

# Expanding the experimental space

**Biomanufacturing requires careful separation of the molecule of interest from other cellular products to ensure the quality and stability of the final product. This is even more important for the manufacture of biotherapeutics, as the presence of unwanted molecules in pharmaceutical preparations can affect the efficacy and safety of biologically-derived drugs. FUJIFILM Diosynth Biotechnologies is using automated chromatography condition screening to generate more data in less time, helping to improve the performance of purification processes and accelerate biological drug manufacturing.**

Biotherapeutics are now the key growth area for pharmaceutical manufacturers globally, but the complexity of manufacturing biological drugs means that there are significant costs associated with the development of scalable production and purification processes. Rather than cultivating in-house expertise in production bioengineering and purification, many pharma and biotech companies now partner with contract development and manufacturing organizations (CDMOs) for the production of new biotherapeutics. FUJIFILM Diosynth Biotechnologies has over 20 years of experience in process development and cGMP manufacturing for biologically-

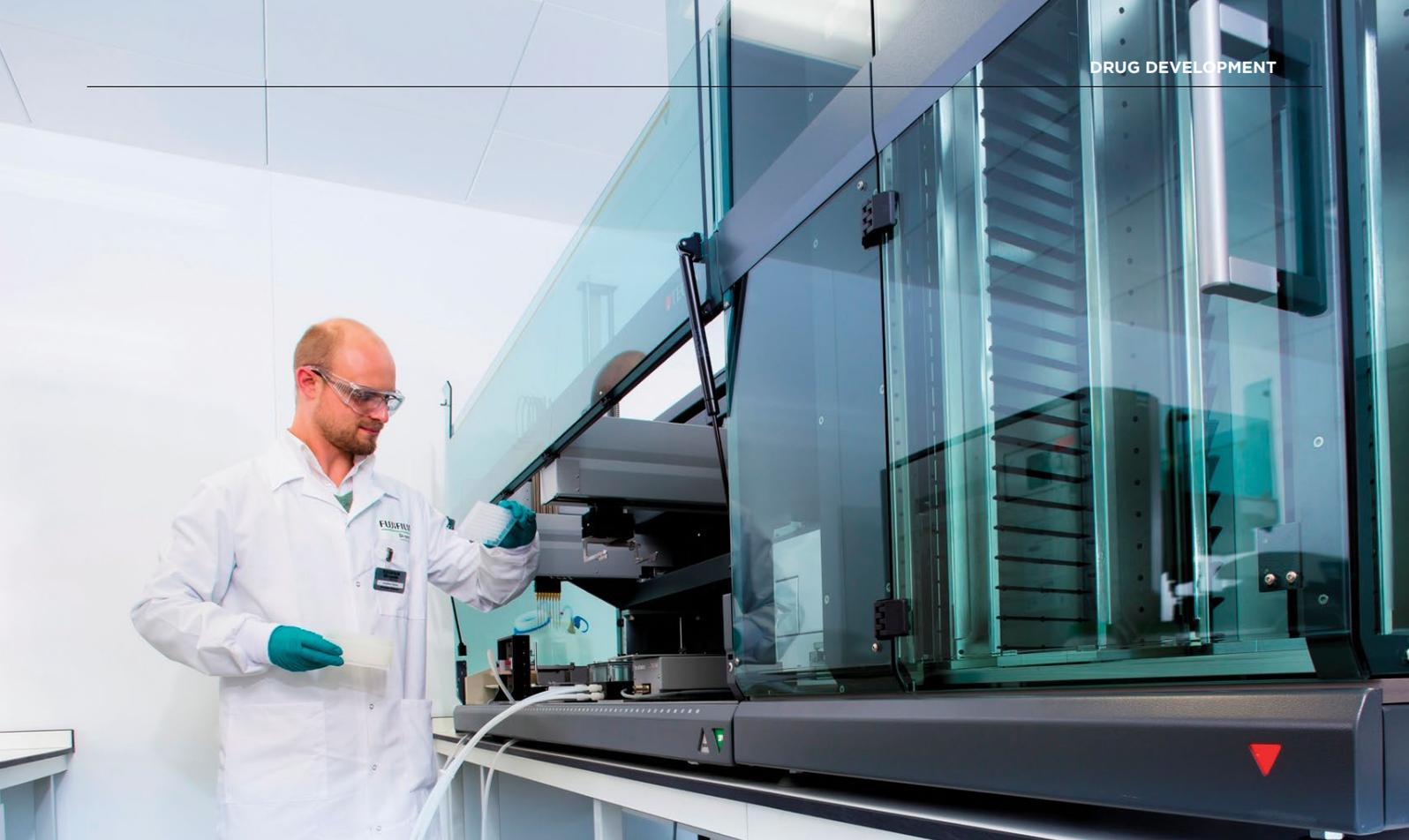
derived medicines, and works with some of the most prominent biotech developers and pharmaceutical companies in the industry.

The company's UK site near Billingham specializes in microbial expression platforms - mainly yeast and *E. coli* - and has developed a high throughput chromatography workflow to help select and optimize its purification processes. Jonathan Rapley, Staff Scientist in High Throughput Process Development, explained: "The cGMP manufacture of biotherapeutics requires the careful separation of the molecule of interest from other cellular products and components to avoid off-target

effects. This process is complex even for large macromolecules derived from mammalian cell lines, such as monoclonal antibodies (mAbs), but is even more difficult when using microbial expression systems. Column chromatography is the method of choice for most biomanufacturing applications, and so we need the ability to screen a wide range of chromatography resins and parameters to ensure high purities and yields for our pharma customers. This is both labor intensive and time consuming to perform manually and so, historically, the scope of these screens has been limited by the development timelines of each project."



Automated chromatography condition screening helps to generate more data in less time



The Freedom EVO 200 offers complete automation of resin and condition screening

“The Freedom EVO platform is a truly open laboratory automation solution; you can make it do almost anything.”

“Automation of chromatography condition screening is an obvious way of increasing the number of parameters that can be investigated with the available time and resources, and so in 2015 we looked at the options available for this application. The combination of the Freedom EVO® liquid handling workstation and RoboColumns® (Repligen) was an ideal solution for our needs, as this would allow us to run eight pre-packed miniature chromatography columns in parallel, without the need for any manual intervention. We invested in a Freedom EVO 200 platform, giving us enough worktable space for all the reagents required to screen eight different resins at three different pHs per run. The increase in capacity offered by this set-up means that we are now able to screen far more parameters for each project within the same timeframe.

Using design of experiment principles, we can fully explore the experimental window, instead of having to investigate a far smaller number of combinations of resins and buffer conditions based on previous experience. This ensures more complete data sets and helps our project managers to make better informed decisions regarding production processes, ultimately benefitting our customers.”

“The increase in the number of experiments we can perform has obviously led to a significant rise in downstream analyses, as each screen generates six 96-well plates of samples. To help us deal with this, we have also invested in a Freedom EVO 100 platform. The system is configured for ELISA testing, but the open architecture of the Freedom EVO workstation means that, as we have become more familiar with the software, we have also begun using it to automate sample preparation for other analyses, such as HPLC or capillary electrophoresis. This broad range of capabilities is a real benefit of Tecan systems. Unlike many other instruments, which are restricted to single applications, the Freedom EVO platform is a truly open laboratory automation solution; you can make it do

almost anything if you put the time into programming it.”

“Both myself and a colleague have been on Tecan training courses to further explore the potential of these workstations, and we are now the ‘super users’ who program new applications and support other users, which is working really well. As more and more people have begun to understand the capabilities and advantages of the systems, demand is really ramping up; we’re increasingly running them overnight and at weekends to meet demand,” Jonathan concluded.

All Tecan products mentioned are for research use only. Not for use in clinical diagnostics.

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