TREND REPORT October 2018

An attractive market: Medtech suppliers need certified QM system

The special regulatory aspects of the medical technology sector are evident not only in its extensive registration processes but also in its requirements in terms of Quality Management. A consistent QM process must be in place from the supplier through to the manufacturer, and in many cases certification of this process is even prescribed by law. At the same time, the industry is structured to enable suppliers and manufacturers to work in close consultation and maintain direct contact. MedtecLIVE has set itself the task of encouraging this process of establishing contact and discussion by offering an international and attractive mix of exhibitors and visitors.

Flat supply pyramid

State-of-the-art medical technology is so complex that hardly any single manufacturer can now reflect the entire value chain. Manufacturers therefore have to draw on the development skills and production capacities of specialised suppliers. A steadily growing market for component manufacturers and service firms in the fields of digitalisation and software has developed in recent years as a result, in Germany and elsewhere.

According to information from NeZuMed – the Network for Innovative Medical Technology Suppliers – the structure of the medical technology sector differs in at least one regard from other industries: whereas the automobile industry, for example, has a complex supply pyramid covering several levels, the supplier relationship in the medical technology industry is characterised mainly by a direct supply relationship between the supplier and the distributor – in other words, most companies are what are known as “tier 1 suppliers”. This facilitates close cooperation and the iterative procedure for design and development transfer that we have described elsewhere. The right suppliers can be found at MedtecLIVE.

Ideeller Träger
Honorary sponsor
Forum MedTech Pharma e. V.
Am Tullnaupark 8
90402 Nürnberg
Germany

Veranstalter
Organizer
MedtecLIVE GmbH
Messezentrum
90471 Nürnberg
Germany
medteclive.com

Geschäftsführer
Managing Director
Richard Krowoza

Registergericht
Registration Number
HRB 35124 Nürnberg

Durchführung im Auftrag des Veranstalters
Realization on behalf of the organizer
NürnbergMesse GmbH
Messezentrum
90471 Nürnberg
Germany
T +49 9 11 86 06-0
F +49 9 11 86 06-82 28
medteclive@nuernbergmesse.de

Quality Management as a key factor

A further point that characterises the cooperation between manufacturers and suppliers is the Quality Management system, which, in the medical technology sector – unlike many other sectors – is not based on voluntary certification in accordance with current ISO standards, but is prescribed by law. And for all medical products categorised higher than Class I, this Quality Management system must be audited and certified by an appointed authority, including regular repeat and monitoring audits. The latest version of ISO 13485:2016, the Quality Management standard for the design and manufacture of medical products, expressly includes processes outsourced to third parties. Identical certification of suppliers and manufacturers ensures consistency of Quality Management across the entire shared value chain. This can result in a genuine saving of effort, in terms of documentation and adhesion to process, if the supply chain is complex and organized at numerous levels in a way that is not typical of the industry – for large devices, for example.

As a service firm, Bytec Medizintechnik GmbH, a development and manufacturing firm based in Eschweiler, goes a step further, and not only relieves the distributors of the production component, but starts right at the doctor's end: working with the medical specialists, it creates and elaborates ideas for products, mainly in the electronic and medical technology fields. "We sit around the table with the doctors, clarify technical questions, and work with our customers to construct a business case, help look for investors, produce prototypes or pre-production series, and monitor the registration process," explains Nicole Kasischke, Head of New Business Development at Bytec. The customers are as varied as the batch sizes that will ultimately be manufactured. "We have start-ups that benefit from our experience, and also large companies that expect rapid development from us that matches their own," Kasischke notes. As a contract manufacturer, Bytec obtains components from other suppliers and then supplies the finished product to the distributor. It is also a committed member of the advisory board of MedtecLIVE, which concentrates on productive exchanges between suppliers and manufacturers.
Further information on Bytec Medizintechnik GmbH is available here.

The right Quality Management is essential

Kasischke therefore considers it essential to have a Quality Management system that works, but is based on more than just ISO 9001. Bytec is certified in accordance with ISO 13485. Her assessment of the importance of ISO 13485 to suppliers is also supported by a study by the Landshut University of Applied Sciences, according to which Quality Management certification is of increasing importance when it comes to obtaining orders from manufacturers. From the manufacturer's perspective, if a component supplier has a QM system in accordance with the medical products standard, this will naturally represent clear benefits for the procurement process. For the suppliers, this implies a degree of cost and effort to begin with. In a study from Switzerland, 80 percent of the surveyed medical technology suppliers stated that the quality and documentation requirements in the field of medical technology represented the greatest challenge. According to the study, 84 percent are working mainly on process optimisation, and these figures will doubtless be comparable throughout Europe.

But it's the exception that proves the rule: Mareike Neumann, CEO of Nuremberg-based 3D printing specialist Dreigeist, is not currently considering ISO 13485 certification. "We perceive ourselves as lateral thinkers and research partners to the medical technology sector. If we make component prototypes for medical products in our clean room using additive manufacturing, or assist businesses with the introduction of 3D printing, certification would be too restrictive, like a tight corset," comments Neumann. "We need more freedom in our projects, although of course clear and uniform processes are mandatory once they progress to small-scale series production. But in most cases that stage takes place at our customer's end, and no longer involves us as the researching supplier."

Contact for press and media

Jens Fuderholz, TBN Public Relations
Benno Wagner, Simon Kögel, NürnbergMesse GmbH
T +49 9 11 86 06-89 02
simon.koegel@nuernbergmesse.de

For all press releases, further information and photos please visit:
www.medteclive.com/news

For information about the MedTech Summit please go to:
www.medteclive.com/presse