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A BIOMANUFACTURING FACILITY BASED ON CONTINUOUS PROCESSING AND SINGLE USE TECHNOLOGY

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Key Words: Continuous processing, Single Use Equipment, Closed Processing, Ballroom production

Bayer's vision of the Biofacility of the Future is developed within the Mobidik project. A pilot plant with a complete production line of monoclonal antibodies from fermentation to final drug substance has been established. All parts in contact with the product are made in single use technology and the process is run as an integrated, fully continuous process. The process control system and the PAT concept are developed to achieve a high level of automation limiting the need for manual handling to a minimum. Issues related to GMP compliance are being addressed at an early stage. A detailed GMP risk analysis and a concept for product release are being developed.

The pilot plant is used to provide a proof of concept for the process technology and to lay the foundation for building a production plant with a capacity of 150 kg/a. In particular, the pilot plant is used to demonstrate process robustness and GMP readiness. The concept for the production plant is based on the four design criteria; 100% single use equipment, continuous processing, closed processing and "ballroom" production. Compared to traditional facilities this concept is significantly less complex which results in a number of benefits. The engineering, construction, commissioning, qualification and validation of the facility are much faster. Flexibility is achieved through the decoupling of the equipment from the building. The facility is smaller, has reduced investment and production cost as well as reduced energy and water consumption. It should therefore be possible to build the production facility in less than two years for less than 20 million €.

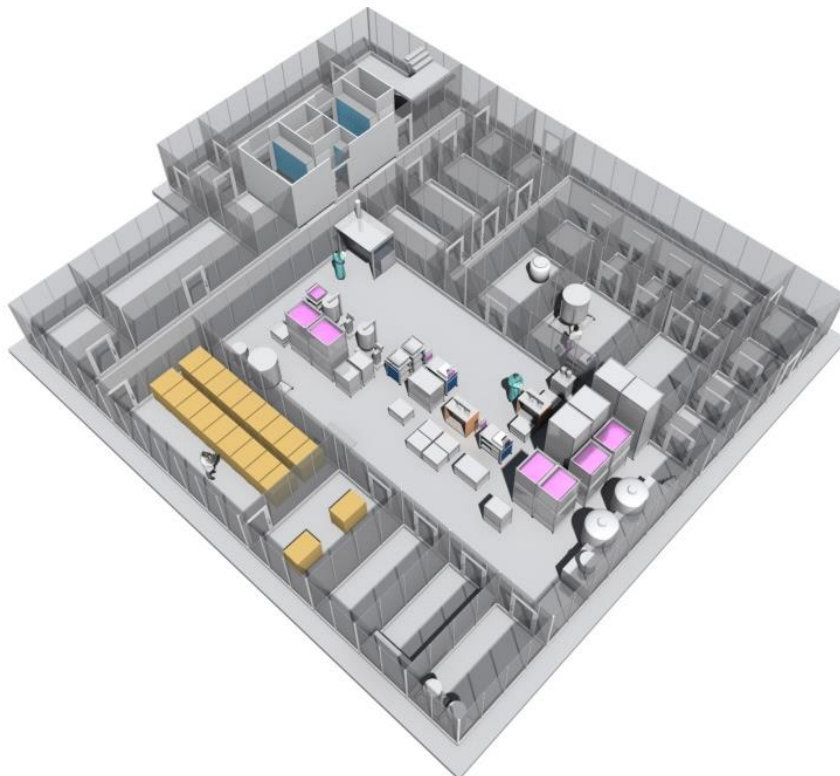


Figure: a 3D model of the envisioned biofacility