Digital transformation: a guide for regulated companies

Organisational & IT considerations when improving GxP processes across departmental boundaries
Digital transformation activity may have reached peak levels in non-regulated industries, but in strictly-controlled markets and use cases progress has been much slower. That’s because the processes and content involved are generally more complex and governed by strict requirements.

But this slowness to modernise is costing those organisations dearly, in compromised efficiency and productivity – not to mention a loss of insight and control along business processes, particularly when these flow across multiple functions.

Too often where attempts at transformation have been made, the focus has been very specific - trained on a single use case, or influenced by a particular IT solution. The risk here is that one element of the organisation and its operation becomes more dynamic, streamlined and efficient, while adjacent departments are still held back by the same bottlenecks and lack of visibility. And even if these other functions do make moves to catch up at some later point, deploying their own solutions simply creates new silos: the benefits will not add up to something greater than the individual parts.

To achieve wide-reaching, impactful transformation of entire business processes, there needs to be a different approach – where the emphasis is at least as much on restructuring teams and putting in place consistent data governance as it is on choosing an appropriate technology solution. Putting in a new system without reviewing the way data is managed or the way teams collaborate and exchange information risks undermining any investment and compromising the scope of any outcomes.

This practical e-book tackles these challenges head on, offering practical steps for those looking to achieve a step change in end-to-end business processes.

But first let’s recap why companies take on digital transformation projects at all.
Digital transformation: why do it?

Most commonly, the driver of digital transformation is a pursuit of efficiency through the removal/reduction or standardisation of human touch points and IT systems across an organisation - both within and across target business processes.

In simpler terms, it’s about making it easier for teams to confidently complete tasks – because the right information and materials are served up as and when needed, in the context of what someone is doing. They are not hidden away somewhere inaccessible, and individual team members are less likely to cause bottlenecks if they are away or otherwise engaged. In many routine cases, processes can be automated, when everything can be reliably brought together in the right context to reach conclusions/complete tasks/determine next actions.

Even in regulated organisations, the impact of digital transformation is already strongly evidenced. But this tends to be for non-GxP (good practice-driven) processes:

Examples of impactful content and process streamlining can be seen in the form of:

- Enterprise content management (ECM) for all non-GxP documents (SharePoint, DropBox, Box, etc)
- Enterprise productivity suites (eg Office 365, Google Workspace)
- Enterprise communications (eg Teams, Slack, Google Chat)
- Enterprise task management (eg Trello, Monday, Click-Up, Jira).

Many of these deployments – aimed at the lowest-hanging fruit’ with the broadest impact - have resulted in strong ROI and a recognisably ‘modern’ and efficient work experience for employees.

Almost without fail, this is because scoping and planning of projects has not required knowledge or facilitation of specific business process requirements.
Transforming GxP processes: untapped potential

To date, the same transformation successes have not typically been seen in GxP systems and processes, leaving huge potential untapped.

Where these kinds of process transformations have been attempted before now, the results have been mixed. Often this is because attempts to truly transform processes have been hampered by point solutions that don't integrate well to enable easy content/data flow and exchange from one function or use case to the next.

Mainstream ECM systems typically only go so far, for instance, then rely on third-party solutions for specialist functionality/to support sector-specific use cases. Meanwhile attempts at data integration between diverse systems across an enterprise typically require complex IT work to overcome incompatibilities, still leaving potential for data overlap/inconsistencies.

Inter-department business process automation solutions are improving, but without the in-context enterprise content management capabilities of a system like Documentum, for instance, or the data management capabilities of a platform like SAP, such platforms can only really address about a third of the digital transformation requirements of GxP systems and processes.

There are organisational/structural issues too, once companies try to achieve end-to-end process transformation spanning the activities, people and data assets of more than one department. Taking on a project with a scope beyond a single function or team requires alignment of interest and shared commitment to delivering change and benefits that will be felt beyond the immediate team. It also needs appropriate coordination, across multiple levels.

Overcoming these challenges will mean bringing down some of these traditional divides, creating new roles and remits, and taking a fresh approach to technology deployment and management.
Rethinking IT-enabled process transformation: organisational changes

High-impact process transformation which transcends specific use cases and departmental divides needs a completely different approach to traditional IT projects – which strives to capture all main requirements up front and then identify a software system that provides for everything. As well as being impossible, or requiring lots of compromise, costly customisation and a big change management programme, this approach is slow and laborious. It also leads inevitably to the same cycle being repeated every 2-3 years as new needs are identified or as the technology moves on.

Big system changes being rolled out almost continuously across the organisation can burn up 100s of millions in costs, not to mention hundreds of thousands of business employee hours in siloed group efforts with misunderstandings and time spent learning on-the-project. As employees move roles, any progress in building cross-functional knowledge is also eroded.

Continuous innovation and process improvement is a much more sustainable way forward. This suggests a more blended approach, too, in which business teams and technology experts work more closely together to keep pace with change, and consider new requirements and opportunities from all angles.

Assigning process transformation ownership

For transformations to extend beyond a single business function, it’s important to identify an individual who owns or is attached to each critical business process that has been earmarked for improvement, to serve as the given process expert and its ‘Head of Transformation’.

Bringing IT expertise closer to business users

A member of the IT team should be assigned to each process, too, to act as a liaison between those trying to effect transformation and the central IT department. This role isn’t so much about taking over the enabling technology, but in guiding the process team in what’s possible and how to maximise local capabilities while achieving closer links and a smoother flow of activity with adjacent functions and teams.

Establishing close contact between adjacent Heads of Transformation

The heads of transformation for different processes should stay in close contact, to build a rounded understanding of everyone’s needs. That could be why a particular format might be needed for a particular type of document, why data should needs to be presented in a certain way, or how new industry requirements are perceived to be pushing changes in the way they work, for example.

In this way, an alignment of transformation priorities can be achieved and any areas of overlap/conflict considered as the overall transformation roadmap is put together.
Think adaptable platform rather than an all-in-one solution

With the collective requirements established, teams can start to consider appropriate IT capabilities. To allow for maximum flexibility, it is unlikely that a single, defined software solution is going to do the job. It’s far better to opt for a platform that transcends individual use cases, allowing each function to adapt the design and implementation to their own specific needs – but without compromising the integration/flow of a process and the exchange of related content between different teams.

Reusability & commonality are key

Basing everything on a reusable, common platform which isn’t owned by a single department and can access the same data and content reserves will prevent new silos from forming – while supporting the different specific ways teams need to view and work with those assets in the context of their current work.

An important aspect of this shift is to empower business process owners to determine and design more of their own IT capabilities, without negatively impacting neighbouring teams and without having to call upon the IT department to take care of thrination or data mapping.

Same easy data & content access in a process-relevant context

By separating the high-level look and feel of the system from the data and content management layer, companies can provide user teams with a sufficiently ‘low code’ experience that means they themselves (in these ‘digital process transformation’ + local IT teams) can determine the data and content assets they need and how they want to view them to best deliver their workflows.

Empower business users to optimise their own experience

Gartner talks about ‘citizen developers’1: business users who can design and implement solutions with little or no coding experience. The key to delivering true process transformation is that these are either existing process owners or process experts, who can combine this in-depth knowledge and experience with a drive to innovate and improve ways of working.

If no one identifies themselves as being capable of defining or tweaking the capabilities they need, note that these skills are now very easy to pick up within just a few weeks, thanks to how accessible ‘coding’ has become in the modern digital age.

Maintaining strong communication between the complementary remits

Before determining the optimum IT solution, the heads of transformation for each process should work with their respective citizen developers and the processes’ IT liaison to achieve a good 360-degree understanding of what’s possible and what’s required from a compliance perspective.

By establishing these roles, structures and responsibilities, organisations will have effectively put in place a Digital Transformation division, which will ideally have its own collaborative structure - to maximise enterprise knowledge and process/system standardisation.

1 How to Define and Guide Citizen Development Practices, Gartner, April 2021
Rethinking IT delivery: from cyclical ‘projects’ to continuous, cross-functional innovation

As long as each part of a company is working with its own system silo, the scope for achieving more seamless workflow and 360-degree data/content access will be limited, so from a technology enablement perspective, there needs to be a rethink.

This is not about throwing out everything that’s gone before, but rather underpinning inter-function fluidity with a foundational platform which supports timely access to the right data and content at the point of need within a process.

This agile platform must suit the business processes of all groups and departments in the organisation. Gartner has talked a lot about the trend in ‘composable’ platforms. Simply put, these are highly-configurable, low-code or no-code platforms that can be adapted readily for each intended audience or use case. In the context of complex, regulated business processes spanning more than one function of the enterprise, this adaptability will be critical to support the necessary functional extensions and design preferences of each team.

Transformation enablement: a platform checklist

To ensure maximum potential, with a low-code enterprise platform that will reliably support the digital transformation of your regulated business processes, it’s important to check:

- Can the vast majority of your regulated business processes be built on the proposed platform without customisation (hard-coding)?
- Are all processes and ‘apps’ truly available on the same platform with an integrated database (or will lots of complex and costly integration workarounds be needed)?
- Does the platform support an agile approach to adding new processes whenever needed, for whatever purpose?

The optimum platform will fulfil all of these requirements and enable the following business benefits:

- Digital transformation teams will be able to innovate and build new capabilities without a heavy burden on IT.
- Each new implementation/each process you transform will not be another massive investment, but rather a new collaboration towards adding another use case to an existing enterprise environment.
- In place of the traditional 3-5 year cycle, you’ll drastically cut IT spending and in the process gain the ability to deliver genuine continuous digital transformation, as and where needed, across the organisation.

Future of Applications: Delivering the Composable Enterprise, Gartner: Dennis Gaughan, Yefim Natis, Gene Alvarez, Mark O’Neill, 2021
The importance of joined-up thinking

By maintaining strong lines of communication, and basing all digital process transformation on a common platform that can surface the same data and content, companies in regulated industries will find it much easier to innovate with GxP-governed activity – both now and in the future.

Again, it all comes back to the need to have the right supporting organisational structures as well as the right platform. Without the collaborative, cross-functional view and approach to process transformation, the danger is that old habits will re-emerge and individual teams will fall back into discrete budget spend, local apps and content silos – taking them back to square one.

With a more open mindset and a holistic approach, in which everyone can play to their strengths with an optimised, context-specific user experience (that draws on the same collective data and insights), the scope to keep innovating and to drive improvements for the benefit of all (eg through the use of agreed language between functions) will multiply.

To find out how Generis can support GxP process transformation via our flagship CARA™ platform, take a look at www.caralifesciences.generiscorp.com