Excellence in Pharma Vials
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

### 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
- **1994** Start of operations in Holzminden
- **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** GMP certification according to DIN ISO 15378
- **2009** Introduction of a siliconization line
- **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

<table>
<thead>
<tr>
<th>Vial types</th>
<th>Raw Material</th>
<th>Sizes</th>
<th>Blowback</th>
<th>Possible inner surface treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection vials</td>
<td>Borosilicate glass clear and amber, Type I</td>
<td>2ml – 40ml or custom sizes</td>
<td>No Blowback, European Blowback, American Blowback</td>
<td>Siliconization</td>
</tr>
<tr>
<td>Screw-neck vials</td>
<td>Borosilicate glass clear and amber, Type I</td>
<td>2ml – 40ml or custom sizes</td>
<td>–</td>
<td>Siliconization</td>
</tr>
<tr>
<td>Roll-neck vials</td>
<td>Borosilicate glass clear and amber, Type I</td>
<td>2ml – 40ml custom sizes</td>
<td>–</td>
<td>Siliconization</td>
</tr>
<tr>
<td>Snap-cap vials</td>
<td>Borosilicate glass clear and amber, Type I</td>
<td>2ml – 40ml custom sizes</td>
<td>–</td>
<td>Siliconization</td>
</tr>
<tr>
<td>Blow-back vials</td>
<td>Borosilicate glass clear and amber, Type I</td>
<td>2ml – 40ml custom sizes</td>
<td>–</td>
<td>Siliconization</td>
</tr>
</tbody>
</table>

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

### Overflow capacity
- **ml**

### Possible types of Blowback
- **NO BLOWBACK**
- **EUROPEAN BLOWBACK**
- **AMERICAN BLOWBACK**

### Table: Size designation of injection vial

<table>
<thead>
<tr>
<th>Size designation of injection vial</th>
<th>Overflow capacity ml</th>
<th>Overflow capacity tol.</th>
<th>a mm</th>
<th>d1 mm</th>
<th>d2 mm</th>
<th>d3 mm</th>
<th>d4 mm</th>
<th>h1 mm</th>
<th>h2 mm</th>
<th>h3 mm</th>
<th>r1 mm</th>
<th>r2 mm</th>
<th>s1 mm</th>
<th>Mass g</th>
</tr>
</thead>
<tbody>
<tr>
<td>2R</td>
<td>4</td>
<td>± 0.5</td>
<td>1</td>
<td>16</td>
<td>± 0.15</td>
<td>13</td>
<td>10.5</td>
<td>7</td>
<td>35</td>
<td>45</td>
<td>22</td>
<td>8</td>
<td>2.5</td>
<td>1.5</td>
</tr>
<tr>
<td>4R</td>
<td>6</td>
<td>± 0.1</td>
<td>1.2</td>
<td>22</td>
<td>± 0.2</td>
<td>16.5</td>
<td>12.6</td>
<td>± 0.5</td>
<td>22</td>
<td>32</td>
<td>8</td>
<td>2.5</td>
<td>1.5</td>
<td>± 0.04</td>
</tr>
<tr>
<td>6R</td>
<td>10</td>
<td>± 1</td>
<td>1.2</td>
<td>22</td>
<td>± 0.2</td>
<td>16.5</td>
<td>12.6</td>
<td>± 0.5</td>
<td>22</td>
<td>32</td>
<td>8.5</td>
<td>± 0.5</td>
<td>3.5</td>
<td>2</td>
</tr>
<tr>
<td>8R</td>
<td>11.5</td>
<td>± 1</td>
<td>1.2</td>
<td>22</td>
<td>± 0.2</td>
<td>16.5</td>
<td>12.6</td>
<td>± 0.5</td>
<td>22</td>
<td>32</td>
<td>8.5</td>
<td>± 0.5</td>
<td>3.5</td>
<td>2</td>
</tr>
<tr>
<td>10R</td>
<td>13.5</td>
<td>18</td>
<td>1.2</td>
<td>22</td>
<td>± 0.2</td>
<td>16.5</td>
<td>12.6</td>
<td>± 0.5</td>
<td>22</td>
<td>32</td>
<td>8.5</td>
<td>± 0.5</td>
<td>3.5</td>
<td>2</td>
</tr>
<tr>
<td>15R</td>
<td>19</td>
<td>18</td>
<td>1.2</td>
<td>22</td>
<td>± 0.2</td>
<td>16.5</td>
<td>12.6</td>
<td>± 0.5</td>
<td>22</td>
<td>32</td>
<td>8.5</td>
<td>± 0.5</td>
<td>3.5</td>
<td>2</td>
</tr>
<tr>
<td>20R</td>
<td>26</td>
<td>± 1.5</td>
<td>1.5</td>
<td>30</td>
<td>± 0.25</td>
<td>17.5</td>
<td>± 0.7</td>
<td>10</td>
<td>± 0.75</td>
<td>5.5</td>
<td>2.5</td>
<td>1.2</td>
<td>± 0.05</td>
<td>1</td>
</tr>
<tr>
<td>25R</td>
<td>32.5</td>
<td>± 1.5</td>
<td>1.5</td>
<td>30</td>
<td>± 0.25</td>
<td>17.5</td>
<td>± 0.7</td>
<td>10</td>
<td>± 0.75</td>
<td>5.5</td>
<td>2.5</td>
<td>1.2</td>
<td>± 0.05</td>
<td>1</td>
</tr>
<tr>
<td>30R</td>
<td>37.5</td>
<td>± 1.5</td>
<td>1.5</td>
<td>30</td>
<td>± 0.25</td>
<td>17.5</td>
<td>± 0.7</td>
<td>10</td>
<td>± 0.75</td>
<td>5.5</td>
<td>2.5</td>
<td>1.2</td>
<td>± 0.05</td>
<td>1</td>
</tr>
</tbody>
</table>
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 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
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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