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Article

Going Global: Deploying Digital Tools Across Pharma Manufacturing

Insights from the MODA User Group Meeting on Successful Multi-Site Digital Deployments

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. However, many organizations struggle with implementing digital solutions. Industry studies commonly citing **failure rates as high as 70%**, especially when it comes to global, multi-site deployments.

Finding actionable solutions to this struggle was the focus of an expert panel discussion at the most recent European 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 the discussion and summarize considerations for smoother deployment of digital solutions, both locally and globally.

Begin With a Current-State Assessment

It shouldn't be 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 a deep understanding of business needs, current processes, and regulatory obligations.

Start with your goals. Defining what the organization actually needs will clarify whether a digital solution (such as an MES) is even the right answer. 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 clear picture of your workflows, equipment, systems, data flows, and the digital maturity of your plant, site, and people. As you go, document inefficiencies, gaps, and challenges using value stream maps (VSMs).

This assessment should also include a regulatory mapping exercise. Identify which systems and data flows fall under applicable frameworks — such as FDA 21 CFR Part 11, EU Annex 11, or regional GMP requirements — and flag data integrity obligations early. Attempting to retrofit compliance into a system that's already been configured and deployed is significantly more costly and disruptive than designing for it from the start.

For this to be successful, make sure you bring the right people to the table from day one. Operators know how work actually gets done on the floor and in the lab. They can share details that won't necessarily be accurately captured in procedure documentation. That input is what turns process mapping from a paper exercise into genuine understanding.

Simplify Before You Digitize

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 gets baked into the system configuration, increasing the risk of performance issues and making it harder for end users to operate. Many projects fail because powerful tools get deployed into plants and labs with workflows that were never simplified in the first place.

To mitigate this risk, companies should:

1. **Bring in the right people:** operators with deep knowledge of site operations, and management with the executive accountability and organizational view to drive process changes.
2. **Challenge *every* step:** question everything the system might need to do. Ask if every step in your process is truly necessary.
3. **Define a simpler process:** one that is fit-for-purpose and free of unnecessary steps. Resist the temptation to accommodate every edge case; exceptions complicate configuration and create new risks.
4. **Pressure test it:** verify the new process holds up across a range of real-world scenarios before it goes digital.
5. **Align across sites:** make sure every site benefits from the simplified process, not just the one it was designed for.

A simplified process makes digital translation significantly easier, and selecting tools that can flexibly adapt to diverse and evolving processes reduces risk even further.

Make IT and Cyber Security a Partner, Not an Afterthought

IT can either be your best friend or a hurdle when deploying new systems and tools. Minimize disruptions by identifying key contacts early, plan ahead together, and maintain regular communication. This keeps deployments and upgrades on track with minimal interruption to plant and lab operations.

IT security teams should be involved from day one. Multi-site and cloud-connected deployments carry a wider attack surface than on-premise systems: data crosses networks, sits in shared environments, and gets accessed globally. Security needs time to assess risk, define access controls, confirm data residency, and align configurations with IT standards. In regulated industries, these controls are inspectable, not optional. Bring security in late, and you risk major roadblocks exactly when you can't afford them.

Early IT involvement should also address system integration architecture. Most manufacturing sites run interconnected systems like MES, ERP, LIMS, and QMS. Decisions about how a new digital tool connects to these should be scoped during IT's early engagement, not discovered during go-live. Late-stage integration surprises are a common and avoidable source of project delays.

Invest Heavily in Training

The success of any digital transformation depends just as much on how effectively end users embrace new tools as it does on selecting the right ones. Comprehensive training is non-negotiable.

Panelists were clear that digital training resources alone aren't enough (especially in pharma). In high-stakes environments like biologics manufacturing, fear of failure routinely prevents operators from building real system familiarity. That’s why it’s critical to deploy a sandboxed "play" environment, where staff can explore freely, make mistakes, and learn to handle unexpected situations without business pressure or risk.

Training should also be embedded into training methods, so staff develop a real-world understanding of how the system works in practice (not just in theory). Regular feedback sessions round this out, giving teams a way to flag issues and drive continuous improvement.

Tips for Multi-Site Training

In addition to general training guidance, the panel also discussed the challenge of training across multiple sites and geographies, with several practical suggestions.

One of the first tips was to evaluate your existing training tools to see which can be optimized and better leveraged for easy wins. For multi-site delivery in particular, companies can:

- **Standardize SOPs across sites**: the leaner and more consistent, the easier training becomes.
- **Leverage eLearning:** build once, deploy everywhere. While best suited to system basics, it also delivers a practical foundation for any multi-site program.
- **Embed process/system training within local production training:** staff can learn the tool in the context of how they'll actually use it.
- **Send team members to user group meetings:** an underutilized source for training ideas and peer insights.

Gamifying training was another suggestion. The idea is for companies to set a site-wide (fun) challenge that has them use the new system without business pressure, and includes a reward for the winners.

Balancing Standardization and Site-Level Flexibility

The more standardized your processes across sites, the simpler digital system deployment and training becomes. For this reason, companies should always strive for standardization. However, it's critical to get the right balance. For example, pushing too much for sites to enforce top-down preconfigured systems will likely invite operator pushback and resistance.

The goal is to find the maximum level of standardization everyone can agree on. That requires bringing together people with deep process knowledge from across your sites to identify what can realistically be kept consistent and where local flexibility is genuinely needed. From there, organizations can extract the core, unchanging elements of a process and turn them into pre-validated digital building blocks.

This approach aligns with the risk-based validation philosophy embedded in GAMP 5: by pre-validating standardized components at the platform level, sites only need to build and validate what is unique to them — a local unit of measure, a site-specific specification, a regional step. This minimizes site-level validation effort and significantly reduces the time it takes to push a new digital process live.

Don't Build a Global Team Without Local Expertise

When it comes to building global digital solution deployment teams, it's extremely beneficial for companies to source on-the-ground experts from each site and in every major geography.

First, local SMEs act as a buffer during new rollouts, standardizations, and system upgrades. They can catch decisions that overlook critical local context, including regional and site-specific nuances. They also help ensure that once decisions are made, the benefits are realized on the ground. And with visibility into day-to-day manufacturing plant and microbiology lab reality, they bridge the gap between corporate expectations and what is operationally feasible.

A globally distributed team also enables round-the-clock support. With SMEs spread across time zones, local experts cover core hours at their sites while others provide out-of-hours coverage elsewhere, utilizing a natural "follow the sun" support model that doesn't need additional infrastructure.

How to Measure Success

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

The discussion began by focusing on non-CGT manufacturing. One suggestion for tracking success was to use Overall Equipment Effectiveness (OEE), a metric that allows you to investigate whether you're achieving the maximum capacity 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.

Broader business KPIs can also signal success, but require careful analysis. Improvements should be traceable back to the system and dips warrant a root cause investigation before drawing conclusions about the deployment itself.

Metrics alone, however, don't tell the full story. Regular engagement with operators is just as important. Biweekly site meetings give teams a structured opportunity to surface what's working and what isn't. Questions like *"if we removed the system, how would you feel?"* are a useful litmus test — if operators would welcome its removal, dig into why.

And finally, visit sites in person whenever possible. Physical presence surfaces things that remote check-ins miss, including signals of whether adoption is real or just on paper.

A Clearer Path to Digital Deployment

Multi-site digital deployments are complex, but the path to success is clearer than it might seem. From thorough Phase 0 assessments to hands-on training programs, the steps outlined here give every organization a practical foundation to reduce risk and deploy with confidence.

As organizations build this foundation, they also position themselves to take advantage of what comes next: AI-powered analytics, real-time quality monitoring, and predictive maintenance capabilities. Getting the fundamentals right today is what makes those advances achievable tomorrow.

Ready to digitalize your pharmaceutical manufacturing and quality operations?
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