

## UK Bioprocessing – An Overview

*an interview with*

**Tony Bradshaw and Malcolm Rhodes**

*Director, bioProcessUK and*

*Technical Director, bioProcessUK*

Dr Tony Bradshaw joined the British BioIndustry Association (BIA) in 2004 and is currently Director of bioProcessUK. He earned his PhD in biochemistry from Heriot Watt University, Edinburgh, in 1988. He then worked as Biotechnology Business Development Advisor for British Sugar. In 1994 Dr Bradshaw was Director of Business Development for University College London's Advanced Centre for Biochemical Engineering from where he moved to Ruston Poole and Harvey Nash to Executive Search in 1999 recruiting senior management for early stage bioscience companies.

Dr Malcolm Rhodes is Technical Director, bioProcessUK. Dr Rhodes joined BIA from Serologicals Corp. where he has worked since 1996 in a number of roles in both the UK and US, most recently as Director of Scientific Operations at Global R&D. He played a pivotal role in the success of Bioscot (now Celliance Ltd.), which has been part of the Serologicals Corporation since 1989. He has also worked as Director of R&D at Archaeus Technology Group and was Head of Process R&D at Celltech (now Lonza Biologics) and in bioprocess development at Pfizer. Dr Rhodes has a PhD in Biochemical Genetics from University College, London.

### Background to bioProcessUK

The BioIndustry Association (BIA) promotes the human health benefits of new bioscience technologies, and encourages the commercial success of the bioscience industry by focusing on emerging enterprise and the related interests of companies with whom such enterprise trades.

In January 2003, the Bioscience Innovation and Growth Team (BIGT) was launched by the UK Department of Trade and Industry (DTI) and the UK Department of Health in partnership with the BioIndustry Association. Its mandate was to formulate a strategic approach to the future of the UK's bioscience industry.

The consequent investigation into the overall UK bioscience sector resulted in the Bioscience 2015 report. Recommendations from the report led to the establishment of bioProcessUK, a DTI Knowledge Transfer Network (KTN).

### Q. What role has the BIA played in shaping the UK bioprocessing sector?

*Dr Tony Bradshaw:* The BIA was part of the team behind the Bioscience 2015 report, which recommended a way forward for the sector. (The report is available online at the BIA website: <http://www.bioindustry.org/bigtreport/>)

One of the six recommendations from the report was that the UK should build a strong biopharmaceutical bioprocessing sector. More specifically, the report recommended building on the existing base in bioprocessing. The recommendations included establishing a network of centres of excellence, conducting next horizon research, building a network of individuals in the sector, and leveraging the expertise to drive trade and inward investment.

In January 2005, the UK government, through the DTI, awarded funding to establish one of 19

knowledge transfer networks in the UK, bioProcessUK. bioProcessUK is managed by the BIA, although it operates as a separate business unit.

bioProcessUK was created with the aim of developing a really strong R&D product, harnessing the UK's capabilities in biopharmaceutical development and bioprocessing to attract companies into the UK, and is therefore the mechanism to deliver the bioprocessing recommendations in Bioscience 2015.

One of the first activities of bioProcessUK has been a benchmarking exercise, which has analysed the UK position in bioprocessing, conducted by our technical director, Malcolm Rhodes. His research shows the UK has a strong platform in this area, which can be improved by further investment.

### Q. There has been a steady growth in the industry over the years. What is the state of the industry at present?

*TB:* The industry is in a state of real change. We know that the UK has the second best portfolio of biopharmaceuticals in the world. Although the US is well ahead, the UK is doing much better than we thought.

Bioprocessing is the life-blood of this sector. It is the key technology that gets these biopharmaceuticals onto the market. The manufacturing of biopharmaceuticals is very important, since the methods used in production define the product. If you change the production method, you get a different product.

The combination of the UK's strong bioprocessing base with its strong biopharmaceutical base gives companies a competitive position.

We are very excited about the potential of the UK's existing biopharmaceutical portfolio. If we achieve greater activity in the bioprocessing aspect and help companies to transition products produced in test tubes to ones that are fit for clinical trials, obviously it will add great value to those companies.

**Q. How do the BIA and bioProcessUK work together in this area?**

*TB:* The BIA and bioProcessUK have quite distinct roles in this area. At bioProcessUK, our role is to help develop the bioprocessing sector in the UK, whereas the BIA's role is to help create the right business environment for biotechnology companies to thrive in. Additionally, being based at the BIA we are closely involved in the activities of the public affairs team, who are pivotal in developing a supportive business environment for biopharmaceuticals.

**Q. What are the key challenges facing bioprocessing?**

*TB:* One of the key points we need to address is the provision of tax concessions for UK manufacturers. Competitor countries, such as Ireland, Switzerland, Singapore and Puerto Rico, provide a favourable environment for pharmaceutical and biopharmaceutical manufacturers, whereas the UK does not. This has kept the UK behind some competitor countries and means we are at a competitive disadvantage with respect to licensed product manufacturing.

the academic base underpins the whole development of bioprocessing technology.

bioProcessUK acts as a co-ordinator and ensures that BRIC is meeting industry needs, without damaging the integrity of academic research.

**Q. What is the current financing environment like?**

*TB:* One of the key issues is that the European investment community is more risk-averse than in the US. Companies in the US have access to greater financing, which they can use to take their products forward. In Europe, because of the more limited funding options, we have seen evidence of merger and acquisition (M&A) activity or relocation of activities to the US as a means of progressing the product pipeline.

Recently, Cambridge Antibody Technology (CAT), which is at the forefront of biopharmaceutical development in the UK, was acquired by AstraZeneca and will no longer exist as an independent bioscience company. Instead, AstraZeneca will use CAT as the core around which it will build its biotechnology drugs capabilities.



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One critical area is the funding of research and education, which has been very piecemeal over the last 10 years.

We have canvassed the industry, and they told us that additional funding is needed to develop the skills base for the sector. In response to this demand, bioProcessUK, along with the research councils, has secured industry financial and in kind investment into a Bioprocessing Research Industry Club (BRIC), which brings together members of the industrial and academic communities. BRIC is investing over £10 million of public sector money into the academic base with a further £1 million contributed by industry. This helps the academics: they see increased funding streams and are able to channel their resources into bioprocessing because they can see a long-term future. This investment in

**Q. What are the prohibitive costs for the small start-up?**

*TB:* The manufacture of biopharmaceuticals to the right standards is vital. The clinical trials directive has required companies to produce Good Manufacturing Practice (GMP)-standard product for use in clinical trials, as well as for products on the market. This manufacturing process can be costly and companies often underestimate the cost of producing a high quality product. As a result, companies with good quality product candidates in the lab are often unable to afford to fund large-scale development required for clinical trials. As their finance runs out they can become easy targets for larger companies.

In the UK we need to identify how to capture the value of the biopharmaceutical pipeline. If companies

are able to get to phase II through their own manufacturing process, they add more value to their products, which gives them a better chance of licensing the product to other companies.

**Q. In your opinion is there a big skills gap in the UK?**

*TB:* You can always be general and say yes, but it is important to look deeper, and it is hard to get good data. We know it is difficult for a company in our sector to recruit large numbers of people, for example five to ten. We are right on the edge of skills becoming a significant bottleneck. A recent piece of research, commissioned by bioProcessUK, confirmed that 80% of industrialists in the UK's bioprocessing sector consider the lack of sufficiently skilled people to be a significant problem, and with anticipated growth of the sector nearly all respondents felt this will become a major issue in the future. Therefore, we will urgently need to address the development of talented people at the bioscience–engineering interface.

*TB:* You cannot underestimate the challenge from China and India, particularly India. However, the UK has a much stronger biopharmaceutical pipeline than most of its competitors. If there is a move to small-scale flexible manufacturing, countries such as the UK, with strong pipelines and supply chains, will be in a stronger position, because the manufacturing needs to be close to the pipelines and the process knowledge base. I think it will be hard for India or China to compete quickly in this area, but they can certainly compete on large scale bioprocessing.

*Dr Malcolm Rhodes:* The bigger question is whether the UK would be able to cope against the countries that have tax concessions. The government has a big role to play in that. It is very simple: anyone wanting to invest in manufacturing a marketed product is unlikely to consider the UK, which is very disappointing. The government needs to take steps to address that. If the UK wants to have a biopharmaceutical or, for that matter, a

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From a research perspective, this is being addressed through the research councils and increased funding through the BRIC initiative. However, we are also looking at the types of skills required. A pure scientist who does not understand other scientific disciplines would be less useful than one who can cross disciplines. We need more people who are numerate biochemists, and who can also apply engineering principles. We are looking at initiatives to address that.

Because many of the companies in the UK bioprocessing sector are small, there is another key issue in that individuals need not only multidisciplinary science-based skills but also a solid understanding of the business environment, where they can be highly exposed.

**Q. Globalisation could effectively move manufacturing jobs overseas where labour costs and regulations are more favourable. What strategies can communities and biotechnology companies use to protect jobs and leadership in the area?**

biomanufacturing base in 10 or 20 years time, the government will have to change the tax position, otherwise it will all move offshore. Currently, the UK has a positive balance of payments in pharmaceuticals but there is a danger of this becoming negative if new drugs entering the market are not manufactured in the UK. The UK should concentrate on getting novel biopharmaceuticals onto the market.

One major advantage the UK has over its competitors is the National Health Service (NHS). Access to this national body that purchases drugs is a very important issue. The BIA, rather than bioProcessUK, plays an active role in trying to get innovative medicines onto the market more quickly in the UK. That might be a real driver for companies to develop their products in the UK.

Already, about one-third of products in development are biopharmaceuticals. It seems inevitable that they will eventually take a bigger chunk of the pharmaceuticals market. Overall, the whole picture is very positive. ■