

Globally Deploying Digital Pharma Manufacturing and Quality Tools

Digitalization continues to drive pharmaceutical manufacturing and quality operations forward, offering organizations the chance to get to market faster by increasing efficiency, reducing errors, and simplifying compliance. Yet many organizations struggle with implementing digital solutions (as many as 70% fail), especially when it comes to global, multisite deployments.

Finding actionable solutions to this struggle was the focus of an expert panel discussion at the most recent European Lonza MODA® User Group Meeting (UGM), an annual event where MODA® Platform users convene to discuss key challenges and strategies to get the most out of their digital quality and manufacturing tools.

Here, we draw on insights from that panel discussion to summarize several tips and considerations for smoother deployment of digital solutions, both locally and globally.

Before Anything Else, Clearly Understand Your Current State

It should not be much of a surprise that something as complex as a multi-site digitalization project hinges on meticulous planning. That's why, before anything else, companies should conduct a Phase 0 assessment, which involves deeply understanding business needs and evaluating current processes.

This is crucial, since defining and knowing organizational goals will help you to clearly see whether a digital solution (such as a manufacturing execution system (MES)) is even appropriate. The rationale for understanding your processes is equally clear; as one panelist put it, "How can you select a digital system when you don't know how your processes and sites work?"

In practice, understanding your processes means gaining a crystal-clear view of everything from workflows, equipment, and systems, to data flows and the digital maturity of your plant, site, and people. As part of this mapping, it's important to pay close attention to any inefficiencies, challenges, and gaps in your processes, carefully documenting them, for example, using value stream maps (VSM).

To get the clearest idea of your processes, though, make sure you bring the right people to the table. For instance, involve operators in process mapping exercises — from day one. Operators will be best placed to know the actual plant and lab processes in detail (processes which won't necessarily be accurately captured in procedure documentation), giving you the clarity and insight you need to unlock true process understanding.

Simplify Processes Before Translating Them into Digital Tools

A key problem noted in the panel discussion was that many companies build out or implement a digital system on top of highly complex processes. That complexity then gets translated into the configuration of the new digital system, making operation difficult for end users, and potentially leading to system performance issues. In fact, many projects fail because companies try to deploy powerful digital tools in a plant or lab with severely overbuilt workflows.

To mitigate this risk, companies should:

1. **Source people qualified to help simplify and optimize processes** — here, ‘the right people’ refers to operators with deep knowledge of site operations, and management with executive level accountability and a global organizational view to help drive the agreed process changes.
2. **Scrutinize and challenge current processes** — question everything that the system might need to do. Ask if every step in your process is *truly* necessary.
3. **Define a new process that makes sense** — one that is fit-for-purpose and doesn’t include any of the unnecessary steps and procedures identified in the previous step. Keeping it simple is the key here. Avoid trying to add elements to a process to accommodate rare exceptions, as this will unnecessarily complicate the digital system and may backfire.
4. **Pressure test the new process** — investigate whether the new process would work in practice under a variety of scenarios.
5. **Secure alignment across sites** — so that all sites can benefit from the newly simplified process.

With a sufficiently simplified process, translation into a digital system becomes much easier. Organizations can also further mitigate risk here by selecting digital tools that can flexibly accommodate and adapt to diverse and changing processes.

Work Closely With Your IT Team to Avoid Roadblocks

To help minimize IT-related project disruptions, ensure that you know the contact details of key players in your IT teams, plan ahead with them to optimally prepare for any changes and activities, and continue to maintain strong, regular communication with them throughout the entire project duration. In this way, you can help deployments and upgrades progress more smoothly and safely, with minimal interruption to plant and lab operations.

It is especially important to involve IT *security* teams from the very beginning. By doing so, you give them ample opportunity to evaluate risk and ensure a digital system’s security, hardware, and software requirements align with

the organization’s global IT standards. Failing to evaluate this alignment early on can lead to major roadblocks later in a deployment.

Invest Heavily in Training

The success of any digital transformation project depends on how effectively end users embrace and use new tools, just as much as it depends on selecting the right tools. That is why comprehensive training is paramount for project success.

On this point, panelists flagged that, while digital training resources are a key part of any training program, nothing can compare to providing staff with a nurturing environment in which to *physically* interact with a digital system — especially in the pharmaceutical space. Unfortunately, given that pharma manufacturing (particularly biologics manufacturing) is such a high stakes operation, fear of failure commonly prevents operators from getting adequate physical system familiarity. It can be immensely helpful, therefore, to create a secure, sandboxed system ‘play’ area where operators can learn a new digital system without business pressure and risk. With risk removed from the equation, staff are free to more deeply explore the system, make mistakes, and learn how to confidently handle the system and process when something unexpected happens.

Ideally, companies should also make system training a key component of training on the method in order to facilitate a real-world understanding of the system, and incorporate staff feedback sessions into training programs to drive continual program improvement.

Tips for multi-site training

In addition to more general training guidance, discussion at the UGM also turned to specific actions companies can take to improve training across multiple sites and geographies. Again, the panellists had several helpful suggestions here.

One of the first tips was to evaluate the existing training tools at your disposal to see which can be optimized and better leveraged for easy wins. For example, companies can better deliver multi-site training by:

- Ensuring SOPs are as lean and standardized as possible across sites
- Leveraging eLearning resources. With eLearning, companies can make one resource and deploy it everywhere with ease (although teams should note that eLearning often works best for training on system basics).
- Embedding process related training within the local onsite production training programs
- Sending team members to UGMs, since these meetings can be a rich source of insights and ideas for better training initiatives

Gamifying training was another suggestion. The idea here is for companies to set a fun challenge for all sites that use the new system — without business pressure, and ideally with a reward for the winners.

Strive for Process Standardization, but Ensure a Level of Flexibility

The more standardized your processes across sites, the simpler multi-site digital system deployment and training becomes. For this reason, companies should always strive for standardization. But it is critical to get the right balance. Pushing too much for sites to enforce top-down preconfigured systems, for example, is likely to elicit substantial operator pushback.

The key thing, then, is to find the maximum level of standardization that everyone can agree on. This will necessitate bringing together personnel with deep process knowledge from across your sites so that you can understand what can be feasibly kept consistent between facilities, and where process flexibility is warranted or needed. With this understanding, organizations can then take the core, unchanging elements of a process and create ready-validated digital process ‘building blocks’. Rather than building out and validating a new process from scratch, sites will only need to build out and validate (at the site level) the elements of a process that will be unique to their site (for example, measurements of an ingredient in pounds vs. kilograms). Taking this approach, where site-level validation is minimized, can help substantially reduce the amount of time and effort it takes to push a new digital process live.

Ensure Global Teams Have Local Onsite Subject Matter Experts

When it comes to building global digital solution deployment teams, companies should ideally source on-the-ground experts from each site and in every major geography. The reasons for doing so are manifold.

First, onsite SMEs can act as an effective ‘buffer’ when it comes to new process rollouts, new standardizations, and new digital system upgrades, shielding teams against decisions that don’t take into account the full gamut of relevant local information (including geographical idiosyncrasies). Onsite SME’s can also help ensure that, once decisions are made, the benefits are realized at every site. And, with a deeper view of what happens on the ground at manufacturing plants or in microbiology labs, onsite SMEs can act as agents for better alignment between corporate expectations and what is feasible based on the day-to-day onsite reality.

With a global team spread across time zones, companies can also offer a ‘follow the sun’ 24/7 technical support

system, where local SMEs offer support during core working hours, and SMEs in different time zones offer OOO support.

Helpful ways to measure success

The panel discussion finished up with some key pointers on how best to track the success of a system post-deployment.

The discussion first focused on non-CGT manufacturing. One suggestion for tracking success here was to use Overall Equipment Effectiveness (OEE) — a metric that allows you to investigate whether you are getting the maximum capacity that your equipment and plant can support. Measuring how close you are to this theoretical maximum before and after deploying a new digital system is one way to quickly determine whether the deployment is adding tangible value. For CGT manufacturing, companies could investigate deviations before and after system deployment, with a reduction in deviations being a promising indicator of system success.

Tracking broader business KPI trends can also help companies understand the success of their digital system deployment. In the case of improvements post-installation, though, it is important to properly investigate whether the improvements can feasibly be connected back to the digital system. Similarly, if performance indicators dip post-installation, companies should do a root cause analysis to clarify whether the system (or the way it has been implemented) is truly at fault.

Metrics, while helpful, are just one part of measuring success. It is just as important to interact with operators at your sites. Organize biweekly meetings with site staff to solicit their feedback on the good and bad of the deployment, and consider asking questions such as “If we removed the system, how would you feel about it?”. Such questions are a good litmus test to see if operators miss the old approach (if they do, be sure to dig into the why). If possible, don’t just keep team feedback interactions digital, either. Physically visit the sites, as this will allow you to pick up on other indicators of how (and if) the system is being used — for example, have staff even noticed that the battery on one of the components has run out?

Smoothing the path to digital deployment success

Deploying digital pharma manufacturing and quality tools is no simple task, especially when it comes to multi-site implementations. But there are steps that every company can (and should) take to help mitigate risks and smooth the path to success — from conducting thorough phase 0 assessments to investing in high-quality, nurturing training programs.

Looking to digitalize your pharmaceutical manufacturing and quality operations? **Contact the Lonza MODA® Team today** to discover how our digital solutions can help.

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