Excellence in Pharma Vials

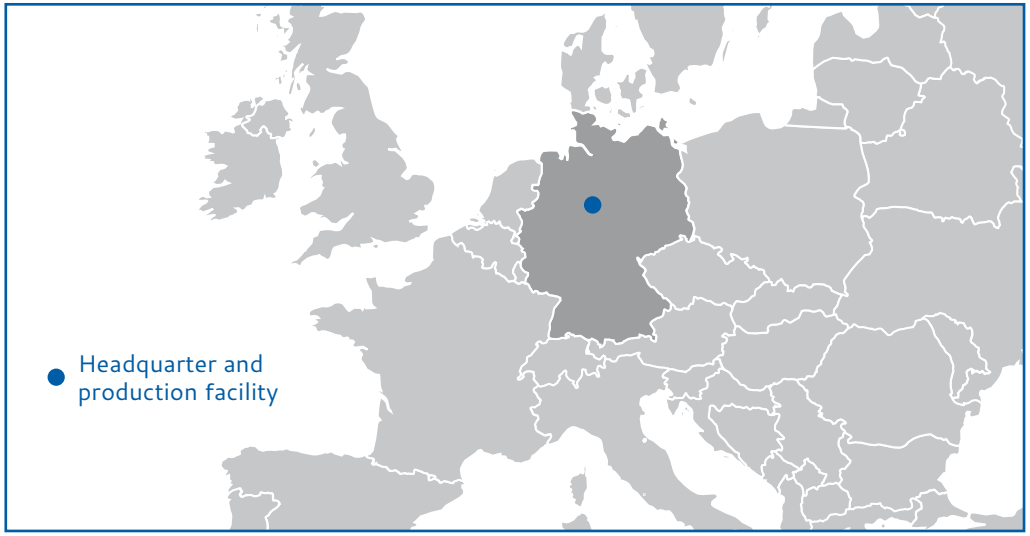
Company overview

Overview

Müller + Müller is a leading producer of primary packaging from tubular glass for the global pharmaceutical industry

- **Products:** injections vials, screw-neck vials, roll-neck vials, snap-cap vials, blow-back vials – also offering customized solutions
- **Customers:** blue chip customer base
- **Quality certificates:** DIN EN ISO 9001 and DIN ISO 15378
- **Support for regulatory affairs:** FDA Drug Master File DMF-No. 14760 (Type III) and Health Canada Drug Master File DMF-No. 2010-064 (Type II)
- **Location:** headquartered in Holzminden, Germany
- **Production capacity:** approx. 300m vials per year
- **Management:** Dr. Hubertus Müller-Stauch (CEO & Partner)
- **Employees:** approx. 130 FTE

Location



Milestones

1924 Establishment in Thüringen

1949 Re-establishment in Holzminden

1983 New production facility with line-production and integrated clean-room class 8

1991 Introduction and subsequent upgrade of camera systems for 100% dimensional control

1998 Introduction of computerized CCD-camera-systems for the detection of cosmetical defects

2000 DrugMasterFile, Type III for packaging materials deposite at FDA

2007 New storage and production hall with 7 new production lines and integrated clean-room class 8

2008 GMPcertification according to DIN ISO 15378

2010 Implementation of an ERP-system into the complete M+M organization

2015/16 Introducing a state of the art siliconization line

Quality-oriented glass vial supplier to the pharmaceutical industry

Vial types

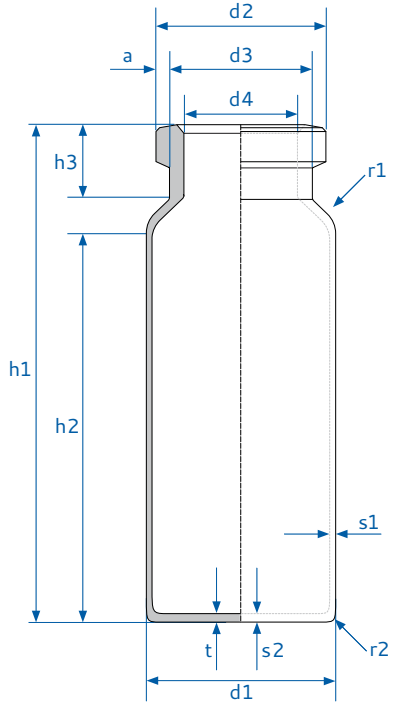
Vial types	Raw Material	Sizes	Blowback	Possible inner surface treatment
Injection vials	Borosilicate glass clear and amber, Type I	2ml – 40ml ISO 8362-1 or custom sizes	No Blowback, European Blowback, American Blowback	Siliconization
Screw-neck vials	Borosilicate glass clear and amber, Type I Soda lime silicate glass amber, Type III	2ml – 40ml ISO 11418-7 or custom sizes	-	Siliconization
Roll-neck vials	Borosilicate glass clear and amber, Type I Soda lime silicate glass amber, Type III	2ml – 40ml custom sizes	-	Siliconization
Snap-cap vials	Borosilicate glass clear and amber, Type I Soda lime silicate glass amber, Type III	2ml – 40ml custom sizes	-	Siliconization
Blow-back vials	Borosilicate glass clear and amber, Type I Soda lime silicate glass amber, Type III	2ml – 40ml custom sizes	-	Siliconization

All vials are produced according to industry standards (DIN vials) or according to customer specifications. The entire manufacturing and packaging process takes place in environmentally controlled areas certified by ISO 9001 and ISO 15378.

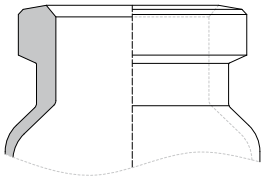
For all vials we can offer the following quality level:

- Production according to cGMP
- Statistical in process-control
- Customized AQL levels for dimensional and cosmetic aspects
- Packaging in clean room class 8 according to ISO 14644-1

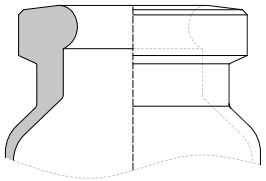
ISO 8362-1 drawings and dimensional aspects



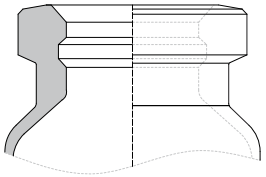
Possible types of Blowback



NO BLOWBACK



EUROPEAN BLOWBACK



AMERICAN BLOWBACK

Size designation of injection vial	Overflow capacity ml	tol.	a mm	d1 mm	tol.	d2 mm + 0.2 − 0.3	d3 mm max.	d4 mm ± 0.2	h1 mm	tol.	h2 mm min.	h3 mm	tol.	r1 mm ≈	r2 mm ≈	s1 mm	tol.	s2 mm min.	t mm max.	Mass g ≈
2R	4	± 0.5	1	16	± 0.15	13	10.5	7	35	± 0.5	22	8	± 0.5	2.5	1.5	1	± 0.04	0.6	0.7	5
4R	6								45		32									6.1
6R	10		1.2	22	± 0.2	20	16.5	12.6	40		26	8.5		3.5	2			0.7		8.3
8R	11.5								45		31									9.4
10R	13.5	± 1		24					45		30	9		4						10.2
15R	19								60		45									12.8
20R	26	± 1.5	1.5	30	± 0.25		17.5		55	± 0.7	35	10	± 0.75	5.5	2.5	1.2	± 0.05		1	17.4
25R	32.5								65		45									20
30R	37.5								75		55									22.7

Manufacturing process

Converting and forming process

Tube loader

1. PRODUCTION PROCESS

2. ANNEALING

3. INSPECTION

4. PACKAGING PROCESS

1. Production process
High quality and process capability through high-precision forming technology and glass expertise

2. Annealing
Annealing oven technology developed by Müller + Müller

3. Inspection
Continuous dimensional and cosmetic control via real-time manufacturing data

Parameters for dimensional control

- *Total height, mouth opening, eccentricity, flange height, flange diameter, neck height, neck diameter, body height, body diameter*

Examples for cosmetic defects that can be detected

- *Cracks, scratches, dark spots outside, knots, impurities, chipped places, airlines*

4. Packaging process
Visual control and final packaging in permanently monitored class 8 clean room conditions according to ISO 14644-1

Quality assurance

Quality assurance throughout the entire manufacturing process

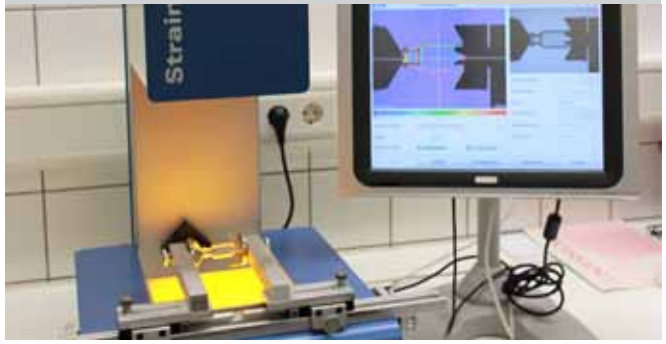
1. Inspection of incoming goods (tubular glass, packaging material)

2. Production-accompanying quality assurance

In process camera-controls

Testing of hydrolytic resistance

Testing of residual stress



3. Final control of finished products with a user-independent CAQ-system

For all employees of our company quality assurance is an interdisciplinary task. All quality checks are conducted according to the latest defect evaluation list for tubular glass vials. Our quality management system is audited and certified annually according to ISO 9001 and ISO 15378. For the continuous improvement of our processes it is an ongoing approach to perform a process-oriented risk analysis according to FMEA.

Optional quality controls

- Examination of the axial compressive strength of the glass vials
- Testing of glass surface (Digital Macroscope for 3D measurements)
- Advanced cosmetic controls in accordance with customer specifications

Your partner throughout the Drug Life Cycle

PACKAGING SOLUTIONS

Extensive support for packaging selection:

- Customer value chain evaluation
- Technical product information
- Sample production

At the beginning of a partnership with Müller + Müller a brief evaluation of the customer value chain is necessary to understand the drug and primary packaging requirements. Our specialized staff will provide you with relevant information about our converting systems. Furthermore, samples and technical product information will be provided. For any kind of special design requirements, our staff will assist you in defining vial specifications and estimates a clear timeframe and cost-breakdown for your project.

REGULATORY SUPPORT

Regulatory filing facilitated by:

- Cooperative audits
- LOA for DMF

To support your regulatory affairs an Letter of Authorization (LOA) for the FDA Drug Master File DMF-No. 14760 (Type III) or Health Canada Drug Master File DMF-No. 2010-064 (Type II) will be provided.

COMMERCIAL MANUFACTURING

Enabling smooth operation and supply chain:

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

Müller + Müller ensures safe and reliable product delivery through a flexible and sufficient supply chain management worldwide. In the case, quality or technical issues occur our specialized staff will provide you with a fast root cause analysis and solution. On-going communication with our customers is the basis for innovation at all levels of the company.

As a privately owned, medium-sized family business our strengths are short decisions and communication pathways. These allow continuous innovation and pioneering new trends in the field of primary packaging.

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