

Managing the development of innovative biopharmaceuticals

Eden Biodesign, which provides consultancy, process development, cGMP manufacturing and analytical development for biopharmaceutical products, and operates the UK's National Biomanufacturing Centre, has established a number of significant research collaborations for innovative therapeutics and is looking to expand its activities on a global basis.

Biomanufacturer Eden Biodesign Ltd has just announced the extension of its collaboration with Cambridge, UK-based ImmBio to develop an innovative influenza vaccine. The manufacturing agreement uses ImmBio's ImmunoBodies™ technology which is adaptable for the different subtypes of influenza, including high-pandemic risk H5 and current seasonal H3. In September, Eden Biodesign signed agreements with Cancer Research UK to provide consultancy, process development and manufacturing services for two of CR-UK's leading gene therapy products: AdhTR-NTR for advanced intra-abdominal cancer and Ad.CP62 for head and neck cancer. The company is providing strategic advice to produce an effective development plan that will optimise the preclinical process with a view to expediting clinical

MEET ROGER LIAS OF EDEN BIODESIGN

Dr Roger Lias was appointed president of Eden Biodesign, Inc last month, and is responsible for identifying and establishing strategic business partnerships and expanding Eden Biodesign's offer to the large US biopharmaceutical sector.

He was previously vice president of sales and business development at Cytovance Biologics, and prior to that was at KBI BioPharma, a start-up contract biomanufacturing company. He has also worked for Diosynth and for Lonza Biologics.

Dr Lias completed his Bachelor of Science in Physiology and Biochemistry at Southampton University followed by a PhD at Cambridge University in 1986.



A bioprocess chromatography system in a cGMP suite at Eden Biodesign.

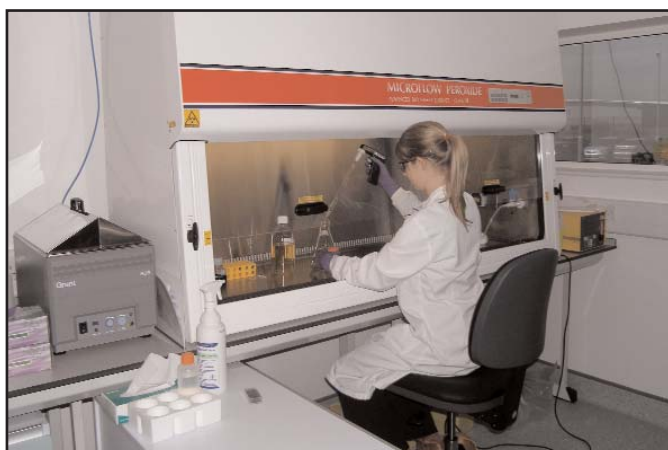
manufacture and supply. It is also developing the manufacturing process and associated analytical testing for these novel therapies.

"We are excited to be working with ImmBio and it once again demonstrates Eden's track record of assisting clients via our consultancy business with the establishment of fundable development plans and continuing to support the client company as it progresses products into clinical evaluation," says Dr Roger Lias, the newly-appointed president of the company's North American operation, Eden Biodesign, Inc. "We seek to form long-term relationships with all of our clients and to continue to work with them as their products progress through clinical development to market launch. It is always gratifying when clients expand existing projects or previous customers return with new projects. We can genuinely say that we measure our success by the success of our clients.

"We have been working with Cancer Research UK to provide support for gene therapy," he continues. "The relationship exemplified Eden's approach: having firstly undertaken consultancy to assist their research team plan their development programme, we then completed technology transfer to ensure that a small-scale process was operating equivalently in our development labs to the process operated at the cancer institute. Only then did we optimise production to establish a prototype process suitable for clinical manufacture which we are now progressing into our cGMP manufacturing suite."

Working across a broad technology range

Eden Biodesign was incorporated as a spin-out company from Celltech Medeva in 2000, initially focusing on CMC consultancy services. During the course of its various projects the company has worked on technologies ranging from products from human cells, recombinant proteins and antibodies through to vaccines and gene therapy.



Performing cell culture in the process development laboratory.

"It became apparent to us during our consultancy work that many of our clients were being under-served by the contract process development and manufacturing market in terms of both the breadth of services being offered and the level and depth of scientific and technical knowledge and experience being brought to bear on client projects," says Lias. "In 2002, we used the opportunity to design and run the UK National Biomanufacturing Centre in Liverpool to leverage our considerable clinical development experience and establish a technically excellent contract services business that promises all clients a committed service plus the knowledge and expertise to guide them through process development, manufacturing, regulatory and technology transfer challenges.

"Eden Biodesign offers its process development and cGMP manufacturing services to the global marketplace on a fee-for-service basis under easily accessible terms. Eden is much more than 'just' a CMO, however. While clinical manufacture is at the heart of the business, we are also able to use our considerable biopharmaceutical development experience and the principles of 'good science' to guide and assist clients large or small through almost every aspect of clinical development," he says.

Centre for biomanufacturing

The UK National Biomanufacturing Centre is owned by a development arm of the regional agency that manages a range of properties in Liverpool. Eden Biodesign pays a rent and has been tasked with a range of outputs relating to training and support for inward investment as an adjunct to the city's claims as the centre for biomanufacturing in the UK and one of the top three in Europe.

"Liverpool is already home to biopharmaceutical manufacturing hubs for such established industry leaders as Eli Lilly, MedImmune and Novartis," says Lias. "Negotiating the complex legal and financial issues was obviously a central part of the project initiation. It took nearly two years to establish approval from central and European government reviews."


Surge in innovation

"Biopharmaceutical production is a very complex and highly-regulated endeavour. The extremely strong growth in the overall biopharmaceutical market and the related increase in demand for biopharmaceutical production, along with the need to manufacture these exciting and important products cost-effectively, has led to a surge in innovation and attracted the interest of many multinational companies that may not be immediately associated with pharmaceuticals. We recognise that Eden Biodesign must stay on top of these developments in order to provide the best service and most appropriate solutions to our

clients. For this reason, we work hard to maintain our extremely good network of industry contacts with companies and academic institutions with interests in expression technologies, disposable processing systems, high-throughput technologies, novel separations and chromatography techniques and so on," he says.

"We also have close relationships with a number of third parties that provide services that are complementary to those offered by Eden Biodesign and other potential collaborators that are able to help us deliver value to our clients. As part of my new role as president of Eden Biodesign, Inc I will be using my previous experience and contacts to increase the number of these relationships that we have with North American organisations."

Eden Biodesign, Inc is a newly-incorporated wholly-owned subsidiary of Eden Biodesign Ltd set up to establish a bridgehead into the critically important North American marketplace. "My first objective is to establish a professional business development organisation 'Stateside'," says Lias. "Beyond that, however, it makes sense for us to establish an operation in the USA that will allow us to properly serve American and Canadian clients; to establish the Eden Biodesign brand and to make it easier for North American clients to get to know us and to access our manufacturing services in the UK. We have established that there is a market need for the development of robust, productive and compliant production cell lines and strains that will not only facilitate rapid entry into the clinic, but will also stand the test of time with respect to long-term process economics and regulatory scrutiny. It is in this area that we will be focusing initially as we develop a range of development services that are highly complementary to our existing business.

"I believe that the prospects for Eden Biodesign, and the contract biopharmaceutical manufacturing sector as a whole, are extremely good over both the short and long term. As I indicated earlier, the overall biopharmaceutical market is very strong at the moment, with an ever-increasing proportion of therapeutic and vaccine products entering clinical development and progressing to licensure being derived from 'biotechnology'. We are seeing dramatic advances in areas such as our understanding of the genome, genetic therapies, personalised medicines, stem cell therapies, immunotherapies and so on. Importantly, both the capital markets and the world's major pharmaceutical companies have recognised these trends and continue to invest heavily. Given the level of innovation, size of the current pipeline, and the length of development cycles for this class of products, I anticipate that demand will remain strong for a long time to come," he concludes. 

FURTHER INFORMATION

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