Complex and Flexible at the same Time

The company BGS, established in 1981 and headquartered in Wiehl near Cologne, covers two major areas of activity: Radiation sterilisation and refinement of materials. With its other branches in Saal an der Donau and Bruchsal, the radiation specialist is represented at three locations in Germany. In an interview with our editorial team, Dr. Andreas Ostrowicki, Managing Director of BGS, provides more details.

MED: Dr. Ostrowicki, just recently, a new gamma radiation plant went officially into operation in Bruchsal. With an annual capacity of 80,000 pallets loaded with medical products, the plant is one of the largest of its kind worldwide. BGS has invested about 15 million euros in the construction of the new plant. In addition to the financial expenditure, the company had to implement extensive permit requirements – a huge investment and high costs for a medium-sized enterprise with currently 170 employees. What were the key factors in taking this step?

Dr. Ostrowicki: Only a few companies are active in the business of radiation sterilisation. The plants are equipped with complex and sophisticated technology and besides a high investment, they also require extensive capacities. Therefore, it

Dr. Andreas Ostrowicki, Managing Director of BGS

makes no sense for individual companies to build their own plant. On the contrary, it is common practice to outsource this process. At the same time, customers benefit from the comprehensive advice of our experts, for example with regard to regulatory requirements, questions on materials and logistic processes. In addition, the market for medical technology has been growing for some years now at an annual rate of 3 to 6 percent, depending on the field of application. In Germany however, there has been little investment in the areas of radiation sterilisation, bioburden reduction & disinfection over the past 20 years, which is why a significant shortage of capacities prevails in the European market.

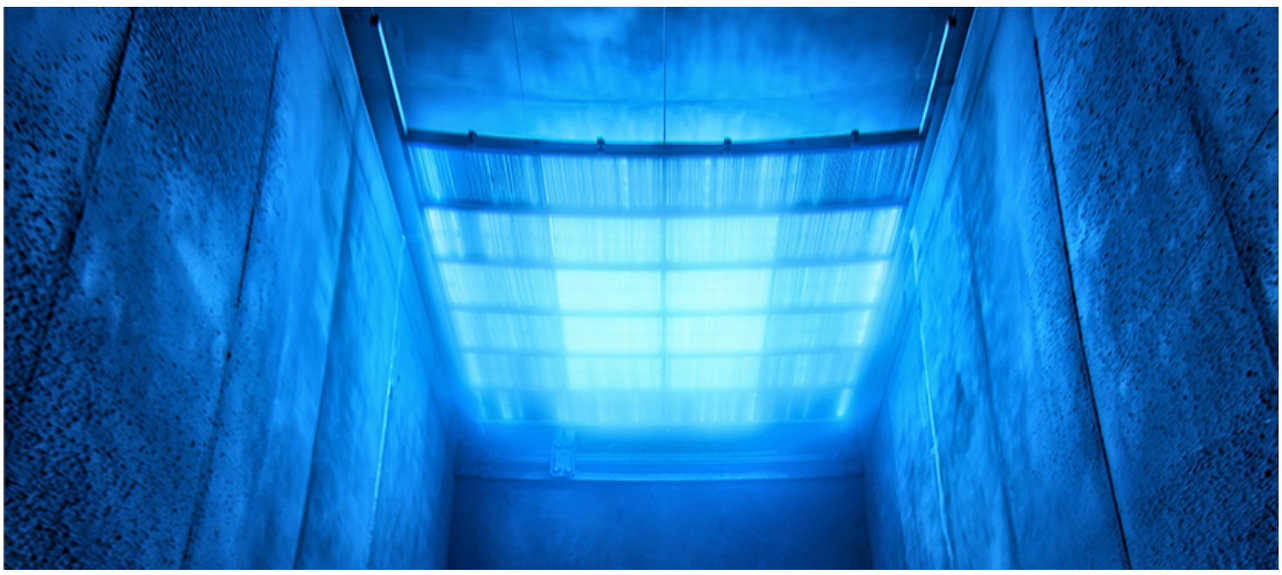
MED: Which advantages does the location in Bruchsal offer?

Dr. Ostrowicki: The medical device industry is very strongly represented in Baden-Württemberg, which almost automatically resulted in choosing Bruchsal. The location is also characterised by its excellent logistical connection to the medical device markets in neighbouring countries. Incidentally, the transportation of many products is oftentimes routed via logistics centres in Germany, and the stopover in Bruchsal is more or less situated en route to the final destination.

MED: BGS offers radiation cross-linking and radiation sterilisation services. What are the characteristics of the processes?

Dr. Ostrowicki: Radiation cross-linking triggers chemical reactions in plastics, which modify polymers. Radiation cross-linking gives commodity plastics and technical plastics the mechanical, thermal and chemical properties of high-performance plastics. Usually, standard polymers melt or wear away at medium to high temperatures or the material is affected by chemicals. The refinement of materials provides plastics with new and high-quality properties for their use. »

The company BGS BETA-GAMMA-SERVICE GmbH & Co. KG, in short BGS, treats products with high-energy rays in order to convert them into a sterile state or to optimise the product characteristics.



Images: BGS BETA-GAMMA-SERVICE GMBH & CO. KG

Beta as well as gamma rays are suitable for sterilisation. The main difference between them lies in their penetration capabilities for materials and the dose rates.

Radiation sterilisation, on the other hand, is used for applications that require a high level of hygiene or sterility. For example, in the field of biotechnology or when materials are processed in the clean room, up to highly sensitive medical devices such as endoprostheses or implants. Gamma and beta rays are used for this purpose. The main difference between both processes lies in the penetration capabilities for materials and their speed. Gamma rays have a high penetration depth and a relatively low dose rate. In this way, complete pallets can be sterilised in a few hours. As a result, the procedure makes it possible to market products without waiting times after they have been treated with the correct radiation dose.

Beta rays however, have a high dose rate and a reduced penetration depth. E-Beam is a particle radiation with accelerated electrons where the mass of the electrons is virtually accelerated to the speed of light. This method provides the same results to be achieved as with gamma irradiation. However, the penetration depth is limited in the case of particle radiation, since the irradiated material absorbs the electrons more readily. Therefore, the cardboard boxes loaded on a pallet are irradiated in layers, whereas the irradiation is completed in only a few seconds. In this way, and under optimal conditions, a full truckload can be sterilised in a few hours.

MED: Are there any other limitations?

Dr. Ostrowicki: The operational step of particle radiation is not suitable as soon as homogenous penetration is no longer possible due to the density. Metal components or inappropriately arranged packaging must therefore be considered separately. Products with integrated electronic components are not suited for any radiation, because the radiation may result in a transformation of semi-conductor properties and consequently impair their functionality. Nevertheless, a broad selection of materials has been specifically optimised for radiation sterilisation in the meantime. These also include materials with very transparent properties such as COP polymers.

MED: On what basis do you specify the parameters for the radiation treatment and how do you examine the sterility level?

Dr. Ostrowicki: The spectrum of pathogenic microorganisms generated during production is determined in a sophisticated qualification process and the radiation dose is adjusted accordingly. Besides the materials to be sterilised, the parameters such as the extent of transport packaging, packing scheme and sterile barrier of a product are also taken into account. The reproducible sterilisation processes can be finally examined with statistical methods as well as through random tests.

MED: Which processes are used for which products?

Dr. Ostrowicki: Generally, our radiation sterilisation covers the entire spectrum of single use materials through to risk class 3. However, we operate in a competitive environment. The customer typically has the choice between the often used radiation treatment and the sterilisation with ethylene oxide gas (EtO). The treatment with ethylene oxide is suggested, for example, in the case of products made from plastics, which react to the radiation by embrittlement or other changes. Principally, both methods are qualified in this regard, as the radiation treatment and the sterilisation with ethylene oxide gas (EtO) complement each other. If products have complicated geometries or large surfaces, radiation sterilisation provides significant advantages over EtO. Moreover, the irradiation with electrons enables a considerably faster completion of the process. In this way, the sterilisation treatment with beta irradiation can be carried out within seconds.

On the other hand, the gamma irradiation process will take about two to four hours. However, the sterilisation with ethyle-

BGS is represented at three locations in Germany. The picture shows the company Headquarters in Wihl, close to Gummersbach/Köln.

ne oxide requires a relatively long dwell time of several days, as the desorption of the gas must be allowed from the material.

MED: Are there any other factors that have to be taken into account?

Dr. Ostrowicki: Compared to gamma irradiation, the sterilisation with ethylene oxide and the irradiation with electrons is slightly less expensive. A fact that is optimally already considered when the products and their packaging are developed. However, the sterilisation with gas involves some disadvantages, because chemical residues may build up on the surface of sterilised products. For products with areas that are difficult to access, such as tubes or closed cavities, it is therefore mandatory to perform the work by using the residue-free radiation sterilisation. By applying this method no radioactivity is ultimately generated, but rather chemical processes are exclusively triggered. Since there is a wide range of products and materials in the medical device sector, consultation on a case-by-case basis is almost always necessary.

MED: Dr. Ostrowicki, thank you very much for your interesting explanations.

Interview conducted by Carola Tesche

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