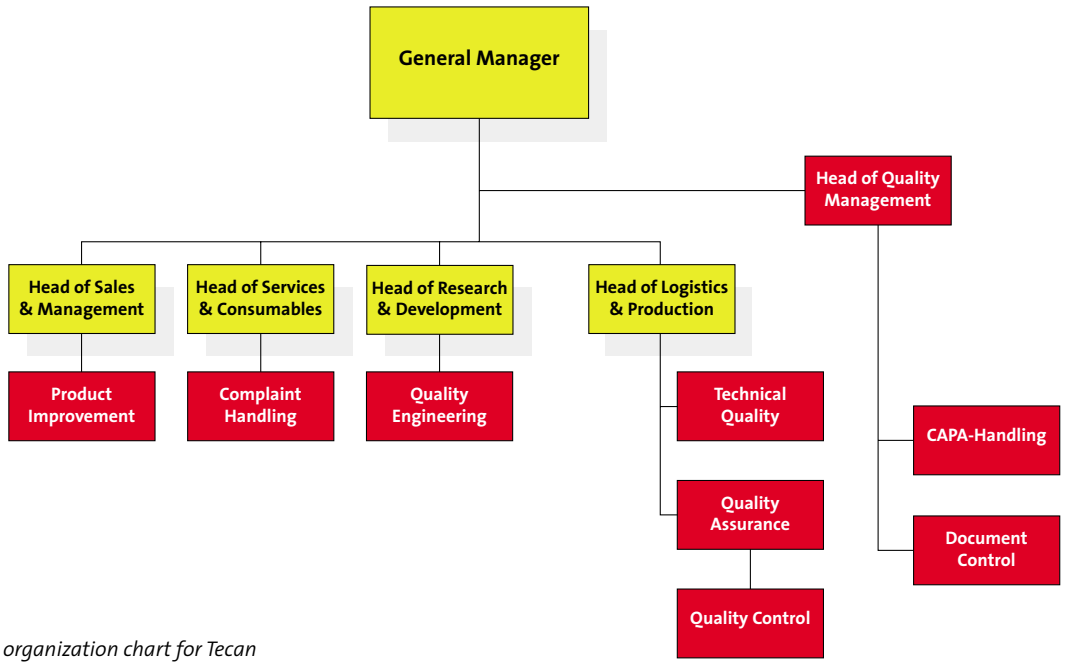
Ahead of the game for quality processes

A recent article in the January 2008 issue of *Qualität und Zuverlässigkeit (Quality and Reliability)*, the most widely read quality journal in German speaking countries, described a new quality management approach with a radically different organizational structure. A similar structure, simplifying QM and making it more efficient, has already been implemented at Tecan Austria in 2006, clearly showing that we are leading the way in the area of quality management.

At Tecan Austria, quality functions are integrated as a part of the whole process and not enclosed within a department. Our customers benefit, because enquiries are dealt with much more quickly, and directly handled by a specialist, addressing the right courses of action. With this structure, QM processes are also much closer to our personnel, so that quality runs through at every level of Tecan's operations. It encourages very open communication, allowing everyone concerned to work together effectively.

Complicated flow charts have been replaced with easy-to-follow diagrams and pictorial 'process arrows', with keywords from the corresponding regulations, which take minutes rather than hours to understand. The new structure is designed to give customers greater confidence in Tecan's quality processes, by being able to see the organizational structure clearly. It simplifies working together with customers' quality departments during audits by saving time that would otherwise be spent on understanding our processes, and focus on actual customer projects – spending the time to discuss the real issues.

The structure still adheres strictly to medical devices laws, but where the pharmaceutical industry (eg. 21 CFR 211) dictates that complaints, as well as final product release of each batch, must be reviewed by a quality assurance department, the corresponding QSR for the medical device industry (21 CFR 820) is



Excerpt of the organization chart for Tecan Austria, showing the business segment structure

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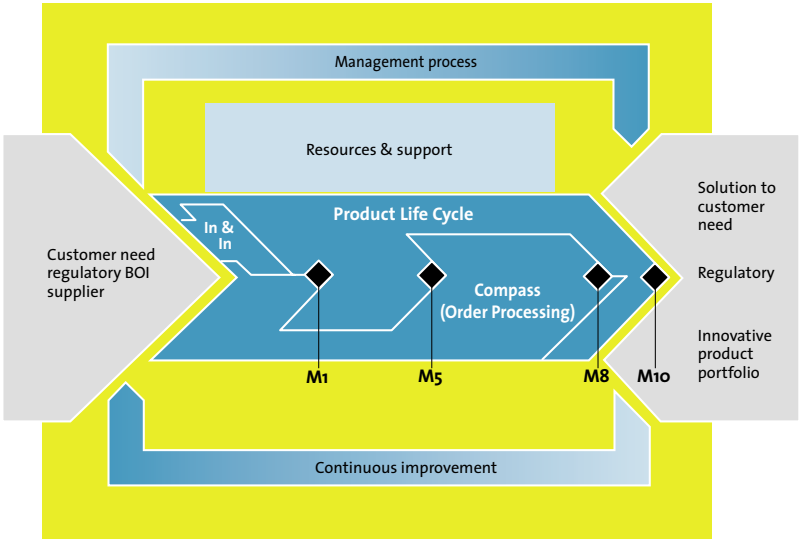

Process overview, based on ISO 9001:2000

more flexible, only specifying a formally designated person or unit. This makes sense, not least because pharma law applies to batch numbers for hundreds or thousands of tablets which could directly influence human health for example, but batch size for device manufacturers like Tecan is just one; one device with one serial number.

"At Tecan Austria, we have replaced the matrix structure with a business segment structure. I now report to the head of business operations, with a dotted line to the vice president of global QA," explained Robert Reingruber-Breitwimmer, head of QM at Tecan Austria.

"We began in 2006 by adding a number of quality engineering specialists to the R&D team, which helps us to take quality requirements into consideration in the early stages of product development. At the same time we reorganized the procedures regarding complaint handling. Eight technical experts, who already know the devices intimately, work in our expert line in Tecan Austria to cover the 17 products produced here; three of them are now trained as quality specialists, and they ensure that their colleagues follow the correct QA procedures."

"We implemented other improvements in 2007. The previous system, where the quality officers were in the QM department, had many connecting points between quality and logistics, production and incoming inspection. With each interface, we have lost time and information, so it made sense for these quality personnel to work within L&P and are therefore much more in touch with what is going on, while still keeping a dotted line to me, the head of quality management. Similarly, we have also installed a new function called 'technical quality' within production, where four specially trained people are responsible for design transfer, and they give the head of L&P a quality status report, which is essential to prevent future problems in production."

The *Qualität und Zuverlässigkeit (Quality and Reliability)* article explained that, for a more efficient quality assurance system, the head of quality management should not be responsible for direct provision of product quality, and instead should have a role that is closer to the general manager and assist him to improve or develop new strategies and processes. Robert explained: "Several rules have been defined regarding the responsibilities of the Business Unit Head and me, which ensure smooth operation as well as safeguarding against changing management positions. The structure has worked well at Tecan Austria, and it has been well received by customers and personnel alike."