

## Weighing up pros and cons of lab digitalisation

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### Digitalisation is the way forward for the majority of pharmaceutical labs

Pharmaceutical labs across the world are facing pressure to go digital. The automation and digitalisation of pharmaceutical labs have gone hand in hand with newer machines that have tremendously improved productivity and the ability to conduct complex analytics and experiments. As a result, almost all laboratories worldwide have started digitalisation, and many have formed phased plans to achieve complete digitalisation. If done well, the benefits are immediately evident.

#### Numerous pros

The first benefit is higher productivity of staff. This is achieved by data generated from machines directly entering virtual lab notebooks, eliminating manual and frequent checks and entries. It also allows supervisors and senior researchers to view and act on the data remotely, thus allowing them to monitor multiple locations at once.

The second is the elimination of human error and enablement of proper track and trace mechanisms by design. Regulators and research funders are also worried about fraudulent data being generated to support a product or research question. With a proper digital system in place, researchers and regulators can be confident that the data generated is direct from the machine and has not been tampered with or transformed in any manner.

The third benefit is being able to run complex and live analysis bringing in data from multiple machines and experiments. The newer machines can analyse hundreds of samples in the same time it took older machines to do one or two.

## Challenges in implementation

The digitalisation of labs, however, is not a panacea and many challenges remain. The major issue is the installation, connection, and calibration of centralised lab management software. While latest editions of equipment come with digital options as standard, many older models are in perfect working condition. Labs may not wish to suddenly incur enormous capital costs and have to buy all new equipment to accomplish a high level of automation and digitalisation from day one. Instead, many would choose to do this incrementally.

Further, there is a problem of vendor incompatibility. Typically, labs work overtime with three to four different vendors, each of which has a particular strength in an equipment area. Getting all the machines to work together despite the industry moving to common standards is still a problem. This is especially true for high-speed systems that need to stream a lot of data and have custom connectors and software to analyse the output.

With complete live analytics suites that bring data from several different sources, there is also a very high risk that if a particular machine is out of alignment or validation, the data keeps getting consumed and only very later is it discovered that there was a problem. In a manual lab, a technician or researcher would quickly see and identify the erring machines and make corrections well before data is consumed and used to make decisions.

Digital record-keeping can drastically reduce the time spent on paperwork, and more advanced systems can also run validation checks live on the data. However, labs need to invest in ensuring that their systems are auditable and compliant.

There is also a long term risk that a new generation of technicians and researchers only trained in digital methods will no longer be able to understand the work behind the machines substantially and this could lead to poor experimental design, not understanding validation, and an inability to troubleshoot problems.

The last risk is security and confidentiality. As we move towards a cloud-dominated world and more interconnected systems, cyber-attacks will increase on labs and lab equipment and the danger of competitors and malicious actors getting hands-on confidential company and personal data.

Digitalisation is the way forward for the majority of pharmaceutical labs. However, leaders need to make sure they have accounted for all the challenges and issues that the transition period will raise.

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