Tecan is the OEM partner of choice for life science and clinical diagnostics companies moving into new markets

For companies planning to produce new products designed specifically for the clinical diagnostics market, successful product development is only part of the challenge. Our expertise in quality and regulatory issues, as well as years of experience in providing instruments to diagnostics laboratories, puts Tecan in a unique position to help you take your application from the life science market to the clinical/IVD market, or to take your existing clinical diagnostics products into new geographical areas.

Any instrument for clinical use has to meet a variety of regulations and comply with national and international standards, such as those set by the US FDA, the *in vitro* diagnostic directives (IVD-D) and CE marking. An instrument's performance must be robust and reliable and, for an application-dedicated diagnostics platform in particular, it must deliver reproducible and valid results.

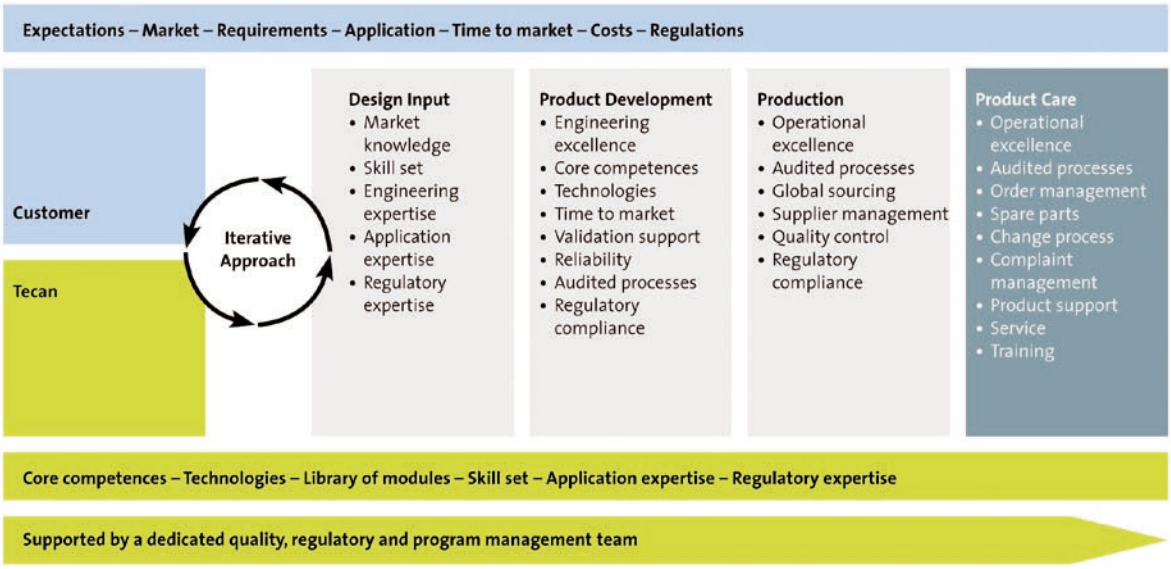
To achieve these standards, an ideal OEM partner needs to provide a great deal more than just the required systems design, engineering and technology expertise. We believe that our understanding of this, combined with our regulatory knowledge and team approach that unites our marketing and dedicated regulatory departments, make our OEM service unique.

What capabilities does Tecan bring to meet your business and compliance requirements?

Tecan's OEM solutions are widely known throughout the life sciences for their high quality and robustness, but you might be surprised if you knew the extent of our partnerships. We design, manufacture and supply complete systems, as well as components, to many well-known companies specifically for use in clinical and/or *in vitro* diagnostics-based processes. We are commonly asked to take existing, manual methods and develop an automated system for them that will meet all necessary US FDA, IVD-D/CE or other marking requirements. With our expertise and support, acquiring the necessary documentation to meet regulatory requirements can be achieved in a smooth and timely fashion, whether you are launching your product in Europe, the USA, Asia or beyond. Our plants are also ISO 13485-certified and are registered with the appropriate governmental agencies as medical device establishments, so you can be sure that your Tecan components are produced to the highest possible standards. Several top-tier IVD and life science companies have already taken advantage of our comprehensive OEM offering.

What does Tecan's OEM process involve?

Each of our customers is different, so at the beginning of every partnership we work together to exactly define the aims. By ensuring that we understand precisely what the product's functions and uses are, we can concentrate our resources



Tecan develops a close partnership with OEM companies

and capabilities in helping that product to meet its market needs. We draw up a detailed development plan together that includes the supply agreement and quality agreement, and clarifies each side's responsibilities.

How is Tecan's team approach of combining marketing and regulatory staff unique?

Our marketing and sales staff work closely with the customers to better understand the application that the customer wants to bring to market. Based on this understanding and on consultation with our regulatory staff, we will assist you in determining whether an off-the-shelf, standard product or an OEM-specific, customer-branded product would be the best option for you, given the various markets intended for product launch. Our meetings with you will clearly define a road map of not only the financial and technical issues that must be addressed, but also how change management will work during your OEM product life cycle, where the areas of responsibility lie for submission of documentation and for validation, and how we can assist you with these various aspects.

The ongoing partnership between our marketing and our regulatory staff helps to guide you through the regulatory jungle and to ensure that there are no surprises for you when the time comes for you to submit your documents or registration in a given country.

Has Tecan made any US FDA submission of its products or registered them as IVD/CE compliant?

Yes. We have not only successfully obtained IVD/CE marking for some of our Tecan products in the EU, but we and/or our OEM customers have successfully registered co-branded and customer-labeled devices in South America, Asia, the Asia-Pacific and the US. Some of these registered systems are used in highly regulated environments in the US, the EU and other countries.

Together, Tecan's outstanding qualities in this sector make us your ideal OEM partner. Contact us to see how we can help you expand your markets.

Quality control and validation tools for your IQOQ needs

qc tools
ensure your results

Most laboratories are subject to increasingly strict regulations, such as GLP (Good Laboratory Practice), GMP (Good Manufacturing Practice), CLIA 88, ISO 9001 or ISO 13485, defined by regulatory authorities like the FDA, EMEA, etc. Our advanced QC tools help you to fulfill all regulatory requirements for your Tecan microplate readers and scanning devices in an efficient, cost-effective way, with accurate instrument checking and complete documentation.

We offer three different QC plates:

- QC Pac™ 1 and QC Pac 2 for all absorbance readers (eg. Sunrise™)
- MultiCheck™ for all multimode readers (eg. Infinite® series, Safire²™)
- LaserCheck™ for all microarray scanners (eg. LS Reloaded™)

Each QC tool verifies the functionality of all major instrument components and checks all measurement modes, allowing a complete one-step installation and operational qualification (IQOQ) of your instrument with a single reusable QC plate, and without the need for any liquid handling steps. The Tecan QC software handles all measurements and calculations automatically, requiring a minimum of effort from the operator, and provides secure computer-generated report files and user administration. For the highest level of quality control, National Institute of Standards and Technology (NIST) traceability is provided for each absorbance and wavelength reference on the QC plates. An annual service procedure within each of these tools ensures that reference values are accurate and still valid and that Tecan's QC tools can be used with the utmost confidence.

For further information on our QC tools, visit http://www.tecan.com/qctools