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BIOPROCESSING

News

Highlighting the latest news in Pharmaceutical Bioproccessing

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Molecular farming of pharmaceutical antibodies from tobacco hair roots

A global team of researchers have reported a novel process for the production of pharmaceutical antibodies from tobacco hairy roots.

A group of scientists have recently reported the production of a model pharmaceutical antibody by molecular farming, offering a process to increase yield and enable a more consistent glycan profile.

The research carried out by the team developed an optimized induction protocol for the production of the full sized monoclonal antibody M12 from tobacco hairy roots. This was achieved by optimizing the medium, using a statistical 'design of experiments' approach, and the expression process used, in which the antibody was secreted into the medium.

Talking to *Pharmaceutical Bioprocessing*, Ritala Anneli from VTT Technical Research Centre of Finland (Espoo, Finland), explained the initiative behind their research, "One of the key problems with all molecular farming platforms is the yield and consistency of the product. Well-established systems such as *Escherichia coli* and mammalian Chinese hamster ovary cells have benefited from many years of cumulative improvements. In certain ways, researchers using plants are having to play catch up." Anneli went on to explain, "The 'design of experiments' approach is so useful because it allows many different factors to be tested at once, in contrast to the earlier procedure of varying one factor at a time while holding the others constant."

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In addition, the process developed by the group can be applied to other biotechnology systems as explained by Anneli, "The 'design of experiments' approach can also be used to optimize other bioreactor platforms, such as aquatic plants growing in bioreactors, and plant cell suspension cultures."

Anneli explained the future work the group has planned, "Now we have established the principles of optimized production and secretion using a model antibody, we can apply a similar process to other pharmaceutical proteins, which will help to develop feasible large-scale processes that can be adapted to a GMP environment." Anneli continued, "The standardized approaches we have developed as part of the FP7 project CoMoFarm will allow us to rapidly test different plant-based platforms against each other to determine which is the most suitable for different products."

– Written by Jessica Thorne

Source: Häkkinen ST, Raven N, Henquet M *et al.* Molecular farming in tobacco hairy roots by triggering the secretion of a pharmaceutical antibody. *Biotechnol. Bioeng.* doi:10.1002/bit.25113 (2013) (Epub ahead of print).

FUTURE SCIENCE

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Contract development and manufacturing organization upgrades facilities

Vetter, who specialize in aseptic filling of vials, syringes and cartridges, are investing approximately US$100 million in their German and US production facilities, due to increasing demands from biotechnology and pharmaceutical industries. The investment will be used to increase efficiency in up- and downstream processes and to accommodate increased capacity at these sites.

This includes the implementation of two new advanced filling lines, which are currently being designed, for Vetter's Ravensburg South facility (Chicago, IL, USA). In addition, a new third line for pre-filling of syringes is being developed for Vetter's manufacturing facility, which is scheduled to be completed in 2014.

Vetter are also upgrading in a number of other areas, including expanding their single-use technology to stay ahead of regulatory requirements. One such technology is the single-use isolator technology which will reduce the risk of compound cross contamination. The investment will also be used to expand Vetter's storage capacity, for frozen, cold and room temperature products.

Thomas Otto, Vetter Managing Director, explained the initiative behind the investment: "At Vetter, we continually invest in meeting the needs of our customers. With these initiatives, we not only satisfy their demand for increased capacity, but continue to provide the kind of industry-leading facilities and high quality standards to be a reliable and efficient partner for our customers."

– Written by Jessica Thorne

Source: Vetter to construct new filling lines to expand capacity: www.vetter-pharma.com/en/newsroom

New tool to enhance cost–effectiveness of biopharmaceutical facilities

A group of scientists have developed a mathematical programming tool, termed mixed-integer nonlinear programming model, to assess the optimal design of chromatography equipment configurations, which can help reduce the costs incurred at biopharmaceutical facilities.

It is essential for facilities to find the most cost-effective processes for monoclonal antibody purification. Purification of monoclonal antibodies by chromatography can represent a significant proportion of a facilities production costs due to the cost of materials, such as buffers and expensive affinity matrices. This is especially important in facilities looking to increase output, as this increases the protein load through chromatography columns and therefore, can lead to bottlenecks in the production process.

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The method developed by the team, which was applied to a case study, determines the most "cost-effective chromatography equipment sizing strategies for the production of monoclonal antibodies." To enable the evaluation of the optimum chromatography settings within the facility the researchers examined the characteristics of the optimal chromatography sizing strategies, comparing different titer values enabled the maximum titer to be determined for a specific facility.

The research in which the researchers describe the new tool as a, "valuable decision-support tool for the design of cost–effective facility configurations and to aid facility fit decisions" was recently published.

– Written by Jessica Thorne

Source: Liu S, Simaria AS, Farid SS, Papageorgiou LG. Designing cost–effective biopharmaceutical facilities using mixed-integer optimization. *Biotechnol. Prog.* doi:10.1002/btpr.1795 (2013) (Epub ahead of print).

The editorial team welcomes suggestions for timely, relevant items for inclusion in the news. If you have newsworthy information, please contact:
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Biologics company granted new manufacturing license

In their recent press release, Fujifilm Diosynth Biotechnolgies, a biologics Contract Manufacturing Organization, have announced the company has been granted a renewal of their manufacturing license for their UK site (Billingham, UK).

The license has been granted from the UK's Medicines and Healthcare products Regulatory Agency, which follows an inspection that included assessment of their new cGMP mammalian cell culture manufacturing facility. Notably, the inspection detailed no critical or major observations and therefore, grants commercial manufacturing at the UK site. As detailed in the press release, the license also covers commercial manufacturing of microbial-based biologics in the company's large-scale manufacturing assets.

Steve Bagshaw, Managing Director of Fujifilm Diosynth Biotechnologies' UK site, commented on the news, "We are delighted to have received a renewal of our Manufacturer's Licence from the Medicines and Healthcare products Regulatory Agency." Bagshaw added, "Our customers can be assured that this demonstrates our commitment to quality and ultimately patient care, and confirms our position as a top player in the CMO field for both microbial and mammalian biopharmaceuticals."

– Written by Jessica Thorne

Source: Fujifilm Diosynth Biotechnologies' UK Site receives renewed Medicines and Healthcare products Regulatory Agency manufacturing licence: www.fujifilmdiosynth.com/about-us-news/news.asp?id=69

TAP Biosystems taken over by Satorius Stedim Biotech

Sartorius Stedim Biotech (Goettingen, Germany), a global supplier to the biotechnology and pharmaceutical industries, has made an offer to acquire TAP Biosystems, (Royston, UK) which specializes in design and development of small-scale, multiparallel fermentation systems. The acquisition by Satorius Stedim Biotech, through a subsidiary, valued TAP Biosytems at approximately US$44 million.

TAP Biosystems launched a novel single-use fermentor, which on a small-scale mimics mammalian cell culture, and therefore, provides an alternative to conventional systems. This technology will add to Satorius Stedim Biotech's single-use technologies range, as explained by Joachim Kreuzburg, the chief executive of Sartorius Stedim Biotech: "TAP Biosystems' fermentors are a great fit extending our reach into the small-scale cell culture applications. Adding capabilities in the early steps of upstream bioprocessing will enable us to provide our biopharma customers highly effective and scalable solutions to accelerate cell line selection, speed up process development and ultimately help them bringing their biologics to market faster."

David Newble, Chief Executive Officer of TAP Biosystems, commented on the acquisition, "As a market leader in bioprocessing technologies with a strong position in fermentation, Sartorius Stedim Biotech is well placed to maximize the opportunities of our novel, highly innovative cell culture technologies." Newble added, "We look forward to joining such a well-recognized organization as Sartorius Stedim that will enable us to grow our business further with a wealth of complementary technologies and products."

– Written by Jessica Thorne

Source: Sartorius Stedim Biotech announces offer to acquire UK company TAP Biosystems Group plc: www.sartorius.co.uk/en/detail/sartorius_stedim_biotech_announces_offer_to_acquire_uk_company_tap_biosystems_group_plc

Novartis acquires exclusive license for ImmunoGen's ADC technology

ImmunoGen, a company that develops targeted anticancer therapies, have announced that Novartis (Basel, Switzerland), which specializes in healthcare products, recently acquired an exclusive license for ImmunoGen's (MA, USA) antibody–drug conjugate (ADC) technology. The ADC technology, developed by ImmunoGen, is based upon an engineered antibody that is targeted to tumors to release a highly toxic agent to tumor cells.

Daniel Junius, president and chief executive officer of ImmunoGen, commented on the licensing agreement, "We believe the therapies Novartis is developing with our ADC technology have the potential to make an important difference for patients."

Novartis holds a second licensing agreement with ImmunoGen from 2010. ImmunoGen can potentially make approximately US$200 million from each license, from initial upfront payments, royalties and milestone payments for the sale of any of the products. In the terms of the licensing agreement, Novartis will undertake the responsibilities of taking the products from development through to marketing stages.

In addition to this licensing agreement, ImmunoGen also has partnership deals with several other pharmaceutical companies, including Amgen (Cambridge, UK) Bayer HealthCare (NJ, USA), Biotest (Solihull, UK) and Sanofi (Dagenham, UK), for products currently in clinical stage studies.

– Written by Jessica Thorne

Source: ImmunoGen, Inc. announces new license agreement: http://investor.immunogen.com/releasedetail.cfm?ReleaseID=796395