

Laboratory Insight. Validation. Pharmacopeia. GMP. Efficiency.

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Nänikon, January 2022 – “It’s crazy efficient, it’s really amazing and compliant,” says Dr. Russell Kinghorn about his GMP contract testing laboratory ‘Pharmalytics’, Australia. Several databases, state of the art analytical instruments by two main manufacturers and significantly fewer staff do the work of 30 employees. This article shows how Russell does this by using the example of the UV7 spectrophotometer and the connecting LabX® software of METTLER TOLEDO.

Compliance and the related validation and qualification is the biggest “pain in the neck,” as Dr. Russell Kinghorn calls it. Similar thoughts may be common amongst those working in the highly regulated field of pharmaceuticals. Whether it is the Pharmacopeia of the US, the EU, or Japan – the used equipment needs to be audited at least annually. For those dealing with the US, the FDA also implies its very stringent regulations. Although there is a considerable amount of harmonization between the US and EU now. One method may make the work of heads of GMP laboratories easier: Increase automation as much as possible to raise data integrity.

Dr. Russell Kinghorn put a lot of thought into which analytical instruments from which manufacturer to use. Instruments of two manufacturers made it to his laboratory benches. One of them is METTLER TOLEDO. For three reasons: Their instruments are second to none. Additionally, all analytical instruments build one network using the same software platform. As all components of this network adhere to the regulations, the entire network is compliant.

Setting up a lean laboratory

With this situation in mind, Dr. Russell Kinghorn founded ‘Pharmalytics’ as a GMP contract laboratory for the pharma industry. As such the business is accredited by the Australian TGA and others. With ‘Pharmalytics’, he set up the first true lean pharmaceutical laboratory in Australia. “By not having any clients when we established the business, we were able to set up everything electronically and correctly. We have almost eliminated all paper from the laboratory”, explains Dr. Russell Kinghorn.

For those in a less comfortable situation, Dr. Russell Kinghorn offers a valuable hint. He only sees one way to turn an existing, working laboratory into a paperless one: “Buy all-new analytical balances, and software and set it up at the side while no one uses it. Get it all compliant, validated, working, get all the bugs out of it, and then one day of one week just switch over.”

Databases in use

“We use five databases in the lab: One is a LIMS, one for METTLER TOLEDO, and three others,” states Dr. Russell Kinghorn. “That is not perfect, but close to.” He continues to explain his decision for METTLER TOLEDO: “The reason is that we have only one platform to validate, train people on, ...” After deciding for METTLER TOLEDO, he spent some time adjusting their software LabX to his needs. Each instrument was separately connected. The UV7 for example was set up and programmed so that all actions required by the SOPs are shown on both the instrument’s terminal and the computer screen. “If LabX is in compliant mode, everything is tracked,” explains Dr. Russell Kinghorn. Usually, no second person is required for a review.

Russell can exactly contextualize the efficiency of his lab. Before founding ‘Pharmalytics’ he sold another contract laboratory with approximately 50 staff. Further supporting numbers are presented by METTLER TOLEDO for weighing processes. Although they may vary according to the kind of instrument used and the actual assays performed, the tendency will remain equal. Research suggests that moving from a manual to an electronic process increases productivity by 194% for each weighing. Even if a laboratory already uses a printer, converting to an electronic process still results in a productivity gain of 134%.

Qualification of instruments

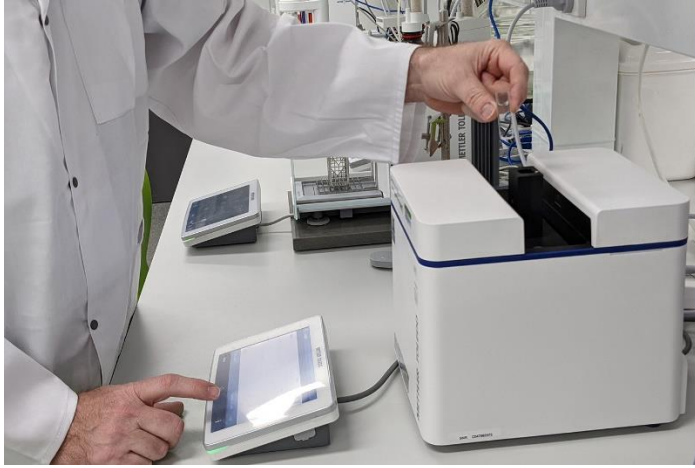
If a person knows how to work with one analytical instrument by METTLER TOLEDO, they can work with all of them. Apart from scales, pipettes, titrators, and so on, Dr. Russell Kinghorn uses the above-mentioned UV7 for UV spectroscopy. This “cute” instrument, as Russell names it, meets the requirements of all GMP guidelines. And when connected to LabX, those of 21 CFR Part 11 of the FDA as well. This means that accuracy, reliability, and data integrity are ensured. In addition, this instrument completes its analysis within a second or two and is very easy to use. Apart from that, the UV7 has about the size of a writing paper. And all it needs to do its work is an electrical plug. He also explains: “Its open sample path is perfect; it has a brilliant calibration – the CertiRef™ is ingenious!” By using the CertiRef™, the UV7 can be easily qualified whenever needed.

Dr. Russell Kinghorn remembers that it took about one day to mix up all the solutions and do the testing required for qualification and validation in the past. “With the CertiRef™ this process takes about an hour and a half.” For that, the CertiRef™ is mounted on top of the UV7 and plugged in. The software starts and it works its way through the required tests.

Start the system and get your work done

The entire Pharmalytics Laboratory works like this, and he is as close to his vision of a paperless lab as it gets. Assays for phase 1 or 2 clinical trials and the testing of raw materials, active ingredients, or finished products is what ‘Pharmalytics’ does for their customers. “There is no high-volume repetitive work,” Dr. Russell Kinghorn explains. Thus, there is no need for him to invest in total automation, which is also possible with the UV7.

He remembers one of the last jobs Pharmalytics has completed with the UV7: A clinical trial required a protein content assay. He had never performed this specific analysis before. In LabX he found a fitting protein content measurement. Russell imported it and adapted the name and the related calculations to what he needed. After saving and validating it, the UV7 simply did its work – fast, accurate, and compliant.



The UV7 meets the requirements of all GMP guidelines. And when connected to LabX, those of 21 CFR Part 11 of the FDA as well.



"It's crazy efficient, it's really amazing and compliant," says Dr. Russell Kinghorn about his GMP contract testing laboratory 'Pharmalytics', Australia.

Find out more on www.mt.com/uv-vis or contact your local sales representative for more information.

About METTLER TOLEDO

METTLER TOLEDO is a leading global supplier of precision instruments and services. The Company is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial, and food retailing applications. METTLER TOLEDO also holds top-three market positions in several related analytical instruments and is a leading provider of automated chemistry systems used in drug and chemical compound discovery and development. In addition, the Company is the world's largest manufacturer and marketer of metal detection and other end-of-line inspection systems used in production and packaging and holds a leading position in certain process analytics applications. Additional information about METTLER TOLEDO can be found at www.mt.com.

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