

# Global quality and regulatory compliance.

QUALITY AWARENESS IS AN ATTITUDE OF MIND





# Innovative quality and regulatory solutions.



For more than 35 years, Tecan has been driven to achieve the highest standards in product quality, customer satisfaction and regulatory compliance.

As a company, this mindset guides our day-to-day business.

This culture is an important consideration for our customers when it comes to choosing partners for their projects. In a constantly changing world, you need a reliable partner that you can count on, particularly for quality and compliance.

I am proud to be part of such a strong, quality-focused organization, adding value to our customers' success.

Günter Weisshaar,  
Senior Vice President, Quality and Regulatory Affairs

## THE HIGHEST QUALITY PARTNER FOR YOUR BUSINESS

Quality is an essential part of Tecan's business. We provide innovative quality and regulatory solutions that ensure success, both internally throughout our organization, and for our customers in all markets, including the highly regulated clinical arena. Our global quality system, the Tecan Management System, outlines every procedure, policy and strategy in all areas of the business, promoting innovation and supporting global growth.

From the simplest consumables to complex workstations, our products are designed to meet our customers' high expectations at every level, from planning and development, through manufacturing and distribution, to precise, reliable and safe operation.

And that's just the start.

## ADDING VALUE TO YOUR INVESTMENT

Tecan offers more than just its high-end products. We recognize that our customers expect added value from their suppliers which, from Tecan, means knowledge, understanding and experience. Our comprehensive quality and regulatory systems apply to every aspect of the services we provide, as we share best practices, help our customers to make improvements and increase the value of their investment.

highest quality partner

adding value

inspirati

# Alternative solutions to every challenge.

## TAKING A REFRESHING APPROACH

Over the past decade, Tecan has established a unique and inspirational approach to quality. We have changed the culture across the entire Tecan organization, sharing our passion for operational excellence, and spreading this philosophy throughout the life sciences industry.

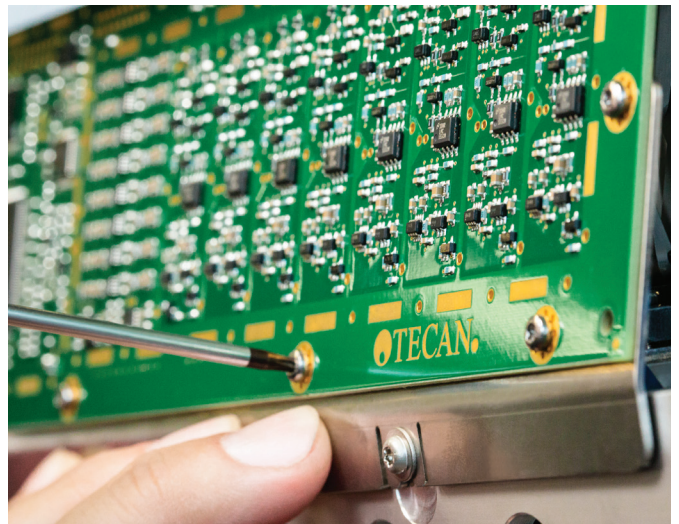
Our quality and regulatory services are very much part of the solution – not part of the problem – supporting the whole business. Wherever possible, we try to offer alternative solutions to every challenge from our unique point of view, helping the business to find an option that not only helps the project but is also fully compliant, achieving the best balance for the needs of different parties.



## SHARING OUR KNOWLEDGE

We use our unique combination of skill and expertise to identify exactly what is required within a project in order for it to improve and meet all necessary standards. We are experts in all quality and regulatory matters and offer these services to all our customers to apply to their own quality processes.

Whether you need assistance with quality systems management or process validation, regulatory advice or enterprise risk management, we can devise a customized program for your organization that defines roles and responsibilities, as well as detailed processes.



onal approach to quality

sharing our knowledge



# Early involvement is key.



## TEAMWORK FROM THE START

Quality is a key consideration from the outset of every project, whether that's multidisciplinary teams within Tecan, or when partnering with our customers' internal quality departments, making improvements, implementing and executing plans, and supporting day-to-day activity.

Early involvement of quality and regulatory personnel is key; influencing how processes are documented, how products or components are tested, and how methods are verified and validated at the beginning of a project saves time and money in the long run and promotes overall operational excellence.



## STRENGTH IN DEPTH

Tecan offers a diverse array of technical capabilities and, from experience, we have developed an in-depth understanding of how technical and regulatory aspects of any project can complement one another. Together, we combine expertise from both disciplines and can advise accordingly, working closely to assure that any relevant international documentation is in place as required.

teamwork from the start

global team solving I

# Flexibility, teamwork and real partnership.

## A GLOBAL TEAM SOLVING LOCAL ISSUES

Quality is an integral part of the global Tecan organization; almost all of our manufacturing, sales and service sites have ISO 13485 and ISO 9001 certification, so you will always be dealing with well-trained people who can efficiently handle any challenges that arise.

It is important for us to keep our processes as transparent and consistent as possible around the world, with every local site following the global model of quality processes. At the same time, we recognise that there will almost certainly be local differences, and regional teams have the flexibility to develop their own documents and procedures if necessary. This culture and inherent flexibility promotes teamwork and encourages real partnership between colleagues and customers.

## EYES ON THE GROUND

Our local teams are truly invaluable; members of our young and highly motivated quality team are embedded in every part of the business, at every location, and in close association with our distributors where appropriate. Their local knowledge, technical expertise and business acumen enable them to develop close relationships with customers as well as national or regional regulatory authorities, encouraging a mutual depth of understanding and saving a significant amount of time in resolving issues should they arise.



local issues

transparent processes

quality



# Successful programs all over the world.



## ALLEVIATING RISK

Risk management helps you to focus on what is most important in your business.

We have developed enterprise risk management programs for customers based on our own internal model. Using a multidisciplinary approach, and involving a cross-functional team from different departments – from finance to manufacturing to operations – we identify all potential sources of risk using a systematic approach, incorporating both operational and manufacturing supply chain risks. Preparing a business continuity plan is essential – a checklist of activities to be done in the event of an unavoidable emergency to recover the business, taking external influences, like the economic situation or health pandemics, into consideration.



## A TRACK RECORD OF SUCCESS

We have already successfully implemented programs with customers all over the world, working closely with them to develop frameworks and procedural templates, identifying and prioritizing risks, and helping them to implement plans – including training, workshops, handbooks, etc. – as part of their quality management.

risk management

knowledgeable partner

# In tune with the regulatory world.

## MAKING SENSE OF THE REGULATORY MINEFIELD

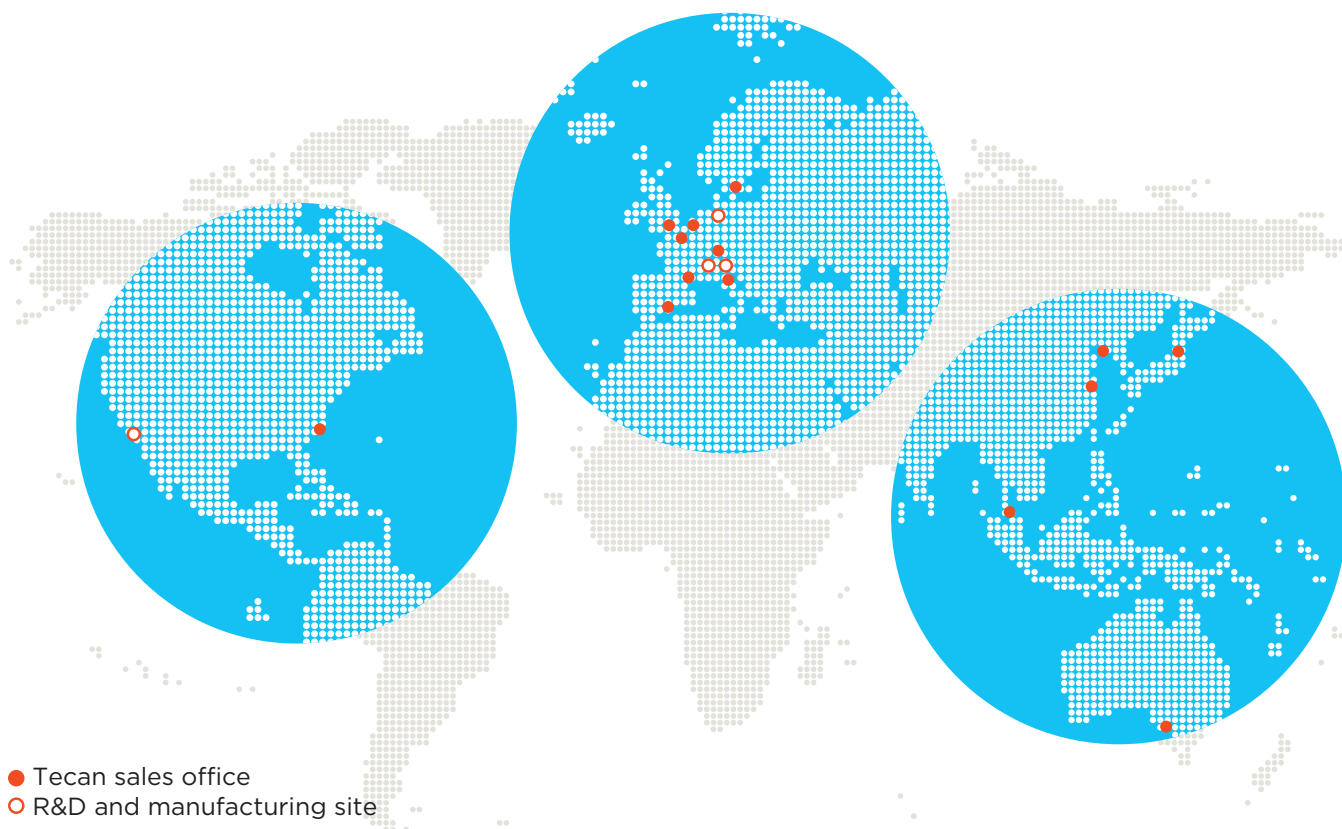
With every new law or guideline, our customers are faced with the uncertainty over how and when it affects their business. And, if that wasn't enough, each country, region and industry has its own set of rules and regulations that must be taken into consideration. Irrespective of whether you're working in a mature market or in a developing country, regulations are constantly changing, getting more detailed and more specific.

## A KNOWLEDGEABLE PARTNER

Tecan's multidisciplinary teams are in tune with what's going on in the regulatory world, actively monitoring changes to standards around the globe. We value being able to share our expertise and understanding with our customers, helping them to benefit from our experience in different geographic areas, as well as our strong knowledge of working with the US Food and Drug Administration. Tecan Quality and Regulatory Affairs department is working actively with several standard organizations worldwide.

It is a huge challenge for companies to keep ahead, and more important than ever for them to choose to work with a compliant and capable partner such as Tecan.





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