Engineering Conferences International
ECI Digital Archives

Integrated Continuous Biomanufacturing II | Proceedings

Fall 11-2-2015

A biomanufacturing facility based on continuous processing and single use technology

Jorgen Magnus
Bayern Technology Services, jorgen.magnus@bayer.com

Maike Temming
Bayern Technology Services

Peter Schwan
Bayern Technology Services

Jovana Micovic
Bayern Technology Services

Martin Lobedam
Invite, GmBH

See next page for additional authors

Authors
Jorgen Magnus, Maike Temming, Peter Schwan, Jovana Micovic, Martin Lobedam, and Stefan Sievers

A BIOMANUFACTURING FACILITY BASED ON CONTINUOUS PROCESSING AND SINGLE USE TECHNOLOGY

Jorgen Magnus, Bayer Technology Services GmbH
jorgen.magnus@bayer.com
Maike Temming, Bayer Technology Services GmbH
Peter Schwan, Bayer Technology Services GmbH
Jovana Micovic, Bayer Technology Services GmbH
Martin Lobedann, Invite GmbH
Stefan Sievers, Bayer Technology Services GmbH

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

Bayers 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 €.

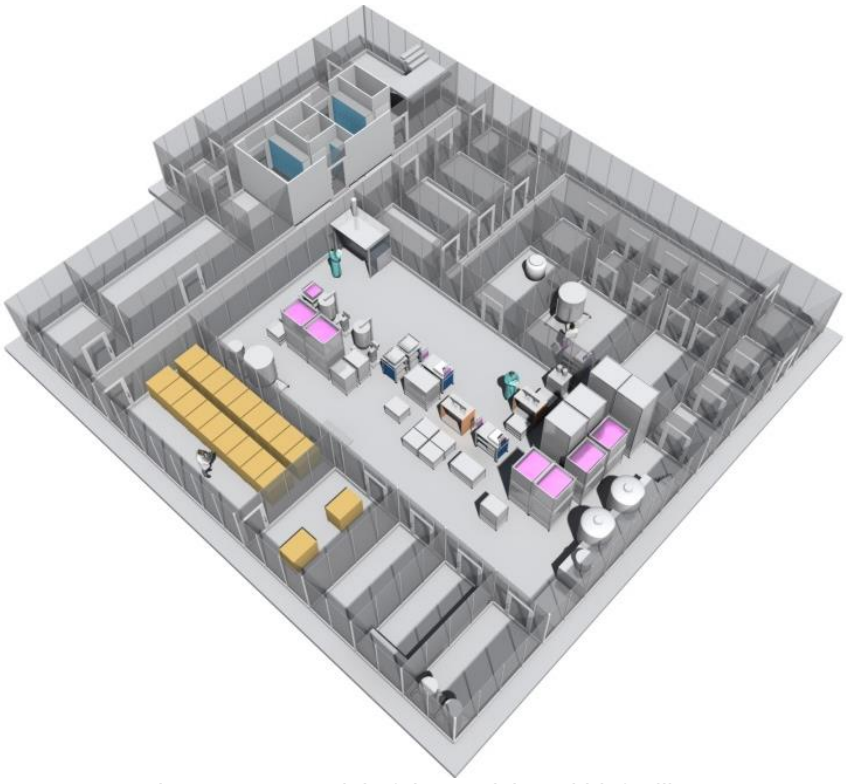

Figure: a 3D model of the envisioned biofacility