Boehringer Ingelheim required an expansion to the capacity of the company’s Clean Utilities to produce a new vaccine. This included two new package units for the manufacture of Purified Water (PUW), Water for Injection (WFI), and Clean Steam (CS). These units were to be installed in the existing production location, connected to the various utilities, and made available in the various production rooms in the building.

The biggest challenge was time as the whole installation had to be ready in six months. A major part of the production process had to continue for a long time while the units were being built.

Stork was main contractor for this project and responsible for the entire process, from design to delivery, of the mechanical and the E&I scope.

The design of the requested installation was realised according to the V model. This way of working verifies the results of each step in the project with the specifications. A particular challenge was presented by the fact that the system had to be installed in an existing building in which space was limited.

In addition, all pipework had to be laid straight through already cramped technical rooms, also keeping in mind the very strict technical requirements that critical utilities have to meet. The controls for the WFI distribution loop and the various user points were fully automated in-house, conforming with the GAMP 5 standard. As a result, all requirements regarding product safety and traceability were met.

During the execution of this project, a number of existing storage and utility rooms were converted into new skids and tanks, and piping was laid throughout the building. As the production process continued during the construction phase, the number of planned disruptions had to be minimised. This was achieved thanks to the smooth matching of activities by production planning and project management. All the orbital welds were
checked externally by visual inspection, and internally by video endoscopy equipment to ensure there were no defects or discolourations.

To demonstrate that the installation has, in fact, been built exactly according to its specifications, all activity was carefully documented, including the materials used, the welding, the tests that had been carried out, the cleaning work and the inspections, the calibrations, and the validations.

**INNOVATIONS APPLIED**

**Energy efficiency**
The system will operate at low speed during a stand-by period thanks to the circulation pumps with frequency converter and pressure control valve, which can be controlled as needed. When a user point requires WFI, the system will be revved up to the point where the supply pressure to the user meets the specified values.

**Sterilisation**
By keeping overpressure on the system with WFI in the pipes, the boiling point of water is raised. As a result, it can be heated up additionally to reach values of more than the required 121°C. After having reached the required period at sterilisation temperature, the system is actively cooled back down to the normal operating temperature of 85°C. This way, it is possible to sterilise the system and prepare it for production within the six hours stipulated by the customer.

**Insulation**
As the production rooms had to remain operational during the construction phase, rockwool could not be used. In addition, the nooks, crannies and protruding fastenings of regular plating would not facilitate the cleaning of the rooms. Stork made use of a layer of closed-cell foam, which had been especially developed for this application. This material guarantees a safe, energy-efficient, and easy to clean finishing.

**RESULT**
The utility installations of Boehringer Ingelheim are ready for the production of the new vaccine. The WFI distribution grid meets all GMP requirements, and has been delivered turnkey, on time, and within budget.

The installation has an availability of 100% and there are no other interruptions except for regular maintenance.

“The most important aspect of this project was how to deal with contingencies. Stork has handled this problem excellently.”

*Gaby Paauw, Project Manager - Boehringer Ingelheim Animal Health BV*