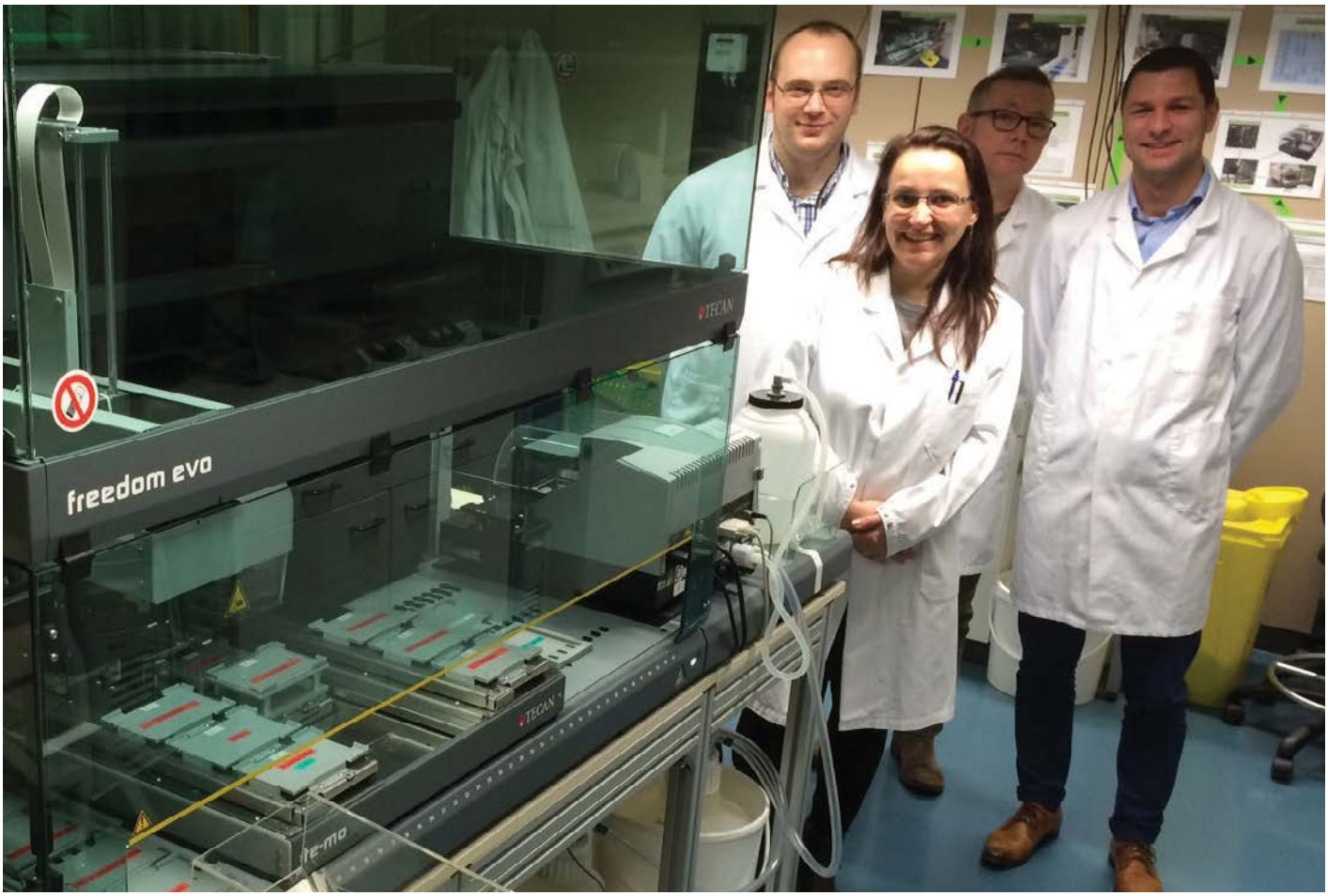
Back-to-back success for bioanalytics

Novartis' Drug Metabolism and Pharmacokinetics (DMPK) Biologics Division, based in Basel, Switzerland, has developed a flexible, fully automated workflow for blood serum sample preparation and ELISA processing by combining two Freedom EVO® 150 workstations. The back-to-back configuration provides the Bioanalytical Group with the features and throughput to support a wide range of automated ELISAs, as well as offering semi-automated sample preparation for other analytical techniques.



Left to right: Lionel Florsch, Sophie Lieb, Christophe Zickler and Ulf Klein with one of the group's Freedom EVO systems

Biologics – therapeutic preparations consisting of antibodies, proteins or other biologically-derived macromolecules – are of ever-increasing importance in the pharmaceutical industry, but their effects on the body are often more subtle or complex than traditional small molecule drug compounds. The Bioanalytical Group of the Novartis DMPK Biologics Division in Basel was set up specifically to identify these effects in preclinical and clinical samples, measuring pharmacokinetics, pharmacodynamics and, crucially, immunogenicity. Dr Ulf Klein, Laboratory Head in the Bioanalytical Group, explained: "Across the industry, biologics portfolios are expanding rapidly compared to small molecule pipelines, and there are evermore sophisticated drug modalities coming in. Where biologics used to be almost exclusively monoclonal antibodies, there is now a broad spectrum of antibody fragments, therapeutic proteins, peptides and other formats in development for various indications."

"This increasing complexity, combined with rising sample numbers, meant that

> "The Tecan instruments are almost like extra analysts."

we needed to look for more efficient ways of performing routine analyses, giving us more time for the development of more sophisticated assays. Automation was one of the options, and so we looked at the various systems on the market. Tecan's Freedom EVO seemed the best fit for our needs, with intuitive software that would enable us to develop and modify assay protocols as required, while still meeting our need for a validated system to operate in a GLP-/GCP-regulated environment."

Ulf continued: "The Tecan team worked closely with us to understand our existing workflow and needs in terms of flexibility and integration of third-party devices. Once we had established the basic specification, Tecan developed the system around two back-to-back Freedom EVO 150 platforms, one to perform sample identification, distribution and dilution, and a second to run ELISAs. This interconnected set-up provides maximum process security while still allowing efficient use of the available deck space."

"Most of our ELISA workflows are fully automated; the operator simply loads the decapped sample tubes onto the system and starts the process. Each sample tube has a barcode which is scanned automatically, and then the system compares the barcode to the assay input list derived from our LIMS. Once matched, samples are distributed into 96-well plates and diluted according to information in the LIMS. Tecan's graphical user interface is very powerful, making it easy to perform these tasks while offering exceptional flexibility, for example we can select a dilution range from 1:1 to 1:1.5 million. Following reformatting and dilution, we either take the 96-well plates off the system and continue the analysis offline – our semi-automated workflow – or the plates are automatically transported through to the second Freedom EVO instrument to run the ELISAs."

"Depending on the project we're supporting, the ELISA protocol can involve simply incubating the sample with an antibody, then washing and reading with the integrated third-party washer and multimode reader respectively, or several wash and incubation steps using multiple reagents. The incubation temperature and times can also vary significantly between assays, which can be easily adjusted. The Freedom EVOware® scheduling software also efficiently arranges the various ELISA steps, allowing us to run several plates without any loss of performance."

"One of the most difficult aspects of the project was building this level of flexibility into a fully validated system that meets our stringent quality assurance criteria and complies with GLP/GCP regulations. With new assay technologies constantly coming onto the market, it was important to have a system that could adapt to changes in our workflow, and Tecan's application knowledge and technical support was invaluable in achieving this. We can now support a number of ELISA protocols, as well as preparing samples for analysis by other methods, such as mass spectrometry."

"Overall, we have been very pleased with the liquid handling performance and reliability of the Tecan solution, so much so that we have now purchased a second system to allow us to automate more of our sample processing and ELISAs. The Tecan instruments are almost like extra analysts – ones that don't mind doing repetitive tasks or working overnight – so we develop our assays manually, then 'hand them over' to the Tecans for routine testing. This ensures reproducible assay performance and a complete audit trail, as well as giving us more time for assay development," Ulf concluded.

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