The Answer's Digitization—What are the Questions OR How to Hit Two Birds with One Stone.

Talks about paperless laboratories have been occurring for 20 years, but progress has been slow. Where is the current urgency coming from?

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Data Integrity is the Current Driver for Digitization

Digitization is being driven by data integrity including issues such as data falsification, poor data-management practices, and testing into compliance where, in the vast majority of GMP laboratories, little has changed in 30 years. We still have hybrid systems with a major emphasis on paper printouts. Data-integrity guidances, such as the WHO (2016) and the PIC/S guidance (2021), do not recommend or encourage hybrid systems; in fact, they suggest replacing them. The PIC/S guide states the controls required to manage two sets of records (hybrid systems) are untenable, and there needs to be improvement in business processes to make them simpler and smoother. Whether you call it digitization, paperless, or electronic, a smoother business process is essential.

Regulatory Guidances Recommend Elimination of Paper

Regulations are perceived as a burden that slow down processes; however, regulatory guidances recommend assessing laboratory systems and processes, and eliminating data vulnerabilities and implementing technical controls in an application to enforce working practices. Technical controls lead to increased automation that inherently reduces errors and speeds up processes. Eliminating manual transcriptions increases the quality and shortens the sample turnaround time, which gives you measurable efficiency gains.

Understand the Meaning of Current in cGMP

The biggest problem understating cGMPs is that very few people actually read and understand the regulations. They have been mostly interpreted by someone for someone else. Therefore, read and reinterpret regulations to assess whether your processes are current. In many cases, labs are not current because they have not embraced new technologies.

Keeping current is also mirrored in the European Union directive 2003/94/EU. Many labs stay static, and they work off the mindset of, "If our lab was OK at our last inspection, it will be OK this time, too." Look at the warning letters in July 2020 to Stason Pharma and Tender Corp.: FDA cited them under two different parts for computerized systems, but the remediation required was word-for-word the same—one of which was automation via interfacing their analytical instruments to laboratory information management system (LIMS). It would seem that FDA is losing patience with the industry and mandating specific remediation. There is no application with an "on" button that, when pressed, provides instant compliance. Data integrity is not an event; it's a journey.

Starting the Digitalization Journey

How can you approach such a journey? It should start with challenges and problems you want to resolve in your laboratory. The digital laboratory should never be a goal, but it is a good means to an end because the goal is, of course, the best error-free and efficient laboratory. And the paradigms and tools of the digital lab will help us get there. You've got to look at processes from

end-to-end and implement systems to show proof of principle that the investment you are making improves a process from start to finish.

Start Small and Focused

You must ensure that instruments are interfaced. Chromatographs are the first instrument to automate if this is a major technique in a laboratory. Sample analysis using chromatography integrated with analytical balances is the second instrument technique to automate. Start automation with a narrow focus to show that the overall lab efficiency can improve with short projects. The key to success is don't try to do everything at once.

Another question is how can we keep the disruption at a minimum throughout this journey? We have to achieve tangible benefits along the way. Start in your comfort zone, which often is the chromatography data system (CDS). Consider replacing Excel with the custom calculations in the CDS or improving an audit-trail review process, which has gained more attention with the latest FDA guidelines. In your attempt to improve laboratory efficiency, question everything. This includes the existing CDS because it may have performed well previously, but very often the effort it takes to replace a CDS is far outweighed by the efficiency gains you'll experience in terms of time, quality, and costs.

Once you have resolved your CDS challenges, the next step is to take care of all the other data in the laboratory. What if you could collect them automatically, index them, and compile them so they are ready for reporting? What if you could do this in the same repository as your CDS?

Interfacing CDS with LIMS

Next, look at the direct connection between the business LIMS and the CDS. This is where the rubber meets the road: It is about morphing your paper procedures into electronic workflows. This is the trickiest part because this process is often the root cause for failed digitization processes in the past. A holistic approach is needed here: Processes for sample management and analysis should guide users, stepwise, through their procedures, including the connections to the instruments, the small lab devices, and inventories in a single software package. This is what a laboratory execution system is about. Try, iterate, and succeed as you go!

Reduce Project Risk with Prototyping and Phased Roll-Out

As part of this overall approach, prototyping new working processes is essential. See how it works with a small team of people; then demonstrate it to get user feedback and buy-in. This results in a system that users want to use rather than put up with. When rolling a system out for operational use, bring different small groups onto validated workflows. There will be a small loss of efficiency, but as users gain experience using the new workflow, the efficiency will increase. Experienced users can then help new technicians/users by sharing their knowledge and experience, resulting in faster uptake of the new application.

Don't Forget Different User Groups When Planning Roll-Out

Digitizing the laboratory is very disruptive, and it fundamentally changes the way people work. Therefore, these changes should be digestible for the lab personnel and implemented with empathy. Yes, there will be resistance to change; the key is knowing your user groups. These users range from hackers, technophiles, and technophobes to dinosaurs—you want to avoid putting dinosaurs first on a new system. Start with the folks who are tech-savvy; then bring on technophobes and dinosaurs. This is where management plays a key role: Management should encourage people to use the system. And not just when the system is ready to roll out but at the start of the project; ask for help from the user base and tell folks their input will be used in the prototype and design.

Ensuring Project Success

It's also important to include successful implementation of new systems into job objectives; this way, users are rewarded for successfully implementing major informatics solutions. This is a better approach to managing informatics projects and the risks associated with them. Users are a key part of a successful implementation of any informatics project, and they must be encouraged to use the system.

Start Now – Don't Delay

Start your projects now. It is easier to do it under your timeframe and momentum than to wait until you have a regulatory boot and are under regulatory pressure. It is better to develop a plan with demonstrable progress to ensure data integrity and regulatory compliance.

There is no point in putting money into informatics solutions unless you get tangible business benefits and regulatory compliance, and that includes data integrity. If you design your informatics solutions from these two perspectives, you should gain dual benefits, but you must invovle the users to achieve this. You can't do it in one go; you need an overarching automation strategy that has laboratory-management backing and potentially, because of the costs, senior-management backing. Think about achievable milestones in this plan, and don't be afraid to revise the plan considering your progress.