Exclusive-Interview with Martin Rümke, VDI Medical Technology Working Group

“A cold sweat when the inspector calls“

Since the EU requires the state of the art to be followed when developing medical products, the latest products are always on the market here. However, the system has its weaknesses because adherence to regulatory requirements is monitored by notified bodies subject to private law. Martin Rümke, Head of VDI Medical Technology Working Group and consultant with Chemgineering Business Design GmbH advocates adopting a more critical attitude towards notified bodies.

Mr. Rümke, the materials and techniques in chip forming and cutting processes are familiar and well-established. Should companies still be concerned about the issue of product liability in this field?

Many manufacturers believe that the technology has reached its limits and that innovative progress is no longer possible. To some extent these companies are hiding behind their expertise - they're protecting a tried-and-tested process they have been using for years which they don't want to see changed. But that attitude is in conflict with the legal philosophy we have here in Europe, which requires the development of a medical product to follow the current state of technology. Also after putting its products onto the market, a manufacturer has to maintain active observation, if necessary make corrective adjustments and provide evidence of these adjustments. If the state of technology improves, the manufacturer can't simply look the other way.

What technological innovations are you referring to?

For example there are fairly recent studies on cutting edge geometry and dynamics on titanium alloys used for very innovative implants. The correct cutting pressure and progress can significantly reduce the negative impact of the process on the product. Clamping geometry can also influence a product negatively. This is a new stage of technology which has not yet become generally established.

Martin Rümke: "The notified bodies subject to private law check that the requirements for CE certification are fulfilled. But there is an obvious conflict of interests here when you consider that these bodies are commissioned and paid by the companies they are supposed to be monitoring and providing certification for."

Why are these innovations so slow to find their way into practical application?
There is not a very high level of willingness to investigate the possibilities of these apparently fully developed techniques because this always involves investment - whether in new machines or the fact that you have to gain experience first before being able to apply the technique in practice. Some companies are hesitant to move forward with these things because of their own quality management system - if changes are necessary, there are a large number of issues which have to be addressed.

If so much effort is required in making changes to the production process, surely the QM system is actually hindering top quality?
The requirement of manufacturers to maintain a QM system has been around since 1995/1996. In practice, you can divide companies into two groups: those who existed before these requirements came in, and the rest. The first group have a hard time because they regard QM as excessively bureaucratic. Younger companies who were familiar with QM from the start and were founded and grew with QM in place regard it not merely as complex and involved but as a tool which gives something back - for example a competitive advantage based on superior quality. In these latter companies, changes are introduced very pragmatically. So improvements are possible here. And even minimal product refinements can be sufficient to increase the lifetime of an implant from 15 to 18 years on average. This type of company would then have a lead over the competition.

"It would be interesting to carry out a supplier audit with a notified body"

Martin Rümke, VDI Medical technology Working Group

To come back to product liability: if damage or injury does occur due to a medical product, where does the problem tend to lie in your experience?
There are a number of possibilities here. If the manufacturer has done everything right and this has been documented, application errors or non-compliant patient behaviour may be to blame. If the manufacturer is responsible and it is a case of product liability, you can essentially assume that something has been done too quickly or carelessly at some point in the development or production process.

How can that occur?
An efficient QM system ought to prevent anything like this happening. And the audit of a medical product by a notified body actually demonstrates that the system is established and works. But it does happen that deviations fail to be eliminated and requirements are not met.

But surely CE certification would be denied in this case?
Theoretically, yes. The notified bodies subject to private law check that the requirements for CE certification are fulfilled. But there is an obvious conflict of interests here when you consider that these bodies are commissioned and paid by the companies they are supposed to be monitoring and providing certification for.

A lot of discussion goes on in this client/agent constellation - also at critical points where the discussion should be brought to a consistent conclusion. A notified body will rarely have the courage to be rigorous and not issue a certificate. You might well ask whether this system is really suited to serving the interests of the ultimate beneficiary, namely the health of society at large. And as the client, the manufacturer should be able to expect feedback from the notified body so as to receive stimulation and the opportunity to improve. Contracts between companies and notified bodies are subject to private law and specifically require the integration of an effective QM system. To some extent this requirement is simply not being met.

What can a manufacturer do to insist on fulfilment of contractual obligations on the part of the notified bodies?
It would be interesting to carry out a supplier audit with a notified body. As a manufacturer of medical products and according to DIN EN ISO 13485 as the basis of my QM, I am required to qualify my suppliers and service providers - and this is exactly what the notified body is. For example, every manufacturer with a QM system undertakes to maintain a training system for staff and to train them according to their assignments. This kind of audit would be sure to reveal a lack of training programs in some notified bodies - whereas these programs are required of companies.

This lack of training allows companies to lead auditors up the garden path if they want to. So an upcoming audit by a notified body might well raise a quiet smile, while a visit from an inspector from an American authority makes many a company break out into a cold sweat.

Why is there such a difference between a German auditor and an American inspector?
An inspector looks at the evidence. He is not allowed to accept anything on a one-off basis. For example, if a specification is exceeded, an inspector will require further documentation on the issue. For the US market, transparent and coherently coordinated verification is absolutely mandatory. If it is not described and signed, it didn't happen.
No matter how many notified body audits a company "passes": if you dig deeper you often find that not even the European requirements have been met - let alone the American ones.

The interview was conducted by Ramona Riesterer. ←

German Summary

Weil in der EU bei der Entwicklung von Medizinprodukten dem Stand der Technik Folge geleistet werden muss, sind hier einerseits immer die modernsten Produkte auf dem Markt. Andererseits weist das System Schwächen auf, weil die Einhaltung der regulatorischen Anforderungen durch privatrechtliche Instanzen, die Benannten Stellen (notified bodies), kontrolliert wird. Martin Rümke, Leiter VDI Arbeitskreis Medizintechnik und Berater bei der Chemgineering Business Design GmbH, plädiert für eine kritischere Haltung gegenüber den Benannten Stellen. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec.miverlag.de/medi0111rum