

DGSV 18 years on – a responsible adult

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With over 600 delegates, this year's congress of the German Society of Sterile Supply (DGSV) was well attended – indeed, so well that the congress centre venue in Fulda appeared at times to be stretched beyond capacity.

Legal principles – what is changing?

The first lecture focused on the EU Regulation on Medical Devices, which is now to be amended by the legal framework established over the past some 20 years at EU level. Dr Andrea Johmann from the Central State Body for Health Protection with regard to Drugs and Medical Devices (ZLG) reported on the relevant amendments from the perspective of the supervisory authorities. She pointed out that the draft of the EU Regulation on Medical Devices was a regulation in the European legal sense. Unlike a directive, there was no need to transpose a regulation into national legislation. It became valid immediately in each Member State, stressed Johmann. She drew attention to a number of areas where changes were to be expected, e. g. reprocessing of single-use medical devices. The reprocessor would in future be equated with the manufacturer, and have the same obligations.

Other important aspects of the new medical devices' regulation from the ZLG's viewpoint included tightening the requirements addressed to the Notified Bodies, clearer definition of accessories, classification of aesthetic products as medical devices and clearer classification of sterilizers and washer-disinfectors as medical devices.

Attorney Dr Christian Jäkel summarized in his talk the amendments to the Medical Devices Operator Ordinance (MPBetreibV), which were published in the Federal Legal Gazette on 25 July 2014. He emphasized that an important point was that the Regulation on the Prescription Requirement for Medical Devices (MPVerschrV) and the Regulation on Distribution Channels for Medical Devices (MPVertrV) had been combined to form a single Regulation on the Supply of Medical Devices (MPAV). MPAV would bring the medical devices distribution channels better into line with everyday practices and create a better understanding of them. Furthermore, the provisions related to maintenance and servicing of medical devices had been separated from those governing reprocessing of medical devices. Based on the new definition, maintenance included in particular maintenance and servicing measures (inspections and servicing needed to continually assure safe and proper operation of medical devices) and maintenance (repairs to restore functionality). Section 4 of MPBetreibV would in future only apply to medical device reprocessing. Accordingly, the new legal requirement was that the quality management system of reproducers entrusted with reprocessing of medical devices subject to stringent reprocessing requirements (critical C) pursuant to the RKI/BfArM Recommendation* would now have to be certified by an accredited body. As such, that optional provision enshrined in the RKI/BfArM Recommendation would henceforth be re-

placed with a compulsory provision. Jäkel emphasized that a legal act in principle took precedence over a recommendation. The exceptions made regarding the critical C devices in the RKI/BfArM Recommendation, for which their manufacturer had provided concrete reprocessing instructions, would no longer apply. These changes were due to come into force on 1 October 2015.

New Guideline for Validation of Automated Cleaning/Disinfection Processes published

Robert Eibl presented on behalf of the Guideline Group the 4th edition of the Guideline for Validation of Automated Cleaning/Disinfection Processes. Compared with the 1st edition from 2005 and 2006, there had been some changes. While the previous versions provided information on old washer/disinfector systems not covered by the relevant standards, that information was now excluded since it was assumed that in the meantime only washer-disinfectors that complied with the pertinent standards were in operation. The limit values for residual protein were already brought into line with the state of the art in the Guideline for Validation of Manual Cleaning and Disinfection published in 2013 (see also announcement in *Central Service 5/2013*). Classification of instruments into different groups also meant that it was now possible to define limit values suitable for various instrument types (e. g. for ophthalmological instruments).

* KRINKO/BfArM Recommendation*: "Hygienic requirements for processing of medical devices" Recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

Overall, the layout of the guidelines had been revised and simplified. A new addition was Annex 9, focusing on measures to assure the cleaning and disinfection performance between the time of commissioning, acceptance and validation. These were based on a catalogue of measures drafted in cooperation with the supervisory authorities in the wake of a hygiene scandal at the hospital Klinikum Munich-Bogenhausen. These measures were particularly useful for newly opened departments. Eibl continued by pointing out that monitoring was very challenging during such transition phases. Therefore the pre-validation interval should not exceed four weeks.

In the afternoon delegates had an opportunity to attend various workshops and engaged in practical exercises. The topics covered this year were the sealing seam process, implementation of an infection

control/hygiene concept in the Central Sterile Supply Department (CSSD), loading the washer/disinfector (WD) with microsurgical medical devices, routine monitoring of automated cleaning/disinfection processes and implementation of the Guideline for Validation of Manual Cleaning and Disinfection Processes.

The second day of the congress began with reports by the DGSV specialist committees. Then Anke Carter and Maik Roitsch spoke about changes made to the specialist training courses. Following expansion of Specialist Course I already in 2013 to 120 h, in addition to a 150-hour practical part, it was now planned to also extend Specialist Course II to 120 h as from 2015. In particular the time allotted to guest visits, e. g. to the operating room (OR and endoscopy department) would be increased, and would also include practical induction of Specialist Course I participants.

Maik Roitsch presented impressive figures showing how from 2009 up till the present over 16,000 employees had successfully completed Specialist Course I – that served as a good argument in favour of the introduction of an independent job description for reprocessing personnel, something that the DGSV was working towards. There was a clear need for qualified staff.

The specialist endoscopy training course initiated only a few years ago had already been attended by over 1600 participants. Ute Wurmstich stressed that the job description was not intended for staff in medical practitioners' offices. Specialist Course I should be able to provide the medical assistants entrusted with reprocessing in medical/dental practitioners' offices with the expertise to discharge their duties.



Dr. U. Beimert, B. Amann, A. Forster (left to right)

Implications of the water quality

The next series of lectures were of particular interest to delegates working in medical dental practitioners' offices. The first talk by Dr Udo Beimert, ENT specialist from Munich, focused on the water quality used in medical practices and on the drinking water tests needed. For medical practices microbiological testing of cold water was needed. That included determination of the colony forming units at 22 °C and 36 °C as well as testing for *Escherichia coli*/coliform bacteria/enterococci and *Pseudomonas aeruginosa*.

In particular when using drinking water in the final rinse for manual reprocessing of medical devices, the RKI/BfArM Recommendation clearly stipulated that only water of impeccable microbiological quality be used (at least of drinking water quality). Beimert pointed out that drinking water testing, including sampling, should be carried out only by accredited test centres and trained staff. Even so, contamination could result from failure to comply with careful working practices, e. g. contamination of the lid of the sterile sampling bottle. Such infringement of the limit values because of mistakes in sampling (artefacts) should definitely be avoided because repeat tests or, in the worst case scenario, the need to decontaminate the water installation system was very expensive. Therefore the practice proprietor should by all means observe the person entrusted with taking the water sample.

Most genuine cases of excessively high limit values were caused by biofilm formation in the piping system and fittings, and that was very difficult to eliminate – especially if the pipes were also calcified. That situation was even worse at rarely used sampling points, where water was allowed to stagnate in the pipes.

If the system had to be decontaminated, specialist firms should be appointed to do so. If necessary, (possibly as a temporary measure) terminal sterile filters could be fitted at the water sampling points.

On the last day of the conference Markus Kamer, from the firm Dr Weigert, likewise spoke about the water quality. He said that the water quality used for reprocessing instruments and other medical devices (MDs) played a major role in preserving their value and in determining the reprocessing results. Kamer pointed out that already at the planning stage of water installations (or media supply) attention should be paid to the water quality required and to the estimated quantity needed. In some areas changes occurred in the water supply throughout the day, thus giving rise to major differences e. g. in the extent of hardness of tap water.

Next, Kamer presented photographic material of various water constituents, showing their impact on reprocessing. Information should in general be available on lime, rust and silicate deposits, but sometimes investigations were needed to determine the cause of certain discolorations.

Kamer stressed that depending on its intended use drinking water should be softened or demineralized. At the time of validation of cleaning and disinfection processes it was recommended to also test and document the water quality for all rinse phases in the washer-disinfector (WD). Demineralized water was recommended for the final rinse step used for automated instrument reprocessing. But in the interest of process optimization, it was advisable to use demineralized water also for the cleaning and intermediate rinse steps.

Reprocessing in the medical practitioner's office – organization and costs

Anke Westerberg spoke about her study carried out within the framework of Specialist Course III, focusing on assuring proper reprocessing in medical practitioners' offices. She drew attention to the fact that the RKI/BfArM Recommendation was applicable regardless of whether reprocessing was conducted in the outpatient or inpatient setting.

The vast majority of physicians who aspired to set up an independent practice were employed in the inpatient sector until doing so. In the latter case, medical device reprocessing was generally carried by specialist CSSD staff.

Therefore physicians should from an early stage pay attention to the topic of medical device reprocessing, ideally before taking on, or setting up a new, medical practice. Already at the time of acquiring the premises for the practice it was important to make provision for a separate room or area for reprocessing.

The medical assistants employed in medical practitioners' offices did not automatically gain the expertise needed for medical device reprocessing as part of their training. It was therefore advisable to make arrangements for the staff training needed before taking on a practice.

Likewise, it could be advisable to find alternatives to reusable instruments – for example to consider opting for single-use devices.

The speaker continued by stating that the Association of Statutory Health Insurance Physicians of Westphalia-Lippe (KVWL) provided information to its members and to physicians wishing to engage in independent practice on the issue of medical device reprocessing. That could be done by telephone or by means of on-site consultations offered by KVWL personnel. The two-year sponsorships offered by the KVWL had proved very successful.

Consultants were trained at the Centres of Competence (CoC) for Hygiene and Medical Devices, found throughout Germany, by the Association of Statutory Health Insurance Physicians and the National Association of Statutory Health Insurance Physicians (based at the Association of Statutory Health Insurance Physicians in Baden-Württemberg). The CoC had,

among other things, developed a tool for calculating the reprocessing costs incurred by a medical practitioner's office.

Juliane and Arndt Ungänz next presented their cost calculation model for medical practitioners' offices. Office-based medical and dental practitioners were as never before required to view their own practice as an economic entity. But so far there was rarely any knowledge of the costs incurred for reprocessing instruments in the outpatient setting.

As part of his final study assignment while completing Specialist Course III, Arndt Ungänz developed software to be used as a basic cost control tool aimed at relieving users from having to engage in complex calculations. All cost types, ranging from personnel costs through equipment and general costs to fixed costs, could be recorded, with the program then generating the final values. Indeed, costs could even be assigned to an individual instrument, for example to decide whether reprocessing a reusable instrument or switching to a single-use device was the more cost effective option. Details of that program could be consulted in a publication in *Central Service* 3/2014.

| Multiresistant bacteria – was must be taken into account when reprocessing?

Dr Karin Schwegmann, Helios-Klinikum Hildesheim, spoke about infection control (hygiene) and medical device reprocessing with respect to multiresistant bacteria, and



P. Nuppeney, Dr. M. Vitr, F. Deinet (Left to right)

in particular to the multiresistant Gram-negative (MRGN) rod-shaped bacteria. She said that Gram-negative rod-shaped bacteria (e. g. *E. coli*, *Klebsiella* spp., *Enterobacter* spp., *Pseudomonas aeruginosa*, *Acinetobacter baumannii*) which were resistant to three antibiotic groups were known as 3MRGN, while those resistant to all four antibiotic groups were called 4MRGN. They were, she said, facultative pathogens, i. e. they could also be present as part of the resident flora of the skin and mucosa and could, e. g. be found in stools, urine, wounds and respiratory tract secretions. That classification gave rise to different hygiene measures in terms of isolation or the use of personal protective equipment. A new aspect was the differentiated approach based on risk and normal areas of an establishment (risk areas included e. g. intensive care units and haematology/oncology wards).

As regards medical device reprocessing, Schwegmann stressed that special treat-

ment was not needed. The increased antibiotic resistance of a pathogen had no implications for the efficacy of disinfectants or of a sterilization process. Medical devices used on a patient harbouring MRGN could therefore be treated with conventional disinfectants and the usual reprocessing processes.

| Reprocessing accessories for lung function tests

Bruno Amann, CSSD manager from Schweinfurt, reported on incorporating a validated endoscope washer-disinfector (EWD) programme into a washer-disinfector (WD) used to reprocess heat-sensitive MDs. The instruments concerned were accessories used for lung function tests in body plethysmographs. So far, it had not been possible to properly reprocess these medical devices using either manual or automated processes because no valid instructions had been supplied by the manufacturer on the appropriate cleaning, disin-

fection, drying or sterilization processes. Even if disposable filters plus a mouthpiece were used, thus greatly underpinning patient safety, the parts coming into contact with the respiratory air still had to be reprocessed at least once daily.

Experience and tests then revealed that certain components/MDs made of polypropylene, silicone or stainless steel could be reprocessed using steam sterilization. For the heat-sensitive components a decontamination process, as normally found in a EWD, had to be incorporated into a WD. In general, an adequate supply of suitable loading trolleys with sufficient injection nozzles for minimally invasive surgical (MIS) and anaesthesia accessories should be available in every CSSD. As in the case of the EWD programme, provision was made for adequate disinfection at 60 °C using glutaraldehyde as a disinfectant.

As far as possible, the chemo-mesothermal programme was validated in accordance with the Guideline for Reprocessing Flexible Endoscopes. The cleaning efficacy was verified using metal discs plus test soil as well as with a routine test used in the foodstuffs, chemical and pharmaceutical industries (with Pascomucil® and Riboflavin). In that way it was possible to develop a satisfactory process for routine operations so as to provide on a daily basis sterile MDs, or MDs harbouring at most only a low microbial count, for the department carrying lung function tests.

I What to do if the CSSD becomes inoperational?

Another paper compiled as a Specialist Course assignment was presented by Petra Nuppeney from Koblenz, describing a concept to counter a breakdown of the CSSD which had been developed in the CSSD of the hospital Klinikum Kemperhof in Koblenz. That concept was aimed at providing reprocessed medical devices in the event of a breakdown or partial breakdown of the CSSD, while complying with the legal, normative and business management provisions. Such breakdowns could relate to WDs or sterilizers.

Nuppeney described first how the collaborating hospitals were compared in terms of capacity, working practices and consumable materials used so as to determine whether in the event of a breakdown the

MDs could be simply reprocessed at another site.

That also entailed e. g. validation of loads normally used at the partner sites. Furthermore, a logistical system had to be established to take charge of MD transport if reprocessed at another location.

I Explants – several unclarified issues

Following an evening event known as the Oktoberfest, the last day of the conference was opened with a talk on management of explants. Time and again explants ended up in the CSSD having been handled in the same way as the used OR instruments. Anton Forster, CSSD manager from Weiden, pointed out that several issues remained unclarified in that respect: who was responsible for adherence to proper procedures? Did explants constitute a piece of evidence? Was the explant the patient's property? How should reprocessing be carried out? There were numerous procedures that could be adopted, e.g. should the explant be simply disposed of with the normal waste or returned to the patient after cleaning and without any further information.

Another possibility was that the physician would retain the explant as a visual exhibit or pass it on to an education centre for training purposes. In the event of any claims, explants were often returned to the manufacturer without any special precautions taken.

However, scientific studies that had investigated implant-associated infections concluded that 80 % of the implants were coated with biofilm and had a high bacterial load.

Forster finished by saying that for that reason a uniform procedure should be devised in compliance with the provisions of the Medical Devices Act (MPG) and the Protection against Infection Act (IfSG), while taking account of the following:

1. Appropriate disposal method (standard operating procedures would have to be compiled for the OR to that effect, e.g. remove tissue residues and drugs such as bone cement, etc.)
2. Effective pre-cleaning in an ultrasonic bath
3. Validated automated cleaning, disinfection and drying

4. Suitable, validated packaging

5. Sterilization with validated processes

I CSSD and OR – optimize cooperation in real time

Dr Eng. Mirco Vitr, IT4process GmbH, and Frank Deinet, CSSD manager at University Hospital Aachen, demonstrated a real-time information system for ordering, management and tracking sterile supplies. They explained that the software was able to automatically generate and assemble ordered trays on the basis of the current OR schedule and that was then displayed to the CSSD staff as a prioritized processing list. The processing list was continuously updated so that at all times it reflected the actual needs of the OR schedule. The processing step undertaken at any moment in the CSSD was automatically and continuously recorded and could be viewed at all times by the OR staff. That kept the work load in the CSSD to a minimum and reduced the need for telephone calls and queries regarding the trays or the reprocessing progress. Further details could be consulted in the article in *Central Service* 2/2014.

I Automated cleaning – influence factors and verification

Gerhard Kirmse, Fa. Aesculap, spoke about factors that influenced automated cleaning. There continued to be problems with obtaining clear reprocessing instructions from the manufacturer or with safeguarding processes in everyday practice.

Kirmse described tests carried out on dismantlable crevice test pieces he had designed himself in which, using the BCA method and the TOC method, two test soils (heparinized sheep blood and Browne test soil) were used in parallel to assess the cleaning efficacy. Elution was performed at a high temperature, backed up by ultrasound. The influence factors detergent, pre-cleaning, cleaning temperature, dosage, holding time, pressure and water quality were investigated separately. Out of these, the pressure proved to be the most potent factor. Conversely, the effect exerted by the water quality and dosage were slight. As regards the detergents, a more potent enzyme component had positive effects. Likewise, a more intensive

precleaning method had a positive effect, while a lower temperature produced much better results. Comparison with the commercially available Crile clamps used for validation revealed residual contamination loads on the test pieces that were between two and three orders of magnitude greater. That was due to the more intensive elution and the more complex geometry.

The overall conclusion to be drawn from those results was that the method devised comprising the test pieces and standard load was suitable for detailed process assessment. The model devised to study influence factors also permitted assessment of processes that deviated from the manufacturer's instructions.

Dr Robert Simmoteit, 3mach GmbH, presented DNA as a new cleaning marker for assessment of automated cleaning. At present, it was only the surface protein contaminants that were taken into account when evaluating the cleaning results. But DNA was able to demonstrate the presence of blood, tissue residues or other biological soils, while providing additional information. He stated that DNA was a robust biomolecule, which was able to survive cleaning processes as well as the subsequent sterilization process and which could be infectious. Under certain circumstances, it could even be detected several years later on surfaces. DNA in 0.1 pg quantities could be reliably detected on surfaces. Hence that method was a million times more sensitive than a standard protein test and produced a linear calibration curve. However, it was difficult to quantitatively dissolve DNA from medical surfaces. In particular, at high temperatures (as in thermal disinfection) it became deposited on stainless steel surfaces if not fully removed during cleaning.

On the other hand, it was around 50 times easier to remove DNA in the presence of a detergent at cleaning temperatures of 93 °C in a cleaning window of 10–20 min than at cleaning temperatures of 60 °C.

A suitable elution process had been developed to detect DNA. Quantities in the pg range could be detected with high sensitivity and in a reproducible manner. Simmoteit concluded by saying that at present DNA produced the best evidence of cleanliness of a stainless steel surface thanks to its detection limit.

As was the case last year, at the end of the congress there was a panel discussion on the current KRINKO-BfArM Recommendation. Panel members were as follows: Klaus Wiese, CSSD manager from Dortmund and member of the DGSV board of directors; Dr Thomas Fengler, Chirurgie-Instrumente –Arbeitsgruppe Berlin (Surgical Instruments Working Group Berlin) and proprietor of a company that carries out validation; Bernd Vogler on behalf of the supervisory authorities in Oldenburg; Marc Thanheiser from the RKI, and who played a pivotal role in drafting the KRINKO-BfArM Recommendation; Dr Edith Fischnaller, hospital infection control officer; Dr Claas Hohmann, administrative director; Dr Wolfgang Kohnen, deputy manager of hospital hygiene at University Hospital Mainz; and Maik Roitsch, CSSD manager in Berlin and DGSV chairman. This exchange of opinions was moderated by Dr Maria Theresia Linner and Dr Winfried Michels, who armed with citations from the KRINKO-BfArM Recommendation guided members through the discussion.

The first point addressed was that validation should be tailored to the respective MDs and its risk assessment. Maik Roitsch stated that in addition to classification into the critical A/B/C groups to determine the reprocessing method to be used, the geometry of the individual instrument was also decisive. But who should decide what should be done with the materials used in a MD, e. g. glues, during reprocessing? A recommendation from industry was needed to that effect. If the reprocessing method used was different from that recommended in the manufacturer's instructions, the relevant test parameters should be included in the scope of validation to assure proper technical and functional safety (cue: material properties). Maik Roitsch believed that here, too, the manufacturer was responsible, e. g. to ascertain in advance the material compatibility with regard to reprocessing.

Dr Hohmann was likewise of the opinion that the manufacturer had to decide whether a different method of reprocessing was possible, e.g. with alkaline instead of a neutral detergents, as commonly used for American devices.

Dr Fischnaller stressed that before purchasing new instruments they should be

tried out first in the CSSD. Only then could the CSSD expertise be optimally put to use.

Risk assessment included the type of use as well as the risks associated with storage, transport and previous use and could therefore only be carried out on site, stated Klaus Wiese. Dr Fengler also made clear that, while the method of use on a patient was clear in the case of several devices, the manufacturer could not be aware of other conditions (e. g. handling, transport). For example, some MDs were repeatedly reprocessed but used only once.

Dr Fischnaller explained that this had already meant that increasingly more single-use devices were being used since risk assessment had become more and more demanding and difficult.

As regards the WD, the accessories were often a problem, stated Maik Roitsch. Users had to fit their own components, in-

cluding also in outpatient settings, in order to at all be able to reprocess certain MDs. It would be desirable if instead of that the manufacturer would supply the necessary adapters. Here, too, communication in advance was important and the management of the respective reprocessing should also be consulted.

Validation should be carried out in accordance with the state of the art in science and technology. Marc Thanheiser drew attention to the presumption of conformity with the KRINKO-BfArM Recommendation: proper reprocessing was presumed when that recommendation was observed. Nonetheless, current developments had to be taken into account and operators were obliged, for example, to respond to product warnings.

Cooperation with the validation engineers was also discussed. Maik Roitsch explained that this was often inadequate. It was advisable to jointly compile a checklist. Validation was not something that could be accomplished by one person alone.

Bernd Vogler explained that validation engineers, just like operators, had to master the fundamentals. But some validation engineers were not properly qualified, therefore it was advantageous if operators had better knowledge of the assessment criteria. In particular in medical practitioners' offices the medical assistants were often challenged when it came to assessment of validation reports. Criteria should be compiled to that effect.

The module "Validation" featured in Specialist Training Course III could help operators obtain better qualifications. But despite all that, it was necessary to have a trustful relationship with the validation engineer, stated Dr Hohmann, because extensive technical knowledge was needed to evaluate the validation reports.

Good cooperation was also needed, e. g. to define the worst case load. Test models could also be useful if it was difficult to try out instruments, stated Marc Thanheiser. But the validation engineer could not define all these parameters alone. Therefore cooperation with the CSSD management was vital.

At the time of validation parameters were also defined for assuring effective cleaning, disinfection, sterilization, including a low microbial count, until the time of use.

That was not always possible, stated Dr Kohnen because of the divergent transport and storage conditions. Dr Fengler stated that the standard operation procedure (SOP) was a key document.

With regard to a further discussion point, periodic tests, Dr Linner stated that the frequency of such periodic tests was also based on financial considerations. A committed approach to QM could pave the way for meaningful decisions to offset cost pressures.

But who should set the frequency of periodic tests? The interval between two validation points was "generally" one year. But the validation engineer could also recommend a longer interval and that could be tolerated by the supervisory authorities, stated Bernd Vogler. Routine tests also helped to gain an overall picture. It was advisable to keep to servicing intervals – after all there was a difference between a medical practice in which one load was reprocessed per day and a CSSD that had 10 times that throughput.

Validation looked at the individual process steps and could therefore give an overview of the entire process, from OR end to the start of the new OR schedule. In that respect, Dr Fengler suggested that properly stored sterilization units (StUs) should be subjected to periodic microbiology testing. Over the years that would give a good overview of the performance capability of the entire process.

With regard to performance qualification, Dr Michels asked how much certainty could we allow ourselves in terms of the time and financial investment. Nor was there any correlation between pathogens and soils. But there were global conventions, e. g. in CEN and ISO; the present consensus was that a residual amount per cm^2 should be expressed as a limit value. Dr Hohmann developed that thought further: how much contamination was a health hazard? 100 μg per instrument? That could quickly add up during an operation where many instruments were used. Was less thus always better? But industry survived on the back of constant technical innovation, to generate new sales. The always better devices were also always more expensive, but the issue of their benefits could not yet be answered. Hence the interests of industry had to be brought into line with the interests of the CSSD.

Dr Kohnen pointed out that the protein load did not give any insights into any hazards; it merely attested to a machine's performance. Meaningful limit values should be defined in discussions, e.g. in the Guideline Groups.

To finish off, Dr Kohnen described KRINKO-BfArM Recommendation 2012 as being very clear; the reference to the guidelines was also very helpful. Maik Roitsch stated that here, too, it was noted that validation amounted to team work and could be accomplished only in collaboration between CSSD, validation engineer, engineering department and the hospital's infection control team. Dr Kohnen said that the status of the CSSD was slowly increasing, thanks in particular to the continuing education programmes offered by the DGSV. But cooperation with the infection control team was vital. It was the sum of pooled specialist knowledge from several professional groups that determined a successful outcome.

The congress also proved to be a success – delegates no doubt gained a lot of valuable information. Next year's DGSV congress will be held from 4 to 6 October – as always in Fulda. ■