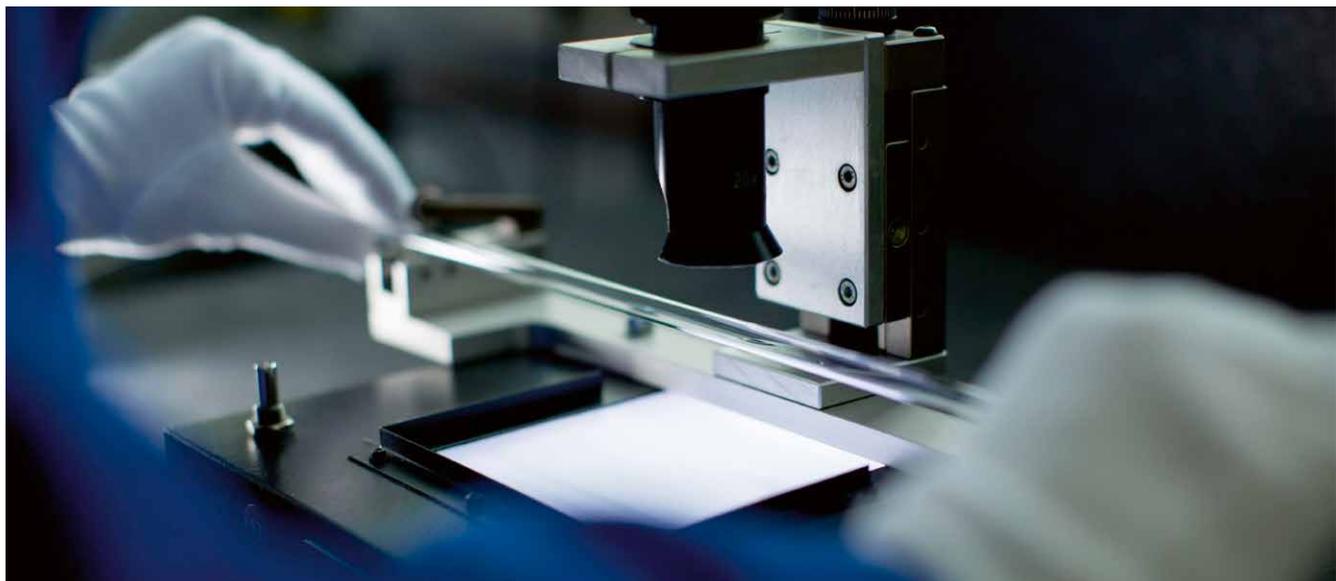
All of our manufacturing sites meet the same outstanding quality standards that are consistently defined in our technical terms of supply. All plants have been certified according to ISO 9001; SCHOTT in Mitterteich was the world's first glass tubing manufacturer to be certified under the relevant European ISO 15378 standard, in accordance to Good Manufacturing Practice (GMP). The production sites of SCHOTT's Business Segment Tubing in India and Brazil are now certified as well according to this standard.

### GMP CERTIFIED



### RISK MANAGEMENT

- Decentralized production improves risk management
- Three production sites on three continents for safe and fast supply
- All production sites certified in accordance to ISO 15378 with reference to Good Manufacturing Practice
- All production sites offer identical Technical Terms of Supply
- Customers worldwide can rely on constant quality and steady supply





## We share our knowledge

### SCHOTT Tubing Competencies

#### Learning from each other

As an international technology group, SCHOTT stands for expert knowledge. Our customers benefit from more than 130 years of experience in glass production and state-of-the-art technological infrastructure – not only through our products, but also through our services.

#### Individual Consulting Services

SCHOTT's Scientific Service team is able to cover process evaluation and fault analysis on an individual basis as well as to provide advice on specifications, regulations, standards and other scientific issues.

#### SCHOTT IdentBox

If you are not sure if your containers are made out of SCHOTT glass, SCHOTT offers to verify their identity; free of charge and with confidential data handling. You will get a quick response with reliable results.

Contact: Dr. Folker Steden

Phone: +49 (0)9633/80-253 | E-Mail: [fiolax.academy@schott.com](mailto:fiolax.academy@schott.com)

### SCHOTT Pharma Services Competencies

#### Specialized analytics and interpretation skills

SCHOTT provides the technical infrastructure and scientific skills to conduct tests and studies resulting in solutions that exclude interactions between the drug and its packaging. SCHOTT supports in choosing a suitable container for a product and brings in our knowledge when it comes to developing new packaging solutions made of glass or polymer. SCHOTT's blend of expertise in materials, products and processes is key to correctly interpret analytical data and draw in-depth conclusions.

This service is provided for pharmaceutical companies.

Contact: Dr. Uwe Rothhaar

Phone: +41 (0)6131/66-7339 | E-Mail: [pharma.services@schott.com](mailto:pharma.services@schott.com)



#### SERVICE & KNOW-HOW

- Trainings like FIOLEX Academy are offered for converters and pharmaceutical companies
- Consulting and analytical services are given, e.g. SCHOTT IdentBox
- SCHOTT supports in selecting and designing new packaging solutions
- Drug manufacturers profit from analytical services, technical infrastructure



# Training on Glass Technology in Injectable Industry

SCHOTT FIOLAX Academy offers in-depth knowledge on the importance of technicality and quality of pharmaceutical glass used in liquid dosage systems. The expert trainers of SCHOTT will take the participants through a set of modules and coach you intensively on the finer nuances of glass in the pharmaceutical industry.

Extract from the module contents:

## Module 1

### Tubing Glass Basics

- Glass basics
- Tubing production process
- Plant tour (if the training is held at a SCHOTT Tubing site)
- Quality control of FIOLAX® and benefits for the converting/filling process

## Module 3

### Glass Defects

- Definition and classification of glass defects
- Airlines, inclusions, particles
- Stress
- Occurrence and prevention of breakage throughout the converting/filling process

## Module 5

### Individual Workshop

- FAQs
- Mix & Match: Bring your own topics and questions to a unique knowledge transfer

## Module 2

### Drug Container Interaction

- Alkalinity and its impact
- pH shift, Extractables and Leachables
- Delamination
- Protein adsorption
- Surface treatments
- Light protection

## Module 4

### Benchmarking

- Glass suppliers: What makes the difference?
- How does the quality of the tubing influence the quality of the final container?
- Tubing or molded? Glass or polymer?

## Module 6

### Regulatory

- International Pharmacopoeia
- International and national standards
- REACH, RoHS, GMP



## TRANSFER OF FIRST-HAND KNOWLEDGE

- Unique and bundled communication for technical professionals from pharmaceutical sector
- Detailed understanding of impact of high quality glass in filling process
- Expert trainers with long-standing glass know-how
- Tailor-made training; modules can be chosen consecutively or individually



## The origin of FIOLAX®

### Innovative partner with tradition

SCHOTT produces more than 140,000 tons of glass tubing every year. Manufactured in a broad range of dimensions, we supply international growth markets such as pharmaceuticals, industrial and environmental technology, as well as electronics with more than 60 glass types. In addition, we offer the industry extensive support including analytical and consulting services. As a global provider of special glass tubing, SCHOTT sets standards in excellence.

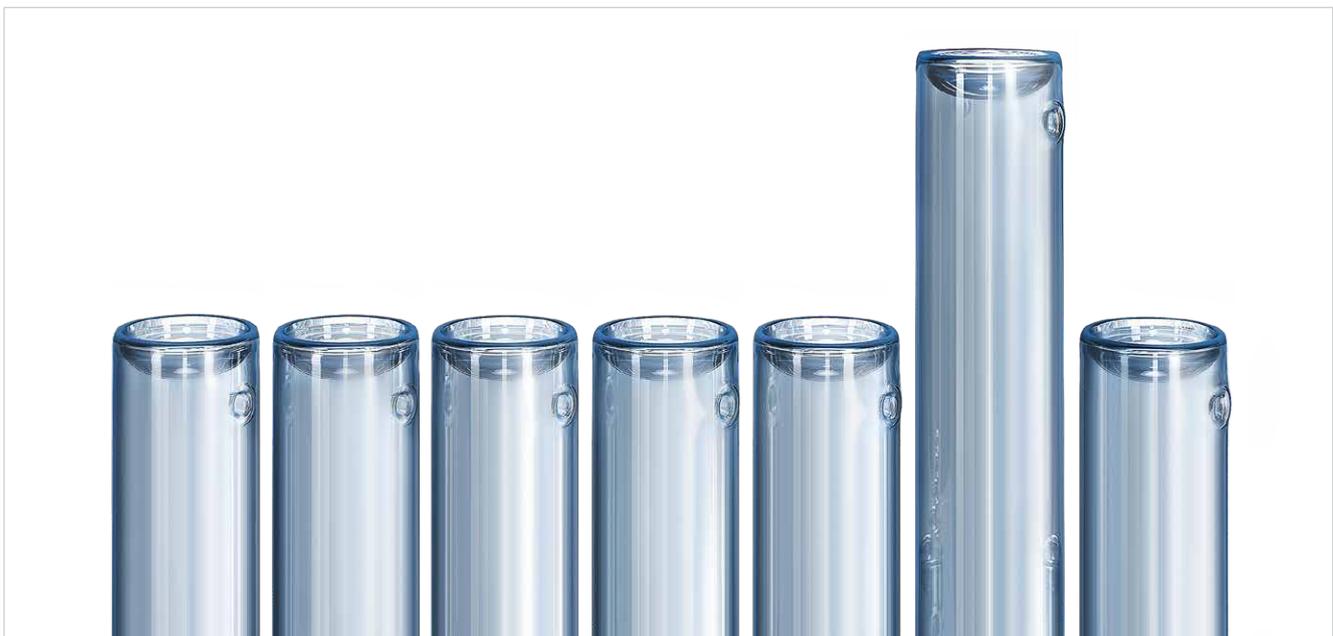
The headquarters of SCHOTT's business unit Tubing is in Mitterteich, Germany. Here, we direct the production, technology transfer, and quality assurance for our manufacturing sites in Europe, Asia, and South America. New products are developed and tested by our in-house laboratories in close coordination with the central marketing and sales management team.

One of our most important products is FIOLAX®. This glass tubing provides the ideal basis for the development of premium packaging solutions for pharmaceutical products. It has also proven to be suitable for biomedical products whose importance in the market is increasing.

The tradition of SCHOTT as a reliable partner of the pharmaceutical industry stretches back to 1911, when Otto Schott started to market FIOLAX®. He was the primal father of modern glass production and founder of the international technology group SCHOTT. In the past as in the future, pharmaceutical companies around the world can rely on FIOLAX® as the packaging material of choice.

### SCHOTT Tubing

- Production capacity of more than 140,000 tons of special glass tubing every year
- Over 60 glass types supplied in a broad range of dimensions
- Tradition as reliable partner of the pharmaceutical industry stretches back to 1911
- SCHOTT offers extensive support including analytical and consulting services
- Worldwide, FIOLAX® is the packaging material of choice for sensitive drugs





## Tubing Production Sites

### **SCHOTT AG**

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