QUALITY STATEMENT

INTEGRA

Implementation of ISO 9001 at INTEGRA: Strategies and Measures for an Effective Quality Management System

INTEGRA Biosciences is committed to provide reliable, high-quality products which are safe and compliant with relevant regulations worldwide.

In accordance with the requirements of ISO 9001:2015, **INTEGRA Biosciences** has decided to identify, understand, and fulfill all relevant legal and regulatory requirements applicable to the Quality Management System (QMS). This includes the requirements that are relevant to products, services, and operational processes.

INTEGRA Biosciences approach is ensured through continuous evaluations and regular updates.

INTEGRA Biosciences implements ISO 9001 through various measures. ISO 9001 is an international standard for quality management systems (QMS) that helps companies ensure consistent quality, improve customer satisfaction, and meet regulatory requirements.

The implementation of ISO 9001 at **INTEGRA Biosciences** is carried out as listed below:

Leadership — The Board management takes the full ownership of the Quality Management System (QMS), define the quality policy, and ensure that quality objectives are consistently aligned with the company's overall strategy. They are also responsible for fostering a culture of quality throughout the organization, ensuring that roles and responsibilities are clearly defined and understood at all levels. Additionally, management must conduct regular management reviews to evaluate the effectiveness of the QMS, identify areas for improvement, control and ensure continuous alignment with both internal goals and external requirements.

Planning — Establishing clear quality objectives and defining the necessary actions to achieve them is essential for success. This includes effective risk and opportunity management, aiming to minimize potential risks to the QMS while identifying opportunities for improvement. The planning process ensures the organization remains proactive in addressing challenges and aligning its actions with both customer requirements and continuous improvement goals.

Support — Providing the necessary resources, training, and infrastructure is critical to effectively implement the QMS. This also involves ensuring the competence of employees through regular training and development programs, fostering clear communication across all levels, and maintaining proper documentation to ensure consistency and traceability. By empowering employees and ensuring they have the tools and knowledge to succeed, the organization supports the effective functioning of the QMS.

Operation — Managing production and service processes to ensure they consistently meet the defined quality requirements is fundamental. This involves careful planning, monitoring, and control of operations to maintain process efficiency, minimize variability, and ensure that all outputs align with customer expectations and regulatory standards. The effective management of these processes is key to achieving high-quality results and customer satisfaction.

Performance Evaluation

Monitoring and measuring the performance of the QMS is essential to ensure that quality objectives are being met. This includes conducting regular internal audits, performing management reviews, and analyzing customer satisfaction. By systematically assessing the effectiveness of the QMS, the organization can identify areas for improvement, address nonconformities, and ensure continuous alignment with customer expectations and strategic goals.

Improvement

Continuously improving the QMS is key to maintaining its effectiveness and supporting organizational growth. This involves using audits, evaluations, and feedback to identify areas for improvement. Corrective and preventive actions are taken to address issues and risks. A structured Change Control process ensures that changes are carefully evaluated and aligned with quality objectives, allowing the system to adapt to both internal and external changes while promoting continuous improvement.

Customer Satisfaction

Focusing on customer needs and expectations is crucial to ensuring that products and services meet their requirements and deliver consistent value. By actively listening to customers, monitoring feedback, and addressing concerns, the organization can enhance customer satisfaction and build long-term relationships. Continuous alignment with customer expectations ensures the company remains competitive and responsive to market demands.

Documented Information

Ensuring effective document control and management is vital to maintaining traceability and consistency in processes. This involves establishing clear procedures for creating, reviewing, and updating documents, ensuring that all relevant information is accessible, accurate, and securely stored. Proper document control guarantees that the organization can consistently meet quality standards and regulatory requirements, while also supporting transparency and accountability.

INTEGRA Biosciences has defined job descriptions, standard operating procedures (SOP) and process forms as part of our quality system. Internal Audits are conducted regularly to ensure our quality requirements are being met. Customer audits are allowed at **INTEGRA Biosciences**. Depending on the effort required, this could be a subject to a fee.

Documented processes for product development, product and material testing, design control, and change management are integral components of INTEGRA's overall system, ensuring consistent quality and efficiency.

These processes are not limited to quality management alone but are applied across all stages of production. To manufacture **INTEGRA Biosciences** products, we rely on qualified personnel, advanced equipment, and appropriate facilities, all of which are essential to maintaining the highest standards.

Not Only Do We at INTEGRA Biosciences, But We Do Much More..."

INTEGRA Biosciences' Head of Corporate Quality is a member of the management board and is responsible for overseeing all quality-related and regulatory topics within the company. **INTEGRA Biosciences** has organized its competencies to ensure that responsibility for quality management is clearly defined in both the USA and Switzerland, ensuring a consistent approach across our global operations.

INTEGRA Biosciences is a manufacturer of general laboratory equipment. Currently, it is not technically feasible for us to ensure that all customers receive highly customized and specific information. Therefore, we communicate significant and major changes, such as a change of company address or a company sale, through general information channels, such as our website.

The supplier qualification process according to ISO 9001 ensures that suppliers meet established quality standards by undergoing regular audits that assess their processes, products, and compliance.
Controlled access to the building and specific training for certain areas ensure that only qualified personnel

with the relevant skills can access critical zones.
Additionally, the test equipment is regularly maintained, calibrated, and properly labeled in accordance with ISO 9001 to ensure the accuracy and reliability of testing processes. This approach supports continuous improvements and ensures efficient and compliant quality assurance.

By consistently implementing these steps, **INTEGRA Biosciences** demonstrates its unwavering commitment to meeting the ISO 9001 requirements. This approach not only ensures the development of a robust and effective Quality Management System (QMS), but also underscores **INTEGRA Biosciences** 's dedication to fostering a culture of continuous improvement and customer satisfaction. The company is fully invested in maintaining the highest standards of quality, enhancing operational efficiency, and meeting customer expectations. Through regular evaluations and the integration of feedback, **INTEGRA Biosciences** strives to improve processes, address challenges proactively, and ensure the long-term success of both the organization and its stakeholders.

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If you require further information or a more detailed explanation on a specific aspect, please do not hesitate to contact us!

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