WHITE PAPER

The Sprint to the Summit:
Unlocking Lab Efficiency through Digital Transformation

revvity signals

What to expect

At such an important juncture in the evolution of India's pharmaceutical sector, this white paper addresses several key facts about how generic pharma companies can rise to succeed:

- See how a strategic approach is essential for an effective digital transformation.
- Learn how a lab where data is not in silos can help increase performance throughout your organization.
- Discover how you can leverage your lab's data to work smarter and run faster.

Breaking the status quo

India's pharma sector is undergoing significant growth, reaching value as high as US $70 billion in 2020 and achieving global market penetration second only to US-based companies. As with every period of rapid expansion, there will be a market shakeout, yielding both winners and others that experience less success. Leading the race will be those who can scale up efficiently as well as effectively – working smarter, rather than simply working harder or adding more capacity by hiring additional employees.

Typically, your business is focused on a series of sprints: A drug patent expires, or an expiration date begins to draw near, and the race is on to be the first to get a generic drug to market. It might be thought of as setting out from base camp in a race to the summit of a mountain. Which team wins is determined by which route you take to the top, but also by how efficiently you can make the climb – something that's often determined by how much baggage you carry on the journey. In this instance, the summit of the mountain is the point at which you have oversight and control of all the data your enterprise produces or accumulates. When you reach that peak, you can realize all the benefits of data integration: deeper, more effective analysis; increased efficiency; and greater ROI. So, the questions you must ask yourself are:

- How effectively are we managing our data?
- Are our approaches to data management slowing or even blocking our journey to the top?

If your company is currently winning its share of its sprints, it is tempting to just keep doing the same thing each time. But "business is usual" is not sufficient for accelerating your company to the next level if you are not making the most effective use of the data and putting in place the means to integrate it and share it effectively across the enterprise. Real change requires a major transformation. A digital transformation.

Powering your digital transformation

A good digital transformation strategy is uniquely influenced by a company's own business objectives, but the best of them hold a few key attributes in common:

- **Champions at the top**
  For a digital transformation strategy to succeed, it requires the active support of a visionary CEO and a leadership team willing to empower those in key transformational roles.
- **Interconnection is its central aim**
  A digital strategy supports the unimpeded flow of data across the enterprise and deploys tools to help visualize and interrogate that data. Harmonization and standardization improve across all internal teams, enabling productivity and pipeline growth.
- **Clear direction to compel forward action, but flexible enough to adapt and scale**
  Successful strategies are developed not only in response to today's competitive realities, but also as protection against future risks. Companies need built-in agility to respond to shifting needs and opportunities.
- **A shared vision at all levels**
  It is one thing for leadership to set a goal for digital transformation, but without agreement throughout all levels of the company the vision can be misinterpreted or unnecessarily complicated. Open, frequent communications is essential.

Why change is needed

Workflow in most pharmaceutical laboratories has not changed substantially in the past decade. Whatever aspect of generic drug lifecycle management you focus on, and whether your company specializes in mass or specialized therapies, your process likely includes ongoing exchanges of samples and test results, and outputs of observations, adjustments, and results. And, like most pharma companies in this space, much, if not all, of this work is in multiple file formats, like PDFs, spreadsheets, text documents, and JPEGs.

The average amount of data generated annually in most labs equals one terabyte. With that much data in multiple formats, including a combination of digital files and paper, you have an increased risk of entry errors, general inefficiency, and a lost opportunity to capture all that data so your organization can wring every possible benefit from it. Data integration is the key.

How much more efficient is a lab that is fully digital and operating on a system that allows data to flow freely from the lab to other parts of your organization? Studies show efficiency improvements can range between 25 to 30 percent–an efficiency that cannot be attained simply by adding more resources to a lab. When you factor in the routine administrative tasks that can be replaced by aligning your digital applications, the time saving increases to about 40 percent. In real terms, that means not just improved process efficiency, but faster product development, a more agile response to the demands to develop the new generic drug, and a shorter time to market, overall.

Why change is needed

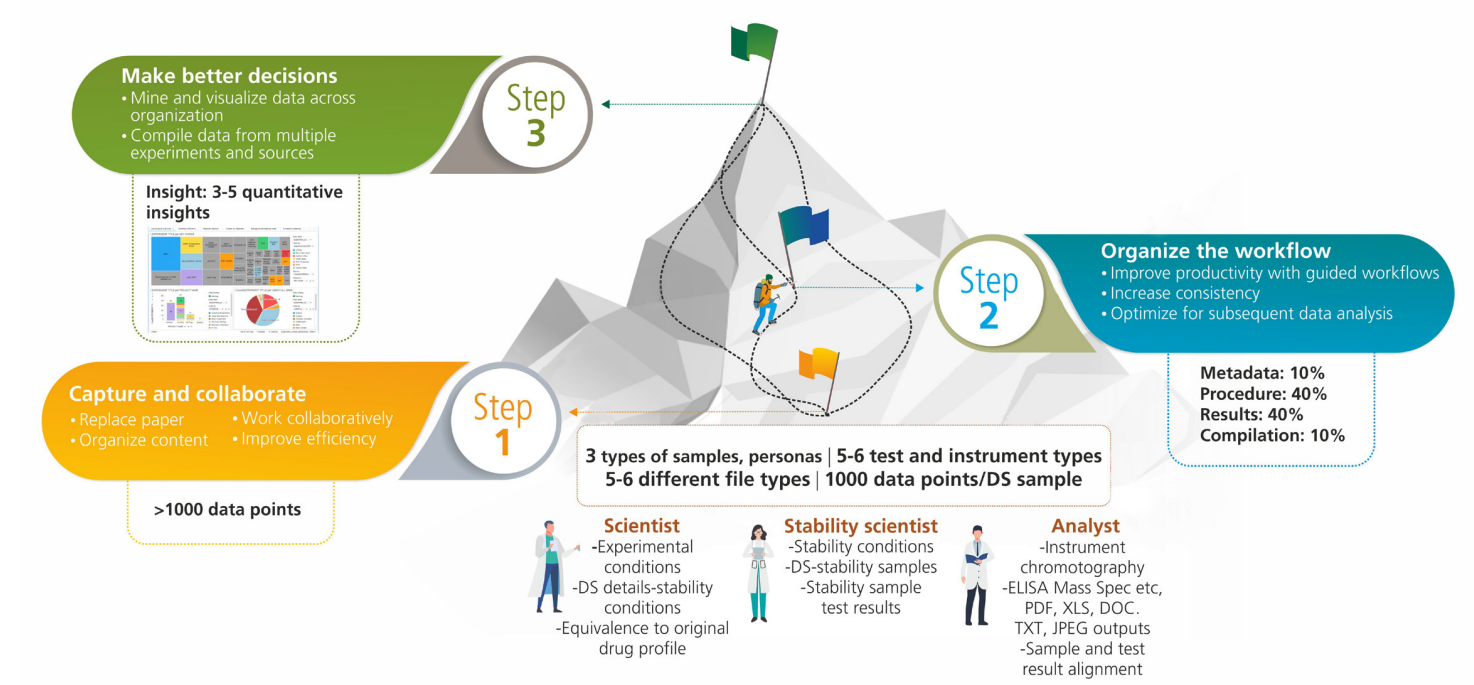
It is essential that all components of the organization be aware of the enterprise's digital transformation goals. For that, there must be a comprehensive digital transformation strategy that encompasses all the elements of the enterprise's workflow.

If parts of the organization are already taking advantage of digital technologies, it is important to examine the interaction and synergies of the various corporate components and functions.

For example, when one of the large multinational generics drug companies headquartered in India implemented Revvity's E-Notebook, most of the discussion centered around the data contributing to the milestones associated with the project's progression. These data points and accessory information were identified as Tier 1 data; critical to the project. The Tier 2 data related to the project's progress were the metadata on objectives, details on whether the project met expected outcomes. So, essentially, each piece of the data related to the experiment was considered from the perspective of its utility, and the strategy for digitization was devised accordingly.

The strategy required to compete in pharmaceuticals today, particularly generics, and achieve new goals involves a thorough digital transformation. And, to be effective, that digital transformation must support the unimpeded flow of data across an entire organization. Tools must be utilized to structure and effectively store that data so it can be found, retrieved, and employed in ways that allow organizations to identify trends, control quality, eliminate risk, remove bottlenecks, and highlight opportunities for innovation.

The term digital transformation has become commonplace in the language of business, but what can it mean – and do – in pharmaceutical development and manufacturing?



Why change is needed

As illustrated in figure 1, the goal of digital transformation is reaching a state where better decisions about your business can be made more quickly. The path to that state begins in the place where most of your critical data changes hands multiple times as samples and test results are analyzed and catalogued – through various instruments, which generate different file types and thousands of datapoints. By organizing the workflow into guided paths, you gain greater consistency, and implementing digital solutions allows for subsequent data analysis, which yields results that flow back into your digital transformation.

As information moves up the chain, from your lab to the upper reaches of your organization, and you compile increasing amounts of data – from multiple experiments and sources-you are enabled to have better oversight of the entire enterprise, and gain the power to make highly informed data-backed decisions as opposed to perception-and assumption-based decisions.

In the generics pharma industry, speed to market and quality have primary importance to capture market share and get ahead of competition. In paper-based workflows, data spread across many lab notebooks is collected, compiled, and analyzed. For example, identifying the optimal formulation equivalent to the innovator drug requires a cascade of experiments.The outcomes and data from excipient analysis studies, dissolution studies, and stability studies – spanning many experiments, months, and investigators-must be collected, compiled, and analysed. In a paper-based scenario, a majority of the time and energy is spent in aligning the multiple pieces of data and compiling it to bring it to a "ready to use" format. The scientific scrutiny the data should undergo gets compromised as a result, due to the lack of time and resources. Also, another major advantage of digital data input/output is in retrospective analysis of data and experiments that can provide insights into which materials/processes were more or less effective.

Cut the risk, boost the quality

Furthermore, improved data management has a direct correlation to better quality control (QC) – a growing initiative in pharma. How important is effective QC? Consider this conclusion from an award-winning article in the journal Pharma manufacturing from late 2019.

For American manufacturers, the emphasis on quality provides an opportunity to leverage high manufacturing standards and maybe, despite the challenges, bring some low-cost drug production back to the United States (US) either way, recent quality events have made one thing very clear whether companies are manufacturing on US soil or abroad, the issue of quality is going to stay top-of-mind for pharma and consumers.

Closely related to QC issues is the subject of regulatory compliance – another challenge that can be effectively managed through a far-reaching and insightful digital transformation policy. Managing the risk of non-compliance can be costly and time consuming, and can distract management and, sometimes, the entire enterprise, from the larger issue of getting to market quickly with a successful product. While managing the compliance risk may seem like someone else's concern, when the task before you is the work of the laboratory, it truly is everyone's responsibility; but one that can be made much easier when the solution to the challenge is easily accessed through data retrieval rather than buried in a mass of paper records.

Getting to the summit

Like any journey, the entire trip must be taken into consideration for it to be successful. To truly realize the benefits of digital transformation in your organization and reach the summit, where all your data is structured and able to be shared, you need to capture data at every point in your journey, from lab intake to product commercialization. That journey cannot be entirely successful if you are not equipped to control all your data, access it efficiently, and analyze it all in context.

Revvity Signals' approach can lead to accelerated, informed decisions, and better corporate results. When you capture experimental data in the lab, and combine it with other data sources, you can gain critical insights, reduce overall cycle time, streamline your workflows, and make better collaborative decisions that fuel your business.

Our digital solutions can make your lab operations efficient and fast, allowing the organization to move rapidly through its journey to success.

Harness your lab's data and leverage its full potential – that is an essential step to true digital transformation.

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