manufacturing CHEMIST PHARMA

PLANT UPGRADE

Vetter invests €300m to update and expand its manufacturing sites

German contract development and manufacturing organisation (CDMO) Vetter is investing around €300m to expand and upgrade its manufacturing facilities over a five-year period.

Structural work for the expansion at Ravensburg Vetter West is complete; the site will be operational by 2017

The firm says the upgrades are being driven by a changing healthcare market facing issues such as ever-more complex molecules, smaller batch sizes, and increasing regulatory requirements.

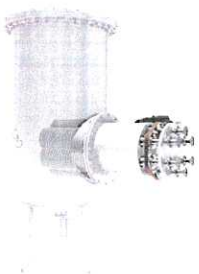
The first of the upgrades is already underway at several of the company's German locations, including at its Ravensburg Vetter West centre for visual inspection and logistics. Structural work for the expansion, which will more than double current capacity, is complete and the site is on schedule to become fully operational by 2017. In addition, the Ravensburg Vetter South production site, as well as the Ravensburg Schuetzenstrasse facility, will be expanded.

A central technology element of the upgrades will be the implementation of a restricted access barrier system (RABS) concept, developed in house, which the firm says will contribute to increased operational excellence in aseptic manufacturing. The core of the approach is a three-hour cycle and fully automated decontamination of the cleanroom using hydrogen peroxide (H_2O_2), resulting from a high level of process innovation. Following a successful pilot project the company will now implement this decontamination concept in all of its cleanrooms within the next few years.

www.vetter-pharma.com

GEA offers filter-in-tank system for fermentation broths

GEA Group has added a Filter-in-Tank (FiT) system for the treatment of fermentation broths in the production of insulin to its portfolio.



GEA Filter-in-Tank system

The system integrates the purification step, previously a downstream process, directly in a buffer tank. This eliminates the need for the downstream filtration process and subsequent associated apparatus. A process of gentle filtration, which makes use of the hydrostatic pressure in the tank, now takes place without damaging the product while delivering optimum yield.

GEA Group says the FiT system sets new process standards in the pharmaceutical industry and offers a number of advantages for the user: the entire post fermentation purification is carried out in one process step using only a buffer tank; the FiT system, as one complete unit, can be hygienically cleaned (CIP) and can also be sterilised (SIP). This results in time, space and resource saving, and a sustainable production process with optimised product quality and yield.

The FiT stem exclusively uses GEA in-house components and has been developed with a leading pharma company as a pilot plant to produce a system suitable particularly for pharma applications, as well as those in food and biotechnology industries.

www.gea.com

Wacker Biotech grants MedImmune licence to use Esetec technology

Wacker Biotech, a subsidiary of German chemical company Wacker Group, has signed a licensing agreement with MedImmune for the use of its Esetec technology in *E.coli*.

No financial details have been released.

The agreement allows MedImmune to use Wacker's Esetec 2.0 cell line exclusively for the production and commercialisation of an antibody fragment (Fab). Fabs are purpose-made constituents of human antibodies and are a promising growth area for the pharma industry.

A feasibility study conducted by the two firms demonstrated that Esetec 2.0 was superior to existing technologies for the production of Fabs. It provided a high yield of correctly folded and biologically active Fab, as well as exhibiting enhanced productivity, which outperformed industrially optimised processes for mammalian cell cultures (CHO cells), said Wacker.

Based on this study, both firms agreed to produce the Fab at one of Wacker's cGMP facilities.

Dr Thomas Maier, Managing Director of Wacker Biotech, said: 'In regards to the production of hard-to-manufacture Fab, our proprietary system significantly outperforms commercially established processes. And our customers benefit from time savings and productivity gains compared with conventional CHO mammalian cell techniques.'

Wacker says the advantages of Fabs over whole antibodies are their ability to penetrate into the tissue and that they can be produced in microbial systems. The second-generation Esetec secretion technology makes high product yields of several grams per litre possible.

www.wacker.com/biologics

www.medimmune.com

EVENTS

17-18 November
Pharma Integrates 2015
London, UK
http://pharma.lifesciencesindex.com/2015-event/

17-18 November
GMP Inspections in Europe: Proven Strategies on How to Prepare
Dublin, Ireland
www.fdanews.com/gmpinspectionsineurope

17-19 November
Lyophilisation Technology
San Diego, CA, US
http://biopharma.co.uk/

18-19 November
Pharma Data Analytics Conference
Philadelphia, PA, US
www.marcusevans.com

23-25 November
Tabletting technology for the pharmaceutical industry
London, UK
www.rpharms.com

24-27 November
Pharmtech and Ingredients 2015
Moscow, Russia
www.pharmtech-expo.ru

25-26 November
Annual bioProcessUK Conference
Hinxton, Cambridge, UK
www.bioprocessuk.org/

25-26 November
23rd Annual Pharmig Conference
Belfry, Nottingham, UK
www.pharmig.org.uk

8 December
Good Distribution Practice (GDP) Symposium
London, UK
www.gov.uk/mhra

25-28 January 2016
15th Annual Temperature Controlled Logistics – Europe
Frankfurt, Germany
www.coolchaineurope.com