FUTURE OF WORK

BUILDING THE FUTURE QUALITY FUNCTION

By Rahul Guha, Vikash Agarwalla and Abhinav Verma

The Indian pharmaceutical sector has faced significant disruptions across its value chain, including the quality function, due to Covid-19. For most pharmaceutical companies, the quality function has been plagued by several challenges such as unavailability of manpower, inadequate remote working infrastructure and significant volatility in supply and demand.

The industry has taken several measures to contain the impact of the pandemic on their ongoing operations. An analysis of these measures and their impact across the pharmaceutical companies has revealed 4 key learnings for the quality function. These include:

- Pharmaceutical companies that had prioritized investments in digitization have been able to minimize disruption in operations and are now even more committed to continue on their digitization journey
- 20-30 percent of time across several roles is spent on low/ non-value adding work that can potentially be eliminated
- Remote working is a possibility for certain sub-functions within quality for a large number of roles, especially in Quality Assurance (QA)
- Imbuing a culture of quality does not require constant supervision. Many advanced global pharmaceutical sites work with a 5:1 manufacturing to quality ratio versus the 2:1 in India

While Indian pharmaceutical companies have successfully responded to their immediate needs, it is the right time to step back and re-imagine the mid to long-term vision and roadmap for their respective quality functions. This is also an optimal opportunity to evaluate ways to step-change the overall first-time right achievement and migrate from the current 3 sigma levels to closer to what industries such as auto and hi-tech achieve (i.e. 6 sigma). Companies can fundamentally simplify ways of working across both Quality Control (QC) and Quality Assurance (QA) functions.

In our view, the future of quality the function rests on 3 key pillars:

- Build the Next-Gen QC Lab
- Reimagine the role of QA
- Design the quality organization of the future

This article provides BCG's perspectives on the above 3 pillars and the roadmap to make this happen in your organization, as shown in Exhibit 1.

The Next-Gen Lab

The three major issues that pharmaceutical companies face in today's quality control function are an excessive amount of manual effort expended on low / non value adding work, variability in execution across QC analysts as well as high attrition rates. This significantly impacts the companies' ability to achieve a high first time right (FTR) on a consistent basis.

We envisage that the future lab will optimally leverage technology to become paperless, flexible, automated, and predictive, thereby significantly reducing human dependence and driving FTR capabilities. In our view, pharmaceutical companies can traverse this journey in 4 steps:

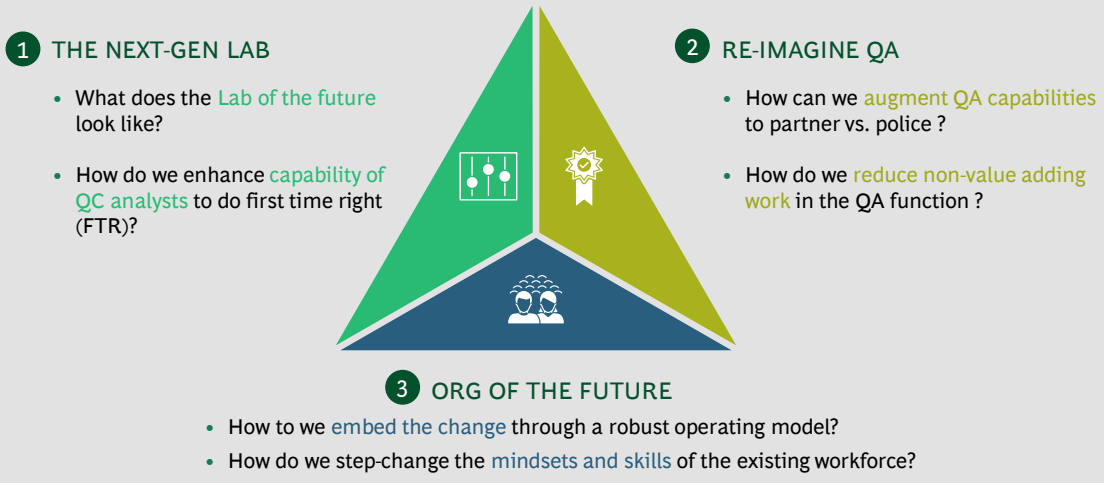
At Level 1, companies can reduce the low / non-value adding activities performed by the analysts. This can be achieved by deploying base technology platforms such as Laboratory Information Management Systems (LIMS), E-lab notebook (ELN) for data capture and building a lab control tower to enable real time visibility of lab performance.

Companies can progress to level 2 by investing in targeted automation of sampling and testing activities to reduce or eliminate the manual work. Some of these investments (for example, use of robots or Augmented Reality (AR)) are likely to be costly. Therefore, the business case needs to be clearly articulated before making these investments.

Level 3 is focused on enhancing the capability of analysts by leveraging AR. Further, advanced analytics can be leveraged to personalize instructions for the analyst via AR enabled smart glasses. This implies that two analysts working on the same test will receive different alerts basis their previous performance, thereby preempting and reducing the chances of error. An example of Level 3 in action is in Exhibit 2.

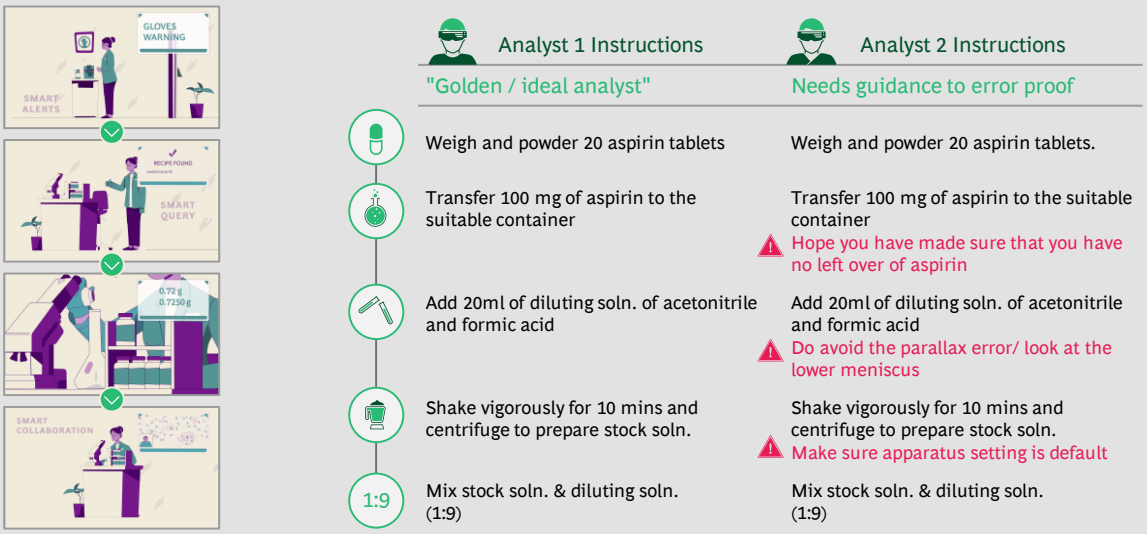
At Level 4, we can look to eliminate the need for a QC lab for product release by moving many of the tests online and using Process Analytical Technology (PAT) / Parametric Release in select products

EXHIBIT 1 | Emerging Priorities for The Quality Function



Source: Discussions with pharmaceutical quality leaders.

EXHIBIT 2 | Personalized Work Instructions to Analysts Using AR



Source: BCG analysis.

where it makes business sense. This is a significant step up for generics companies. Considering the fragmented portfolio of these companies, it will be important to identify high volume, high value products which can yield the desirable return on investments. Enabling PAT requires pharmaceutical companies to follow 3 key steps for real time release (Exhibit 3).

Basis our experience in this field, we envisage that the journey to building the Next-gen lab (till level 3) is a 2-year process. It is likely to be executed first at a pilot site followed by network-wide roll-out, as outlined in Exhibit 4. In our view, pharmaceutical companies need to consider 2 important aspects as they build their vision and roadmaps.

- Start with a 4 to 5 year vision of the end-state and how things will integrate with each other. This is integral to avoid investing in "white elephants"

- This is not an IT project. In our view, 60-70 percent of the effort is in change management and therefore, focusing on that from start is going to be critical to the success of this program

Re-imagine QA

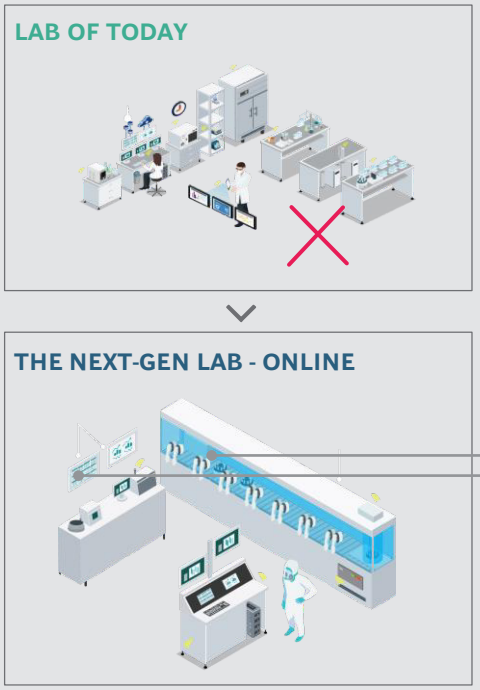
In most of the Indian pharmaceutical companies, we estimate that the QA function spends almost 40-50 percent of time on activities such as document review and report preparation. A large part of this time is purely a manual effort which restricts the time available for more value adding work for example, identifying and enabling process improvements. We re-imagine the future QA function to be one where most of the manual effort activities (such as "boiling the data ocean") will be done through automation and algorithms, thereby freeing up significant time for value added thinking. This then positions the QA function well to play the role of strategic business partner that drives quality by design versus "policing".

The evolution of the QA function initiates from Level 1 where a company automates data entry and monitoring processes across functions (for example, E-BMR and E-logbooks). In addition, core QA activities and reporting such as QMS, documentation, and APQR generation also get automated. Level 2 is integrating the technology platforms across warehouse, manufacturing and QC functions and using this integrated data to further simplify work for example, moving to an exception-based review system.

Level 3 moves to the use of artificial intelligence (AI) to augment the capability of QA.

EXHIBIT 3 | Move to Parametric Release / PAT

Illustrative



PROCESS AND MATERIAL ATTRIBUTE ANALYZERS

- Inline or at-line equipment for continuous capture of process parameters and material attributes of each tablet to generate big data
- E.g. NIR probes, visual inspection machines, etc.

ADVANCED DATA ANALYTICS

Customized ML algorithms to :

- Develop correlation between process parameters and quality attributes
- Identify acceptable process/material parameter ranges
- Assess deviations

APPROVAL FROM REGULATOR

- Prefer right from product launch, but bolt-on model can be used
- Require initial use of both PAT and lab testing to compare results as a proof of equivalency
- Typically requires a PAS filing

Source: Expert discussions, Desk research, BCG analysis.

EXHIBIT 4 | QC : The Next-Gen Lab

ROADMAP FOR IMPLEMENTATION

Need to put in place the strategic vision upfront, before embarking on this journey

		Today	6 months	1 year	2 years	2+ years
			Level 1: Deploy base technology systems	***Level 2:*** Invest in targeted automation in sampling and testing	***Level 3:*** Enhance capability of analysts by leveraging AR	***Level 4:*** Eliminate QC labs for product release
Key focus areas			• Automate workflows using technology • Implement paperless solutions • Augment IT solutions with I 4.0 solutions for monitoring	• Invest in select automation in the labs – particularly in sample prep. and microbiology testing • Standardize work by complementing with augmented reality	• Deep learning engines to determine predictive recommendations	• Setup select online testing eg: NIR • Implement predictive systems for quality outcomes • Implement real time release
Key enablers to put in place	*Process/ Tech*		• LIMS • E-lab notebook • RFID for sample identification • Lab control tower	• Augmented Reality for QC analysts • Robotics solutions for sampling and testing	• Machine learning based personalized recommendation systems	• Online testing • Analytics for PAT/ parametric release
	People		• Training on use of new tools • Monitor & enable adherence	• Redeploy people to value adding roles • New org structure	• Up-skill team for new age systems • Embed new roles	• Comprehensive change mgmt. program (across functions)

Source: Expert discussions, Desk research, BCG analysis.
Note: Timelines indicated for 1-2 pilot sites, rollout across network may require additional time.

Two use cases we have seen deliver significant value for pharmaceutical companies are machine learning (ML) driven deviation resolution and critical process parameters range recommendations. ML driven deviation resolution is an insightful digital product that can reduce deviation closure time by 70 percent and identify root causes that are 100 percent accurate. It is centered around 4 features:

- Search Engine to explore historical data for similar deviations
- Cluster Browser to understand main types of deviations within each area
- Root cause analysis assistant to find a root cause by comparing deviating batch to the golden batch
- Deviations performance dashboard for the function leadership

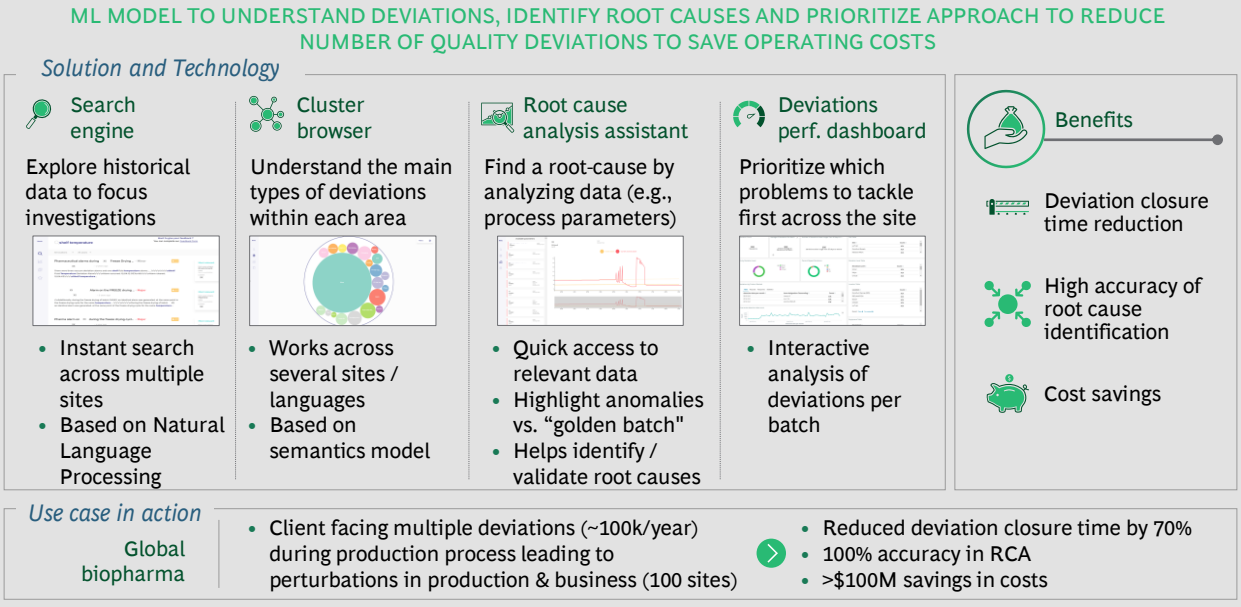
The details of the ML driven deviation resolution are shown in Exhibit 5 below.

In addition, ML can be employed to suggest optimal critical process parameter ranges for the process to reduce batch failure rates. The approach includes identifying the correlation between process parameters and quality metrics. Once the correlation is established, the algorithm helps narrow down the ranges for the process parameters so that right quality outcomes are achieved. The deployment of the method has seen reduction in batch failure rates by almost 40 percent.

QA in more mature industries such as semiconductor manufacturing and automotive has evolved to a driver of quality at source across own plants as well as at the supplier end. The function drives process improvement initiatives along with manufacturing, works with suppliers to enhance their process capabilities to drive FTR, and collaborates with R&D to strengthen the future product development. Similarly, QA in pharma needs to transform from a cost center to a strategic business partner and assume a leading role in assessing the process capability gaps, providing visibility of cost of poor quality (CoPQ), and working collaboratively with cross-functional teams to drive improvements in current as well as future products.

Similar to QC, pharma companies need to undertake a journey to re-imagine the QA function. Basis our experience, a practical roadmap that can be adopted by compa-

EXHIBIT 5 | ML Driven Deviation Resolution



Source: BCG experience.

nies can be seen in Exhibit 6. As highlighted earlier, change management will be critical to ensuring adoption and stickiness.

Org of the Future

Our past research has revealed that almost 2/3rd of the large transformations fail to deliver the desired benefits. In most of these cases, the single most important root cause has been lack of focus on change management and building the people capabilities in sync with the desired transformation. Therefore, a focus on building the organization (org) of the future is the most critical element that will define the success or failure of this transformation. In our view, there are two critical forces that will shape the quality org of future. Firstly, considering the expected duration of COVID-19, it is imperative that companies build an effective remote working model. Secondly, the rise of digital across QA and QC will necessitate new skills, capabilities and roles to be embedded into the quality function.

The first level will be to set up digital infrastructure to enable remote working, including team collaboration tools and remote access to data. This will have to be augmented by employee trainings focusing on their optimal usage.

Progression to level 2 will require redesigning the operating model for remote working. The current roles, KPIs and governance mechanisms will need to be redefined to ensure that productivity is equivalent to supervision. Further, companies can establish shared services for Analytical Assurance and QMS functions which can remotely cater to multiple sites. In the remote setting, supervisors need to define standard work at a granular level and provide visibility a week ahead. While employees will need to be agile to accommodate any changes, aligning upfront on the weekly plan and micro-deliverables can ensure high productivity.

At the next level, companies will need to invest in upskilling their managers so that they can optimally leverage digital tools and are adept at managing the workforce of the future. The managers need to be technically upskilled to derive the right insights from the analytics tools and leverage them in decision making. Beyond technical skills, a program focused on behavioral skills that ensures mindset change should be embedded within the manager's learning journey.

EXHIBIT 6 | Reimagine QA

ROADMAP FOR IMPLEMENTATION

Need to put in place the strategic vision upfront, before embarking on this journey

	Today	6 months	1 year	2 years	2+ years
		***Level 1:** Build integrated data acquisition & monitoring system*	***Level 2:** Implement systems to move to exception based review*	***Level 3:** AI to enhance capability and reduce non-value adding work*	***Level 4:** Transform process capability*
Key focus areas		• Automate workflows using technology • Implement paperless solutions • Augment IT solutions with I 4.0 solutions for monitoring	• Integrate manufacturing and quality systems • Automated review of parameters to highlight exceptions	• Deep learning engines to determine predictive recommendations • Deployment through AI for root cause analysis	• Drive measurement of process capability and its impact on costs • Transition QA role to transform core mfg. processes across internal sites and at suppliers
Key enablers to put in place – *Process/ Tech*		• E-log books • E-BMR • MES • QA automation eg: Trackwise, Automated APQR	• Integrated view across systems – LIMS, MES, SAP, QMS • Exception based reviews	• ML driven deviation resolution • ML based CPP range recommendations	• Automated visibility of COPQ • Identification and implementation of CI initiatives
Key enablers to put in place – *People*		• Training on use of new tools • Monitor and enable adherence	• Redeploy people to value adding roles	• Upskill managers • Comprehensive change mgmt.	• Re-design op model (role, KPIs, competency set)

Source: Expert discussions, Desk research, BCG analysis.
Note: Timelines indicated for 1-2 pilot sites, rollout across network may require additional time.

This upskilling can be driven by regular sprints of classroom learning followed by implementation of capstone projects. Expertise certificates can be awarded for various skills to motivate the managers. To ensure continuity of learning, companies should provide a 24/7 virtual / digital coach, powered by AI chatbots and a personalized e-learning journey.

Lastly, at level 4, we will need to ensure that the digital initiatives have a strong pull from the bottom instead of a push from the senior team. Learnings gleaned from other industries reveal that concepts of human centric design and gamification are critical to enabling this. A simpler way to understand this is to view every new digital tool from the lens of "how an Apple or Amazon" would have designed this. Personalized nudges to guide and motivate employees in their daily activities can help drive the right behaviors. This ensures that the employees are motivated to practice and adopt new behaviors. An example of how nudges can be embedded into the daily life of a QC analyst is shown in Exhibit 7. Companies can leverage gamification to design a recognition program that enables desired behaviors. In addition, companies will also need to start building a few tech capabilities around data science and visualization within the function. This will enable the creation of real and sustainable value.

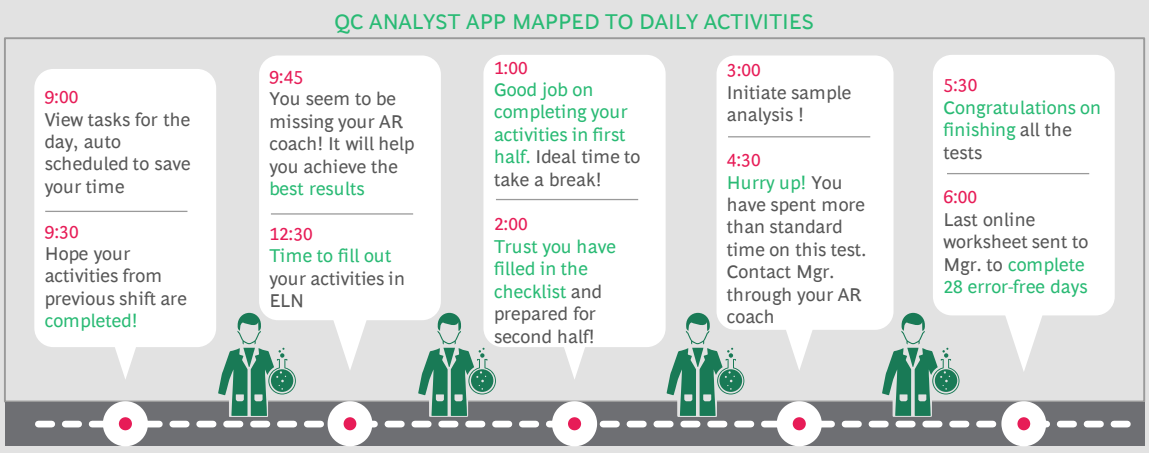
A roadmap for implementing initiatives for organizations of the future can be seen in Exhibit 8. As you would notice, the overall timelines for setting up the org of the future is slightly lesser than that needed for implementation of next-gen lab and re-imagine QA. This is to ensure that people are ready for the new normal and the change becomes seamless.

Summary

The "Future of Work" in quality function is defined through a maturity model across the elements of next-gen lab, re-imagine QA and the organization of the future. A summary view across the 3 elements has been depicted in Exhibit 9. Pharmaceutical companies can view this as a chessboard and assess where they currently lie and where they want to play basis their strategy and investment willingness, over the next few years. It is important to build a network wide strategy upfront so that the entire network reaches a consistent level over time.

Pharmaceutical companies can fundamentally transform the quality function with these initiatives and the business case is very significant. In our view, moving to a Level 3 across initiatives can lead to 1.5X increase in productivity, reduce the time spent on non-value adding activities by 50 percent, and take first time right to 4 sigma. Moving to Level 4 is a further step up that can lead to 2X productivity, eliminate almost all the time spent on non-value adding activities and take first time right to 5 sigma and above.

EXHIBIT 7 | Gamification Example for QC Analyst



Source: Expert discussions, BCG analysis.

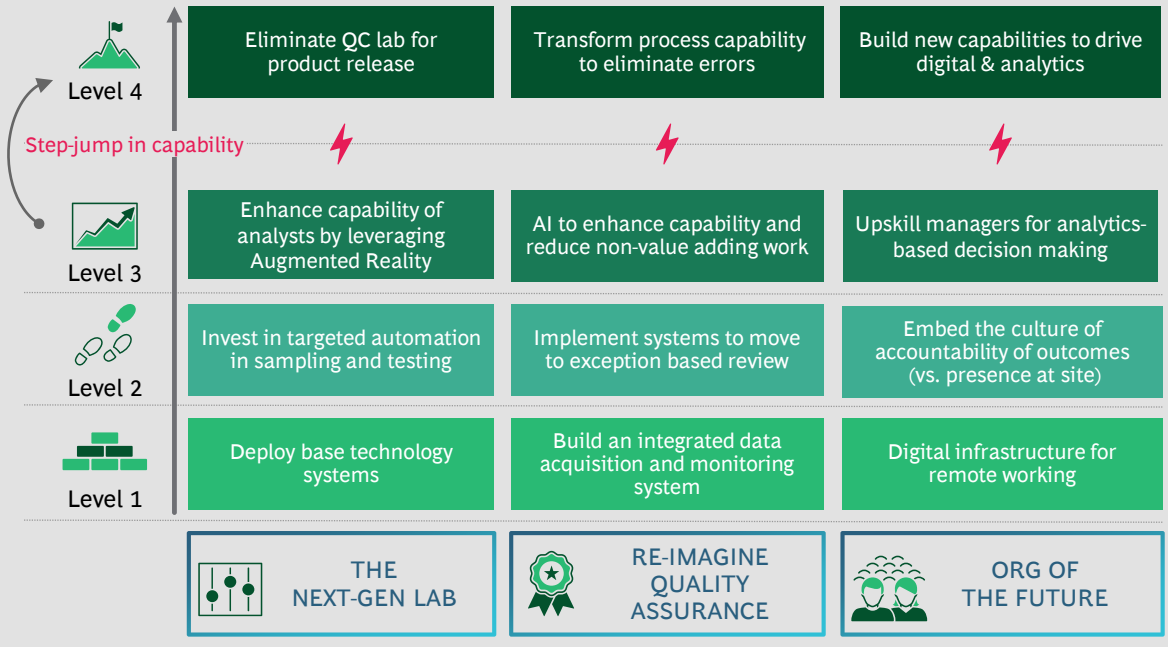
EXHIBIT 8 | Org of the future

ROADMAP FOR IMPLEMENTATION

	Today	6 months	9 months	1 year	1-1.5 years
		Level 1: *Digital infrastructure for remote working*	***Level 2:*** *Embed the culture of accountability of outcomes*	***Level 3:*** *Upskill managers for "Analytics driven decision making"*	***Level 4:*** *Creation of new roles & capabilities to drive analytics*
Key focus areas		• Digital solutions to set up remote working • Train people to work remotely	• Redesign HR processes to achieve equivalent / higher productivity and compliance • Design shared services center (SSC) across cluster/ all sites	• Multi modal learning for managers to adopt and drive insights from analytics	• Drive "pull" for tech adoption through human centered design of digital tools, gamification • Embed new roles with digital & analytics expertise
Key enablers to put in place		• Automated data entry and monitoring (as highlighted in QC, QA)	• New roles, KPIs and governance mechanisms • SSC for non-IPQA part of QA	• Comprehensive learning program across class-room, & action learning	• Best in class UI/UX for digital tools • Nudges for driving tech adoption • New roles – data scientists, visualization experts etc.

Source: Expert discussions, Desk research, BCG analysis.
Note: Timelines indicated for 1-2 pilot sites, rollout across network may require additional time.

EXHIBIT 9 | Summary: "Future of Work" for The Quality Function



Source: BCG experience.

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