The quest for quality

IN THE SECOND ARTICLE OF A TWO PART SERIES, SOPHIA KTORI, EXPLORES THE ROLE OF LABORATORY INFORMATICS SOFTWARE IN MAINTAINING ACCURACY AND DATA INTEGRITY IN A QA/QC LABORATORY

Janet González, senior product manager at Abbott Informatics, notes that while manual systems can struggle to document and follow procedures a LIMS system is ideally suited to this functionality.

'Data integrity and transparency can be verified through the use of secure audit trails, which track every activity in the lab, record who carried out which function, and when, using which instrument,' commented González. 'All this makes it much easier to satisfy requests for data during an audit, and to use analytics to identify what, in the process, may have led to out of specification results, or adverse trending.'

Informatics platforms can similarly prevent the time and cost associated with rework due to the use of unqualified equipment, for example. 'In a paper-based lab it may be possible to miss if your equipment is due for maintenance or calibration.

If you carried out tests using this equipment you would have to go back and validate the data that was generated, or perform additional tests to justify that the system was suitable, not to mention that you will have to document the event in an investigation and determine corrective and preventive actions' González notes.

'It is time-consuming and costly. A LIMS solution can prevent that, by ensuring that samples are only sent or assigned to instruments that have been correctly calibrated and maintained, and also by managing maintenance scheduling. Similarly, LIMS platforms can be configured to assign work only to those analysts who are qualified to do that work,' González added.

Implementing a solid informatics infrastructure will help ensure that all current regulations are met at each point in the workflow, as well as facilitating automation and integration,' states Ionut Mihai-Jitariuc, head of LIMS research and development at Abbott Informatics.

Mihai-Jitariuc continues: 'The bottom line is compliance, and data integrity. Your lab needs to have a quality management system as well as a laboratory management system in place, down to equipment maintenance, quality control limits studies and calibration records. What are the reagents and standards you have used in the process, and how do they link to the performed analytical methods?' All this has to be documented.

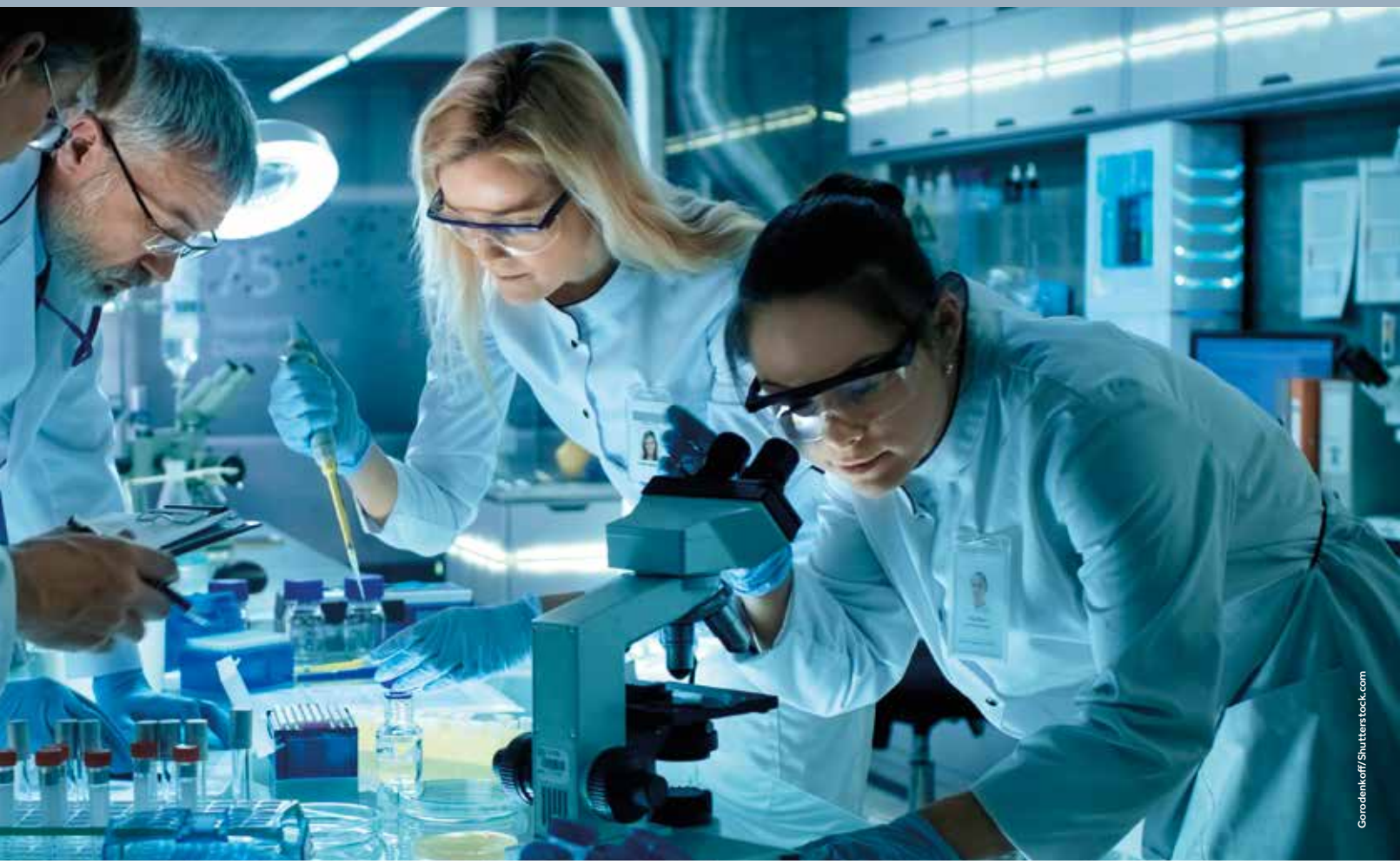
Informatics platforms are inherently good at flagging up deficiencies that must be addressed, and in particular by guiding scientists to follow procedures to the letter, González states. Using an ELN, for example, makes it possible enforce the execution of methods, as prescribed, step-by-step, and capture all procedural and results data and metadata through the LIMS. Effectively we can enforce the consistency of what is documented, and how it is documented.'

Instrument integration is also critical, comments González, concurring with Randall. 'Instrument integration reduces the need for manual recording, or transferring data from one system to another, which negates the potential for errors, gives back operator time, and reduces data redundancy.'

The bottom line is the ability to verify that the product you are manufacturing meets quality standards, and has been manufactured according to all regulatory requirements. 'And all your data must be defensible,' Mihai-Jitariuc states. 'This is critical for any laboratory operating in a regulated environment, regardless of the industry. To do this you have to ensure that your data comply with ALCOA principles laid out in the FDA guidance. Whether recorded manually or electronically, it must be attributable, legible, contemporaneous, original and accurate. These principles should underpin all data and its life cycle.'

Working with paper-based systems in principle is still possible, but for the QA/QC lab it is no longer cost- or time-effective, suggests Gabi Koberg, country manager D-A-CH, at Abbott Informatics. 'Today's informatics platforms also allow us to look at results with a greater depth of business intelligence. Using analytics software you can look at results trending, and mine historical data to understand how issues arise, so that protective measures can be put in place. But these kinds of retrospective and predictive analytical approaches can only be carried out when you have all your data and metadata available in context.'

Abbott's STARLIMS platform offers advanced analytics capabilities that can



add an extra layer of business intelligence over and above that of a day-to-day sample and test management system, González states. 'In contrast with most 'static' analytics capabilities offered with some platforms, the advanced analytics packaged within STARLIMS looks at data in real time, in combination with historical data. And in addition to these advanced analytics capabilities, STARLIMS offers integrated ELN and SDMS functionality, and mobile features.'

The STARLIMS LIMS platform is architected on segregated business logic and technology layers, being highly flexible, versatile. This enables the STARLIMS solutions to evolve together with organisations, allowing them to take advantage of the technological advancements and to tailor the LIMS to their organisational configuration, business model or changes driven by regulations and procedures, Mihai-Jitariuc notes. 'STARLIMS continuously evolves, and technology upgrades can be implemented with minimum or no impact to the business logic layer and master business static data.'

The ability to mine all your data can therefore help to make operation more efficient, as well as provide product-related analytics and trending, Eliot Randle, director of the UK-based informatics consultancy firm e-Science Solutions, points out.

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'Analyses of information may involve simply comparing time spent on projects, use of instrumentation, analysts' time and reagent consumption. On a practical level this can highlight where and how efficiencies can be made in the lab, how processes can be streamlined and time spent by scientists on particular tasks reduced through additional automation. If you can reduce workflow time you can often increase overall capacity by processing higher numbers of samples, with faster throughput.'

The message that rings out clear in any discussion on QA/QC operation is that laboratories are leveraging informatics to reduce error-prone, manual tasks, improve efficiency, and make data flow more seamless throughout the workflow to ensure traceability and integrity, comments Bob Voelkner, VP of sales and marketing at LabVantage. 'Compliance issues and evidence of violation at audit can be bad for image in the marketplace, which can also have financial implications on top of the direct costs associated with falling short of regulatory requirements.'

The activities of the QA/QC lab are, fortunately, good candidates for automation, Voelkner continues. Much of the work is routine and repetitive, and as cost centres that are not directly generating profits, one of the biggest drivers for automation in the QC lab – compliance issues notwithstanding – is cost containment.

The QC lab operation is not unlike a factory production line, but in this case the product is test results, Voelkner suggests. 'You still have to figure out the most effective and efficient way to use resources (including personnel), instruments, supplies and consumables, and fit those resources to the workload. Interfacing the lab operations with business applications including manufacturing resource planning systems, inventory software, etc., can also provide key intelligence to help refine processes and operations further. What vendors are trying to do is to reduce the cost and the complexity out implementation, and reduce →

→ some of the risk and the fear out of the process.'

The LabVantage LIMS software incorporates LES functionality so that scientists can follow electronic worksheets to execute each method. The firm has also packaged tailored solutions of the LIMS solution to meet the needs of specific QA/QC environments. 'The LabVantage Pharma package, for example, is preconfigured for use in a tightly regulated pharma QA/QC environment. We created and fully executed all the validation documentation so the platform is ready for use out of the box. This means our customers can significantly reduce all the costs of implementation, because the solution is already validated for use in a regulatory environment.'

Similarly, LabVantage offers preloaded methods for some of the most common tests, so that the customer doesn't have to build them from scratch. Like many informatics solutions today, LabVantage LIMS takes advantage of cloud hosting, which means that in house and service-related IT costs are greatly reduced. 'A major impact of cloud computing has been to facilitate mobile applications,' Voelkner states. 'Tablet technology is becoming much more prevalent in the laboratory, and in some labs you may not see a PC, everything is recorded using mobile devices.' This is a trend that is increasing in the QA/QC environment, just as in other laboratory settings. 'Mobile technology is enabling 'observable monitoring,' for example, for checking microbial contamination in food or pharmaceutical manufacturing environments. Using tablets, you can be very mobile at different sampling points anywhere in the plant.'

The ultimate aim of the QA/QC lab is to enable release of products that are of the right quality, states Katie Evans, senior product manager at Thermo Fisher Scientific. 'QA/QC labs essentially carry out an enabling function – routine laboratory sampling and analysis. The aim is to check that the product or output of the production process is actually what it is supposed to be, meeting all specification that the end user or downstream customer is expecting, and so the more seamless the operation of these testing laboratories, the faster the products can get shipped.'

Automation solutions play a key role in optimising lab operation, efficiency and compliance. Intelligent informatics will ensure that labs are testing the right samples, using the right methods, and against the correct specifications, Evans notes.

'All of that business logic should just happen. It's not something that people should have to be manually working out. And that overall laboratory automation function can encompass everything from alerting people to when samples are coming in, to scheduling environmental monitoring within production areas, scheduling and tracking retests, and managing reagent stocks and ordering' said Evans

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An informatics platform has to manage all that lab data, but for a QA/QC operation the software should also guide scientists to ensure that all processes are being implemented correctly, and that the raw data are collated and secured in an SDMS-type platform. This will ensure that the data is future-proofed and available at any point in the future should an audit or recall be necessary' Evans continued.

Serious bottlenecks in product manufacture and release can occur as a result of out of specification test results or indications that a sample is compromised. The ability to track every action and piece of data can help to help prevent that bottleneck.

Highly regulated industries, such as pharma, in particular, must be able to verify that every part of laboratory function meets compliance, as well as verifying that the product meets or even exceeds specifications notes Evans. 'In the oil and gas industry, for example, an oil product that tests above specification can be upsold as a higher grade, for a higher price.' Conversely, if the output is lower than specifications, downstream customers, who are expecting a certain grade or oil, may not accept the product and the producer's revenues will be affected.

It is becoming increasingly common to outsource QA/QC testing to specialist laboratories, Evans adds. 'QA/QC testing can be seen as a subcontract part of the main business. Whether that laboratory is part of your organisation or is external to your organisation, you still have to have the same level of confidence in its compliance.' However you 'pay' for your QA/QC, the laboratory is effectively still a cost centre.

'The flipside of that cost centre financial drain is that the QA/QC lab is functioning to prevent substandard products from being released, which could lead to recall, and significant financial losses through manufacturing stoppage and potentially fines, explains Patty McDermott, senior marketing manager, digital science at Thermo Fisher Scientific.

The firm's SampleManager LIMS is used in most sectors that require QA/QC functionality, incldling pharmaceuticals, food and beverage, oil and gas, and chemicals. 'Our LIMS offers LES functionality, so you have the assurance that when people are running processes in the lab they are running them as prescribed,' Evans explains. Personnel are guided through each method and process stepwise, from preparing the sample, to loading the instrument.'

SampleManager also incorporates a fully featured SDMS, which means that customers 'don't have to purchase multiple pieces of software, licences and service contracts, and they also don't have to undertake integration of another informatics system, or carry out additional staff training,' McDermott adds. 'This also eases the IT burden with respect to installing, configuring and validating multiple software with standard laboratory practices. It's not just a cost issue, it's a time issue as well.'