

Know How for the „Hot Cell“

Sterilization of radioactive pharmaceuticals



The French firm CISBIO operates a number of just-in-time production facilities for radiopharmaceuticals all over France. In 2005, it awarded a basic engineering order for the development of a production line to Gravatom, an international engineering company with over 30 years' experience in the development, production, installation and validation of production facilities for the radiopharmaceutical industry. In turn, Gravatom approached SBM, a Bosch Packaging Technology company, with a basic engineering order for a steam sterilizer to be fitted into a radiation-shielded cell.

Radiopharmaceuticals are special tracer substances, which, in conjunction with radionuclides, are used in the diagnostics or therapy of diseases. Given their short half-life these must be produced „on demand“ and used as soon as possible. Due to radiation levels, the manufacturing process has to be conducted in so-called hot cells - areas shielded by lead plates and lead glass. Production, filling and final sterilization are therefore highly automated and outside intervention is only possible by using manipulators.

Following the conclusion of basic engineering, Gravatom was also commissioned to manufacture the fully fitted production unit. At the core of this system is a specially designed sterilizer for final sterilization of the product. For this part of the unit, Gravatom contacted SBM Schoeller-Bleckmann Medizintechnik, a company which had previously delivered sterilizers to CISBIO for a similar project. One of the most important requirements for a sterilizer of this type is that it has to function reliably without requiring servicing. Hot cells, due to radiation levels



1



2



inside, cannot be opened until several days after completion of the production process, so any intervention for servicing purposes would delay production for days.

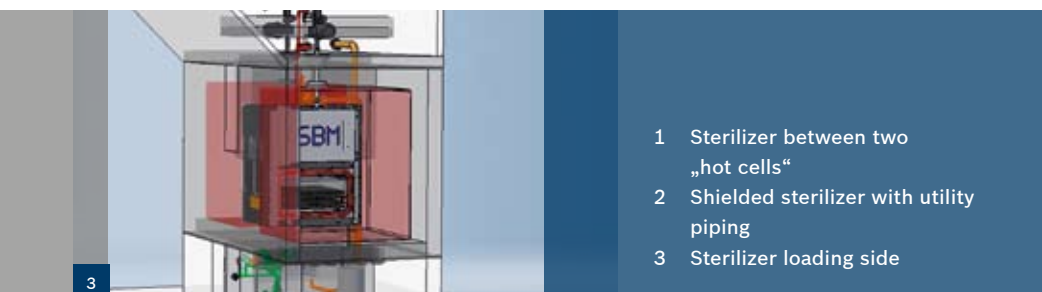
In addition, this project required the sterilizer to be adapted to the particular space conditions inside the shielded unit. Further tasks were the integration of an E-steam generator and the fitting of a sterilizer for loading and unloading using manipulators.

Competent cooperation and optimal customer focus

When starting the project for the engineering order in January 2006, basic specifications as well as close project-related cooperation were agreed. One of the key challenges for this particular project was to design the installation in such a way that changing a door seal, should it become necessary, could be carried out by using a single manipulator. The overall aim was to access the hot cell only once per year for maintenance purposes.

Towards the end of 2006, Gravatom was awarded the production order for the entire hot cell and, in March 2007, SBM received an order for the sterilizer. In October 2007 the FAT for the sterilizer was carried out successfully in the presence of representatives from Gravatom and CISBIO. Some additional modifications were agreed and, finally, in November, the sterilizer was delivered to Gravatom in England where it was integrated into the hot cell in January 2008.

In the course of this sophisticated project, SBM was able to demonstrate its ability as a producer of high-quality sterilizers as well as its successful role as a technology partner, dealing with specific tasks and challenges.



- 1 Sterilizer between two „hot cells“
- 2 Shielded sterilizer with utility piping
- 3 Sterilizer loading side

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