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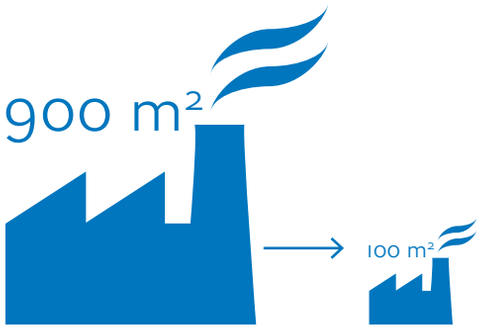
News

Highlighting the latest news in pharmaceutical bioprocessing

GlaxoSmithKline launches continuous processing technology

GlaxoSmithKline inputs US$50 billion technology into Singapore plant in a bid to improve cost efficiency.



"The technology...will require 100 m^2 in comparison with the current 900 m^2."

GlaxoSmithKline (GSK; London, UK) has recently announced that its Singapore plant will be switching to a manufacturing method of continuous processing. The technique, which has been in development for 5–6 years, will rely on much smaller sites with decreased operating costs.

GSK has reportedly invested up to US$50 million in testing the technology, which will require 100 m^2 in comparison with the current 900 m^2 used. The company expects that up to a half of its current portfolio of drugs will be produced by this method, which will replace old catalysts, often heavy metal-based, with enzymes.

"It will mean a shift from synthetic chemical reaction to enzymatic reactions, and a whole reframing of how we do analytical testing in all of our facilities. The net gain of all of that is a very significant reduction in process time, cost, carbon footprint inventory and speed," Andrew Witty, CEO of GSK, recently informed shareholders.

The company expects to improve yields and reduce energy costs as a result of a reduction in raw material use and wastage. According to Witty, the process will lead to "a massive reduction in capital deployment and space occupancy."

GSK has already started to deploy the method for some of its pipeline assets, such as for rare disease drugs. The company aims to accelerate the technology across the rest of the organization.

Sources: GlaxoSmithKline – Continuous manufacturing: www.gsk.com/explore-gsk/our-planet/continuous-manufacturing.html; GlaxoSmithKline commits to continuous processing: www.fiercepharmamanufacturing.com/story/gsk-commits-continuous-processing/2013–02–19?utm_medium=nl&utm_source=internal

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US FDA drafts guidelines on risk-based immunogenicity testing to boost protein development

Guidelines set out for developers to prevent adverse immunological effects of therapeutic proteins

The US FDA has recently set out draft guidelines on the immunogenicity assessment for therapeutic protein products. The guidelines, aimed at manufacturers and clinical investigators, will help to determine whether candidate protein drugs elicit dangerous immune responses and whether risk-mitigation strategies should be put in place.

The proposals set out in the guidelines are the first to cover the risk management of therapeutic protein products and according to the FDA Center for Drug Evaluation and Research, should be used in conjunction with the draft guidance on assay development for protein therapeutics issued in 2009. The recommendations include that immunoassays are created as part of the whole product development programme and that clinical trials should be used to establish baseline antibody responses to protein drug candidates, in order for them to be compared with trials at later stages.

The FDA believes that product efficacy and patient safety problems could arise from immune responses to therapeutic protein products. According to the FDA Center for Drug Evaluation and Research, past adverse immunological events "have caused sponsors to terminate the development of therapeutic protein products or limit the use of what might otherwise be effective therapies." The FDA hopes the guidelines will minimize the risk of "clinically significant immune responses."

Sources: US FDA – Guidance for Industry Immunogenicity Assessment for Therapeutic Protein Products: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM338856.pdf; FDA: risk-based immunogenicity testing will boost protein development: www.in-pharmatechnologist.com/Regulatory-Safety/FDA-Risk-based-Immunogenicity-Testing-will-Boost-Protein-Development

INDUSTRY NEWS

Merck and Samsung Bioepis enter into biosimilars agreement

Merck & Co. (NJ, USA) and Samsung Bioepis Co. Ltd, a joint venture between Samsung (Seoul, South Korea) and biotechnology company Biogen Idec (MA, USA), have formed a partnership for the production of multiple pre-specified and undisclosed biosimilar candidates. Merck will be responsible for the commercialization of the products, while Samsung Bioepis will supervise the candidates from preclinical and clinical development, to manufacturing, clinical trials and registration. According to Rich Murray, Senior Vice President of Biologics and Vaccines Research at Merck Research Laboratories, "The combination of Merck's global commercial presence with Samsung Bioepis' biologic development and manufacturing capabilities positions the two companies well to increase access to biosimilars to improve human health." The joint venture will receive an upfront payment from Merck and product supply income. According to Hansung Ko, CEO of Samsung Bioepis, "With this development and commercialization agreement, Samsung takes a significant step toward becoming a major player in the biopharmaceutical industry."

Source: Merck press release – Merck and Samsung Bioepis Enter Biosimilars Development and Commercialization Agreement: www.mercknewsroom.com/press-release/corporate-news/merck-and-samsung-bioepis-enter-biosimilars-development-and-commerciali

»» "The proposals set out in the guidelines are the first to cover the risk management of therapeutic protein products." ««

INDUSTRY NEWS

Selexis and Amgen agree licence for cell line expansion

Life science company Selexis SA (Geneva, Switzerland), has recently announced its partnership with Amgen (CA, USA), to expand its R&D licence agreement to include an evaluation of the Selexis SURE CHO-M cell line for research and development. The partnership will work towards improved R&D with the agreement allowing Amgen to evaluate the SURE CHO-M cell line, in conjunction with the Selexis SUREtech Vectors. Selexis focuses on drug discovery, cell line development and scale-up to manufacturing of therapeutic proteins. According to Igor Fisch, President and CEO, "Selexis is continually optimizing its proprietary cell line and technology platform to enable partners such as Amgen to make better R&D decisions by generating reliable data points faster and more cost efficiently."

Source: Selexis press release – Selexis Announces Expansion of R&D License Agreement with Amgen: www.selexis.com/Selexis-Announces-Expansion-of-R-D

Continuous processing plant for solid-dosage pharmaceuticals opened in Finland

Center to provide R&D on the continuous processing of solid-dosage form pharmaceuticals.

The PROMIS Center (Kuopio, Finland) was recently launched with the aim of increasing cost efficiency of processing solid-dosage form drugs. Located at the University of Eastern Finland, developers claim the site will be used for training purposes within the fields of pharmacy and engineering.

The production line is a collaboration between the University of Eastern Finland (Kuopio, Finland), the VTT Technical Research Center (Espoo, Finland), and the Savonia University of Applied Sciences (Kuopio, Finland). Also involved in the project are 20 corporate partners representing the pharmaceutical industry, measurement device developers and groups from the control and modeling sectors.

The PROMIS Center is the first of its kind in Europe and relies on process analytical technologies to monitor reaction conditions in real-time. In this method, raw materials are fed through the front of the system while continuous processing and synthesis steps allow for a constant supply of the end-product. According to PROMIS, "Continuous processing in pharmaceutical manufacturing is a way of making the manufacturing process simpler and faster while reducing the need to perform intermediate and final product analyses."

The plant consists of feeders, mixers, conveyers and a tablet machine, with the core component comprising a roller compactor for dry granulation. According to representatives at PROMIS, the project is "a good test bed for the pharmaceutical industry to study what kind of products can and should be manufactured using continuous processing." The team hopes that the technology will provide insight into the modifications needed in product composition.

Source:VTT technical research center press release – Unique continuous processing pharmaceutical production line to be introduced in Finland: www.vtt.fi/news/2013/22022013_pharmaceutical_production_line.jsp

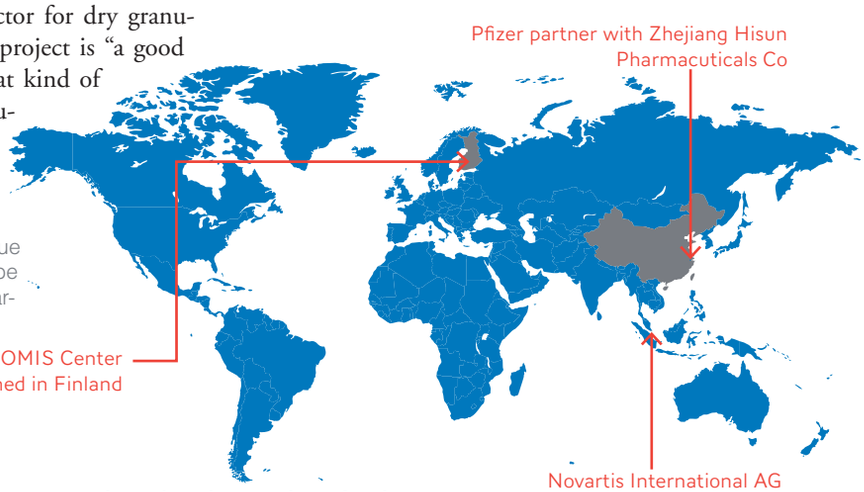
– All stories written by Phoebe Heseltine

INDUSTRY NEWS

Pfizer intensifies relationships with Chinese partners to aid growth

Global pharmaceutical company Pfizer (NY, USA) has announced that its growth within the Chinese market lies in a number of partnerships. The company has formed a joint venture with Zhejiang Hisun Pharmaceuticals Co. (Zhejiang, China), in which it aims to double staffing and collaborate on generic drug production. Pfizer also has a minority stake in Shanghai Pharmaceuticals Holding Co., Ltd, (Shanghai, China) a key drug distributor, with aims to expand its Prevenar vaccine sales in rural China. According to Wu Xiaobing, manager of Pfizer in China, "We are open for collaboration, if we were alone, it would take such a long time to make our drugs accessible to patients."

Sources: Pfizer press release – Pfizer And Hisun Announce Progress On Potential Joint Venture To Increase Access To High Quality Branded Generic Medicines: www.pfizer.com.cn/news/news_en.aspx?id=293; Pfizer eyes more chinese partners to speed growth: www.fiercepharma.com/story/pfizer-eyes-more-chinese-partners-speed-growth/2013–02–25?utm_medium=nl&utm_source=internal



INDUSTRY NEWS

Novartis opens first biopharmaceutical plant in Asia

Novartis International AG (Basel, Switzerland) has announced the opening of its first bio-manufacturing facility in Singapore. The plant will focus on commercial and clinical-scale manufacturing, engaging in process development. In October 2012 it was reported that the company had invested over US$500 million into the construction of the new cell culture production site, co-located with the organization's pharmaceutical production site in Tuas. According to Joseph Jimenez, CEO of Novartis, "This investment further strengthens our strategy to establish key strategic sites based on technological competencies. Singapore will be strengthened through a new facility for biotechnology, which is a growing segment of our business." The company expects the investment to build on its strategy of establishing sites based on the grouping of technical competencies.

Novartis press release – Novartis to start construction of new biotechnology facility in Singapore with an investment of over USD 500 million: www.novartis.com/newsroom/media-releases/en/2012/1653814.shtml