BIOVOX

BIOVOX Standards

Safety, Transparency & Consistency

Quality Management

The BIOVOX quality management system according to **ISO 13485** includes a batch documentation of all relevant processes from procurement, production, packaging to delivery and their continuous improvement.

Formulation Consistency

With regard to formulation consistency, BIOVOX raw material partners may only use approved key components. We have specified this in **quality assurance agreements**. Secondary components must remain comparable at all times by having at least the same CAS number and purity.

Supply Reliability

To ensure security of supply for our customers, regulatory changes or discontinuations are announced two years in advance, unless otherwise agreed. This is implemented in our change management system. BIOVOX sources its raw materials exclusively from an **established and stable network of suppliers**.

Change Management

BIOVOX Change Management includes multi-year lead times (typically 2 years) for changes. We approach you proactively in the event of changes and take into account any longer lead times that may be required, e.g. through appropriate warehousing.

Material Quality

BIOVOX is guided by the regulatory requirements of the **MDR**, including biocompatibility and contamination risk, or food contact requirements and physical-technical testing.

All BIOVOX compounds are tested for biocompatibility according to **ISO 10993**. All BIOVOX compounds are tested for biocompatibility according to ISO 10993. Please refer to our data sheets for details or request further testing directly.

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Checkbox Quality

- ☑ **ISO 13485** quality management
- ☑ Changes require your approval
- ☑ Quality assurance agreement with raw material partners
- ☑ Oriented towards **MDR** regulatory requirements
- ☑ **ISO 14971** risk assessment
- ☑ Employees trained in MGP handling

Additional Notes

The qualification and validation of production facilities includes a **risk assessment** ccording to ISO 14971.

We provide our customers with **information material** on shelf life and appropriate storage, as well as processing, and are happy to offer supervised sampling and joint parameter optimization.

Our employees are qualified to handle Medical Grade Plastics (MGP) according to VDI 2017 through our training program.

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Book your free consultation now!
>>www.calendly.com/biovox

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