

Digital Transformation in the Life Sciences Industry

Key Risk Considerations

Private and confidential
2018

Risk Advisory





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Digital Transformation is rapidly being recognized in the Life Sciences Industry as an important enabler for innovation and business growth. The value created includes areas like patient community experience, key clinical opinion leader interactions, clinical and research personnel engagement, new models of care and overall operational efficiency for the industry.

However, while embarking on digital transformation, it is imperative to be aware of the potential risks that may derail your journey.

Managing risks in the digital era is critical to the ability of the Life Sciences industry to accelerate time to market and create a system of continuous collaboration.

Potential risks

01 - Engaging the digital consumer through the application of the right risk controls

Life Sciences industry is in the wellness business. The objective of the industry has changed from catering to the sick, to helping the consumer prevent illness. As the industry embarks on this journey, new paradigms of care have emerged. Concepts like Connected Health have become mainstream. Many consider this as the healthcare model of the future. Consumers are now using wearable devices and keeping track of key health indicators like blood pressure, heart rate and the number of steps taken. Many wellness programs are being run by the Life Sciences firms leveraging digital platforms.

At the centre of this transformation is the digital consumer. The digital age is defined by customer networks, hence the mass market strategies, which have worked in the past have not been effective.

Let's take an example: medical device company launches a new glucometer. The glucometer is launched online as well with a website and a mobile application. The consumers should be able to experience the features of the glucometer virtually, both on the web interface and the mobile application. Finally, when the consumer decides to purchase it, he should be able to buy it online. But, if for some reason the consumer wants to see the product before buying it, then the physical store selling the device should give him a similar experience. This an apt example giving the consumer a seamless experience between the digital and physical world.

Consumers are constantly connecting with each other, shaping and changing the reputation of various brands. Their adoption of digital tools has changed the way they interact with the healthcare ecosystem. So, traditional methods of discovering, evaluating and purchasing have been replaced by faster methods where all three stages happen simultaneously.

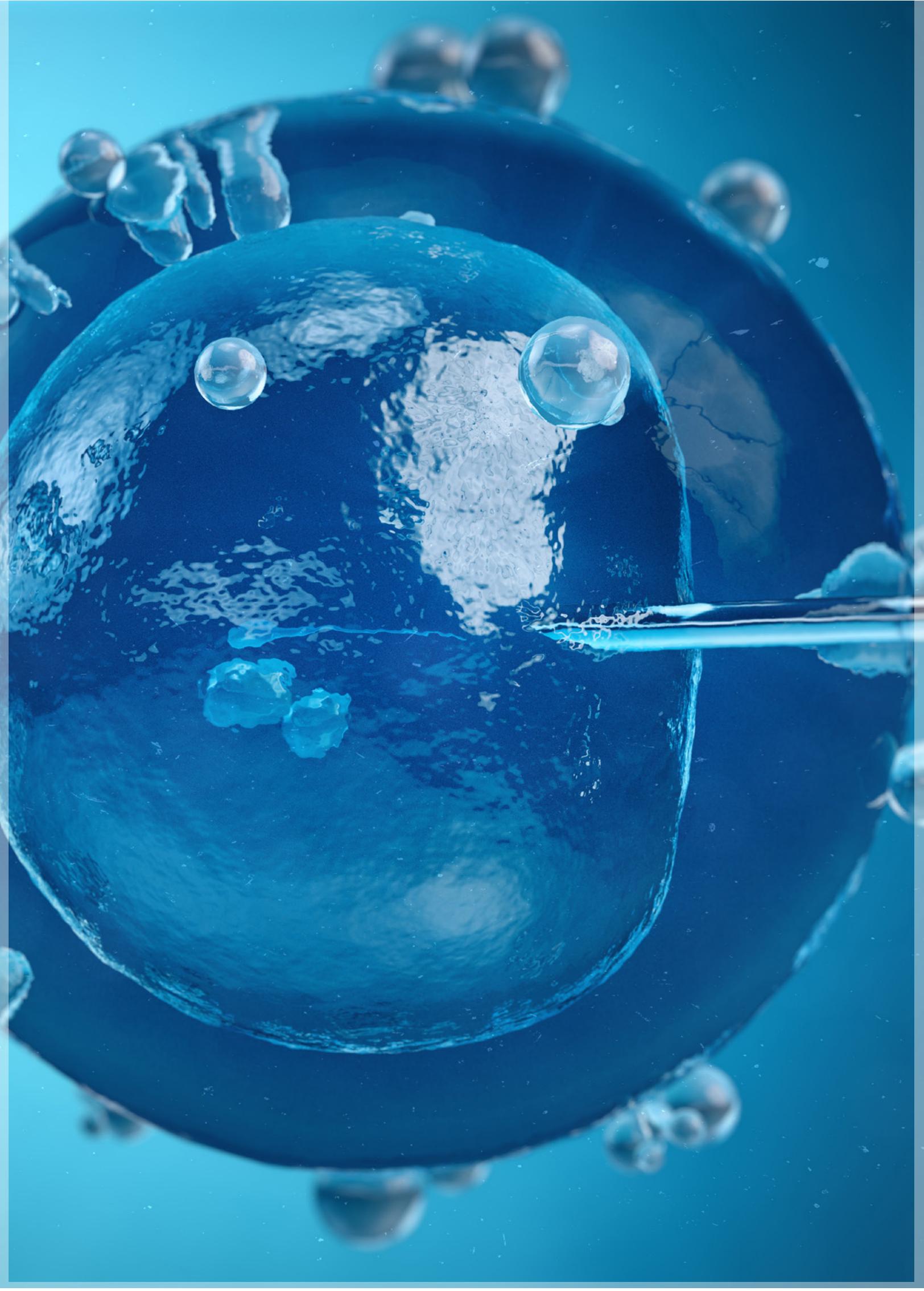
The digital consumer today is more aware than before. Hence, he looks for information across the digital- physical ecosystem. Most patients today use the search facility of the internet even before consulting the doctor.

This new paradigm means organizations would have to find ways to apply their risk controls on their digital presence. While these controls and protocols exist for the

sales teams and marketing teams that have served the industry well in the past, but their application needs to be modified for the digital era.

In this scenario, there are multiple touch points for the consumer- Web Interface, Mobile Application, Digital Payments, Physical Store (Chemists/ Health Store) among others. Hence, organizations will have to create a seamless experience across these channels while ensuring regulatory compliance, data-integrity, and privacy of the consumer.

It is important to apply the risk controls across all of these channels. While in most cases the controls would exist, it would be important to modify the application of controls in the digital context.



02. Derisking process automation through the right controls

Automation has become an important driver of operational efficiency. Healthcare companies are trying to find ways of optimizing human interface in an array of operations, and trying to make it more process and system driven. Such an approach minimizes errors and enhances efficiencies.

Life Sciences organizations are no different and they have been leveraging automation to increase the accuracy of processes in finance, supply chain, procurement and regulatory affairs. With the help of Automation and Analytics, organizations have the opportunity to reduce cycle time and increase the economic value.



01. While automation has its advantages, it would be important to understand the risk controls around the intelligent bots that are performing the functions. Today, Life Sciences organizations have controls and policies that govern the employees working on these processes. There are checks and balances in place for people. And as specified earlier in the document, the controls remain but the application of those controls would change when it comes to automation by intelligent

bots. We believe the key to de-risking automation is to follow a clear process. The key steps towards inducing automation is the selection of processes and POC. This selection is done through our proprietary tool that maps key parameters against the processes, and comes up with procedures that are ideal for automation.

02. Creating the business case for automation- Based on the process selection and POC, organizations should create a business case. Also, it would be ideal to conduct a platform evaluation at this stage to choose the right platform for automation.

03. Implementation- Based on the business case and platform, it is important to start implementation of the program

04. Sustain and Run- Post implementation, there is a need for continuous monitoring of the processes and leveraging the analytics produced for continuous improvement.

This also creates a scenario where regulatory bodies are also preparing themselves in auditing these processes and facilities which are automated, and to keep themselves updated with the emerging, technologies.

In this entire process, there are 2 key risk aspects that come out.

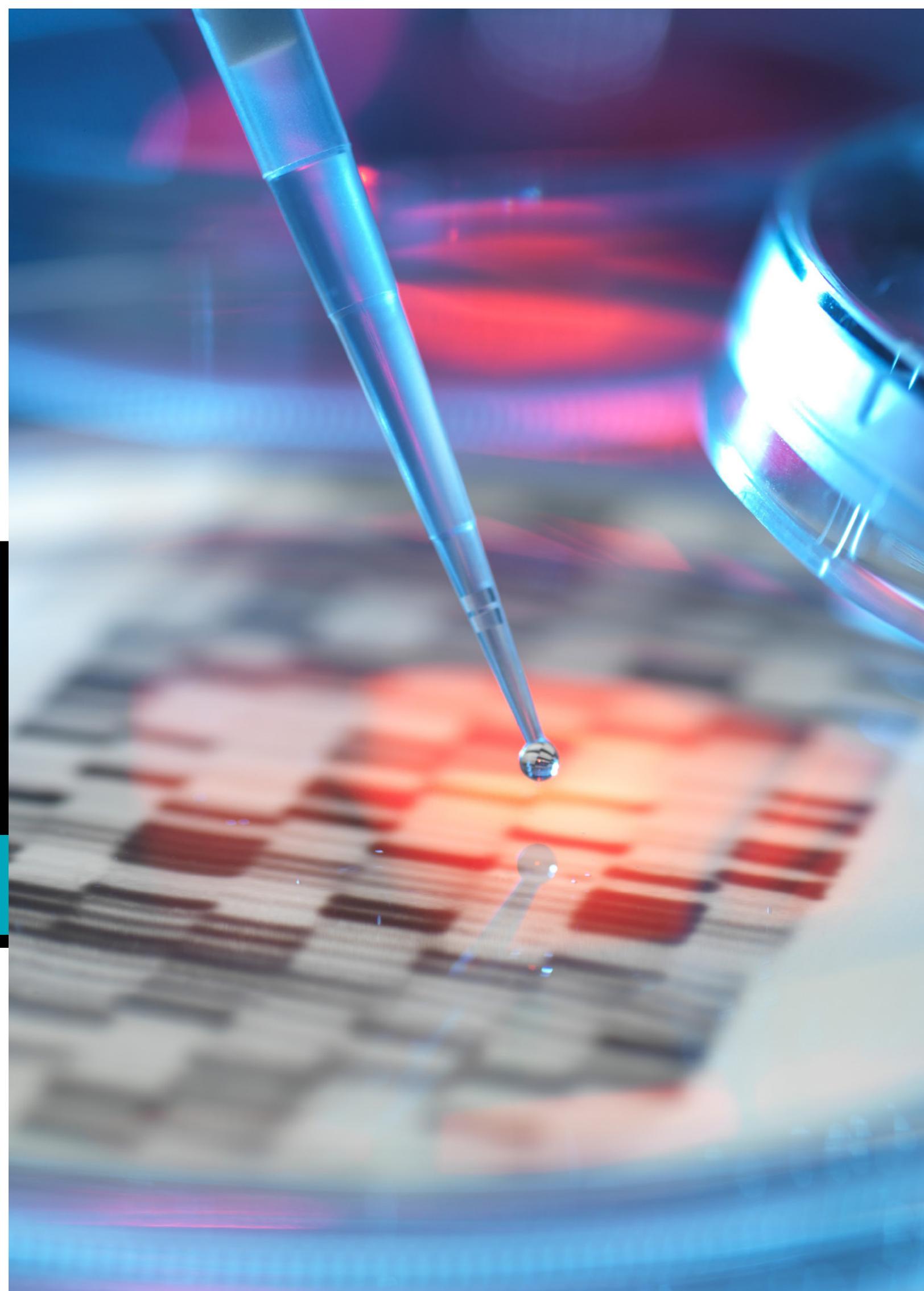


Risk Management by the bot, where the bot applies the controls to the processes, ensuring compliance and creating audit logs that would help internal auditors to monitor the processes.

Risk Management for the bot, which includes key areas like identity and access management for the bot and security for the bot among others.



There are different steps that can be taken to ensure both these aspects are covered and the organization can enjoy the higher efficacy produced by the bot while ascertaining that the risk standards are not compromised.





03 Building a resilient manufacturing construct

Manufacturing is a key area for the Life Sciences Industry. India, today, has one of the largest numbers of FDA approved manufacturing sites outside of the US. This is a testament to the key advances made by the industry in the manufacturing space. Manufacturing also involves adhering to key compliance processes like Good Manufacturing Processes (GMP).

With cheaper and more reliable sensors now available, these can be applied to machines that can help track performance,

detect anomalies, and predict component failure through machine learning. Data is fed into real-time dashboards that can reduce operational downtime, improve asset reliability, and diagnose component-level performance issues as they arise.

An IoT enabled manufacturing environment has to be guarded against any security breach at the device and network level. So, a regular security assessment has to be done to ensure that the system is not compromised. Risk has to be baked into

the design phase of a smart factory set up and governance protocols established to ensure that controls have been applied to the environment. Also, it would be sensible to have a periodic vulnerability assessment and proactive penetration testing to ensure system preparedness and resilience. Finally, the success of the IoT deployments would depend on a robust analytics architecture that creates a mechanism for the data and analytics. The data generated by the IoT devices and sensors can be used as inputs into the exercise of strategic planning.



04 Gearing up for the Digital mind-set

People are key to the success of any digital transformation initiative. Life Sciences organizations have been built on the foundation set by their people including doctors, biologists, virologists, geneticists, molecular biologists, clinical researchers and others. It is often seen that doctors are busy with diagnosis and clinical work and tend to delegate data entry to nurses or support staff. Though this might not hamper the digital progress in the organization but definitely slows down the intended acceleration that the initiatives had hoped to achieve. Various efforts to digitise clinical records are apt examples in this context. Almost all the efforts have been around areas like asking the doctors to enter the records themselves. The other approach has been asking nurses to enter the records on behalf of the doctor. And sometimes, even the Para Clinical or administrative staff has been entrusted with this duty.

Creation of a digital CoE is a key step towards the success of digital transformation initiatives.

Following are the reasons why we recommend building a central digital Centre of Excellent (CoE) in the organization:



Constantly evaluate the digital environment, keep track of new and emerging digital areas

Conduct Proof of concepts (PoCs) with emerging digital technology to improve patient centricity, operational efficiency and create new care models



In addition to the CoE of each department would need to identify and groom digital champions. These champions would CoE ensure that there is constant evaluation of emerging technologies and their applicability for their departments. Digital champions should be encouraged to spearhead digital initiatives and keep interfacing with the CoE to update processes and governance protocols to enable rapid adoption of digital.

In conclusion

Digital Transformation in the Life Sciences Industry has led to a rapidly changing environment that provides opportunities for operational efficiency, patient experience, employee engagement and launching new care models. But managing the risks that come along with digital transformation initiatives would be the crucial for sustainable business transformation.

In this context, there are 3 key considerations:

- 01. Contextual Risk-** Adequate selection of the digital enablers in the transformation program, keeping in mind the business objectives
- 02. Implementation Risk-** Leveraging a Risk based architecture for digital keeping in mind the technology, operations, vendor ecosystem, FDA and other government compliance, security and resilience
- 03. Governance Risk-** Effective governance around digital transformation initiatives to ensure cross functional synergies and eliminate risks from interdependent processes.

But the greatest risk that an organization runs is the risk of obsolescence. In the digital world, the consumer demands that the organizations serving him keep up with the emerging trends, and managing risk would be a good starting point for accelerated adoption of digital.

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