Pharmaceutical
BIOPROCESSING

News

Highlighting the latest news in Pharmaceutical Bioproccessing

Pharm. Bioprocess. (2013) 1(3)
229–232

Reducing downstream processing costs: a winning formulation

Chromatography reagent reduces cost of downstream processing and wins OneStart award, the largest biotech business plan competition in the world.

OneStart, the biotechnology business plan competition launched by Oxbridge Biotech Roundtable and SR One (the corporate venture arm of GlaxoSmithKline), has recently announced its inaugural winner. UCL-spinout Puridify won the coveted prize with their chromatography reagent FibroSelect. The team, consisting of Oliver Hardick, Tom Haywood and Iwan Roberts, won OneStart's GB£100,000 non-dilutive prize, in addition to laboratory space and membership to various life science networks. Also included in the prize is business and intellectual property support, to further develop their technology to bring it into the pharmaceutical market.

Fibroselect is a chromatography reagent that aims to reduce downstream processing costs by 90% – it achieves this by overcoming current limitations in downstream steps. The company has proven at research scale that the technology can operate at 50-times throughput – attributing this to "better permeability and fast mass transfer." In addition to increasing productivity, this offers an advantage for the processing of labile products.

Speaking exclusively to *Pharmaceutical Bioprocessing*, the team explained how the evolving pharmaceutical market highlights "the limitations of current purification operations demanding a step-change improvement in processes." By increasing the productivity of purification steps, the new technology addresses these limitations, whilst reducing production costs. The team commented on how this affects the bigger picture. "Such cost reductions can facilitate product development and ultimately help broaden patient access to expensive biotherapeutics."

Commenting on the impact of winning the competition to the company, they continued, "winning OneStart has allowed Puridify to take the first steps to becoming a successful UK biotechnology company … the exposure from the competition has allowed us to build connections across the industry and we see this as being crucial to our development."

Looking to the future, the company describes their prime goal as "developing and building a production-scale prototype to fully test the technology". This, they hope, will demonstrate the full performance advantages offered by their system.

– Written by Alice O'Hare

Source: Oxbridge Biotech Roundtable News: www.oxbridgebiotech.com/review/onestart/onestart-winner-announced

/// The company has proven at research scale that the technology can operate at 50-times throughput. ///

FUTURE SCIENCE

10.4155/PBP.13.35 ISSN 2048-9145

Long-term pharmaceutical industry alliance formed in Japan

Pharmaceutical partnership to develop and commercialize five drugs.

Amgen and Astellas have forged a long-term alliance to develop and commercialize five Amgen drugs in Japan. The partnership will operate under the name "Amgen Astellas BioPharma KK", and hopes to launch the first of the Amgen drugs under development there in 2016. It is anticipated that with this joint venture, Amgen will build new facilities in Japan – another step towards bringing to an end the absence of Amgen across Asia.

The announcement comes soon after the confirmation of a new joint venture between Amgen and a Chinese firm, Zhejiang Beta Pharma CO, to sell Vectibix™, a colon cancer drug.

The alliance plan to start operations 1 October 2013, with a view to launching its first medicine, romosozumab (which is currently in Phase III testing), by 2016. Other pipeline medicines the partnership will focus on include those to treat gastric cancer, two types of blood cancer, osteoporosis and hyperlipidemia.

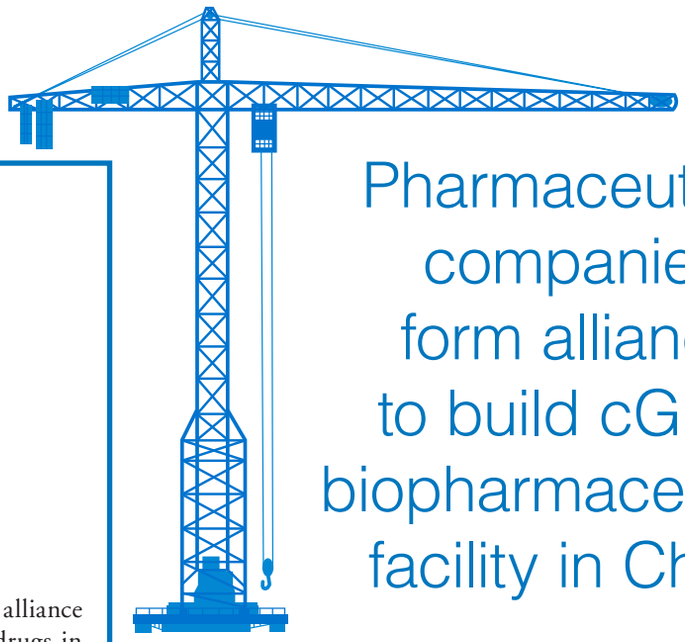
"Through this alliance, Amgen will work closely with Astellas to leverage its extensive knowledge of the local market," said Robert Bradway, chairman and chief executive at Amgen.

Yoshihiko Hatanaka, President and Chief Executive of Astellas, said: "We look forward to entering this alliance with Amgen and believe it will strengthen our pipeline to address unmet medical needs, as well as enable us to obtain growth drivers. We will work closely with Amgen to build the joint venture, which will provide innovative medicines to patients in Japan."

It is anticipated that the collaboration will be wholly owned by Amgen by 2020, yet the partnership between the two companies will continue after this and will enable Astellas to develop more oncology drugs.

– Written by Rosanna Hill

Source: Amgen and Astellas forge long-term alliance: www.pharmatimes.com/Article/13–05–29/Amgen_and_Astellas_forge_long-term_alliance.aspx



Pharmaceutical companies form alliance to build cGMP biopharmaceutical facility in China

Boehringer Ingelheim enters strategic alliance with aims to raise cGMP standards for contract research organizations.

Global pharmaceutical company Boehringer Ingelheim (Ingelheim, Germany) has recently announced its partnership with Zhangjiang Biotech and Pharmaceutical Base Development Company (Pundong, Shanghai), with aims to build a cGMP biopharmaceutical facility.

Christian Boehringer, Chairman of the Shareholders Committee at Boehringer Ingelheim, commented on the alliance, "Our partnership with Zhangjiang Base Company is an important step in our global China strategy as it opens a further opportunity for Boehringer Ingelheim to participate in the growing demand for high-quality biopharmaceuticals in China." He continued, "Shanghai is our ideal partner with its advantages in investment environment, service system and talent resources."

The facility will be the first set up by an international company to utilize mammalian cell-culture technology in China, providing a range of development and clinical services to customers both Chinese and multi-national. Boehringer Ingelheim will reportedly invest more than €35 million in the facility.

Zhangjiang Base Company aims to initiate the contract manufacturing organization framework at the plant. According to Lanzhong Wang, General Manager of Zhangjiang Base Company, "We are very pleased to start the partnership with a leading biopharmaceuticals company such as Boehringer Ingelheim. Through the cooperation, we hope to bring the know-how, technology and experience all up to international standards. With a number of innovative medicines being developed by a cluster of middle to small-sized innovative companies in Zhangjiang, plus the government support, we plan to initiate the CMO manufacturing framework at this plant on a trial basis. This will provide an effective platform for middle and small-sized companies to industrialize their innovations. Thus, it will greatly prompt the development of China's biopharmaceuticals manufacturing industry." The facility is due to be completed for operations in early 2016.

– Written by Phoebe Heseltine

Source: Boehringer Ingelheim press release: Boehringer Ingelheim pioneers biopharmaceuticals move to China: www.boehringer-ingelheim.com/news/news_releases/press_releases/2013/06_june_2013_biopharmaceuticalsinchina.html

Automated technology for fast protein sample preparation to be co-marketed

Perfinity and Thermo Fisher to collaborate on automated system.

Perfinity, a biotech company based at Purdue Research Park (IN, USA), has recently signed agreements with Thermo Fisher Scientific Inc. to co-market an automated system for protein sample preparation and analysis.

The system will incorporate the expertise of both companies – with Perfinity offering the automated sample preparation system, and Thermo Fisher offering LC–MS instrumentation. The automated system offers a much faster turnaround time for the time-consuming trypsin step that must be followed prior to MS analysis of peptides – reducing this from an average of 18 h to less than 2 min.

Robert Ellis, chief executive officer at Perfinity, explained the importance of such technology in pharmaceutical bioprocessing. "Pharmaceutical manufacturers cannot wait for 24 h to monitor the purity of each batch of protein-based product. When proteins oxidize, things can go bad quickly, and this is very costly. We developed our automated sample preparation platform to generate results quickly enough to let customers protect the value of each batch before it is too late. Now, with the Thermo Scientific LC and MS instruments, we offer a complete system from automated sample preparation through data reporting."

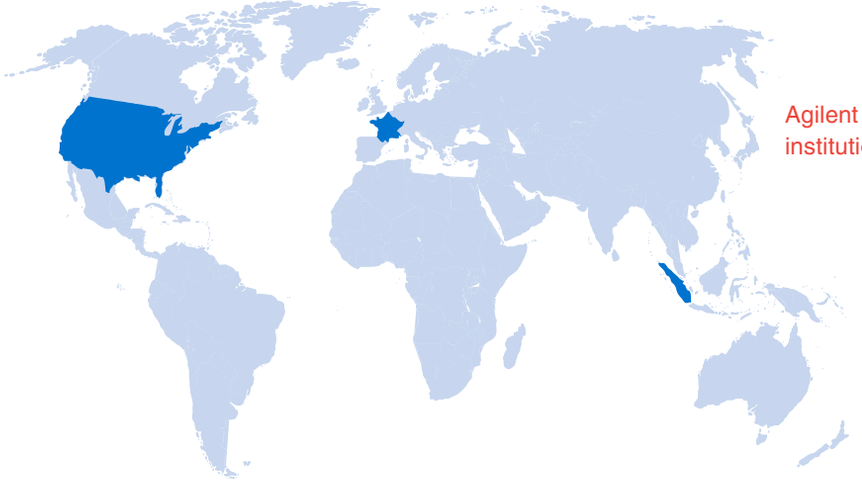
Based on Perfinity's trypsin columns, the system will incorporate three columns, alongside the automation elements. This will be linked with Thermo Scientific UltiMate 3000 UHPLC systems and, depending on customer's requirements, a choice of Orbitrap-based hybrid or triple quadrupole mass spectrometers.

Patrick Bennett, Thermo Fisher's director of marketing for the pharmaceutical industry, commented on the collaboration: "A major goal at Thermo Fisher is to create efficiency and productivity throughout the biopharmaceutical value chain, and Perfinity's approach to in-process analysis meshes nicely with these plans."

– Written by Alice O'Hare

Source: Purdue News: http://purdueresearchpark.com/news/perfinity-thermo-fisher-scientific-sign-co-marketing-agreement-automated-online-biopharmaceutic

Collaboration announced for development of biologics analysis



Agilent Technologies to collaborate with two academic institutions to further biologics research.

Agilent Technologies (CA, USA), the University of Rouen (France) and the Bioprocessing Technology Institute (BTI) at the Agency for Science, Technology and Research (Singapore) are to collaborate in developing analytical tests for biologics – molecules such as antibodies that are used in combination with vaccines. Biologics are a particular bioanalytical challenge due to their size and heterogenous structure.

The collaboration will pool the expertise of the three partners. The glyco-MEV laboratory at the University of Rouen provide expertise in the production of biologics in plant cell systems; the researchers at BTI are currently developing methods to analyze biologics in animal cells; and Agilent bring expertise in developing new methodologies that are both sensitive and high-throughput.

Agilent's director of science and technology, Rudolf Grimm, commented on what Agilent brings to the partnership. "This research initiative enables scientists to optimize glycan analytical workflows on the Agilent HPLC-Chip/MS system. We look forward to working with these leading organizations to drive discovery in this important field."

When used in combination with vaccines, biologics – normally processed in living cells – are used in the prevention and treatment of numerous diseases and conditions. An important part of the R&D process is being able to confidently analyze such pharmaceuticals in biological samples. Commenting on the importance of such studies, Executive Director of BTI, Lam Kong Peng, stated: "With increasing use of biologics to treat human diseases and with more biosimilars coming to market in the next few years, it is timely for BTI to develop novel technologies that would improve the characterization and analysis of protein-based drugs."

Peng commented on additional benefits of this agreement: "This collaboration would enhance Singapore's reputation as a world-class destination for biologics manufacturing and R&D." Patrice Lerouge, director of the Glyco-MEV laboratory at the University of Rouen, also commented on the benefits of this collaboration to their institution: "We hope that such a research initiative will facilitate exchanges of laboratory members and PhD students between Singapore and France."

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– Written by Alice O'Hare

Source: Agilent Press Release: Agilent Technologies, University of Rouen and A*STAR's Bioprocessing Technology Institute to Further Innovation in Biopharmaceuticals and Glycomics: www.agilent.com/about/newsroom/presrel/2013/22may-ca13030.html

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