

SCHOTT
glass made of ideas

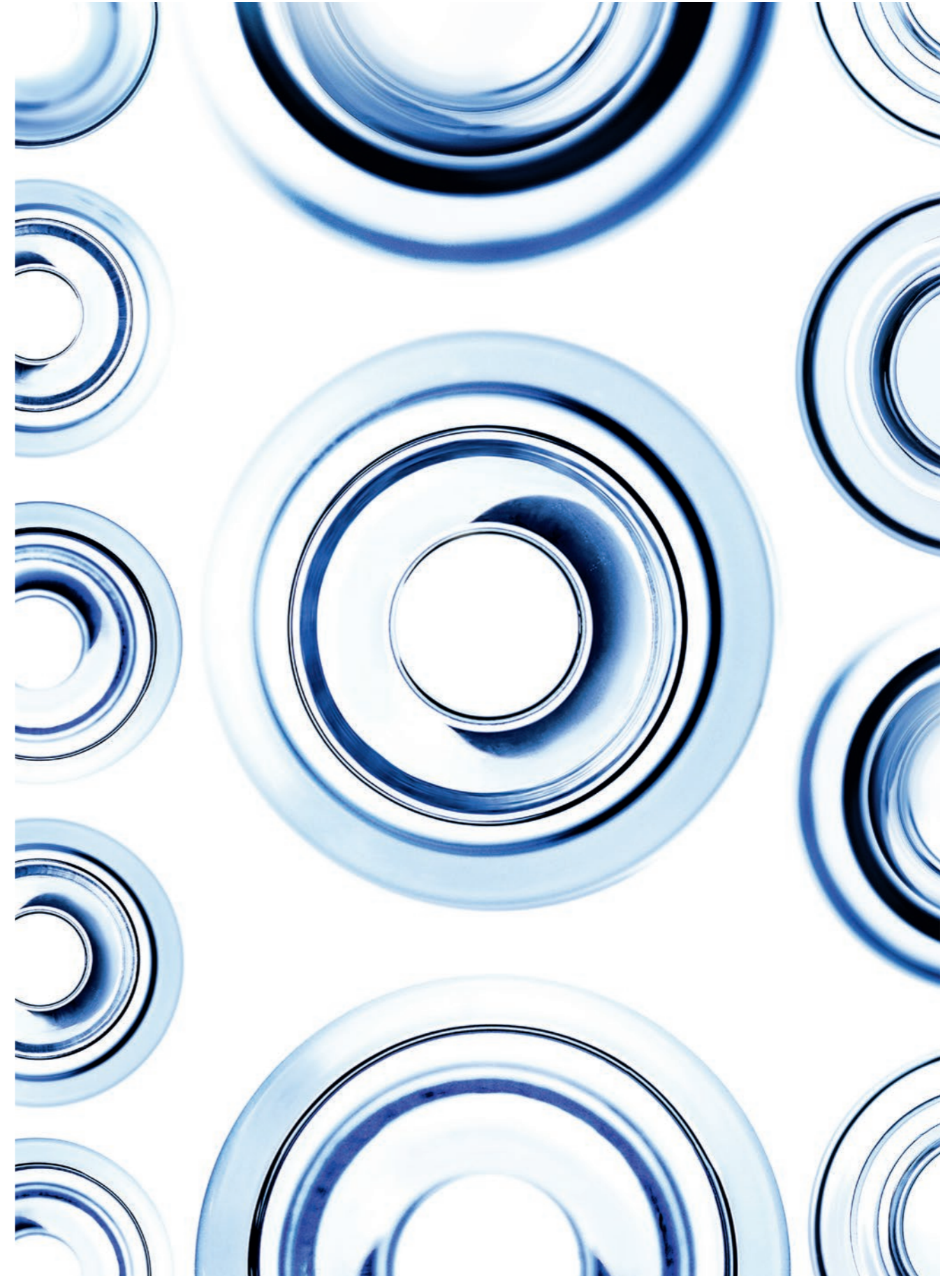
SCHOTT Cartridges

Dedicated to Performance



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.

SCHOTT Pharmaceutical Systems is one of the world's leading suppliers of primary packaging and specialized analytical lab services for the pharmaceutical industry. We provide our customers with quality solutions while meeting their highest demands with our expertise and broad product portfolio; including ampoules, cartridges, vials and syringes made of glass and COC polymer. Our state-of-the-art production facilities and our products comply with the highest international quality standards for pharmaceutical needs.



SCHOTT Cartridges – Dedicated to Performance

Our mission at SCHOTT is to convert decades of pharmaceutical packaging research and investment into sustainable success. Working closely together with you, our team of forward-thinking professionals – spanning from R&D to sales – is dedicated to developing, producing and delivering a broad variety of cartridge formats that are dedicated to performance.

Extremely tight dimensions, superior break resistance and excellent surface quality result in advanced processing capability and reliable device compatibility – finally enabling what matters most: patient safety.

So, tell us – What's your next milestone?



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FIOLAX® – Superior Tubing Quality for Outstanding Container Performance

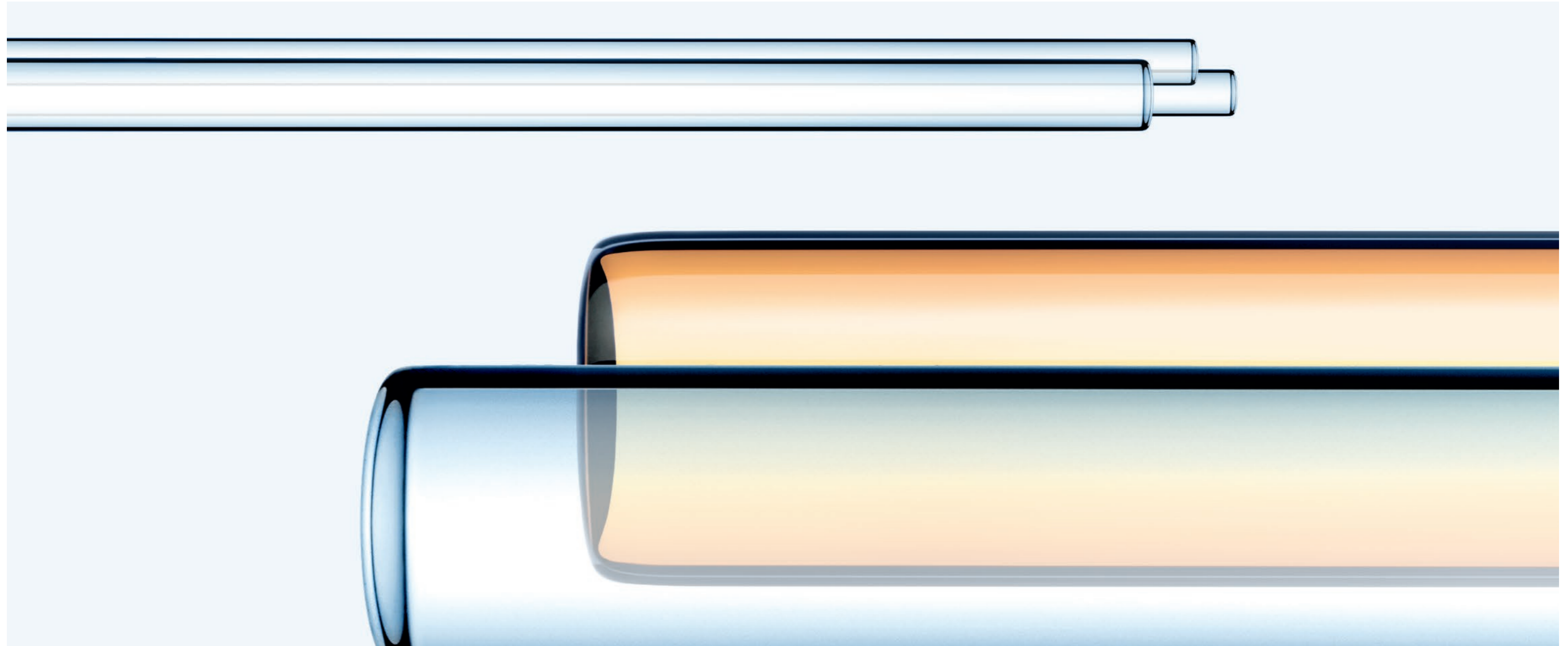
FIOLAX® – The first choice for pharmaceutical packaging

Glass has numerous advantages over other primary packaging materials available on the market. Otto Schott, founder of the present-day SCHOTT AG, was far ahead of his time when he introduced FIOLAX® tubing in 1911 for pharmaceutical packaging. Since then, FIOLAX® has been synonymous with premium quality glass of the first hydrolytic class.

This unique product is renowned for its outstanding chemical resistance, neutrality and impermeability, not to mention its exceptional strength. Containers from FIOLAX® are geared to storing and delivering a wide range of injectable, as well as sensitive biotech drugs. Today, FIOLAX® is still a key base component for top-of-the-range pharmaceutical packaging containers such as SCHOTT break resistant cartridges and double chamber cartridges, etc.

FIOLAX® and SCHOTT cartridges – the perfect match for outstanding performance and patient safety

- Reduced glass particles, airlines, inclusions and scratches for improved camera inspection
- Tight geometric tolerances
- Medical device compatibility



Broad Product Portfolio – Designed for a Variety of Applications

Safe and convenient self-administration of injectable drugs has been the key driver behind the success-story of diabetes care pen systems. By complementing innovative pen devices or patch pumps, the smart combination of drug protection, storage and administration



function in one container is perceived as highly relevant for a growing number of therapy fields. And there is more to come: By using double-chamber cartridges, even the reconstitution of drug formulations forms part of the container's capability set.



SCHOTT Cartridges – Dedicated to Performance

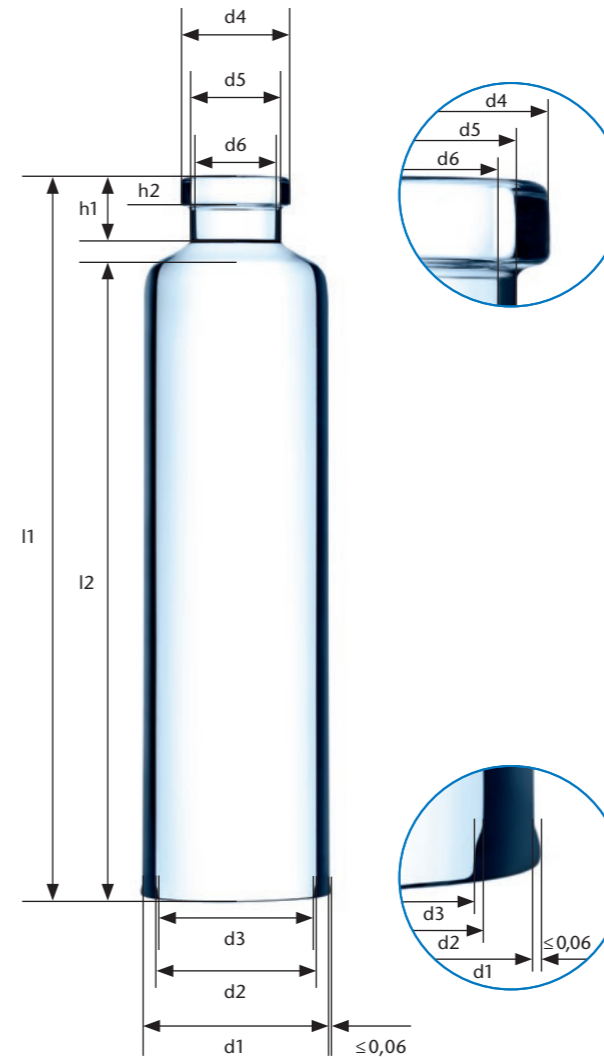
With the ever-evolving significance of biotech drugs in the healthcare sector, drug delivery systems find themselves contending with increased requirements from a market shift towards tighter regulations. Our most accurate production and gentle cartridge-handling to date facilitates tight dimensions and premium surface quality that reliably ensures superior container processing, device compatibility and reliable performance at point of use.

Outstanding processability

- Tight geometric tolerances due to 100% camera inspection for tubing and containers
- Low cosmetic defect level owing to cosmetic defect detection during tube drawing and avoidance of glass-to-glass contact during container forming

Reliable product at point of use

- Accurate dosing
- Break resistant
- Low residual volumes



Following options upon request:

- Customized length and diameter
- Reduced (tighter) tolerances
- Customizable cosmetic quality level
- Printing / graduation / ring
- Double chamber geometry with bypass
- Mechanical strengthening

Lengths l1 and l2 shall be agreed upon between manufacturer and customer.

Tubing OD d1 mm	Tol	Tubing ID d2 mm	Tol	d3 min mm	d4 mm	Tol	d5		d6	Tol	h1		h2	Tol
							mm	Tol			mm	Tol		
8.65		6.85		6.55										
10.75		8.65		8.3										
10.85	±0.1	8.65	±0.09	8.35	7.15		5.5	±0.25	3.15					±0.1
10.95		9.25		8.95							5.0		2.9	
11.6		9.7		9.35						±0.2		±0.2		
14.0	±0.11	12.0	±0.1	11.65			7.2							
14.45		11.85		11.5	9.5		7.75	±0.35	4.5					±0.15
17.05	±0.17	14.25		13.9										
18.25	±0.13	16.05	±0.15	15.5										
22.05	±0.17	19.05		18.55	13.0		11.0	max.	7.0		8.0	±0.5	3.6	±0.2

SCHOTT Cartridges – From Standardized to Customized Quality Options

A broad range of container geometries, quality levels and controlled surface chemistry enable us to tailor the primary packaging solution to your specific needs. All SCHOTT Cartridges are manufactured and packed in environmentally controlled areas certified by ISO 9001 and ISO 15378 and comply with PH.Eur., USP and JP international standards.

StandardLine – Standardized quality level according to ISO

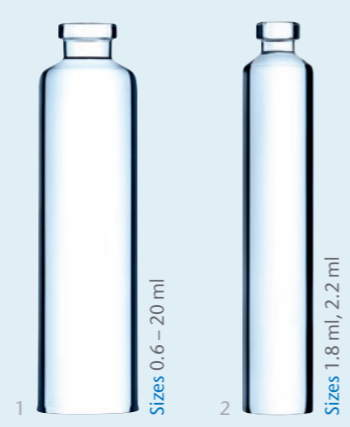
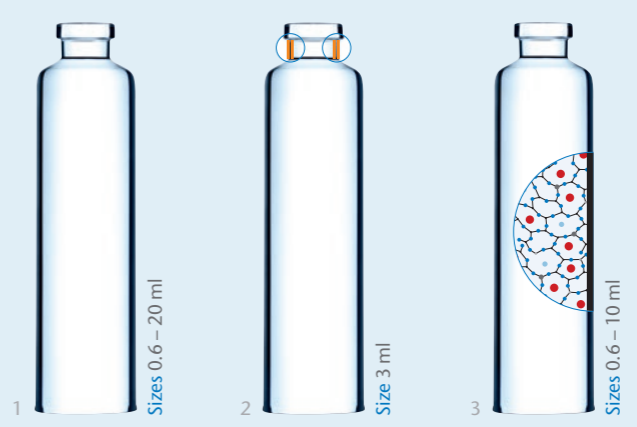

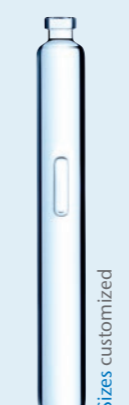
The StandardLine includes:

- Production in cGMP environment
- Statistical in-process control
- Dimensional and cosmetic AQL levels according to ISO
- 100% camera inspection of dimensional parameters
- Pen Cartridges: ISO 13926-1: 2004
- Dental Cartridges: ISO 11040-1: 1992

TopLine – Customized product specifications and quality levels

The TopLine options include:

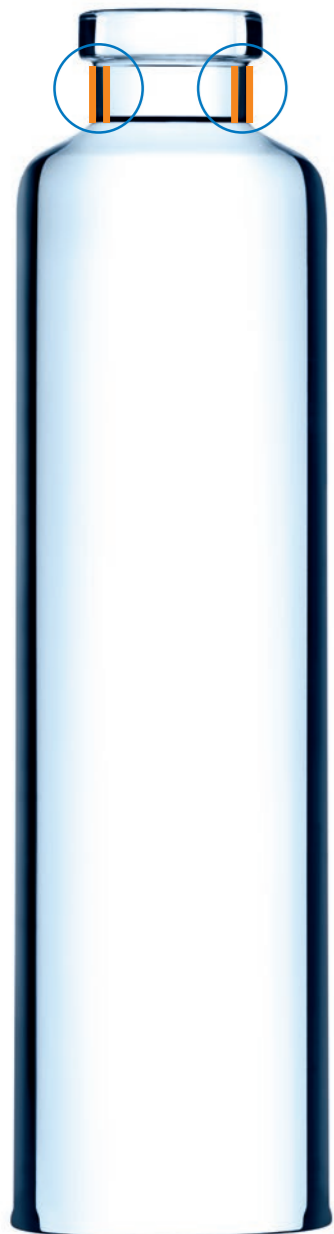
- Production in cGMP environment
- Statistical in-process control
- Customized dimensional and cosmetic AQL levels
- 100% camera inspection of dimensional and cosmetic parameters
- Double chamber geometry for liquid/liquid, liquid/powder or liquid/lyophilisate product combinations

Drug Type		StandardLine	TopLine
Injectables	Liquid	1 SCHOTT Cartridges 2 SCHOTT Dental Cartridges 	1 SCHOTT Cartridges 2 SCHOTT Cartridges High Speed 3 SCHOTT Cartridges Break Resistant 
	Lyophilized	SCHOTT Cartridges Double Chamber 	SCHOTT Cartridges Double Chamber 

SCHOTT TopLine Options for Superior Performance

SCHOTT Cartridges HS (High Speed)

With regulatory emphasizing dosage accuracy, the combination of high speed filling and superior level measuring has become a key requirement, especially in the area of highly concentrated drug formulations.



The superior cosmetic quality and precise neck geometry of SCHOTT Cartridges HS allow for highly accurate and efficient filling on laser controlled high-speed filling lines.

Properties:

- Optimized laser transmission through superior cartridge design and cosmetic quality
- Compatible with laser-controlled, high-speed filling lines

Benefits:

- Improved dosing accuracy through precise level measuring
- Improved filling efficiency through reduced overfilling and increased line speed
- Improved Total Cost of Ownership (TCO)

Sizes:

- Standard 3 ml Pen Cartridge
- Other dimensions upon request

SCHOTT Cartridges Double Chamber

With an increasing number of sensitive biotech molecules dominating the pharma pipelines, shelf life stability has surfaced as one of the key challenges. Lyophilised formulations, when reconstituted by using separate containers for lyophilisate and diluent might compromise handling efficiency and dosing accuracy.

With two chambers separated by a plunger and a bypass that allows for two substances to mix or reconstitute before (self-)administration, SCHOTT Cartridges Double Chamber support shelf-life stability of sensitive drug formulations.

Properties:

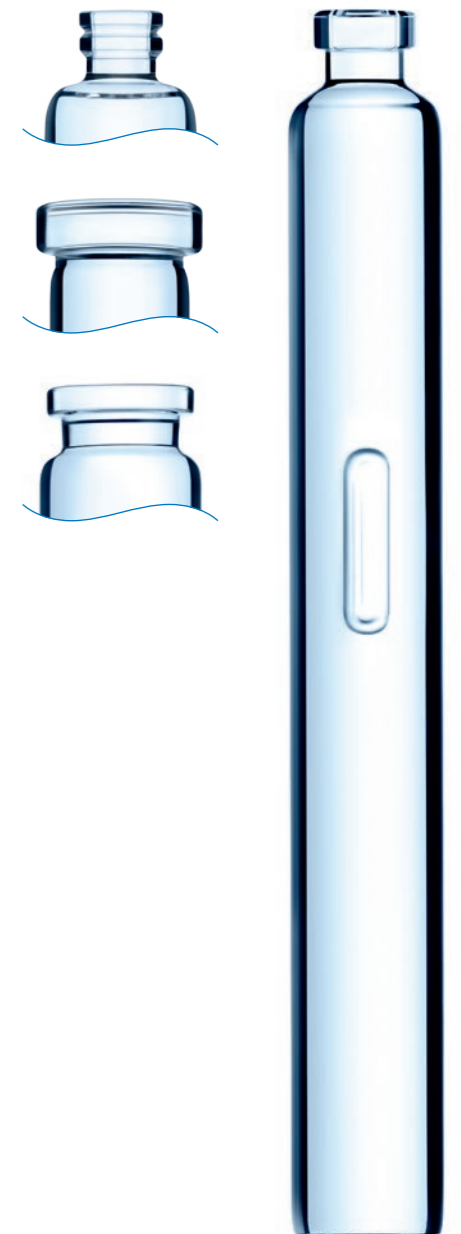
- Storage & integrated reconstitution of liquid/liquid, liquid/powder or liquid/lyo formulations in one container
- Very high dosing accuracy because of very tight inner diameter tolerances
- Compatible with many injection devices

Benefits:

- Shortening Time-To-Market
- Convenient self-administration of lyophilised medications
- Improved patient safety through superior dosing accuracy
- Facilitate reconstitution

Sizes:

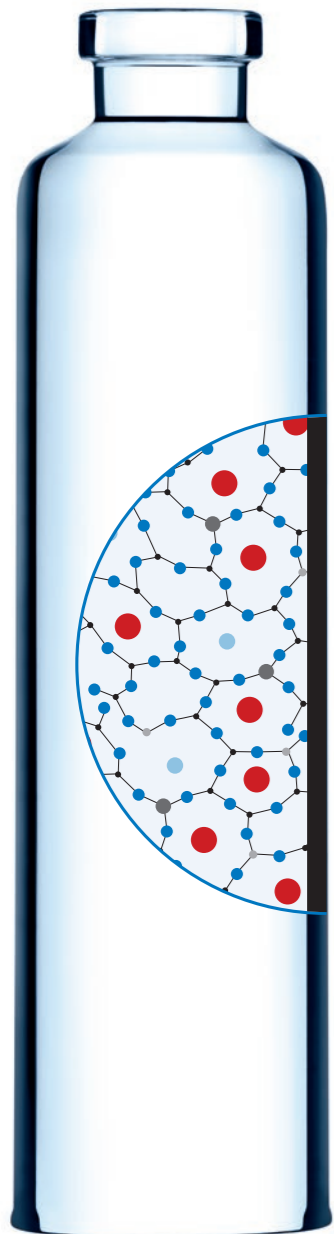
- Standard double chamber cartridge with OD 10.75 mm, injection volume: 0.1 – 1.0 ml
- Customized double chamber cartridges upon request



SCHOTT TopLine Options for Superior Performance

SCHOTT Cartridges BR (Break Resistance)

SCHOTT Cartridges BR are 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.



- Potassium
- Sodium
- Oxygen
- Boron
- Aluminium
- Silicon

The superior break resistance of SCHOTT Cartridges BR results from an exchange of sodium ions in the glass surface with larger potassium ions. This chemical strengthening of the glass matrix in a potassium nitrate bath comes without compromising the extractables and leachables profile (E&L).

Properties:

- Extreme high breakage resistance – up to three times as resistant to breakage as traditional glass cartridges
- Customizable to auto injector needs – no design limitations

Benefits:

- Safer filling, handling and administration of toxic drugs
- Improved Total Cost of Ownership (TCO) because of reduced breakage during fill & finish
- Ultimate protection of the drug
- High pressure administration
- Application in emergency situations

Sizes:

- Upon request

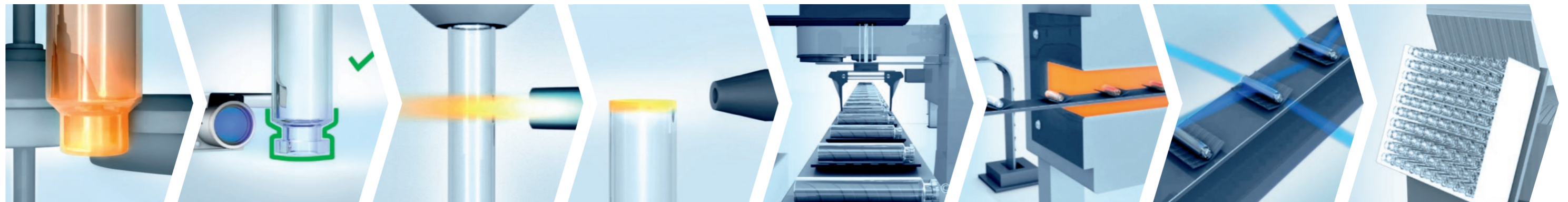


Our Manufacturing Process – A Clear Commitment to Quality

SCHOTT Cartridges are manufactured on state-of-the-art production lines with highly stable and validated processes. Permanent process optimization through Six Sigma principles, along with ongoing professional training for employees, helps uphold quality of the highest levels.

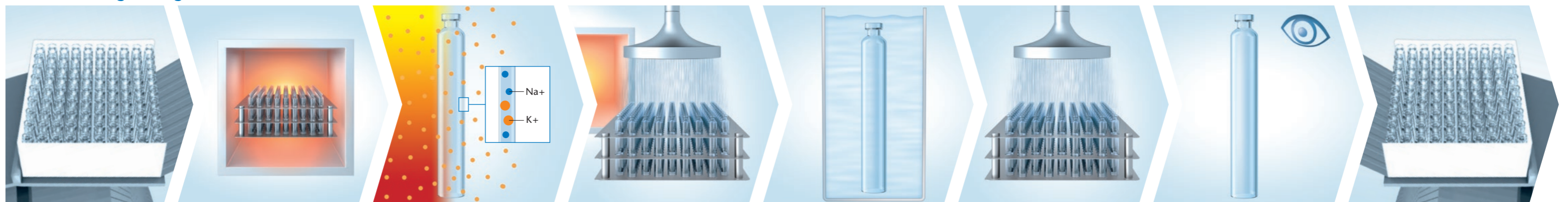
Throughout the process, cartridge-handling is continuously optimized to decrease glass-to-glass contact, thereby resulting in cartridges with increasing in mechanical strength and exceptional cosmetic quality.

Hot forming



Neck Forming Crimp Forming and Dimensional Collar Inspection Thermal Cut Glazing Dimensional Inspection Annealing Cosmetic Inspection Packaging

Chemical Strengthening



Unpacking and Basket Loading Preheating in Oven Ion Exchange Process Washing Chemical Treatment Washing 100% Visual Inspection Packaging

Compliance with International Norms: Quality that Exceeds Standard Expectations

As a fundamental basis for quality, SCHOTT Cartridges benefit from:

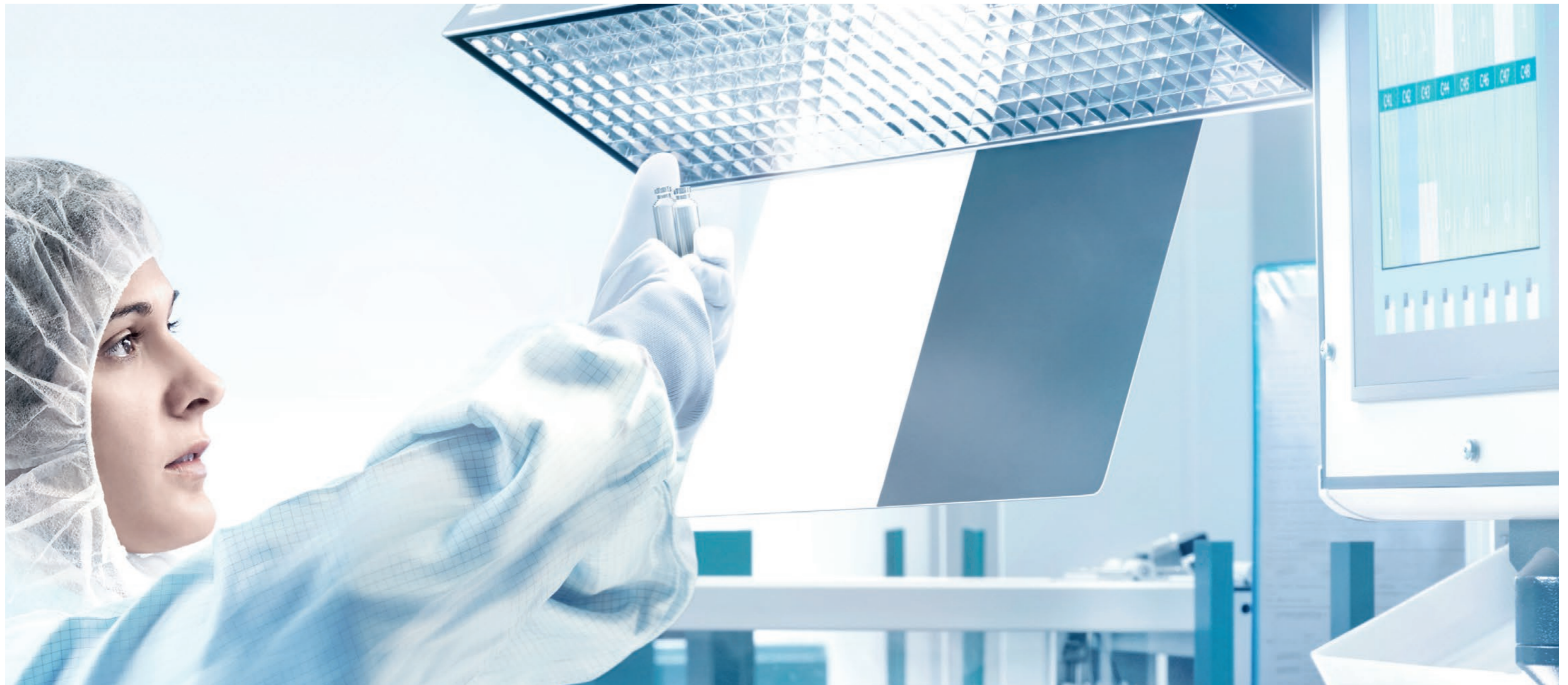
- Fully automated production lines and packing robots
- Advanced SCHOTT-made camera systems for dimensional and cosmetic control
- Rigorous In-Process-Control (IPC) and self-inspection to ensure compliance with specified cartridge dimensions, cosmetic quality and functionality

Quality management system

- All SCHOTT Cartridges are manufactured according to ISO 9001 and ISO 15378
- The production process is continuously optimized using a program based on Six Sigma principles
- Reliable quality system and strict quality control

Regulatory compliance

- SCHOTT Cartridges comply with the international norms such as EP, USP and JP
- For its comprehensive cartridge portfolio, SCHOTT has filed individual DMFs with FDA and Health Canada
- SCHOTT adheres to relevant cGMP production regulations



SCHOTT – Your Partner throughout the Drug Life Cycle

Our dedicated cross-functional team offers sophisticated customer consulting services through every stage of the drug life cycle, delivering optimal, tailored solutions to meet your individual needs.

Drug development

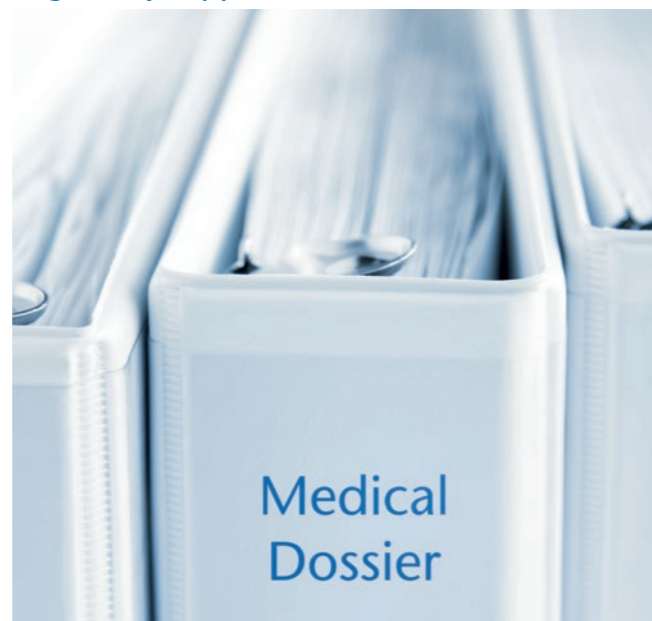


Extensive support for packaging selection:

- Customer value chain evaluation
- Technical product specifications (TPS)
- Samples from stock
- Project management

Your partnership with SCHOTT begins with an evaluation of your value chain in order to understand the drug and primary packaging requirements entailed. SCHOTT will provide you with all the relevant information on our cartridge systems, along with samples from stock and standard Technical Product Specification (TPS). Should you have any special design requirements, we will support you in defining cartridge specifications and in managing the development along the agreed milestones and timeline to save time at customers side.

Regulatory support

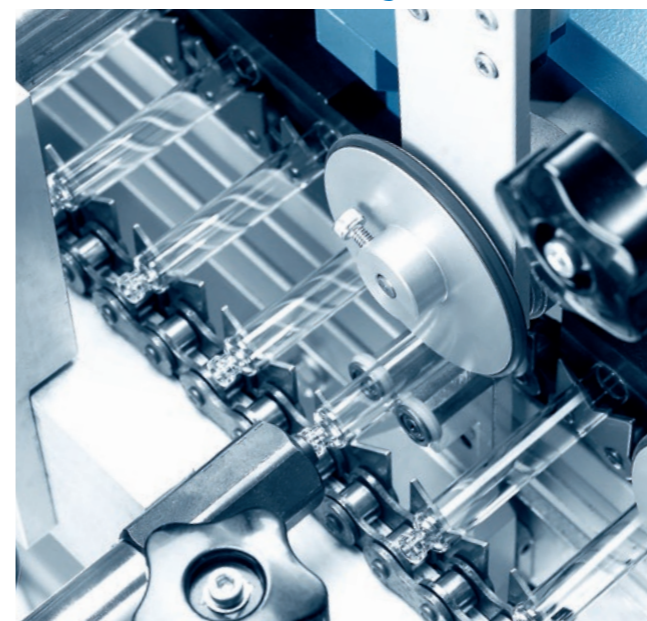


Regulatory filing facilitated by:

- Cooperative audits
- LOA for DMF
- Test method development and alignment

To support your registration activities, an established TPS and Letter Of Authorization (LOA) for the Drug Master File (DMF) will be provided. Not only can SCHOTT provide product functionality tests and analytic support with regard to mechanical stability, material analytics and surface chemistry but also documented evidence for drug product packaging.

Commercial manufacturing



Enabling smooth operation and supply chain:

- Reliable supply from multiple production sites to shorten lead times
- Competent complaint management
- Improved machinability
- Support fill & finish by technical experts

In the commercial phase, we ensure products are delivered securely through flexible and efficient supply chain management, thereby minimizing total cost of ownership. Should any issues relating to quality or technical improvements occur, our expert problem-solving team at SCHOTT – drawing from Quality Management, Process Engineering, and R&D – is on hand to provide you with a fast, reliable root cause analysis and solution.

Life-cycle management



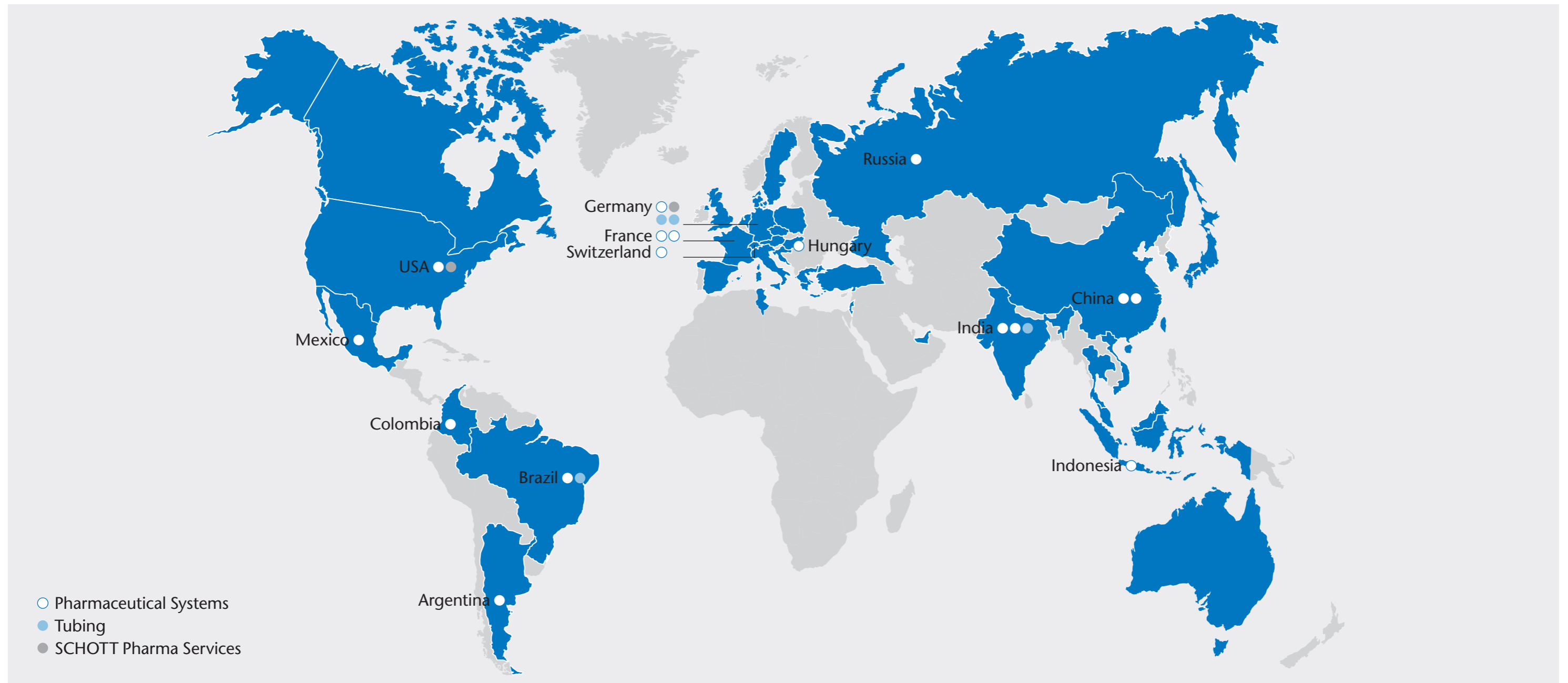
Added value through innovative solutions:

- Continuous technology development
- Constant product improvement
- Product innovation
- Support change management and technology transfer

Primary packaging is considered a differentiating factor in a competitive marketplace. Life-cycle management of existing products may involve a change in primary packaging. In such cases, a dedicated, cross-functional project team is appointed to evaluate feasibility, development costs and timeline.

SCHOTT – Global Player. Local Partner.

When you team up with SCHOTT, you are embracing a truly global partner. Our extensive production network of 16 packaging, 4 tubing production sites and 2 SCHOTT Pharma Service centers offer safe supply, technical support and local, on-site servicing.



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