

SCHOTT
glass made of ideas

SCHOTT Vials

Perfection in Every Detail



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 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 Vials – Perfection in Every Detail

Our mission at SCHOTT is to convert decades of pharmaceutical 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 vials that are detailed to perfection. By achieving

extremely tight dimensions and excellent surface quality, we enable your product to enjoy a notably reliable shelf life.

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



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FIOLAX® – Improved Process Stability through Superior Dimensional Quality

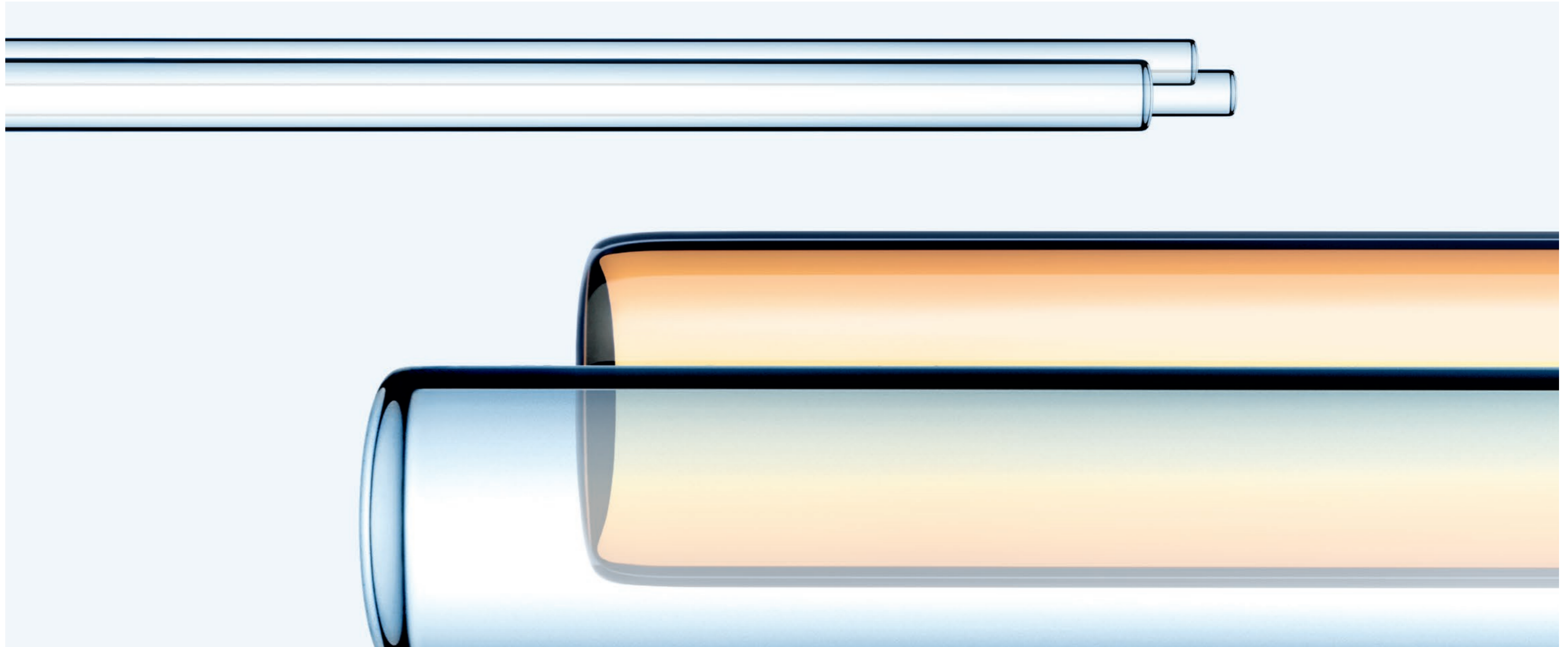
FIOLAX® – The first choice for pharmaceutical packaging

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 Vials DC, SCHOTT Type I plus®, etc.

FIOLAX® and SCHOTT Vials – The perfect match for improved fill + finish processing

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



SCHOTT Vials – Perfection in Every Detail

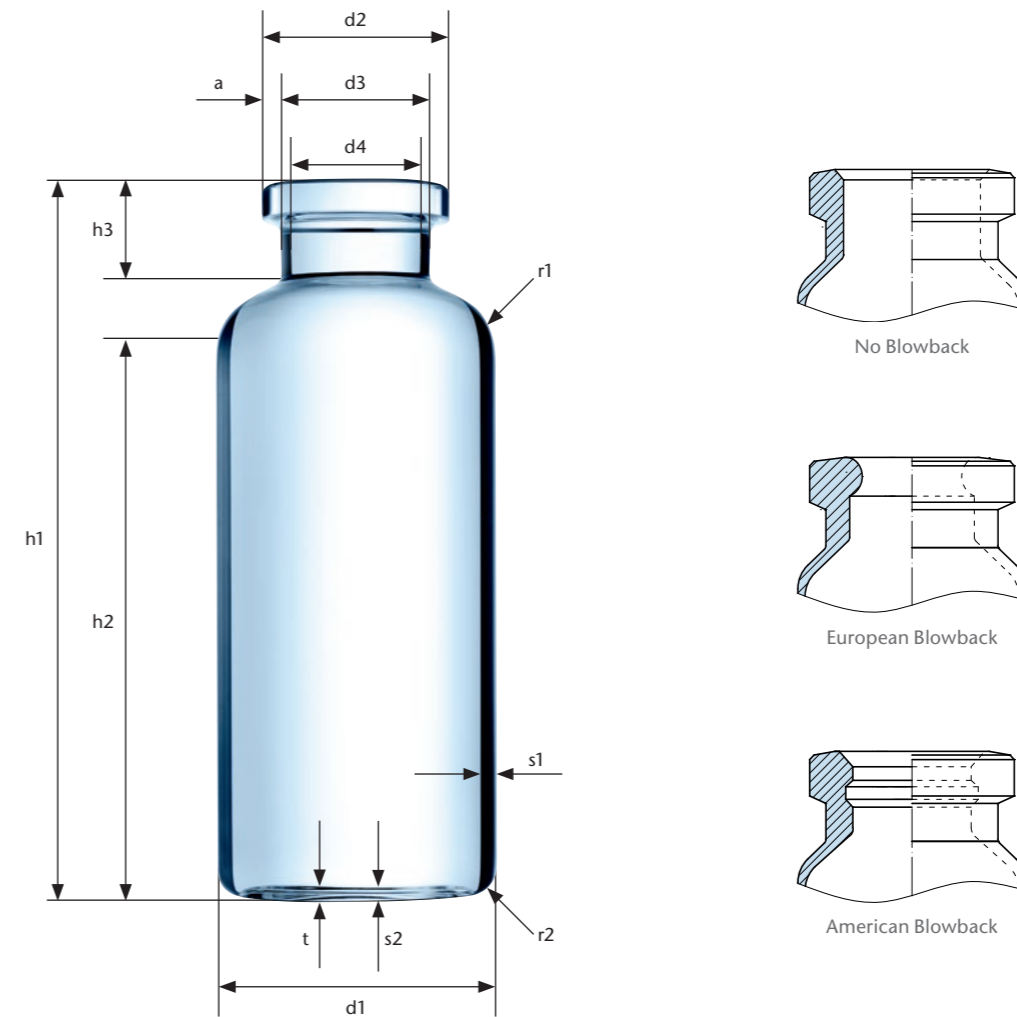
With the ever-evolving significance of biotech drugs and cost sensitivity in the healthcare sector, drug delivery systems find themselves contending with increased requirements from a market shift towards tighter regulations. Our most accurate production and gentle vial-handling to date facilitates tight dimensions and premium surface quality that reliably ensures your product’s shelf life.

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
- Lyo bottom forming and blowback geometry upon request

Reliable product shelf life

- High hydrolytic resistance of tubing and container
- Smooth converting process thanks to in-house process development



Size designation of injection vial	Overflow capacity		a	d1		d2	d3	d4	h1		h2	h3	r1	r2	s1	s2	t	Mass	
	ml	Tol		mm	Tol				mm	mm									mm
2R	4	±0.5	1	16	±0.15	13	10.5	7	35	±0.5	22	8	2.5	1.5	1	±0.04	0.6	0.7	5
4R	6								45		32								6.1
6R	10								40		26								8.3
8R	11.5	±1	1.2	±0.2	16.5	17.5	12.6	45	±0.7	31	8.5	±0.5	3.5	2	1	±0.05	0.7	1	9.4
10R	13.5							45		30									10.2
15R	19							60		45									12.8
20R	26	±1.5	1.5	30	±0.25	20	12.6	55	±0.75	35	10	±0.75	5.5	2.5	1.2	±0.07	0.9	1.5	17.4
25R	32.5							65		45									20
30R	37.5							75		55									22.7
50R	62	±7	2.5	40	±0.4	47	±0.5	73	±0.75	49	6	4	1.5	±0.07	0.9	1.5	1.5	34	
100R	123							100		75								60	

SCHOTT Vials – 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 Vials 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
- Available blowback geometries: NBB, EBB and ABB
- Dimensional and cosmetic AQL levels according to ISO
- 100% camera inspection of dimensional parameters

TopLine – Customized product specifications and quality levels

The TopLine options include:

- Production in cGMP environment
- Statistical in-process control
- Available blowback geometries: NBB, EBB and ABB
- Customized dimensional and cosmetic AQL levels
- Specific lyo-geometries
- 100% camera inspection of dimensional and cosmetic parameters
- Advanced glass surface treatment e.g. functional coatings and delamination controlled-surfaces
- Available as sterile and nested packaging configurations

		Bulk		Sterile	
Drug Type		StandardLine	TopLine	TopLine	
Injectables	Liquid	Crimp neck  Sizes ISO 1–30 ml, custom	1 Crimp neck 2 SCHOTT Vials DC 3 SCHOTT Type I plus®  Sizes 2–100 ml  Sizes 2–10 ml  Sizes 2–100 ml	Crimp neck adaptiQ™  Sizes 2–30 ml	
	Lyophilized	1 Crimp neck 2 Double chamber  Sizes ISO 1–30 ml, custom  Sizes 1, 2, 4, 8, 10 ml, custom	1 Crimp neck (lyo bottom) 2 Double chamber 3 SCHOTT Type I plus® (lyo bottom) 4 SCHOTT TopLyo®  Sizes 2–100 ml  Sizes 1, 2, 4, 8, 10 ml, custom  Sizes 2–100 ml  Sizes 2–10 ml	Crimp neck (lyo bottom) adaptiQ™  Sizes 2–30 ml	
Non-Injectables	Diagnostic	Screw neck  Sizes 2–100 ml, custom			
	Solid	Flip cap  Sizes 10–50 ml, custom, bigger sizes on demand			

SCHOTT crimp and screw neck vials are made of SCHOTT FIOLAX® or BORO-8330™. SCHOTT flip cap vials are made of ILLAX®.

SCHOTT TopLine Options for Superior Shelf Life

SCHOTT Vials DC (Delamination Controlled)

Glass delamination resulting in barely visible glass flakes has led to recalls of numerous injectable drug products over the past few years. In order to prioritize patient safety, the FDA has reacted to this phenomenon by emphasizing the importance of container/drug compatibility testing in line with USP 1660.

SCHOTT Vials DC – An optimized manufacturing process combined with quantitative laboratory test procedures on delamination resistance has proven to significantly reduce the risk of glass delamination, which represents the primary risk factor in manufacturing.

Properties:

- Chemically homogenous inner surface thanks to cutting-edge hot forming technology
- SCHOTT patented Quicktest to verify the reduced delamination risk of each production batch using a predefined quantitative limit value
- Reproducibly improved chemical stability of container's inner surface

Benefits:

- Significantly reduced delamination risk
- Applicable to all products already registered – hence no re-registration required
- SCHOTT Delamination Quicktest-related batch certificate
- All manufacturing-related risk factors for delamination are covered by one single limit value

Sizes:

2R, 4R, 6R, 8R and 10R ISO formats without blowback using FIO LAX® Type I glass. Customization available on request.

- Sodium
- Oxygen
- Boron
- Aluminium
- Silicium



SCHOTT Type I plus® – Reduced Drug Container Interaction

Protein adsorption and leaching from primary packaging are known to be root causes of reduced shelf life in sensitive formulations. Metal ion leaching from type I glass leads to a pH shift in water for injectable or unbuffered solutions and can decrease stability or activity of biopharmaceuticals.

SCHOTT Type I plus® vials have an inside SiO₂ coating with outstanding barrier properties. This reduces the interaction between drug product and container surface to a bare minimum, thereby providing a superior packaging solution for sensitive ingredients.

Properties:

- Chemically uniform: pure silica (SiO₂ coating)
- Layer thickness: 100 – 200 nm
- Non-porous, covalent bond between glass matrix and coating layer
- Fill + finish processability equivalent to uncoated type I glass containers
- Verified barrier owing to a predefined quantitative limit value of 0,17 ppm NA₂O for all vial sizes

Benefits:

- Increased shelf life stability for sensitive drug formulations
- Minimized adsorption of proteins in liquid formulations – also prior to lyophilization
- Minimized adsorption of radioactive molecules

Sizes:

2R, 4R, 6R, 8R, 10R, 15R, 20R, 25R, 30R, 50R and 100R ISO formats. Customization available on request.

Protection of formulation and API against glass components (ions, metals etc.)

SiO₂ coating

Protection of glass matrix against attacks caused by formulation and the buffer SiO₂



SCHOTT TopLine Options for Enhanced Processing

SCHOTT TopLy^o® – Efficient Lyophilization

Due to a need to accelerate time-to-market cycles and increase shelf life stability of biopharmaceuticals, a keen interest in robust and cost-efficient lyophilization has leapt into the limelight. A streamlined lyo cake is crucial for better-automated inspectability – and indeed fundamentally vital to the chief priority of ensuring patient safety. For crystalline formulations, any lensing effect of the vial-bottom during freezing must be avoided.



Thanks to their hydrophobic coating and optimized geometry, SCHOTT TopLy^o vials demonstrate higher mechanical stability during – and less disruption of the lyo cake after – the lyophilization process, in addition to reduced residual volumes and higher dosing accuracy after reconstitution.

Properties:

- Chemically uniform (Si-O-C-H hydrophobic coating)
- Layer thickness: ~40 nm
- Non-porous, covalent bond between glass matrix and coating layer
- Processability equal to non-coated type I glass vials

Benefits:

- Cost reduction due to decreased overfilling – given lower residual volume
- Reduced glass breakage through refined geometry
- Prevention of lyo cake disruption and sidewall fogging for improved automated inspection
- Lyo cake stability during transportation
- Reduced protein aggregation compared to siliconized vials

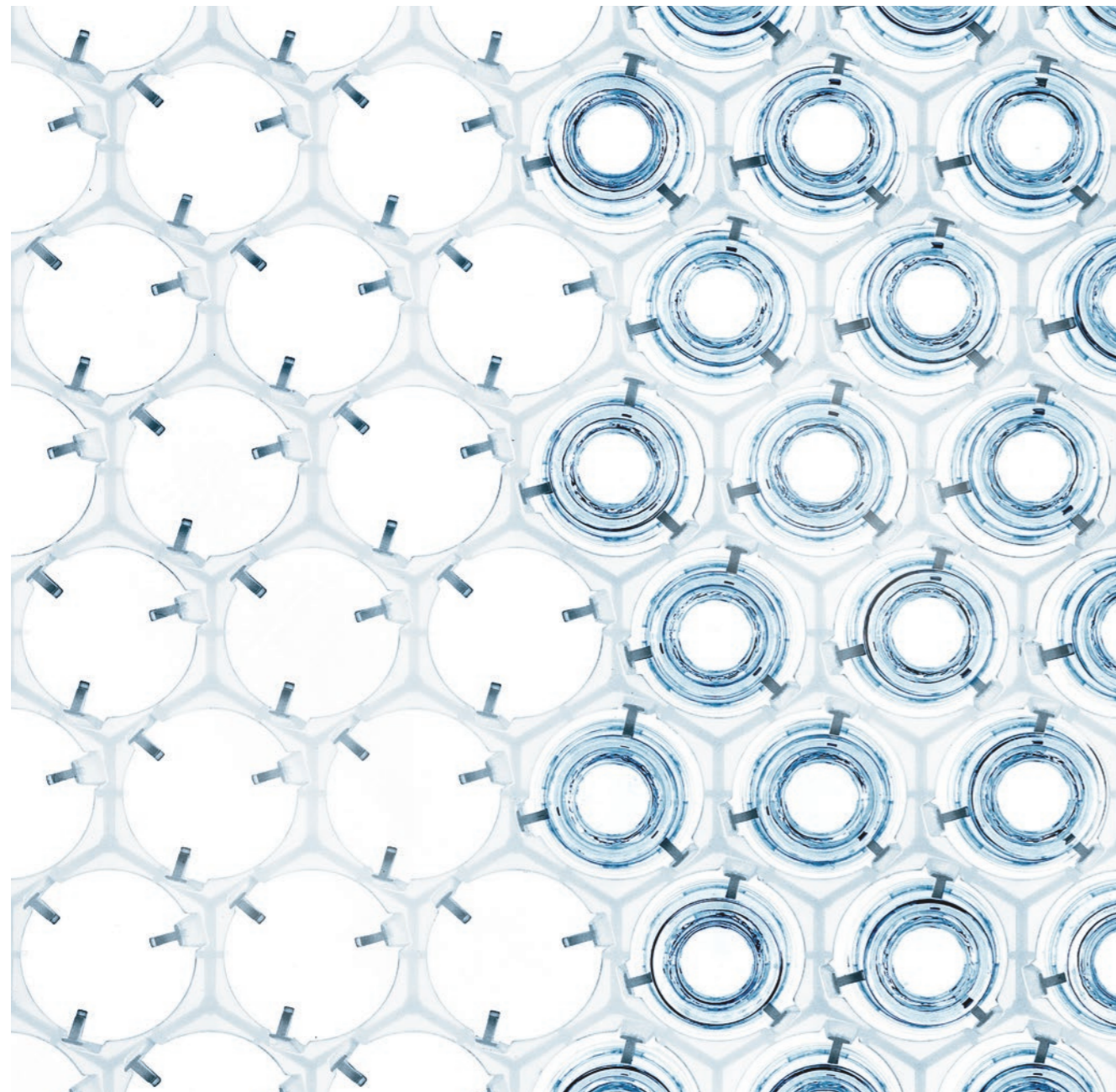
Sizes:

2R, 6R and 10R ISO formats and lyo bottoms. Customization available on request.



adaptiQ™: The Future Fast Forward

With adaptiQ™ ready-to-use vials you will be accessing a new era of cutting edge manufacturing. You will gain more freedom with a leaner process, improved quality and more flexibility. Developed in cooperation with innovative and highly regarded machine suppliers, adaptiQ™ vials can be processed on a wide range of existing and new fill + finish equipment, allowing the vials to remain nested throughout the fill + finish process including lyophilization.



* Tyvek® is a registered trademark of E. I. du Pont de Nemours and Company
 ** Industry Standard Tub Format

Improved total cost of ownership

Processing sterile and nested vials can result in lower investments, reduced running costs (WFI, electricity) and less required clean room space as well as improved line yields.

Superior quality

adaptiQ™ nest design operates completely glass-to-glass contact free. This reduces the risk of glass breakage throughout the entire fill + finish process and maintains the high cosmetic quality of SCHOTT TopLine vials.

Greater flexibility & efficiency

As SCHOTT combines the adaptiQ™ nest with an industry standard tub, you will be able to fill multiple containers efficiently on the same machine.

Simplified lyophilization

Quick and easy loading and unloading of nests into the freeze dryer without the need of additional loading tools.

Standard packaging

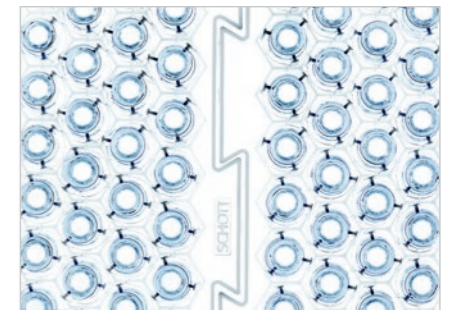
The adaptiQ™ nest is positioned in a tub. The tub is covered with a Tyvek®* inlay, placed in the tub followed by a Tyvek®* seal. After being packed in header bags, the tubs are sterilized.



Nest with unique support for the vials, that keeps the vial bottom accessible for handling as well as nested lyophilization and minimizes glass-to-glass contact



Freely accessible vial bottom allows for lyophilization in nest



High density of vials to reduce waste and maximize productivity

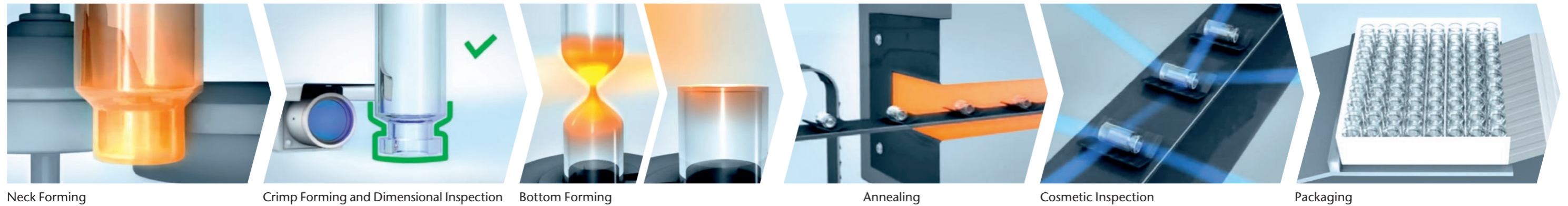
Vial Format	Vials per nest and tub**
2R	100
4R	
6R	48
8R	
10R	
15R	
20R	25
25R	
30R	

Our Manufacturing Process – A Clear Commitment to Quality

SCHOTT Vials 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, vial-handling is optimized to decrease glass-to-glass contact, thereby resulting in vials with mechanical strength and exceptional cosmetic quality.

Hot Forming



SCHOTT PICVD Coating



Nesting and sterilization process



Compliance with International Norms: Quality that Exceeds Standard Expectations

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

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

Quality management system

- All SCHOTT Vials 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 Vials comply with the international norms such as EP, USP and JP
- For its comprehensive vial 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

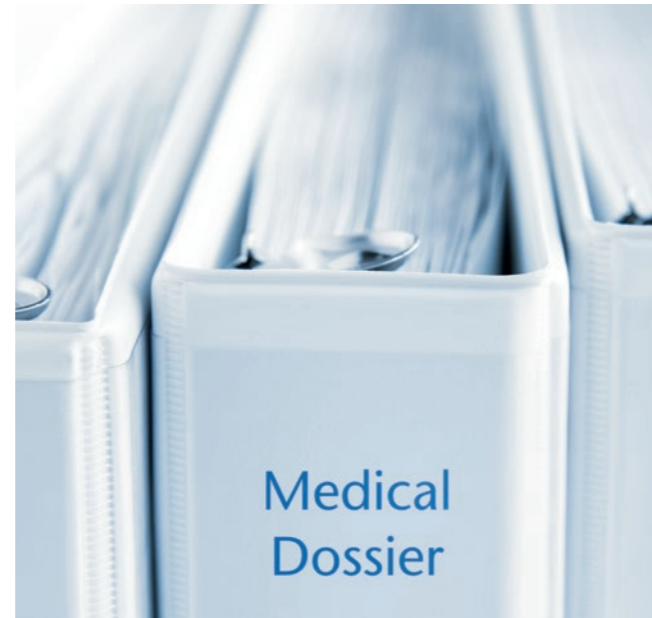


Extensive support for packaging selection:

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

Your partnership with SCHOTT begins with a brief 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 vial 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 vial specifications and in estimating development efforts for project cost and timeline.

Regulatory support



Regulatory filing facilitated by:

- Cooperative audits
- LOA for DMF

To support your registration activities, an established TPS and Letter Of Authorization (LOA) for the Drug Master File (DMF) will be provided.

Commercial manufacturing

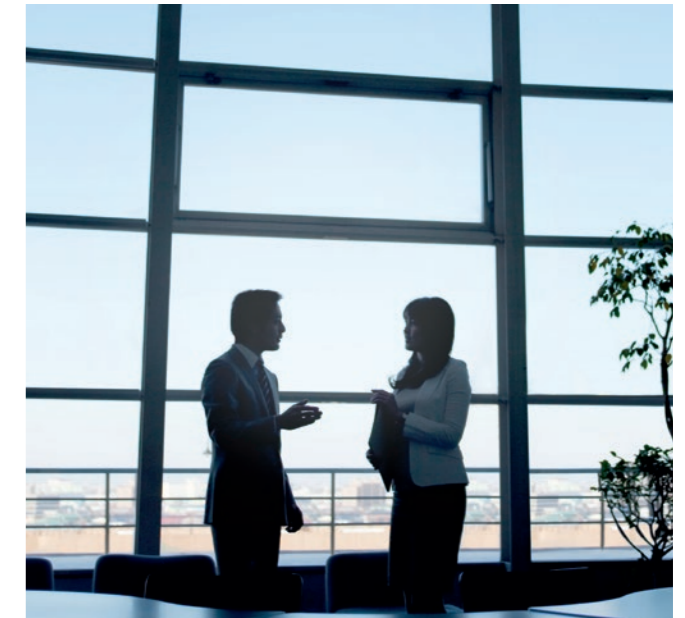


Enabling smooth operation and supply chain:

- Capacity and supply security
- Short lead times
- Competent complaint management

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



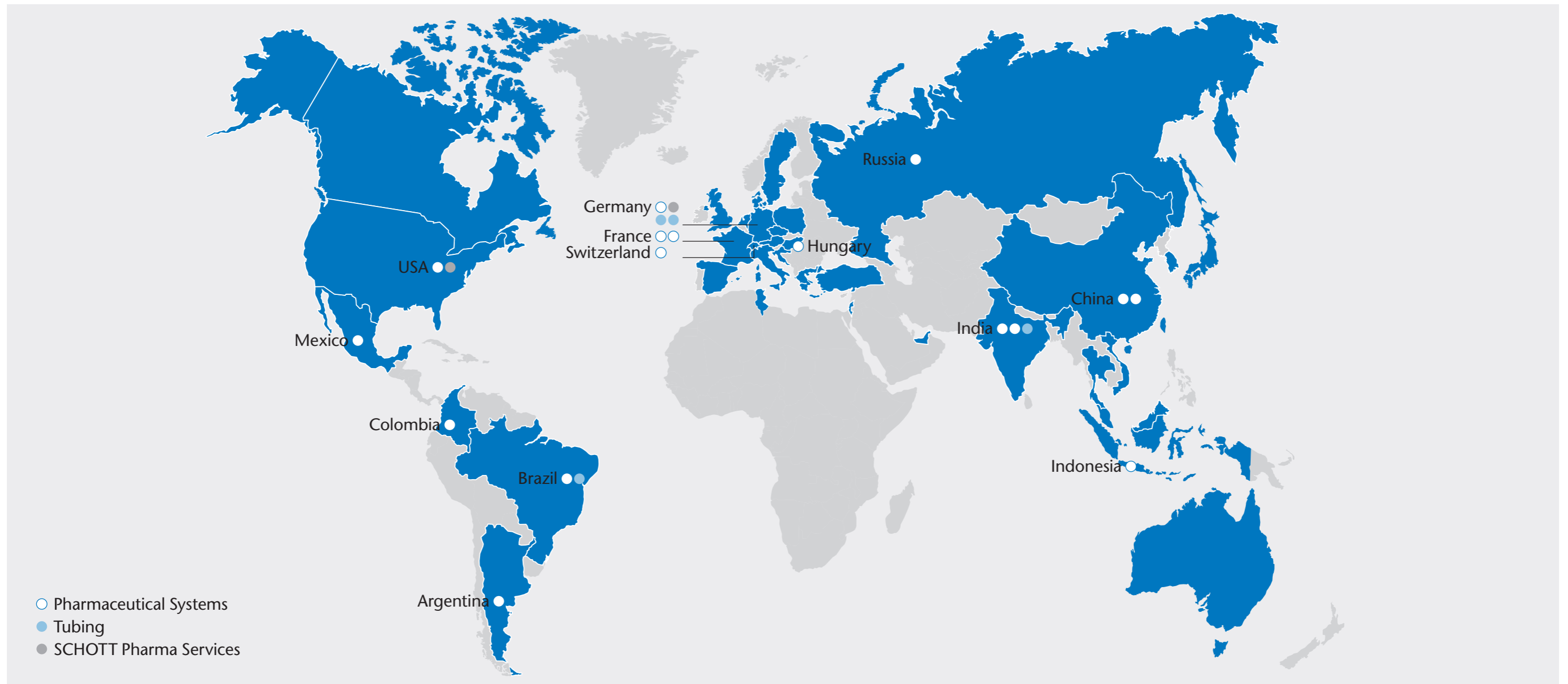
Added value through innovative solutions:

- Continuous technology development
- Constant product improvement
- Product innovation

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.

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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