Tecan Casebook.

FLUENT® SPECIAL EDITION 2019

Interesting Cases in

FOOD TESTING
GENETIC SCREENING
STEM CELL RESEARCH
ANTIBODY SUPPLY CHAIN
...AND MUCH MORE

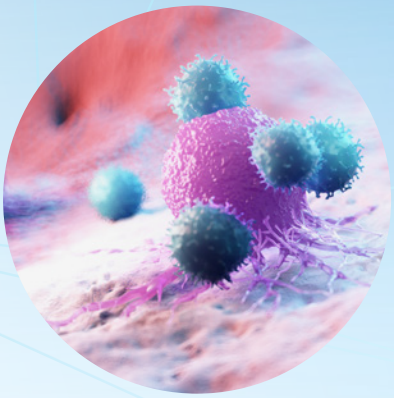
Welcome.

Our customers' research is changing the world for the better, furthering our understanding of our surroundings, from fundamental science to diagnostics and applied markets. In a constantly changing environment, balancing the demands of a busy laboratory and the need to achieve reliable results can be a challenge, with manual processes reducing productivity and leading to errors.

At Tecan, we have made it our mission to empower every laboratory, every day, with our technologies, automation solutions and support. We're helping our clients to achieve their goals and improve processes, increasing efficiency and streamlining workflows. Discover how Tecan could help you achieve your goals in this casebook, where we've collated some truly inspirational stories from our customers – and your colleagues – who have been able to achieve more with products from Tecan. Have a read and see what you could accomplish.

Every Lab.
Every Day.
Empowered.

Hal Wehrenberg
Head Product Management of Tecan Life Sciences



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Confidence in drug discovery

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Taking a Fluent® approach to genetic screening

Contents.

How can custom automation accelerate commercialization of biotechnology breakthroughs?

BY DOMINIK BELL

You've done your testing on the benchtop and proven that your new biotechnology innovation works in your hands. Now comes the exciting part – turning your solution into a breakthrough product that is ready for broader use and commercial launch. To get there, you need to optimize your processes so that you can ensure they are robust, operate within defined tolerances, and facilitate scale-up. What's the fastest and most efficient way to get this done so that you can focus on your next bioscience advancements?

Biotech innovation requires automation innovation

Optimization requires changing multiple parameters and generating statistically-sound results based on the use of many replicates. Scale-up for production demands speed, reproducibility, and reliability. Once you have protocols that work in your hands, it simply isn't practical to continue with manual processes to optimize product performance, validation procedures and production workflows, while still meeting your time-to-market targets. Taking innovative concepts through to commercial application is a job for automation. However, off-the-shelf automation solutions may not be up to the task – especially when innovations entail entirely new protocols.

Biotech innovation drives custom engineering

Your latest biotechnology innovation may not conform to the existing laboratory automation standards for consumables, components, automatable modules or software. Innovation does not develop within such constraints. Attempting to build an automation solution using components that don't meet all of your requirements can limit your flexibility as you try to optimize your workflow. Creating a de novo solution could divert your efforts and sacrifice your time-to-market. An automation solution that combines both custom-engineered developments and existing products may enable you to optimize your workflow, while maintaining the flexibility and speed you need during your final stages of product development.

Biotech automation solutions: moving beyond the ordinary

When you have automation needs that don't yet exist as standard lab solutions, it's time to consider collaborating with dedicated laboratory automation system engineers who will work with you to investigate, invent and integrate new approaches that will take you beyond standard options.

You'll know it's time to consider collaborating with a custom engineering team when:

- You need to focus your expertise on bioscience, not inventing lab automation instrumentation
- You have unique application workflows
- Even a custom-configured instrument isn't exactly what you need
- You need innovation in automation to match the innovation in your biotechnology

A custom-automation engineering partner should listen to your needs and be able to offer the dedicated resources needed to work with you throughout the most dynamic phases of your project, to create fully optimized and tested systems that are tailored to your unique requirements. Collaborating with system engineers who will push the boundaries in laboratory automation can help you to push the boundaries in biotechnology.

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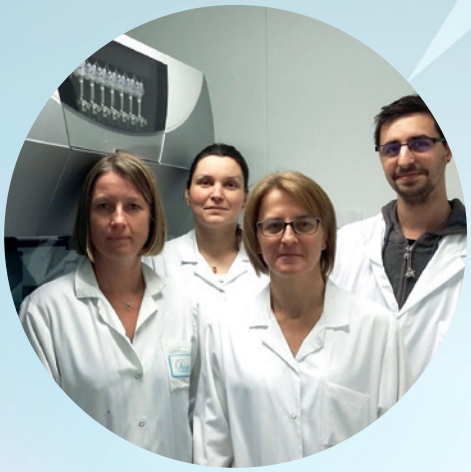
A revolution in milk sample analysis.



Quality control of milk is important to ensure compliance with regulations and to support dairy farmers in their herd management. However, analyzing multiple milk samples from many individual cows is a time-consuming process. French laboratory AGRANIS is using a new, automated genotyping technique to analyze bulk tank milk samples, saving time and money on its testing services.

Members of the AGRANIS team with Dr Florent Perrin (right)

AGRANIS, based in Laval, specializes in milk analysis on behalf of dairy farmers, livestock consulting companies and vets. Founded in 2005, the company now employs around 30 people and is growing its services, as Genomic Manager Dr Florent Perrin explained: "We work mainly with milk samples, performing biochemical and microbiological analyses to determine, for example, protein or diuretic content, as well as carrying out ELISA tests and qPCR. We process around 4.5 million samples per year from across the country, and focus on two primary activities. Firstly, we assess the quality of milk from farmers according to industry regulations and, secondly, we support dairy farmers and livestock consulting companies to improve herd management by determining the somatic cell count (SCC) for each cow. The SCC is quantified as the number of cells per milliliter of milk, and is used as an indicator of quality, since a high SCC is typically the result of an increase in white blood cells in response to an infection. Generally, the SCC is determined by flow cytometry, requiring analysis of individual milk samples from each cow in a herd, which involves a large number of samples. However, prior genotyping of cartilage samples from each cow in a herd makes it possible to determine the SCC of each animal in a single bulk tank milk sample."

"This patented approach – called Genocellules® (Groupe Seenergi) – is rather groundbreaking in agriculture, and relies on reliable DNA extraction from both milk and cartilage samples. This was not an activity we had done before, and so we decided to purchase a Fluent® Automation Workstation in October 2017 to help us achieve consistent results and cope with the number of samples we would be processing.

We already had a Freedom EVO® 150 liquid handling workstation and two Sunrise™ absorbance microplate readers, and so it made sense to add a Fluent so that we could consolidate service and support. We had also had good reports about its reliability and reproducibility from other laboratories, which made us even more confident of our decision. The Tecan team installed the platform and provided training, allowing us to create our own programs."

"Our workflow is separated into two parts – the first step is to extract DNA using a Nucleospin® Tissue 96 Kit from Macherey-Nagel. The two matrices present different challenges; the cartilage samples are processed in a non-standard tube format, and the milk contains high levels of protein and fat. To overcome these issues, we developed two separate protocols to handle each sample matrix appropriately, benefitting greatly from the Fluent's precise pipetting, which allowed us to validate the protocols within two weeks of the system being installed. Following DNA extraction, genotyping is carried out on a Freedom EVO 150 liquid handling workstation using a BovineSNP50 v3 DNA Analysis BeadChip protocol from Illumina."

"There were a number of experimental requirements that made the Fluent our platform of choice. We use a BioShake® 3000-T elm (Quantifoil Instruments) for shaking and homogenization of samples, as well as heating buffers up to 70 °C. We also have a Te-VacS™ module to perform filtration steps without needing an external centrifuge, and have developed a custom suction force profile to optimize the process. Automating the protocol would not have been possible without the Robotic Gripper Arm™, which moves the plates and allows the workflow to be performed without the need for manual intervention.

"Automating DNA extraction has saved us time, and the enhanced speed allows us to achieve reliable batch processing of 96 samples in just two hours, running several plates a day."

This set-up has given us high DNA extraction yields, which are essential for genotyping. The entire extraction process – lysis of samples, binding, washing and elution – also needed to be carried out in such a way that we could carry out other procedures in parallel, which was straightforward thanks to the user-friendly TouchTools™ interface. It guides us through the worktable set-up step by step – where to place different elements, number of samples, etc. – helping to minimize the risk of errors."

"Automating DNA extraction has saved us time, and the enhanced speed allows us to achieve reliable batch processing of 96 samples in just two hours, running several plates a day. Today, we can analyze around 1,300 samples a week, rapidly genotyping each cow of a herd, then determining individual SCCs from a bulk tank milk sample. This is a real benefit to our clients, as they only need to routinely supply us with bulk tank milk samples, and we can carry out twice as many analyses in the same amount of time. I'm happy to say that the two protocols are running perfectly and, to date, we have not encountered any problems. We are very pleased with the Fluent's performance, and are already considering how we can develop and program new protocols to support future projects."

To find out more about Tecan's nucleic acid purification solutions, visit www.tecan.com/NAP

To learn more about AGRANIS, go to www.seenergi.fr/en

Article first appeared in TJ1/2019, pages 12-13

Transforming peptide synthesis for the 21st century to fill a GAP in the market.

GAP Peptides has developed a novel approach to synthesizing high crude purity peptides that minimizes solvent and raw material consumption, while simultaneously reducing waste. Laboratory automation is helping this start-up company to accelerate its research and development, a process crucial to achieving commercial success. The company founders have collaborated with Tecan to establish a unique liquid handling platform, designed and built specifically to meet its workflow needs.

Cole Seifert (left) and Carder Brooks co-founded GAP Peptides in 2017

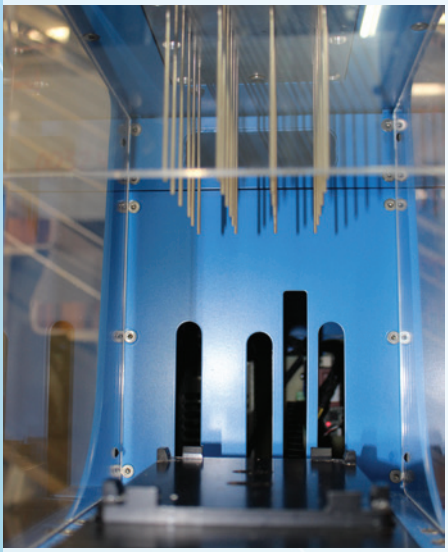
Scientific interest in peptides has expanded exponentially over the past decade, and today these biomolecules are ubiquitous across a range of sectors. The marketing potential is huge. In the therapeutic sector alone, a compound annual growth rate in excess of 10 % – in the region of 25 to 40 billion dollars – is projected over the next few years. The complexity of synthesizing these peptides presents a challenge for manufacturers, who must achieve high purity in a cost-effective manner and, at the same time, adopt more environmentally friendly processes.

GAP Peptides, based in Lubbock, Texas, has developed an innovative process that addresses these issues, helping manufacturers to bring new synthetic peptides to market at an affordable price point. When performed manually, simultaneous synthesis of the multiple peptides needed for research can be very time consuming, so the company has automated the process on a Fluent® 1080 Automation Workstation. CEO and Managing Director Caroline Brooks explained: “Our work is based on a novel synthesis strategy, Group Assisted Purification-Peptide Synthesis (GAP-PS), developed by our CSO Dr Cole Seifert and his research adviser, Dr Guigen Li, during his PhD studies at Texas Tech University. This unique synthesis approach will help manufacturers to improve yields, reduce the consumption of raw materials and minimize solvent waste, producing peptides faster and with higher purity compared to other methods.”

Cole took up the story: “Traditional solid phase peptide synthesis is performed on a polymer support. However, the peptide never actually dissolves in the reaction solvent, and that means that the synthesis is often not very efficient, resulting in lower purity. The process also uses a large volume of solvent to swell and suspend the resin, requiring a larger reactor and increasing the amount of solvent waste generated. With GAP-PS, we attach a specifically designed small molecule protecting group to the C-terminus of the first amino acid, which ensures solubility in the reaction solvent; with everything in solution, we can use a smaller reactor and reduce solvent waste.

The synthesized peptide is isolated by selective precipitation after an aqueous extraction step, offering a simple purification process to match that of solid phase techniques.

> “A single person working manually could synthesize one, amaybe two, 10-amino acid peptides in about a week. In contrast, the Fluent can generate 24 peptides, completing the process in about three days.”



Fixed steel tips provide reliable septa piercing

This allows us to keep the benefits of solid phase synthesis while increasing the reaction efficiency – which enhances the peptide purity – and the scalability of the process.”

To enable commercial adoption of its GAP-PS technology, the company needs to provide substantial data demonstrating the purity, yield, length and complexity of the peptides produced. Implementation of a fully automated liquid handling system is the key to achieving this, and GAP chose a Fluent 1080 to increase throughput, enabling reliable, consistent data to be generated more rapidly. Tecan tailored the system to the company’s workflow, integrating a SciRobotics TubeEyeX™, a ppSPE device, an IKA shaker and a Porvair sample concentrator – the first time this has been done on a Fluent workstation. Partnering with Tecan was an obvious choice for Caroline: “Tecan is well known in the life sciences arena for its experience and in-depth knowledge of chemistry and automation, and we very quickly discovered the company’s expertise in designing and planning a customized instrument to meet our needs. This expert insight made it stand out and gave us the confidence to choose Tecan.”

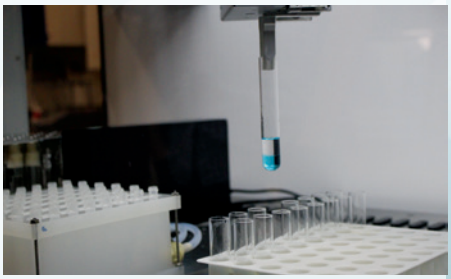
Carder Brooks, General Counsel at GAP, added: “Tecan’s experience in developing customized platforms and integrating third-party devices into the hardware and software played a major part in our choice of system. We explained that we needed a custom-designed workstation to automate a novel peptide synthesis. While others said it could not be achieved, Tecan’s response was that, although it had never done anything like this before, it had all the components necessary and was confident that it could assemble and program a platform to meet our needs, supporting us all the way from design to implementation.”

“The beauty of the Fluent is that it enables us to show the capabilities of our technology in a way that would be impractical without an automated liquid handling platform,” said Caroline. “It gives us a tremendous capacity that we just wouldn’t have if we did our research manually, enabling the synthesis of as many as 24 peptides at any time. This allows us to go to market with all the proof necessary to gain credibility, giving potential customers confidence that our technology works. Without an automated liquid handling system, this would be a very slow and painful process.”

Cole expanded on the time savings offered by automation: “A single person working manually could synthesize one, maybe two, 10-amino acid peptides in about a week. In contrast, the Fluent can generate 24 peptides, completing the process in about three days, which makes a huge difference to our throughput.”

“Peptide chemistry is very complex, as is the integration of all the third-party modules into the Tecan operating software, but the company has managed to create a user-friendly interface that simplifies the workflow, allowing us to make changes to meet our specific needs relatively quickly and easily. It’s been a good collaboration,” concluded Caroline.

The Fluent Automation Workstation has been customized for GAP-PS peptide synthesis



Blue food coloring is used to allow the TubeEyeX to distinguish between the layers during the aqueous extraction step

Article first appeared in TJ2/2019, pages 18-19

To find out more about Tecan’s Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about GAP Peptides, go to
www.gappeptides.com

Real-time insights for better productivity.

Understanding how and when laboratory automation assets are being used is crucial to maximize productivity and enable effective resource planning in high throughput facilities. California's Ambry Genetics has a portfolio of almost 60 Fluent® and Freedom EVO® liquid handling platforms, and has worked closely with Tecan on the development of Introspect™, a cloud-based service that provides a comprehensive overview of precisely when and how laboratory automation systems are being used.

Members of the Ambry Genetics automation team

Ambry Genetics, a Konica Minolta company, is a leading provider of genetic clinical diagnostic services, including familial cancer screening and exome testing. In 2016, the company built a state-of-the-art 'Superlab' designed to increase the efficiency, precision and quality of its testing workflows, while reducing the risk of human error. This CLIA/CAP-certified facility was initially equipped with 30 Freedom EVO liquid handling platforms to perform a wide range of assays, and the lab's automation portfolio has since grown to include almost the same number of Fluent Automation Workstations.

Managing the lab's huge testing workload of up to 3,000 samples a day, and ensuring that resources are used as effectively and efficiently as possible, is a major challenge, as Director of Assay Automation Joy Rae-Radecki Crandall explained: "The Superlab was designed to be as efficient and high throughput as possible, while still offering us the flexibility to run numerous different assays and chemistries on each workstation. Being able to see when and how effectively each system is being used is therefore key to ensuring we can maximize our throughput, and still have built-in redundancy to cope with peaks in sample numbers or instrument downtime for maintenance."

"This information is available as part of the log files for each instrument, but we had no way to centralize and visualize that data without a lot of manual processing. We initially looked at creating a software script to retrieve and compile the relevant data from each platform but, after discussing the issue with our local Tecan representative, we discovered that the Tecan software development team had been exploring the same idea. We decided to collaborate and act as the alpha user for this project, which later became Introspect."

"Our primary requirement at the outset was to have a software tool that provided a visual representation of when we were using our various instruments," Joy continued. "I'm a big advocate of color-coded graphical data, as it makes it much easier to understand and digest. And once we began looking at that data, we started to notice patterns and pick up on all sorts of things we hadn't even considered before. For example, we noticed that certain assays or times of day had higher error rates, prompting us to investigate and address the cause – from providing additional staff or training on a certain workflow to identifying bugs in our scripts. Regardless of the reason, resolving these issues has led to fewer errors and re-preps – which are both costly and time consuming – and has simultaneously increased staff confidence. We hadn't even considered this as a potential benefit when we began the software development with Tecan."

"Looking at the basic utilization data by instrument, Introspect obviously highlights which platforms are being used to capacity, and where we have redundancy. For example, if a system is being fully employed during the day, but not overnight, then there is potential for it to be used to perform a different assay in the evenings – as long as we have enough staff to run it. This level of visibility makes it very easy to build a business case for the purchase of new platforms, as we can clearly see how much instrument time and capacity is available relative to the number of tests we're performing. It also makes it much easier to deal with fluctuations in sample numbers, allowing us to forecast how many consumables we are likely to need and ensure we have enough disposable tips and other labware in our inventory."

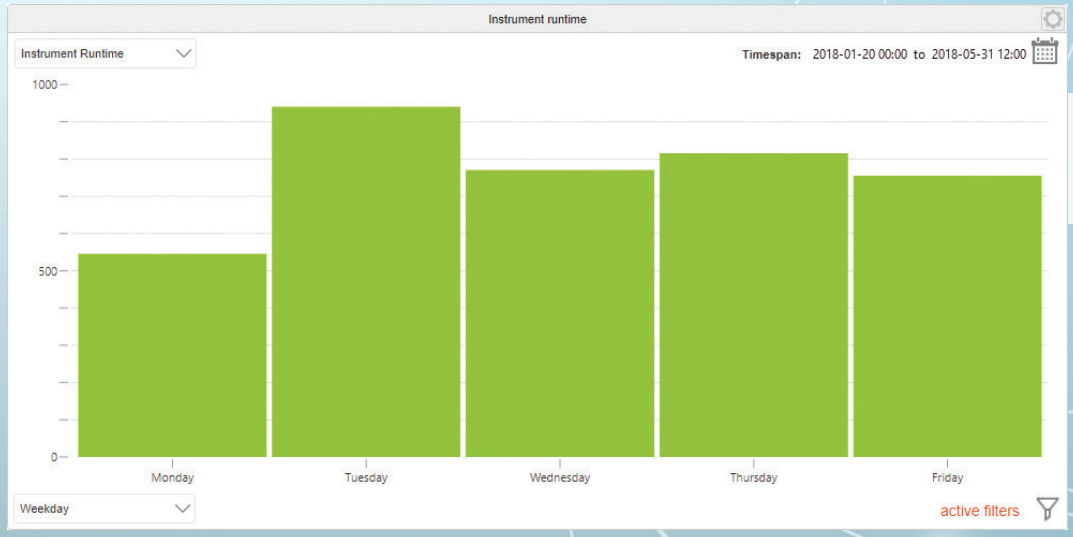
"Another interesting aspect, which we hadn't considered, was the software's ability to track the amount of time we spend on research and development activities to validate newly commissioned assays or platforms. This can have tax implications, so being able to easily show when the platforms have been used for non-profit generating activities without having to manually record hours is important.

This is another example of how having easy access to your instrument data makes Introspect such a powerful lab management tool, allowing us to be proactive in our approach to resource utilization."

> **"Having easy access to your instrument data makes Introspect such a powerful lab management tool, allowing us to be proactive in our approach to resource utilization."**

Article first appeared in TJ2/2019, pages 24-25

Track utilization of an instrument on single days in the time-of-day chart

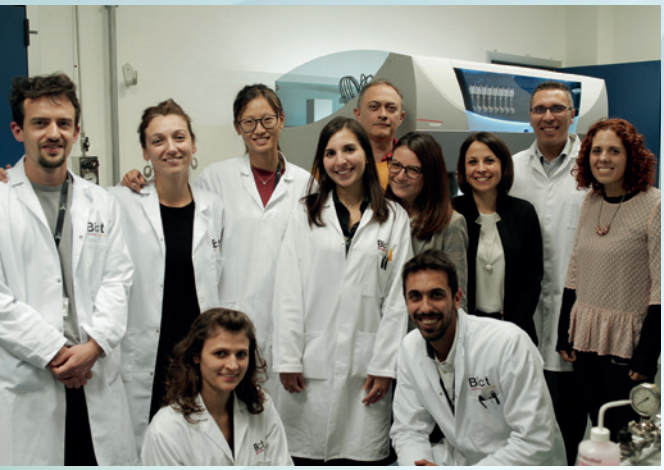


Identify low performing weekdays in Introspect dashboards

To find out more about Tecan's Introspect service, visit
www.tecan.com/introspect

To learn more about Ambry Genetics, go to
www.ambrygen.com

Automating protein purification.



The initial screening of chromatographic conditions can be a major bottleneck in the development of protein purification protocols. Italian company BiCT – Biological and Chemical Technologies – has turned to automation to overcome this issue, implementing parallel processing of miniature chromatography columns on a liquid handling platform to enable rapid simultaneous screening of a range of conditions. This maximizes the prospect of achieving the best result for each project while saving time and resources.

The BiCT team with the Fluent Automation Workstation

Lodi-based BiCT began life nearly a decade ago as a contract research organization (CRO) focused on the pharmaceutical sector, establishing a core business developing biocatalysis and biotransformation protocols using enzymes and micro-organisms. Subsequently, the company expanded its field of interest, applying the same technologies to other sectors, including nutraceuticals, cosmetics and agrochemicals. More recently, it has turned its attention to production, and now operates as both a CRO and a manufacturing facility. Silvia Rapacioli, Co-CEO and Marketing Manager of BiCT, explained: "We provide services to customers from all around the world who appreciate our industrial focus. Our services include everything from initial research all the way through optimization to pilot-scale production and technology transfer to the customer's own lab for use on an industrial scale, with minimal adjustments to the process."

Silvia continued: "One of our biggest assets is automation. We offer a broad range of automated high throughput screening protocols for molecular biology, fermentation, purification and biocatalysis, developing efficient, cost-effective processes. Automation allows us to design our experiments to test numerous variables, increasing throughput and enabling many different protocols to be evaluated to ensure we provide the best possible solution. The data is critically analyzed and forms the basis of innovations that progress to the pilot plant and, ultimately, become manufactured products."

BiCT is set to move to larger premises in the near future that will include a dedicated automation unit. In preparation for total laboratory automation (TLA), the company is implementing, among other applications, parallel processing of miniature chromatography columns on a liquid handling workstation to increase the speed of development of new protein purification protocols. "The core role of the automation lab in the new facility will be strain improvement and chromatographic purification, from strain development to purification of enzymes, important metabolites and proteins of pharmaceutical value. Chromatography is a key step in our workflows, and we chose Tecan because, in our opinion, it is the best system available."

As a prelude to establishing a dedicated automation hub, BiCT worked with Tecan to explore the use of the Te-Chrom™ and Te-Chrom Shuttle with Repligen OPUS® RoboColumns® on a Fluent® Automation Workstation for sample purification. "We initially evaluated the RoboColumn technology on a Freedom EVO® workstation, and have now implemented this application on the Fluent.

The system is very intuitive with straightforward software, and allows us to automate parallel purification on miniature chromatography columns," said Silvia.

Roberto Verga, Co-CEO and Business Development Manager, took up the story: "There are several things to consider when you are developing a purification protocol, such as the column volume, type of resin and screening conditions, which is a bottleneck when you can only run one column at a time. The big advantage of implementing the RoboColumns on the Fluent is that we can run eight columns in parallel – 96 in one run – simultaneously studying a lot of parameters, including the kind of resin, flow rate, binding capacity, sample clean-up and the best ratio of sample to resin. This allows us to speed up the all-important screening process and move on to the next stage – process scale-up – more quickly. The system is very reliable, and we can easily change our protocols to use the larger volume RoboColumns, which have proved representative of the subsequent industrial scale-up. We have also been able to engage with chromatographic media manufacturers by, for example, comparing different resins, developing specific resins suitable for customers' applications, or evaluating the performance of new resins to generate data for technical brochures prior to the product launch."

> **"[Automation] gives us the opportunity to try as many options as the team can think of, exploring their creativity to its maximum potential, which increases success rates and the potential for devising innovative, 'out of the box' solutions."**

"The success of our company depends on the satisfaction of our customers," Roberto continued. "With automation, we increase the chance of finding the right candidate biologic and the best purification protocol quickly and cost effectively. Previously, we could only evaluate one column at a time. This was a huge effort, consuming a great deal of time and resources, with the risk of missing the best results that can come from testing several conditions simultaneously. A purification protocol that used to take a month to set up can now be established in just one week, which is a huge saving in terms of both time and resources."

"The potential to integrate the entire strain improvement workflow into our lab automation is very important. It is a real benefit not only for our customers, but also for our staff. It is like having an extra five or six collaborators that never get tired. It gives us the opportunity to try as many options as the team can think of, exploring their creativity to its maximum potential, which increases success rates and the potential for devising innovative, 'outside of the box' solutions for every project. TLA will undoubtedly be a key resource for contract research in the future," Silvia concluded.

Article first appeared in TJ1/2019, pages 28-29

To find out more about Tecan's protein purification solutions, visit
www.tecan.com/bioprocessing

To learn more about BiCT, go to
www.bict.it

Stem cell research offers muscular dystrophy hope.

Access to human pluripotent embryonic stem cells is enabling Genea Biocells to pioneer novel therapies to treat a number of neuromuscular diseases.

Drawing on almost 30 years of research heritage, the company is using its expertise to model spinal muscular atrophy and facioscapulohumeral muscular dystrophy to identify potential therapies.

Cullen Pivaroff and Charles Martin with the Fluent Automation Workstation

Genea Biocells was established in 2017 as an independent company born out of the R&D arm of Genea Fertility – a world-leading IVF clinic in Australia. The team of 20 scientists based in San Diego, California, specializes in drug discovery and therapy development to treat neuromuscular diseases. Monica Hayhurst Bennett, director of preclinical research at Genea Biocells, explained: "In the early days, the IVF clinic made a concerted effort to collect pluripotent embryonic stem cells that were excluded as part of preimplantation genetic screening. Patients were asked if they wanted to donate these cells for research and, over time, we've created one of the world's largest and most varied private banks, with over 150 cell lines representing more than 30 diseases."

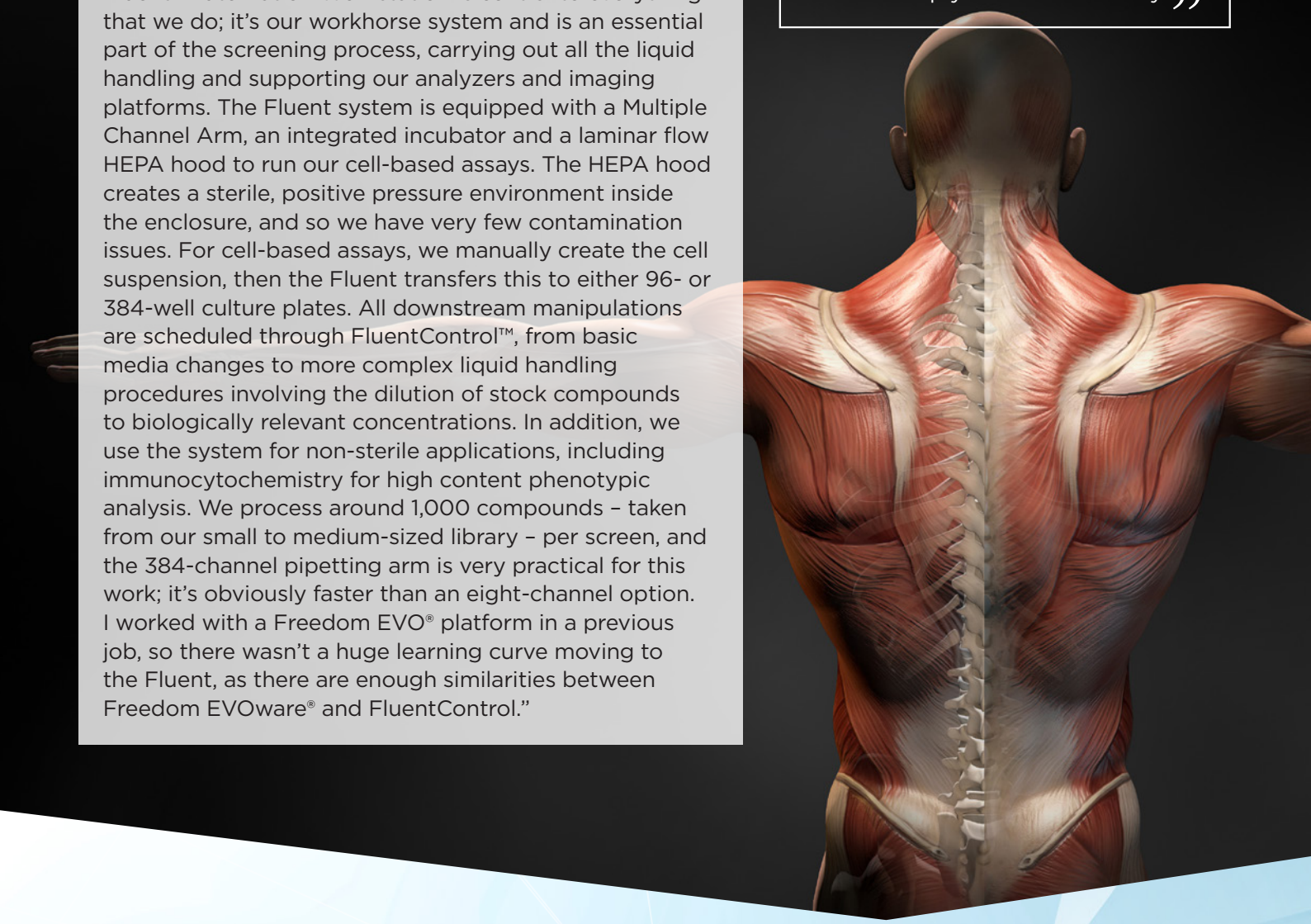
Monica continued: "We are in our early days as a drug discovery company, and have three main facets to our organization. Firstly, we supply stem cells and media reagents to strategic academic partners. We also carry out CRO work in collaboration with pharma companies that want to focus on muscular dystrophies we are not actively pursuing ourselves, such as Duchenne. Finally, we have our scalable discovery platform that differentiates skeletal muscle cells from human pluripotent stem cells and supports our in-house assay development."

Genea is primarily focused on two conditions; spinal muscular atrophy (SMA) and facioscapulohumeral muscular dystrophy (FSHD). SMA affects one in 10,000 people, with a carrier frequency of one in 40 in the general population. FSHD is another of the most common muscular dystrophies – affecting one in 20,000 – and causes progressive loss of muscle strength. Genea has used its expertise to develop the world's first human stem cell model of FSHD, and is using this platform to search for therapeutic drug candidates. "SMA and FSHD are monogenic diseases, which makes them good candidates for screening," Monica added.

"This has resulted in an abundance of stems cells to work with, and has naturally focused our research efforts. We primarily concentrate on generating phenotypic assays for screening, elucidating different metabolic pathways in cells and understanding pretranslational gene expression. Once the team has consolidated an assay, it can be passed on to the automation team."

Charles Martin, an automation scientist, continued: "Our Fluent® Automation Workstation is central to everything that we do; it's our workhorse system and is an essential part of the screening process, carrying out all the liquid handling and supporting our analyzers and imaging platforms. The Fluent system is equipped with a Multiple Channel Arm, an integrated incubator and a laminar flow HEPA hood to run our cell-based assays. The HEPA hood creates a sterile, positive pressure environment inside the enclosure, and so we have very few contamination issues. For cell-based assays, we manually create the cell suspension, then the Fluent transfers this to either 96- or 384-well culture plates. All downstream manipulations are scheduled through FluentControl™, from basic media changes to more complex liquid handling procedures involving the dilution of stock compounds to biologically relevant concentrations. In addition, we use the system for non-sterile applications, including immunocytochemistry for high content phenotypic analysis. We process around 1,000 compounds – taken from our small to medium-sized library – per screen, and the 384-channel pipetting arm is very practical for this work; it's obviously faster than an eight-channel option. I worked with a Freedom EVO® platform in a previous job, so there wasn't a huge learning curve moving to the Fluent, as there are enough similarities between Freedom EVOware® and FluentControl."

> "There are things the Fluent can do that I simply can't do manually."



Cullen Pivaroff, a scientist at Genea Biocells, added: "I'm fairly new to laboratory automation and I have discovered that, in addition to eliminating manual work and improving the accuracy, there are things the system can do that I simply can't do manually. I have a background in cell culture and handling fragile cell types, but the Fluent is so much gentler than working by hand; it's a well-configured and well-built system."

Charles continued: "There are so many diverse applications for the Fluent, and Tecan really values its working relationships with people who are using the system.
I recently went to a users' round table meeting, and it was great to see the Tecan engineers and software developers responding to our suggestions. They seemed really keen to hear our feedback, and I'm sure a number of the ideas discussed will make it into future software updates; they are always looking for ways to keep developing the platform."

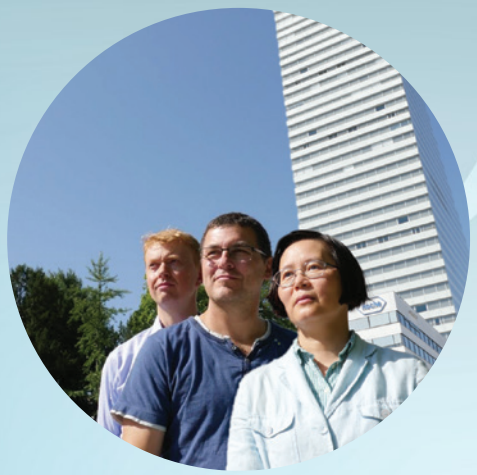
Article first appeared in TJ1/2018, pages 16-17

For more information on Tecan's drug discovery solutions, visit
www.tecan.com/drugdiscovery

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about Genea Biocells, go to
www.geneabiocells.com

A flexible lab for the future.



Automated laboratory workflows are commonplace in the pharmaceutical sector, offering increased throughput and process security throughout the drug discovery process. Most of these systems are dedicated to a specific task or assay, and have been optimized to streamline these repetitive tasks. Roche has taken a different approach for drug metabolism work, creating a centralized automation facility that is agile enough to respond to the changing demands of R&D.

Roche's Stephen Fowler, Pascal Schenk and NaHong Qiu are 'looking to the future of automation' to meet the company's changing R&D needs

As one of the world's largest biotech companies, Roche develops diagnostic tests and pharmaceutical drugs, from initial discovery through to clinical trials and commercialization. In 2014, Roche announced a decade-long venture investing three billion Swiss francs in a new Basel research center, with an emphasis on improving sustainability and strengthening communication between research staff. Dr Stephen Fowler, who heads up the automation team within the drug disposition and safety department, said: "Our current way of working has evolved both naturally and intentionally. Right now, in preparation for the new center, the company is asking for our input on how to redesign labs to encourage flexibility and support increased collaboration. We are drawing upon our past experience in former companies and other Roche labs to help us plan for the future. People are spending less time in the lab than before, as automation frees us to focus on the areas where we add most value – analyzing data and designing experiments to answer specific project questions. We continually ask ourselves how we can make the most of our knowledge and expertise. And how our familiarity and proximity to the projects offer something that we cannot buy externally."

"In the drug disposition and safety department, we work closely with our modeling and clinical colleagues to design in vivo pharmacokinetics studies, predict the potential drug-drug interaction liabilities of a compound, and investigate the enzymes involved in the clearance of our compounds. We work across the entire spectrum of the process; there is no split between discovery and development as there is in many drug metabolism departments, and we are responsible for collating the information for new drug applications to bring to the regulatory authorities."

"Our automated systems are centralized in a core facility with dedicated technicians to organize and program them, providing a service for all 80 researchers in the department. As most of the assays don't require a high throughput approach, we have decided to use each instrument for multiple assays. We operate nine Tecan instruments – seven Freedom EVO® and two Fluent® instruments – and the two identical Fluent systems can each run 16 or 17 different assay scripts. Different people from the department use the instruments on a weekly or fortnightly basis, and they can book either system using an electronic calendar when a slot is available; one person can run one assay in the morning, and someone else an entirely different assay in the afternoon. Researchers are responsible for running their assays, but we help the process along by hosting the equipment and supporting them to optimize the automation and gather good quality data. They don't need to reconfigure the Tecan instruments; they simply load up the experimental protocol, import their variables, add reagents, and set it running."

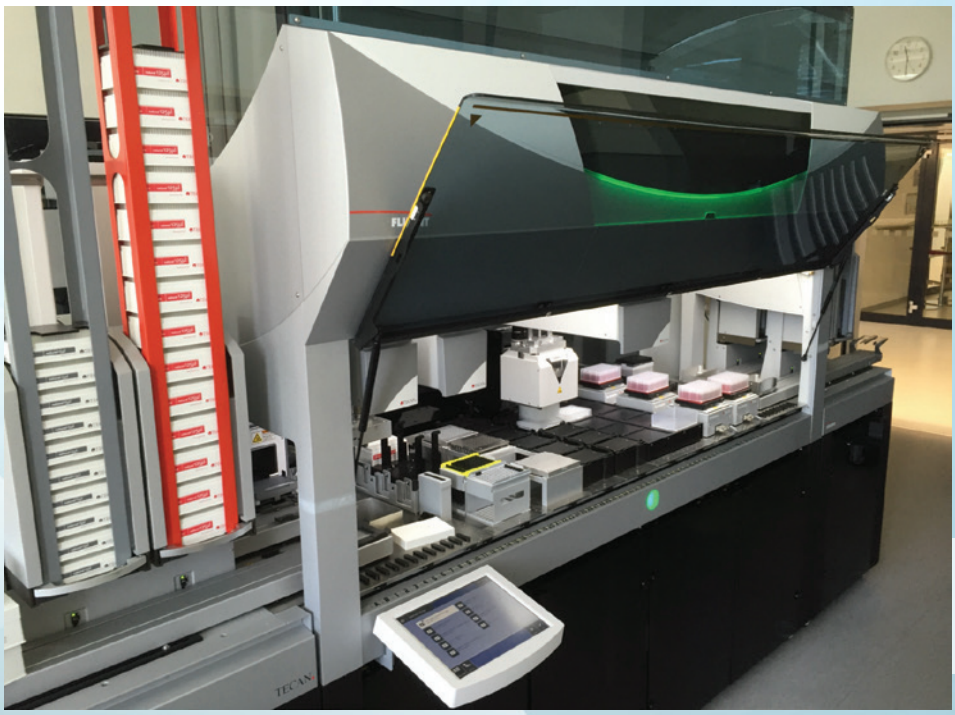
Stephen continued: “The Tecan devices are well suited to running multiple different assays. We were fortunate enough to work with the Fluent during its development, and we’ve been involved throughout the planning phases of the system. Tecan has developed the software in line with some functionality we desired, and they’re very open to hearing our ideas.

> “Automation frees us to focus on the areas where we add most value – analyzing data and designing experiments to answer specific project questions.”

For example, we work with lots of different users and every so often an experiment will be set up with a reagent in the wrong place or with a misaligned plate, which disrupts the assay. We inserted a simple step into the software that brought up a screenshot of a correctly prepared assay for comparison, prior to the user pressing ‘Start’. If one in 20 assays now works where it would have failed, it’s a worthwhile intervention. It’s great to see Tecan build on this idea, and you can now import JPEGs, videos and different file formats.”

“The future demands flexibility and the ability to quickly adapt to embrace new opportunities – we can’t simply go out and buy a new instrument for every new assay that we need to run. If one of our assays is no longer needed, there is always another awaiting automation. We’ve been able to demonstrate that the systems can be used for multiple tasks, and reconfigured and reprogrammed quite easily. Tecan has provided very good support whenever we have questions or encounter programming problems, and has been willing to adapt software and hardware to suit our needs. We’re really happy with improvements that Tecan has made to the software system, so much so, that we have just bought a third Fluent.”

Article first appeared in TJ1/2018, pages 8-9



Two Fluent workstations are the latest additions to Roche’s core automation facility

For more information on Tecan’s drug discovery solutions, visit
www.tecan.com/drugdiscovery

To find out more about Tecan’s Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about Roche, visit www.roche.com

Confidence in drug discovery.

A Fluent® Automation Workstation is providing exceptional flexibility for small molecule screening at IME ScreeningPort in Hamburg, Germany. This groundbreaking system offers straightforward automation of complex assays, enabling both in vitro and cell-based assays to be performed on a single, compact instrument.

Left to right: Philip Gribbon, Gesa Witt and Markus Wolf with the Fluent system

Fraunhofer IME

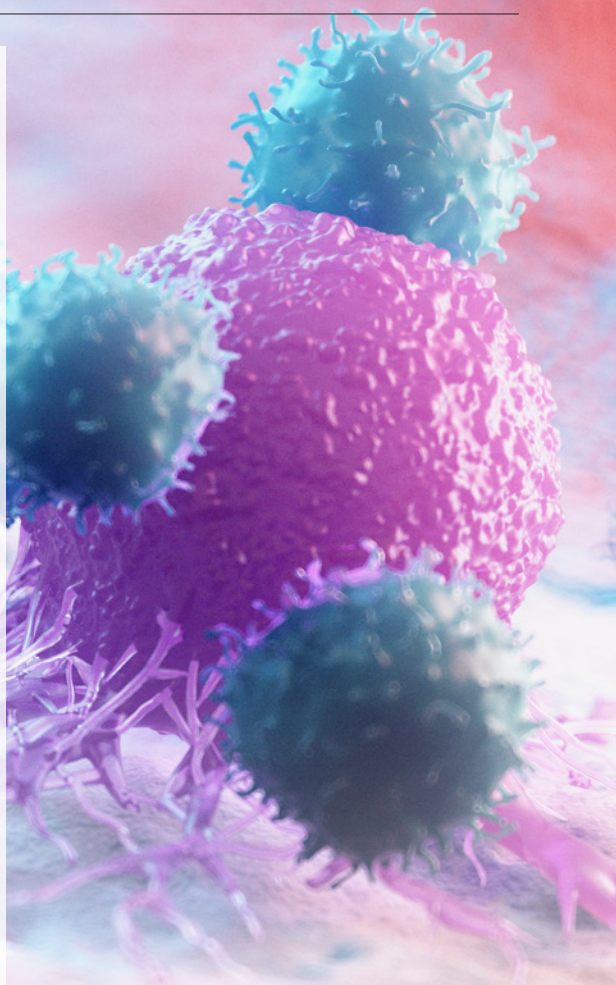
IME ScreeningPort – part of the Fraunhofer Institute for Molecular Biology and Applied Ecology – offers a full range of drug discovery research activities to academic and public research institutes, helping to bridge the gap between fundamental research and the pharmaceutical industry. Partnering with laboratories across the globe, IME ScreeningPort provides industrial-scale assay development and small molecule screening services, using advanced laboratory automation and informatics systems to provide high quality, validated drug candidates which can be transferred directly into preclinical pharmaceutical development pipelines.

As an industrially-focused research institute working across multiple life science disciplines, IME ScreeningPort requires highly flexible, user-friendly automation solutions to ensure the necessary throughput and efficiency. Dr Philip Gribbon, Assistant Department Head of IME ScreeningPort, explained: “We have a completely open approach when it comes to therapeutic areas, so we usually have around 20 projects ongoing at any one time across a variety of indications, including oncology, neurodegenerative, cardiovascular and metabolic diseases, as well as a number of neglected parasitic diseases. Our major strength lies in target-based assays – both biochemical and cell-based – but we also perform a large number of phenotypic assays, so need the flexibility to quickly switch between various assay formats to meet the timetables and demands of each project.”

Automation is an essential part of IME ScreeningPort’s laboratory workflow, and the increasing popularity of high content, multiplexed assays meant that the company was looking for a new liquid handling and automation workstation capable of running these applications. After initial project discussions with Tecan in late 2013, it was clear that the Fluent platform offered both the flexibility and precision required for the drug discovery projects at IME ScreeningPort. Philip continued: “Having worked with Tecan in several of my previous roles, I was aware of what the company could offer in terms of automated solutions to run microplate-based assays. A partnership was also a very good fit for both parties, providing a unique opportunity for us to benefit from Tecan’s application expertise and latest generation of liquid handling instrumentation, and for the company to test the performance of this innovative solution in a real-world setting.”

Following a one week training course for two IME ScreeningPort researchers at Tecan's Männedorf headquarters, the Fluent platform was installed in March 2014, and was quickly brought into operation for cell-based assays. Liquid handling and automation scripts for many of the assays were established in a very short time frame, enabling a rapid start on instrument testing and validation. "We initially identified five assay groups that would be good candidates for running on the Fluent and, working hand-in-hand with the Tecan technical team, we were able to develop protocols very quickly. The Fluent workstation's fully-integrated design is ideal for our needs, allowing us to incorporate many of the auxiliary devices needed to perform our assays into a single, compact workstation. Our platform has an Infinite® M1000 PRO multimode reader and a HydroSpeed™ plate washer – both of which are extremely good instruments – as well as an incubator and a carousel to store labware and assay plates. This gives us the capacity and flexibility to quickly switch between, for example, a kinetic assay that only takes a few hours and a cell-based assay with long incubation times that can take several days, helping to ensure project deadlines are met and the instrument is being used efficiently."

One of the IME ScreeningPort assays now benefitting from complete automation on the Fluent platform is screening for anti-cancer agents. Using the CellTiter-Glo® Luminescent Cell Viability Assay (Promega) and cell lines from the NCI-60 panel, IME ScreeningPort has developed a protocol that allows triplicate dose-response curves to be generated for up to 100 compounds against 20 different cell lines in a single, unattended run.



> "So far, we haven't found anything that we can't do."

Performed in 384-well culture plates, this workflow offers exceptional throughput, and uses Fluent's three, task-specific arms and the integrated Infinite M1000 PRO to provide precisely controlled liquid handling and analysis, ensuring consistent, high quality results. "The Fluent solution offers far greater flexibility than the high throughput screening systems we were used to, allowing us to precisely define how liquid transfers and other operations are scheduled and performed. Although this level of functionality requires you to devote time and effort to fully understanding the system's capabilities, the interface and software are very user-friendly, and you are amply rewarded for your investment. So far, we haven't found anything that we can't do, and we've already identified a second tranche of assays that we'll be transferring to the Fluent platform," Philip concluded.

Article first appeared in TJ3/2014, pages 10-11

For more information on Tecan's drug discovery solutions, visit
www.tecan.com/drugdiscovery

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about IME ScreeningPort, go to
www.screeningport.com

Redesigning the drug safety workflow.

Detecting adverse off-target effects is crucial to ensure the safety of potential therapeutics, but limited throughput and ethical considerations have traditionally forced pharmaceutical companies to perform safety pharmacology studies at a late stage of the drug development process. Human stem cell-based cellular models and automated screening processes are revolutionizing drug safety studies, enabling much earlier testing, with companies such as Ncardia at the forefront of this workflow transformation.

Stefan Braam and Farbod Famili with Ncardia's Fluent Automation Workstation

Ncardia
Stem cell experts

Safety pharmacology is an important part of the drug discovery process, identifying and investigating any potential undesirable pharmacological effects of candidate drugs before they enter clinical development. These effects are often hard to characterize in cellular or simple in vivo models, requiring animal testing – usually in canine models – to ensure the potential therapeutic is safe to proceed to the next phase. The cost and ethical issues associated with such testing mean that safety pharmacology studies have traditionally been performed at a late stage of pre-clinical development. This can lead to late stage failure of candidate drugs, resulting in significant financial losses.

Avoiding these expensive failures is a major goal for pharmaceutical companies, creating a real need for new technologies – such as organ-on-a-chip approaches – that enable drug safety studies to be performed far earlier in the development process. Ncardia is a pioneer in this area, developing and commercializing highly predictive cellular assay systems derived from human stem cells to accurately assess drug safety. Dr Stefan Braam, co-founder and CEO of Ncardia, explained: "Our aim is to put 'human' testing at the forefront of drug discovery, by developing the best possible human cellular models. This is very attractive from an industry perspective, as it ensures only viable candidate drugs are progressed through the pipeline, while avoiding the risks and ethical considerations associated with animal testing. Our expertise in the manipulation and differentiation of stem cells into cardiac cell lines allows us to create a synchronously beating layer of human cardiomyocytes in culture. In combination with predictive safety tests – such as multi-electrode arrays – these cells provide a convenient and cost effective cardiac model, allowing safety studies to be performed much earlier in the overall process. Our technology has already been adopted by many of the world's top 20 pharmaceutical companies, demonstrating the huge potential of this approach."

Assay development is at the forefront of Ncardia's offering, and the company is actively involved in the design and validation of assays intended for day-to-day use by pharmaceutical and biotechnology companies. Stefan continued: "Safety pharmacology is just one potential application of human-derived cellular models, and we are also interested in using this technology to enable high throughput drug efficacy testing.

By culturing cardiomyocytes in a 384-well microplate format, we can provide our customers with the tools to screen tens of thousands of potential drug molecules in a human model. This ensures more reliable and accurate screening data, reducing the risk of throwing out the baby with the bath water."

Farbod Famili, Assay Development Scientist at Ncardia's Leiden facility in the Netherlands, took up the story: "Pharmaceutical companies understandably demand assays that are robust and reliable, and compatible with high throughput automated screening platforms. When I first arrived at Ncardia, almost all of our processes were performed manually, which worked when handling a limited number of compounds for safety pharmacology studies using multiwell multi-electrode array chips, but was not compatible with high throughput efficacy testing applications. We therefore wanted to automate the entire cell culturing process, performing each step as quickly as possible to avoid variations across a microplate. We looked at the various liquid handling solutions on the market, and were impressed by both the speed and flexibility of the Fluent® Automation Workstation. With three independent arms, it offered us the potential to significantly accelerate the process, while still being a very versatile platform.

We had already had a positive experience working with Tecan when we purchased a Spark® microplate reader, and so we were confident in both the service and support the company offers."

> "We had already had a positive experience working with Tecan... so we were confident in both the service and support the company offers."

"The system was installed at the beginning of the summer, and has everything required to culture and differentiate stem cells integrated into it, including an automation-friendly incubator and a laminar flow HEPA hood to ensure sterility. We knew that setting up such a complex workflow for highly sensitive cells would be challenging, and finding the optimal labware and workdeck configuration was the first obstacle, but the 3D simulator in FluentControl™ makes it very easy to visualize your protocols, speeding up process development. It also gives you the option to define everything – labware, protocol availability, dispense volumes, etc. – for inexperienced operators, which makes it much easier for everyone in the lab to use the system once it is in routine use. Working in 384-well microplates, we're currently handling 40 plates in a single run. This would take at least five times as long to do manually, so the benefits are felt immediately."

Article first appeared in TJSE/2018, pages 12-13

For more information on Tecan's drug discovery portfolio, visit
www.tecan.com/drugdiscovery

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about Ncardia,
go to www.ncardia.com

Darting from plate to plate.

Dart NeuroScience specializes in the development of novel therapeutics targeting neurological disorders, with an emphasis on impairment of cognitive functions such as memory. The company generates over a thousand new compounds every week to feed into its active drug discovery pipeline, creating a significant challenge for the compound management team.

Joe Zer, Research Scientist

Dart NeuroScience

Medical advances over the last century have dramatically increased life expectancies in developed countries, placing ever-greater importance on geriatric care. The aging process, together with cognitive disorders such as Alzheimer's disease and Parkinson's disease, can lead to significant loss of memory function, creating a niche for therapeutic agents specifically targeting memory disorders. Dart NeuroScience – headquartered at Scripps Ranch in San Diego, California – is one of the few companies globally to be addressing this largely unmet medical need, aiming to discover new technologies and develop novel therapies to help maintain cognitive vitality throughout life.

The company's multidisciplinary strategy includes the identification of new therapeutic targets, the generation of closely-related compound libraries and the creation of novel functional assays, as well as the development of specialized clinical therapies. This multi-faceted approach requires a large number of compound plates to be generated for high throughput screening, as Joe Zer, a scientist at Dart NeuroScience, explained: "Like any drug discovery company, we need the ability to test large numbers of compounds quickly and effectively. The advent of high density microplate formats – particularly 1,536-well plates – has considerably increased our ability to screen many compounds in parallel, but this has created a number of logistical challenges for compound management."

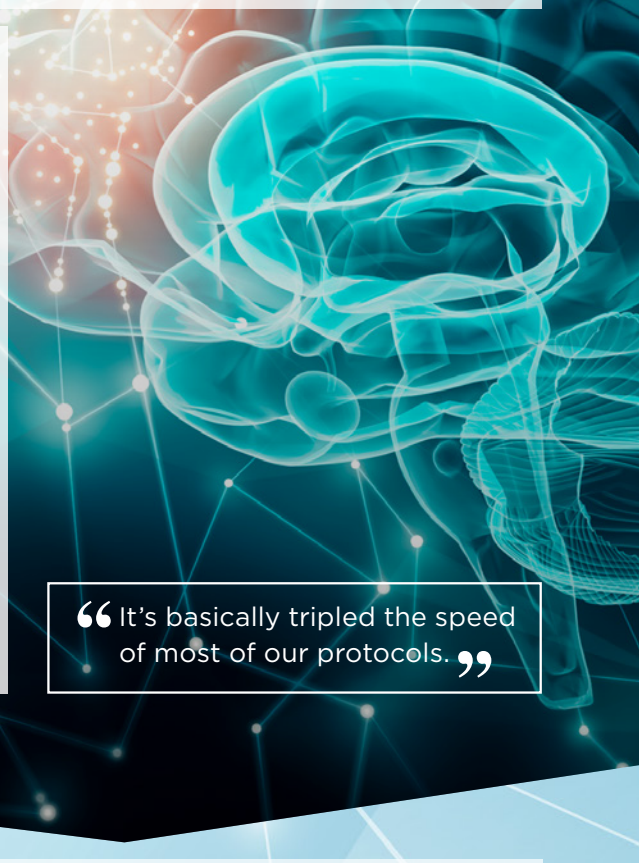
"Our synthesis group produces over 1,000 new compounds every week which need to be transferred to compound plates for screening and profiling. We also periodically buy in compound libraries from commercial manufacturers – sometimes up to 30,000 compounds at a time – which need to be accurately aliquoted and diluted without introducing manual handling errors that could affect downstream processes. As a result, automated liquid handling has become an essential part of our workflow, enabling us to achieve the throughput necessary to keep pace with our various drug development programs, generating hundreds of precisely filled assay plates a day."

"We have been using Tecan liquid handling workstations since the company was founded in 2007, and have over half a dozen Freedom EVO® workstations performing a range of activities," added Jose Quiroz, Manager of Laboratory Systems. "As the company has grown, the number of projects we have running at any one time has obviously increased, and so we were keen to purchase a new platform to increase the throughput of assay plate generation. We evaluated several solution providers and decided to partner with Tecan, using the company's with Fluent® Automation Workstation. The huge on-deck capacity offered by this system, combined with its high speed pipetting capabilities, was very appealing to us."

Joe continued: "The only potential drawback was that we use a unique 1,536-well microplate format. Although these plates conform to ANSI/SLAS standards, they have rounded flat-bottom wells to allow use of a pin tool in downstream operations. Our local Tecan representative was confident that this wouldn't be an issue, so took one of our plates to run on a demo system. He simply loaded the plate onto the system, and it ran perfectly first time using the standard 1,536-well microplate definitions pre-installed in the FluentControl™ software! Following that demonstration, we ordered our system straight away, and it was installed in June 2015. After a few weeks of familiarizing myself with the new instrument, I went on the Tecan training course in North Carolina, and we have had the platform in routine operation since that August."

"The increased throughput the Fluent platform has already given us is fantastic. Where we could previously generate 16 compound plates at a time, we can now produce 32 in parallel, and in a short time frame. And it's even better for dilutions; where we could previously create about 20 single dilutions in parallel, we can now do 56 in duplicate. It's basically tripled the speed of most of our protocols. We are also considering installing a bulk dispense module for DMSO below the workdeck to further increase throughput, as the system's Robotic Gripper Arm can easily access this below-deck area without too much compromise in the instrument's overall capacity."

"Although our workstation is very simple in automation terms, the Fluent platform's high definition liquid handling capabilities are still very impressive. The Multiple Channel Arm moves very quickly compared to most pipetting robots on the market, and the Path Finder™ feature means that it always takes the optimal route between plates.



> "It's basically tripled the speed of most of our protocols."

The Active Stop and Resume function – introduced with the latest software update – is also fantastic; if you see something wrong with the set-up on the workdeck, you can just open the door and it stops. Once you've dealt with the problem, you just press 'Retry' and it picks up where it left off, avoiding the need for laborious resetting or reprogramming of the instrument. The software is also both powerful and very convenient to use; the Zero G teaching capability makes it extremely quick and easy to define plate positions, and almost every aspect of instrument control can be adjusted to make operations faster and more robust."

"We are still in the process of learning the Fluent platform's full capabilities and transferring existing protocols to the new system, but we are already very impressed with its performance. Once more of our staff have been trained on this instrument, we plan to consolidate as many of our standard compound management functions as possible onto the system, providing a single 'go to' solution for plate generation," Joe concluded.

For more information on Tecan's drug discovery solutions, visit
www.tecan.com/drugdiscovery

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about Dart NeuroScience, go to
www.dartneuroscience.com

Article first appeared in TJ1/2016, pages 12-13

Faster food testing.

The Institute for Product Quality, based in Berlin, has grown into a service laboratory that provides virtually any and every test required by the food market, from microbiology to pesticide testing. Using its expertise in food analytics and kit development, and with new, state-of-the-art equipment and facilities in the Berlin-Adlershof science park, ifp provides testing services and kits to the industry and public alike.

From left to right: Nicole Menzel, Victoria Bode and Wiebke Hammers

ifp®
Institut für Produktqualität

The Institute for Product Quality (ifp) is an independent laboratory offering a complete range of services and testing products for the food, feed, water and pharmaceutical industries. Founded in 2004 and now employing 230 staff in its purpose-built facilities in Berlin, Germany, ifp provides comprehensive analysis of allergens, vitamins, genetically modified organisms, pathogenic agents, mold toxins and pesticide residues to food producers and caterers worldwide, as well as sterility testing and other microbiological services for the pharmaceutical industry. In 2013, ifp hit the headlines after detecting non-declared horse meat in frozen ready meals, provoking a media response that boosted its profile in the public eye. Today, householders are also turning to ifp to test the quality of drinking water.

Alongside its extensive service portfolio, ifp also develops and manufactures test kits for many food-related analytes, based on techniques such as real-time PCR, immunoassays, enzymatic assays and microbiological tests. The production facility naturally relies on automation to ensure both high throughput and reliability for its kit manufacturing processes, and has used Tecan liquid handling systems since operations began. Tobias Hein, head of marketing and sales at ifp, said: “We are producing large quantities of kits per lot, and automation is always the better option than having to produce thousands of kits manually. Reproducibility is very important for us and for our customers; significant differences, either within or between kit lots, would be a serious issue, and automation helps us to prevent this.”

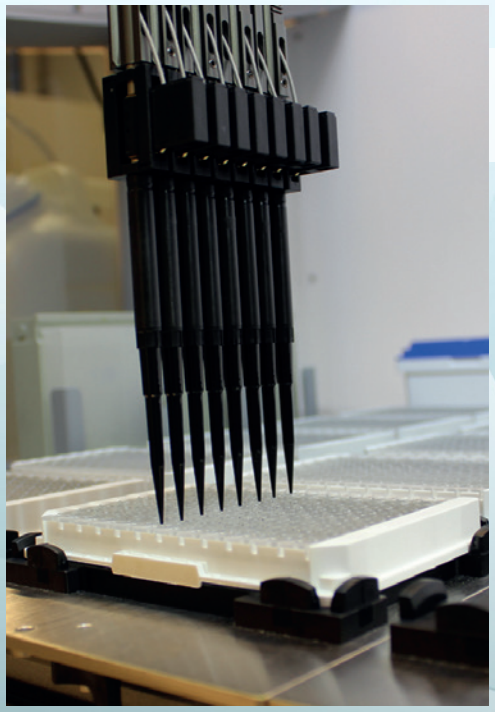
ifp has a suite of Tecan equipment on different production lines, including a HydroSpeed™ that washes microplates as part of the plate coating process involved in the production of the AgraQuant® Plus test kits for food allergens. Genesis™, Freedom EVO® and Fluent® workstations are used to pipette reagents and controls as part of the manufacturing process of various kits. The most recent addition, a Fluent Automation Workstation, was chosen to increase production of ifp’s VitaFast® microbiological kits, as Victoria Bode, VitaFast production and R&D specialist, explained: “VitaFast is a ready-to-use test kit devised for the microbiological detection of all water-soluble vitamins and selected amino acids. The test kit contains all the required reagents – standards, media, and a microplate containing specific micro-organisms – making it remarkably easy to use.
As it is microplate-based, this fast microbiological method can be easily automated, and is ideal for food manufacturers who fortify their products with nutrients and need a precise method for performing batch controls.”

"We chose the Fluent system for the production of VitaFast kits because we wanted to be able to increase our batch size. The high on-deck capacity of the platform – up to 47 microplates with our current configuration – means that we have been able to more than double the number of plates per run. It is also very quick and intuitive to use; new operators find it incredibly easy to learn, and we were able to use it in production just a day after it was installed!"

"Thanks to the workstation's rapid liquid handling capabilities, we can now dispense small volumes of bacterial solutions into each well of the test microplates much faster than was previously possible, saving up to 20 minutes per run. As it does not need to be monitored during operation, staff are also free to walk away while it is running. This allows them to perform other work sooner than would otherwise be possible, further increasing productivity."

> "...ideal for food manufacturers who fortify their products with nutrients..."

Article first appeared in TJ1/2016, pages 16-17



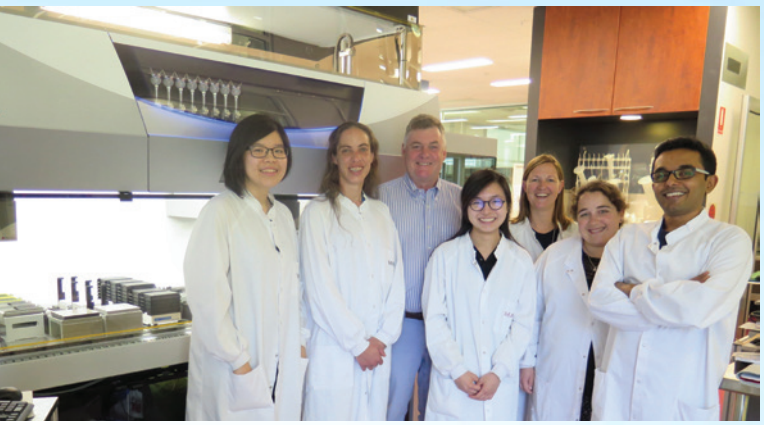
Reliable and reproducible liquid handling is vital for consistent assay kit manufacture

For more information on Tecan's food sciences solutions, visit
www.tecan.com/food

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about the Institute for Product Quality, go to
www.produktqualitaet.com

Building functionality into the antibody supply chain.



The Monash Antibody Technologies Facility (MATF) in Victoria, Australia, has added a new dimension to its high throughput service, offering screening for antibody functionality. This time-consuming phase is crucial for many projects, and can now be outsourced to MATF, where comprehensive and flexible automation completes testing in a fraction of the time.

Members of the MATF RoboCore team

MONASH University

MATF is a core facility based at Monash University with a global reputation for producing high quality, high affinity monoclonal antibodies for biomedical research projects around the world. Approximately half of the MATF's projects stem from the medical and biochemistry faculties at the university, with the remainder from academic institutes, large pharmaceutical and small biotech companies further afield. Dr Caroline Laverty, Head of Robotics and Manager at MATF, explained: "Our core business is monoclonal antibodies. We are quite unique with regard to our high throughput capabilities, but our important differentiating factor is delivery of a high quality product. We are an ISO 9001 certified facility, and have a great deal of combined knowledge in the antibody field, including pharmaceutical industrial experience from myself and the facility's director Professor Mark Sleeman. Our projects are highly varied, because they all depend on customer-focused, versatile screening strategies that deliver exactly what the customer wants. We have tried-and-tested core methodologies which we add specific details to, according to what is required – How many antibodies? What sort of antigen? How many screening samples? What is the intended end use? – which is where we build in the flexibility."

"Our robotic systems are very much integrated into how we find antibodies, and how we screen them. We also operate a smaller liquid handling facility – RoboCore™ – and automation makes the job easier for us and gives us the power to be diverse. For every project, we are able to generate far higher numbers of hybridomas – and hence a bigger pool of antibodies for potential screening – than would be possible manually. Most of the time we're effectively looking for a needle in a haystack. The robotics we have mean that we can start with a really big haystack, and still effectively screen it to find the needle. Automation also gives our staff 'headspace' to think about the science; it reduces the amount of staff needed in the lab. We looked into this a couple of years ago, and without our automation we would need upwards of 20 people to achieve the same output – that's five times our current head count."

Until recently, MATF has supplied its customers with antibodies that have been tested by microarray and ELISA to confirm that they bind to the corresponding antigen, at which point the customer has screened them in house for functionality. This is particularly true for the growing field of therapeutic antibodies. However, this is a very time-consuming part of the process which often takes months. For this reason, and at the request of customers, MATF has invested in a new Fluent® Automation Workstation that can complement this phase of screening. Caroline explained that the new system will enable them to scale up functional cell-based assays developed internally or by customers to screen hybridomas. "We will be able to tell them at an early stage that the antibodies not only bind, but that they are also functional, potentially saving the customer months, if not years, of work."

Caroline's background is in the application of automation to varied laboratory procedures, and she said of the Fluent: "This system is fundamentally different, in ways which are essential when you're trying to deal with so many projects on the go at the same time. The demographic of our customers' projects is quite wide – these antibodies may be for anything from veterinary medicine to medical research and diagnostics – and we expect to be running up to 10 screening campaigns at any one time.

> "Without our automation we would need upwards of 20 people to achieve the same output – that's five times our current head count."

The Fluent has been configured to give us maximum flexibility; it is slick, smooth and very easy to teach.

The way the deck is configured is ideal for us; we can add or take away modules, carriers or other pieces of equipment very easily. And there are other simple, yet really useful things. For example, if an assay stops halfway through a protocol for any reason, it can find itself in space rather than having to go back to home each time. The 10 Freedom EVOs® we have are brilliant – they're very reliable and robust – but the Fluent is something quite different."

Caroline concluded: "Our relationship with the Tecan team in Australia is really the icing on the cake, and we actively promote this well-built partnership. We rely on the service Tecan provides, because we have an obligation to our customers. We quote timelines and quality and, to achieve that, we need all of our instrumentation to be working all of the time. The back-up and application support are fundamental for our processes, and I don't believe that any automation company other than Tecan can provide us with that level of assurance."

For more information on Tecan's protein sciences solutions, visit
www.tecan.com/proteinscience

To find out more about Tecan's Fluent Automation Workstation, visit
www.tecan.com/fluent

To learn more about the Monash Antibody Technologies Facility, go to
platforms.monash.edu/matf

Article first appeared in TJ2/2016, pages 16-17

Faster processing for biosimilars.

The biosimilars market is expanding rapidly as the patents expire for an increasing number of high profile biopharmaceutical agents. The complex nature of biologics requires extensive characterization of the production techniques and *in vivo* effects of new biosimilars before they can be released onto the market. Coherus Biosciences is using advanced laboratory automation to help screen chromatography conditions as part of its downstream purification processes for new biosimilars.

Brian Williamson with Coherus' Fluent Automation Workstation

Coherus BIOSCIENCES

The importance of biologically-derived therapeutics is of ever-growing importance to the pharmaceutical sector, offering more specific and targeted therapies for the treatment of a wide range of conditions and diseases. Unlike generic versions of small molecule drugs, which have chemically identical active ingredients to marketed products, most biologics are heterogeneous preparations composed of multiple protein or antibody subspecies, as well as a variety of other closely associated biomolecules. They are therefore complex to both manufacture and purify, and this presents a major challenge for follow-on manufacturing of generic versions of these medicines – known as biosimilars – once their patents expire.

Coherus Biosciences – based in Redwood City, California – develops, manufactures and markets high quality biosimilar therapeutics with the aim of reducing healthcare costs for treating chronic or life threatening diseases. Founded in 2010 by a group of like-minded industry veterans with extensive experience in the biopharmaceutical industry, the company focuses on inflammatory diseases and cancers, aiming to expand access to biologically-derived medicines.

Downstream processing is an essential element of the biosimilar workflow, ensuring reliable and reproducible manufacture of a product showing the same in vivo effect as the original biologic. Chromatography is commonly used to separate target molecules from the rest of the production cell culture, requiring rigorous screening of chromatography conditions to enable efficient extraction and recovery. Brian Williamson, a senior scientist in Coherus' downstream laboratory, explained: "In our development program, we screen many different chromatography conditions and media to identify protocols capable of separating out various proteins of interest from all the other cell culture components, such as degraded proteins and product-related contaminants. We built up our laboratory from scratch on a limited budget, but I requested automated equipment to help accelerate the whole downstream development cycle. It's obviously a commitment on my part, as there's a significant learning curve with any advanced laboratory equipment, but being able to automate chromatography experiments is very helpful; it allows us to very quickly screen conditions to find a protocol that is suitable for use in a manufacturing environment."

> “Our Tecan systems are enabling us to run new types of experiments that were not previously possible, generating much more data and making it much easier to answer questions and find solutions for our manufacturing environment.”

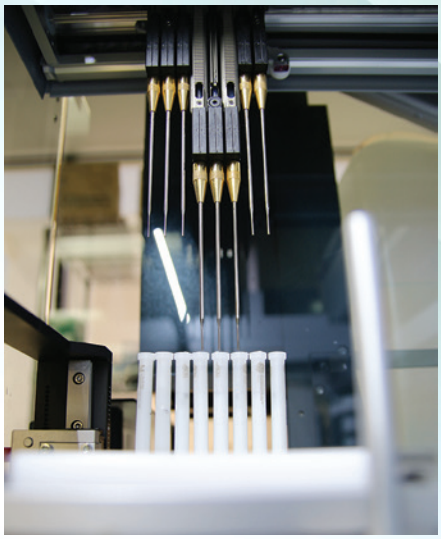
“I was already familiar with the various options on the market, and chose Tecan liquid handling platforms because I had some limited experience of using the company’s instruments in a previous role, and I could see how well they would fit into our whole development workflow.
A lot of work has been done in this field with OPUS® RoboColumns® (Repligen) – it’s clearly a front runner in the sector – and combining this technology with the Freedom EVO® platform is ideal, allowing us to run eight chromatography separation experiments in parallel. There are other systems on the market that offer a similar approach, but they just don’t have the degree of fidelity that this combination does.”

“We are now running about 16 columns every day, with each cycle of eight experiments taking six to 10 hours.
This gives us an eight-fold increase in throughput compared to manual methods, as a researcher could only run two or three columns a day. The samples collected from the RoboColumns are then either analyzed in our laboratory to find chromatography conditions that can be scaled up for manufacturing purposes, or by our analytical laboratory to support other studies or regulatory filings.”

“We have also purchased a Fluent® 480 Automation Workstation to perform general liquid handling tasks in the lab, as this frees up the Freedom EVO platform for large-scale screening of chromatography conditions,” Brian continued.

“The Fluent has an eight-channel Flexible Channel Arm™ with disposable tips, which not only allows us to quickly perform repetitive liquid handling tasks – such as preparing cultures and batching plates – it also gives us the flexibility to run PhyTip® columns (PhyNexus) for small-scale and lower-fidelity separations. This technology is ideally suited to sample preparation applications, offering rapid clean-up of eight samples in parallel for our analytical laboratory.”

The Freedom EVO allows complete automation of the RoboColumns workflow



Up to eight chromatography experiments can be run in parallel

“Our Tecan systems are enabling us to run new types of experiments that were not previously possible, generating much more data and making it much easier to answer questions and find solutions that are appropriate to implement in a manufacturing environment. Both systems, each with a different focus, are great time savers and really benefit our workflow; the Freedom EVO/RoboColumns combination is clearly the way to go for large-scale chromatography condition screening, and the Fluent offers more advanced automation, with higher precision and reproducibility. The support we receive from Tecan is also fantastic; we always get a quick reply to any questions we have, which is a really good way to resolve issues that come up,” Brian concluded.

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What is normal? Understanding the vaginal microbiome.

Microbiome research is still in its infancy, with little currently understood about the role micro-organisms play in both maintaining our day-to-day health and the genesis of disease. Researchers at the Karolinska Institute are using next generation sequencing to establish a baseline of the microbiota present in healthy individuals as a starting point for the development of new therapeutic strategies for a wide range of diseases.

The human microbiome – the collection of micro-organisms living on or within our bodies – plays a vital role in our health, from assisting in the digestion of foodstuffs within our gut to causing or preventing certain diseases or cancers. Despite this, the composition and maintenance of the microbiome is poorly understood. Although some progress has been made in this area over the last decade, a majority of current research initiatives are directed towards the gut or skin microbiomes, with little focus on other tissues and biofluids.

The Centre for Translational Microbiome Research (CTMR) – a collaboration between Sweden's Karolinska Institute, Science for Life Laboratory (SciLifeLab) and Ferring Pharmaceuticals – and the Human Microbiome Translational Research Program (HMTRP) aim to better understand the contribution of the human microbiome to human health, with the goal of developing novel therapies. Its current focus is on the microbiomes of the gut and the female reproductive organs. Maike Seifert, Laboratory Engineer at CTMR, explained the center's approach: "The gut microbiome was the first microbial population to be investigated, and initiatives such as the Human Microbiome Project mean we are now beginning to understand the composition and interplay of microbial populations within the gastrointestinal tract. However, microbiota are also thought to play a significant role in women's reproductive health, and so we are looking into this field too. The major problem with this is that, in order to understand what is abnormal, first we need to know what is 'normal'. Because so little comprehensive research has been done in this area, a 'normal' baseline of the micro-organism population has not been established, and so we have just begun a large study to better define this."

"When samples arrive in our laboratory, we begin by extracting and aliquoting the DNA using a Freedom EVO® workstation. The resulting extracts are quantified using a Spark® reader, then one aliquot is sent to the biobank, and a second is used for sequencing. Most of our studies rely on 16S rDNA sequencing to identify the micro-organisms present, which starts with DNA normalization. This is performed by our Fluent® Automation Workstation, which uses the concentration data from the Spark to calculate the exact pipetting volumes to achieve normalization. The system then performs the library preparation, generating sequencing-ready samples that can be run on our MiSeq™ platform."

Maike continued: "We chose the Fluent system for this application because our previous liquid handling platform was not able to perform eight-channel pipetting. This meant that normalization had to be done one sample at a time, taking two and a half hours per plate and creating a major bottleneck in our workflow. In comparison, our Fluent can perform the same normalization in just 15 minutes, saving a huge amount of time. Another benefit, which we hadn't appreciated until we began validating the system, is that the Fluent pipettes incredibly precisely; I've never seen an automated platform anywhere near as accurate – it's wonderful. This will be particularly useful for whole genome sequencing, which requires extremely precise amounts of DNA from very low concentrations of starting material – as little as 0.2 µg/µl – to achieve high quality libraries."

"Using the Fluent has certainly improved the quality of our library preparations, and our laboratory staff are happier. It has also virtually eliminated the risk of pipetting errors during normalization – a task that requires a lot of focus to perform manually. Human error is one of the greatest risks to results in any lab, and so I am a big fan of using automation to reduce hands-on time as much as possible, especially for high throughput studies. We currently perform one sequencing run a week, which could potentially be done manually, but using the Fluent workstation is better for both our staff and samples, and will allow us to increase this to two runs a week as our sample numbers increase," Maike concluded.

Article first appeared in TJ2/2017, pages 20-21

> "Human error is one of the greatest risks to results in any lab, and so I am a big fan of using automation to reduce hands-on time as much as possible."

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To learn more about the Centre for Translational Microbiome Research, go to
ki.se/en/research/centre-for-translational-microbiome-research-ctmr

Flexibility for speed.

Maintaining a flexible approach can be difficult in biopharmaceutical research; core laboratories must balance the ability to adapt to individual project requirements with the need for efficient, high throughput processing of ever-increasing sample numbers. Novo Nordisk's Research Bioanalysis Department has adopted a semi-automated workflow, which combines the versatility to work across the company's various research areas with accurate and reproducible testing of thousands of samples a day.

Left to right: Kirsten Jensen, Anita Svendsen and Johannes Fels with the Fluent platform

Originally established in the early 1920s to manufacture insulin for the Nordic market, Novo Nordisk has retained a strong focus on the treatment of diabetes. Today, this expertise in protein and peptide technologies is also being used to develop products for hemophilia and other bleeding disorders, as well as growth and hormone replacement therapies.

Biopharmaceutical development and biomanufacturing rely on an in-depth understanding of the complex in vivo actions of therapeutic products to ensure their safety and efficacy. The Research Bioanalysis Department, based at Novo Nordisk's research center in Måløv, Denmark, is responsible for investigating the pharmacokinetic and pharmacodynamic profiles of drug candidates from across the company's research pipeline. Samples from animal or cell culture experiments are tested with a panel of 100 to 200 immunoassays to gain a thorough understanding of their activities. Around 15 years ago, the laboratory automated its ELISA procedures to increase throughput, and improve the accuracy and reproducibility of testing.

The sensitivity and convenience offered by bead-based AlphaLISA® immunoassays have made it the technology of choice within the department, and these chemiluminescent assays now account for over 70 percent of the total immunoassay workload. Johannes Fels, Principal Scientist, explained the department's workflow: "We have a total daily throughput of around 35,000 tests, and use a combination of fully and semi-automated set-ups to ensure rapid turnaround times, and to give us the flexibility to adapt to changing project priorities. We purchased a Fluent® Automation Workstation last year to further increase our throughput, and it is now used to perform various liquid transfers and sample dilutions as part of both our automated and semi-automated workflows. AlphaLISA is a very easy technology to run in a relatively high throughput format – there are only two reagent additions and two incubations – and so, although many of our protocols could be completely automated on the Fluent, semi-automation frees up the platform for other users to perform fast assay set-up or dilutions during the incubation steps. This way, each plate only takes two or three minutes, occupying the liquid handling workstation for just a short time."

"A typical semi-automated AlphaLISA protocol starts with the Fluent diluting samples 10-, 20- or 40-fold from mother to daughter plates. Next, the Fluent is used to transfer samples from both mother and diluted daughter plates into a 384-well assay plate containing two replicates of each source plate.

After this step, the assay plates are manually transferred to a benchtop dispenser, where assay buffer containing biotin-labeled antibodies and AlphaLISA acceptor beads is added. By running both the mother and daughter plates, we can more than double the experimental window for each assay, helping us to overcome large variations in sample or analyte concentration without performing repeat testing. Plates are incubated offline for one hour, and then moved back to the benchtop dispenser for addition of streptavidin donor beads, followed by another 30 minutes incubation. Finally, the plates are transferred to a reader for chemiluminescence measurements."

"Accurate and reproducible low volume dispensing is vital to achieve reliable assay performance using this very sensitive immunoassay technology, and we worked closely with the local Tecan team to design a site acceptance test that would demonstrate the suitability of the system for our needs. We were immediately able to achieve very low CVs of 2-3 % for 1 µl plasma transfers into dry 384-well assay plates, so we were confident that it would perform as expected. Another nice feature is the extended volume tip adaptor, allowing us to combine four channels of the Multiple Channel Arm to perform 96-well dispensing of up to 500 µl at a time. This makes it very versatile; you can perform 100-fold dilutions in a single step, something we have not seen on any other liquid handling system."

"Staff like the Fluent platform – it is completely reliable, very fast, accurate and nice to work with – and everyone in the department runs the same set of universal scripts, simply changing the dispense volumes, dilutions, matrices and buffers between the various assay procedures. Everything we need is programmed into the user-friendly FluentControl™ interface, and I especially like the way the liquid classes are built up within the software. Our local Tecan application scientist helped me to do the initial scripting, so we were able to get the various protocols up and running as we wanted within two weeks of delivery," Johannes concluded.

Article first appeared in TJ2/2017, pages 22-23

> "Staff like the Fluent platform – it is completely reliable, very fast, accurate and nice to work with."

Kirsten Henriksen (left) and Annette Larsen return samples to the hotel

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Keeping an eye on stem cells.

Stem cell research has seen explosive growth in recent years, with the technology holding promise for the treatment and cure of a wide range of conditions, from cancer, diabetes and heart disease to neurological conditions, inherited disorders and conditions of aging, including age-related macular degeneration (AMD). The Stem Cell Institute (SCI) at the University of Minnesota, founded in 1999, was the first integrated stem cell institute to be established in an academic environment, and focuses on basic and translational research with these versatile cells.

Associate Professor James Dutton and Professor Deborah Ferrington in the dedicated stem cell laboratory

The ability of stem cells to differentiate into a variety of other cell types offers the potential to treat and cure a range of diseases and benefit patients worldwide. The University of Minnesota SCI is a collaborative center for researchers from 25 university departments, focused on gaining a greater understanding of stem cell biology and the potential uses of this technology. It has an emphasis on the study of induced pluripotent stem cells (iPSCs), primarily because they can be generated from any individual, and can be used to model diseases, discover patient-specific drug responses and potentially generate autologous cells for transplant therapies.

Dr James Dutton, Associate Professor at the SCI and the Department of Genetics, Cell Biology and Development, and Director of the SCI Innovation Facilities, explained: “My group researches an array of diseases that currently have no cure or effective treatment. One major focus is dry AMD, a disease affecting older individuals that causes patients to lose their central vision. This condition is highly prevalent in the Northern European population that settled in Minnesota, and I work closely with Professor Deborah Ferrington from the Department of Ophthalmology and Visual Neurosciences to investigate this area. Our studies center on mitochondrial dysfunction in the retinal pigment epithelium (RPE) – a single cell layer at the back of the eye – that is damaged in the eyes of AMD patients. Much of the initial work was conducted using eyes donated to the Lions Gift of Sight eye bank, however, to move this research to our AMD patient population, we needed to find a way to look at RPE cells from living individuals. We have done this by taking a 2 mm biopsy of the conjunctival layer covering the white part of the eye, reprogramming these cells to produce iPSCs that then undergo a differentiation protocol that causes them to become RPE cells. Using these iPSC-RPE cells, we are able to screen a range of potential candidate drugs, aiming to find effective ways of maintaining or improving mitochondrial function.”

“Scaling up this process of making iPSC-derived RPE and testing the cells in a targeted drug screen would be extremely difficult without automation; we would need a large team of people, and it would be very slow and prone to error. However, until recently, automation of iPSC derivation, culture and differentiation has been complicated and technically challenging. We needed to find a user-friendly, cost-effective automation platform that would perform these methods efficiently, demonstrate scalability and commercial viability, and would fit in the space we had available.”

"With support from a generous philanthropic donor, we looked at a number of options and chose two Fluent® 780 platforms, and the department refurbished laboratory space specifically to house these units. The systems are excellent; we can perform the whole end-to-end process of derivation, culture and differentiation of the iPSCs into RPE and set up for the drug screening process on them. We designed the systems to suit our needs, including an integrated HEPA filter hood to create a sterile environment, a LiCONiC automated incubator to hold the plates, a Cytation™ 1 Cell Imaging Multi-Mode Reader to monitor cell confluence and morphology, and an integrated centrifuge for spinning down cells during passage. Additionally, there are two EchoTherm™ IC20 dry baths on the deck for sample and media temperature control, and a barcode reader to track samples throughout the process. The platform has three arms: an eight-channel Liquid Handling Arm™, a MultiChannel Arm™ 384 and a Robotic Gripper Arm™, which together, are able to perform all tasks associated with cell handling. The Tecan Labwerx™ Group has been especially good at ensuring full connectivity between all the equipment from third-party manufacturers."

"The platforms are very intuitive to use and can replicate everything that we used to do by hand – we can even control the speed, pressure and pattern of pipetting. We can measure colony size and cell density to track growth using the integrated imager, and the systems automatically perform daily media changes at the differentiation stage when the iPSCs are converted into RPE cells, saving us hours of 'people power'.

"The platforms are very intuitive to use and can replicate everything that we used to do by hand – we can even control the speed, pressure and pattern of pipetting."

The Tecan team is now refining its scheduling software to further complement our system, so that we can connect our entire protocol and minimize the need for human input.

This will increase efficiency and, using multiple platforms, the workflow could easily be scaled up to a commercial level if necessary."

"We now have data from both donor eyes and living patients, and we are building up a patient cell bank of conjunctival cells, iPSCs and iPSC-derived RPE, as well as generating results from the preliminary drug screens. The aim is to add to our data over the next few years so that we can start to see what drugs can help AMD patients. At the same time, we are planning to automate a number of other differentiation protocols on the platforms to make other cell types from iPSCs, such as glial cells and neurons. From there, we would like to expand into more technically difficult procedures such as organoid and 3D cultures – it's an exciting time," concluded James.

The University of Minnesota SCI is supported by the UMN Academic Health Center.

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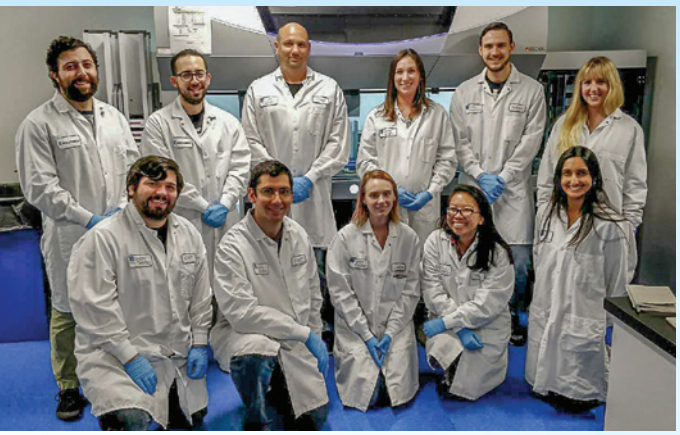
Taking a Fluent® approach to genetic screening.



Clinical diagnostics company Ambry Genetics focuses on the identification of germline mutations, detecting large deletions and duplications primarily by next generation sequencing. Automation holds the key to efficient high throughput assays, ensuring optimum productivity.

Members of the Ambry Genetics automation team (left to right): Omar Alwatter, Chris Ramirez, Muaeen Obadi, Parker Sankey, Chris Yenzer, Emily Greene, Joy Rae-Radecki Crandall, Nina Do, Andrew Haling, Aarani Arulmoli and Sinead Hawker

Ambry Genetics, based in Aliso Viejo, California, specializes in genetic clinical diagnostics, offering services such as screening for familial cancers and exome testing to identify previously undetected mutations. In addition, the company collaborates with universities and other research groups via the AmbryShare™ program, sharing its large disease database of aggregated anonymous data from 11,400+ human genomes. Fast and flexible liquid handling workstations are essential in this high throughput environment, as Director of Assay Automation Joy Rae-Radecki Crandall explained: "Automation is vital for our work, and we are long-term users of Tecan's liquid handling platforms, with more than 30 Freedom EVO® systems. With the business growing rapidly, we recently expanded into the adjacent building, known as the Ambry Superlab, and this led to the acquisition of 16 Fluent Automation Workstations to increase our capacity, speed and flexibility."

Joy continued: "The Superlab was designed to be as efficient and high throughput as possible, with a capacity of thousands of samples per run, and the flexibility to swap out different assays and chemistries. I looked at a range of liquid handling platforms for the new facility, evaluating them for their speed, capacity and flexibility – we wanted to be able to customize the systems – and the outstanding capabilities of the Fluent quickly became clear. As we were already using the Freedom EVO platform, we were also familiar with the liquid classes, making the transition to the Fluent easier. Validation of our workflow scripts was quicker and simpler too, as the systems use the same worklist file formats."

"Each of our systems has been tailored to our specific requirements, whether it is a large Fluent 1080 with a carousel and stacker, or a medium-sized, dual arm Fluent 780 platform. We customized every system for an individual assay, with different liquid handling arms and integrated third-party devices where necessary, and took advantage of the Multiple Channel Arm's capability to switch pipetting heads on-the-fly, changing between 96- and 384-channel formats depending on the assay. Combined with the large deck capacity, this tripled our throughput for these assays. Fluent's 'teach-free' feature also proved very useful with so many workstations to set up, and within six months we had transferred all of our current methods and completed the validation. Critically, the Fluent system's design gives us the flexibility to easily change the deck layout. Not only does this provide built-in redundancy – switching from a layout customized for NGS to a microarray set-up is quite straightforward – it also allows new chemistries and assays coming onto the market to be explored without major time and cost implications."

"We are benefitting from time and cost savings as well as the increased capacity. We run numerous hit-picking scripts for PCRs, and a 96-well plate that previously took around eight minutes to complete can be done in about five minutes on the Fluent, trimming at least an hour off our overall preparation time for that step. The parallel arm movements are a great advantage, allowing the Robotic Gripper Arm™ to dispose of a used tip box while the Multiple Channel Arm simultaneously picks up new tips, saving about 15 seconds of time, which adds up when you are running numerous plates per day. We have also been able to miniaturize some assays, changing from a 96- to a 384-well format, reducing the amount of sample and reagent used and decreasing the number of tip mounting and disposal movements from four to one. This saves time and decreases waste, providing considerable additional cost savings."

"FluentControl™, with its TouchTools™ interface and 'wizard-like' guidance, simplifies user management and the day-to-day operation of the systems. Sample security and integrity is our number one priority and, with more than 30 users per instrument, we rely on the user management feature to assign individual permissions and access to scripts. Operators can only see and run those scripts that they have been certified competent for. Automated barcode reading enables sample tracking and eliminates the potential for human error, identifying plate loading errors and notifying the user to take corrective action.

> "I looked at a range of liquid handling platforms for the new facility, evaluating them for their speed, capacity and flexibility... the outstanding capabilities of the Fluent quickly became clear."

To help avoid accidental click-through errors, we even have the option to include a 'Confirm' button on the opposite side of the screen to the rest of the commands. It's a small thing, but it's had a big impact. The video feature is useful too; we can make instructional videos showing the user how to set up the deck, troubleshoot a run, and perform infrequently used protocols, avoiding the need for hands-on refresher training."

"We write all our scripts in house, and people really like using the FluentControl software. They find it logical and easy to use, and can usually start writing scripts after about a week's worth of training. There are a lot of variables to set for each script, and the way that they are displayed makes troubleshooting very easy. It's a clear, linear thought process, which makes the software very powerful. Operators also enjoy having the option to personalize scripts, changing the color of the indicator lights, and even including background music to indicate which step of the protocol is being performed! They are really engaged with the system," Joy concluded.

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