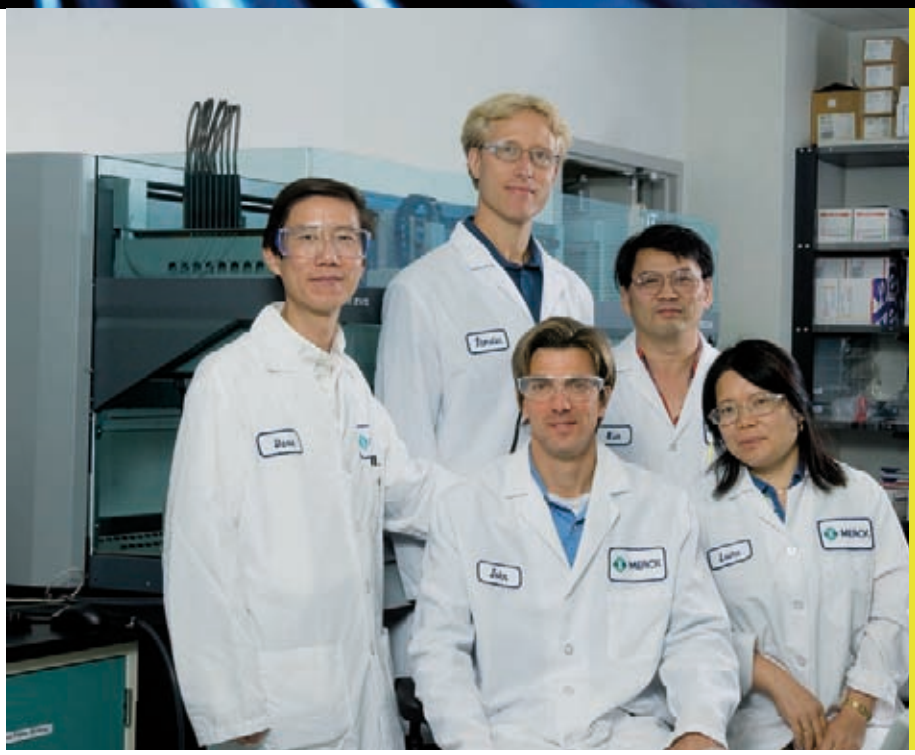
Speeding up drug development at Merck

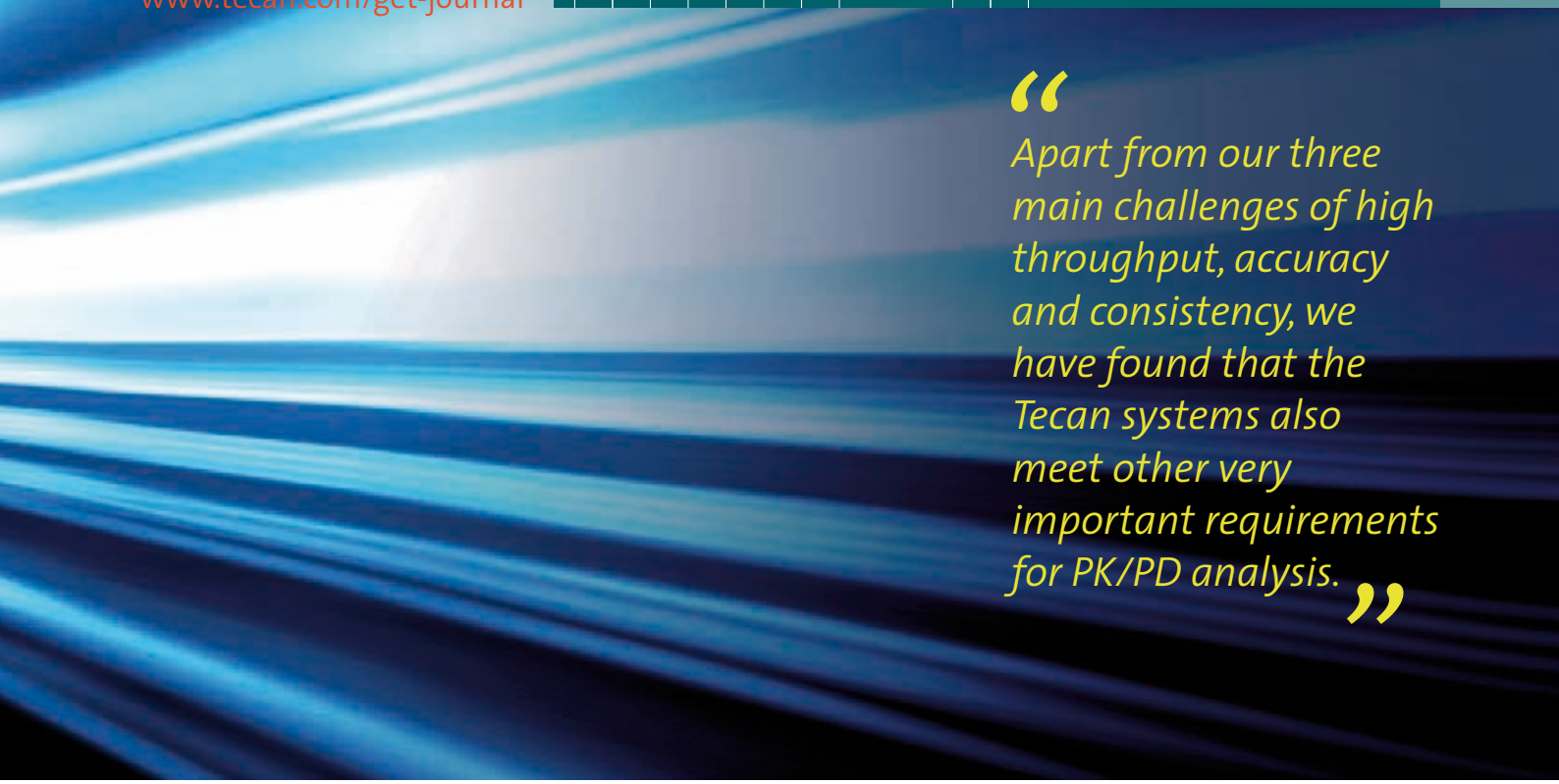
Scientists in the Drug Metabolism and Pharmacokinetics Department at Merck Research Laboratories, Pennsylvania, USA, value the flexibility of their two Freedom EVO® platforms for handling sample preparation and ELISAs in pharmacokinetic/ pharmacodynamic modeling studies.



(L to R) Dave Chen, Thorsten Verch, John Mehl, Kou-Chang Yin and Laura Hong

Drug metabolism and pharmacokinetics (DMPK) is indispensable in drug discovery and development, spanning all stages through pre-clinical and clinical trials, and into the post-marketing phase. An important area within DMPK, pharmacokinetic/pharmacodynamic modelling (PK/PD), helps to improve the prediction of drug action, and can potentially bring costs down for complex drug development programs.

Pharmacokineticists working on large molecule clinical PK/PD projects rely mainly on data from the ELISA method for their PK/PD modelling. Head of the Clinical PK/PD ELISA Lab, Dave Chen, explained the importance of automation in his laboratory: "Our ELISA results have to be of the very highest quality so automated systems are essential to give us very high throughput, accuracy and, in the long term, consistent results from our samples. We provide a bioanalytical



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solution for large-scale analysis of proteins, such as antibodies in serum, and we routinely support two types of project, each with quite separate needs. Firstly, there are pre-clinical studies, where the most important concern is throughput – dealing with a very high sample load in a very short space of time. Secondly, for clinical trials, consistency of results over a long period of time is the crucial factor. I came to Merck with several years' experience in establishing just the kind of system that I could see was required here in the Clinical PK/PD ELISA Lab. In that time, I had evaluated many different systems on the market and had decided that Tecan instruments were my choice for very high throughput protein analysis, largely because they could meet the requirements of both pre-clinical and clinical studies."

There were already two Tecan Freedom EVO platforms available in the Clinical PK/PD ELISA Lab and Dave quickly set to work to optimize these instruments for the department's routine workload. "I had already had good experiences of working with the Tecan support team in the US so knew I would be able to rely on them again to help me establish an efficient workflow with the Freedom EVO systems. Within a few months, both platforms were fully functioning. The Freedom EVO 150 is equipped with a Liquid Handling (LiHa) arm and handles standard calibrations, quality controls, sample preparation and plate loading steps, while the Freedom EVO 200 platform is potentially adapted for fully automated, very high throughput, ELISA processing, complete with a Multichannel Arm™ (MCA), a microplate reader and a washer. Each instrument is controlled through Freedom EVOware® Plus software, which fully coordinates preparation of standards and quality controls, sample dilution, ELISA processing and data interface with LIMS.

"Apart from our three main challenges of high throughput, accuracy and consistency, we have found that the Tecan systems also meet other very important requirements for PK/PD analysis," Dave added. "Flexibility is essential because we are continually changing the ELISA methods that we're working on. Freedom EVOware software is a critical aspect here because it allows us to change the programmed ELISA protocol according to each specific project. Freedom EVOware is an open system that is very easy to use – we have established a number of protocols and don't need to reprogram each time, the software does that for us, automatically matching the program with our requirements. At the end of all this, the platform itself is so easy to operate, just a matter of clicking a button and walking away."

He continued "In addition, there are a few complications specific to our work in protein analysis, all of which the Freedom EVO systems handle without problems. These include biological matrices rather than buffers, various dilution factors and the necessity to dilute samples within that calibration range. These are all crucial to our work in PK/PD studies and the results we have in comparing manual methods with the Freedom EVO in validation were very impressive."

In conclusion, Dave predicted that automation will continue to grow in his laboratory: "We need to continue to develop our automated systems in order to support the increasing demand for the results of our studies. I am preparing to have Freedom EVO platforms working 24 hours a day when studies need."

For more information about Tecan's ELISA solutions, visit **www.tecan.com/elisa**