Assuring Trust in a Converging Life Sciences Ecosystem: The Emerging Role of Quality Assurance

Quality Assurance in a Changing Life Sciences Industry

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Bringing value back into life sciences

Patients and consumers have a trust deficit issue with life sciences firms for a variety of reasons:

- **Adverse events and drug reactions**: The industry has seen a steady rise in Adverse Events (AEs) over the past six years. Over 100,000 people in the United States alone die every year due to undisclosed/undiscovered pharmaceutical side effects.

- **Drug development efforts**: At the same time, the time (10-15 years) and cost (approximately US$2.5 billion per drug) of drug development is creating significant time-to-value challenges, with delayed and often, expensive therapies.

- **Pharmaceutical pricing**: Drug pricing is a significant concern for consumers, particularly given high profile situations, such as the Turing Pharmaceuticals incident and the U.S. administration’s posture forcing Pfizer and Novartis to temporarily suspend price hikes.

- **Drug recalls**: In spite of the fact that global life sciences firms have tripled their annual pharmacovigilance (PV) spend as a percentage of total sales – from 0.3% in 2003 to over 1% in 2017 – drug recalls have not significantly declined.

- **Poor GxP compliance**: Poor adherence to good manufacturing practices have led to several trust-deficit situations. Wockhardt has seen three of its plants being issued import bans by the FDA, and a subsequent warning letter on similar issues. The FDA has frozen imports of Valsartan from ZHP, a Chinese API supplier. All of these lead to significant financial and reputational losses.

EXHIBIT 1

Life sciences’ compliance burden

| Source: FDA, Gallup, Public Citizen |

<table>
<thead>
<tr>
<th>Number of AEs reported for drugs / biological products</th>
<th>Jul 2012 – Dec 2017</th>
</tr>
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<tbody>
<tr>
<td>Jul-12</td>
<td>40,308</td>
</tr>
<tr>
<td>Jul-13</td>
<td>67</td>
</tr>
<tr>
<td>Jul-14</td>
<td>65</td>
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<td>Jul-15</td>
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<td>Jul-25</td>
<td>-17</td>
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<tr>
<td>Jul-26</td>
<td>-23</td>
</tr>
</tbody>
</table>

Pharmaceutical companies paid a total of $38.6 billion to federal and state governments from 1991 and 2017 resulting from 412 penalties.

**U.S. adults’ perceptions, by business sector**

<table>
<thead>
<tr>
<th>2017, Net score</th>
<th>Net positive</th>
<th>Net negative</th>
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<tr>
<td>67</td>
<td>Computer industry</td>
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</tr>
<tr>
<td>65</td>
<td>Restaurant industry</td>
<td></td>
</tr>
<tr>
<td>58</td>
<td>Farming &amp; agriculture</td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>Accounting</td>
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<td>38</td>
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<td>Banking</td>
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<tr>
<td>8</td>
<td>Legal</td>
<td></td>
</tr>
<tr>
<td>-2</td>
<td>Oil &amp; gas</td>
<td></td>
</tr>
<tr>
<td>-7</td>
<td>Healthcare</td>
<td></td>
</tr>
<tr>
<td>-17</td>
<td>Pharmaceuticals</td>
<td></td>
</tr>
<tr>
<td>-23</td>
<td>Federal government</td>
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</tbody>
</table>
As healthcare and life sciences entities converge (payers and providers coming together, Pharmacy Benefit Managers (PBMs) being disintermediated, and pharmaceutical firms collaborating with payers and providers), the ecosystem is evolving and simplifying around patients as the core constituent. This change has a number of implications for stakeholders, particularly life sciences firms, which now need to interact closely and work collaboratively with different parts of the ecosystem to drive enhanced value through care outcomes and cost efficiency.

Life sciences firms have to help patients manage health outcomes more effectively, while also coordinating with payers, providers, converged healthcare entities, regulators, and digital healthcare platforms via a sustainable patient-centric business model. The primary determinant of success in this journey is about driving patient outcomes and building trust within the broader ecosystem. Therefore, the orientation has to be adjusted to focus on improving care outcomes for patients (both improved healthcare and a superior experience) and business outcomes for other ecosystem participants (streamlining healthcare costs and improving access to care).
Changing role of life sciences in the converged ecosystem

**Everest Group take**
Given the confluence of changes, life sciences firms to need to step up engagement and coordination with various stakeholders and take control of the quality/value narrative. These interactions will be underpinned by:

- **Outcome-based business models**: assuming risk and helping demonstrate improvement in care outcomes
- **Shift from B2B to B2C**: directly engaging patients and building trust by fostering communities and conversations
- **Regulatory compliance as a business-value driver**: Proactive engagement with compliance stakeholders to drive consensus and shape the ecosystem
- **Technology disruption**: Adapting to emerging digital platforms to reinvent business functions and ecosystem interaction

Engaging these strategies will lead to a reimagination of the life sciences value chain as silos collapse to unlock hidden value and enable true patient-centricity.

As life sciences firms prepare to shift to value-based care models and patient-centricity, there is an increasing urgency to include all market participants in the conversation. As a result, the life sciences business model is changing and becoming inextricably linked to care value delivered.

These changes fundamentally alter the manner in which life sciences firms interact with other participants in the ecosystem. Life sciences firms now need to engage with different components of the ecosystem, such as:

- **Converged payer-provider entities**: In the U.S., Amgen signed an outcomes-based refund contract with Harvard Pilgrim Health Care pertaining to evolocumab (Repatha), the company’s cholesterol-lowering medication. As part of the deal, Harvard Pilgrim will receive a rebate for the cost of evolocumab if an eligible patient is hospitalized with an MI or stroke after taking the medication for six months or more and maintaining an appropriate level of compliance
- **Patients and advocacy groups**: Because patients reach out to online health communities to seek information and assistance, and share stories, life sciences firms need to engage them. For instance, AbbVie started AS1, a Facebook community for sharing information about Ankylosing Spondylitis (AS). This platform shares information about AS to help people to have informed conversations with their doctors. Community members can find a symptoms quiz that helps them to understand their condition and have better conversations with their doctors
- **Government and regulatory bodies**: Novartis, the Catalan Institute of Oncology (ICO), and Catalonia’s health ministry (CatSalut), signed an agreement that includes a payment-by-results (PbR) plan for a specific breast cancer therapy regimen. To enable the plan, Catalonia developed health IT tools for monitoring using a personal health ID to link data sets
- **Digital healthcare platforms**: Platforms such as Apple ResearchKit/Watch and Verily Study Watch seek to reshape clinical trials. GlaxoSmithKline and some partners launched
the Patient Rheumatoid Arthritis Data from the Real World (PARADE) Study using a customized Apple ResearchKit App, with the goal of investigating the feasibility of using a mobile app to recruit and enroll patients in a study and to gain insights about rheumatoid arthritis in a real-world setting.

**Value chain disruption**

As incumbent participants evolve interactions and new entrants bring fresh thinking to life sciences, patient-centricity and ecosystem-orientation are becoming dominant industry themes, leading to a reimagining of the industry value chain.

- **Drug discovery, research, and clinical trials** are focused on enhancing data sharing, shortening time-to-market, and enabling personalized medicine. They are enabling technology proliferation in various sub-aspects such as clinical data management, virtual trials, e-consent, and patient recruitment. These functions are also collaborating with sales and marketing to incorporate real-time feedback back into the drug development and clinical trial phase. Mobile health platforms (Apple’s Research Kit and Verily Watch) are also leading to a dramatic change in how clinical data is collected—directly from patients. Firms are also pooling scientific knowledge and expertise through consortiums such as TransCelerate, to gain access to common resources and accelerate time-to-market.

- **Manufacturing operations** are becoming smarter. There is a shift from static batch manufacturing to Process Analytical Technology (PAT)-driven continuous and flexible manufacturing. Given the global and complex nature of the portfolio (different therapies, specific product needs, and local compliance), life sciences firms want to make manufacturing more nimble and reduce time-to-market.

- **Sales and marketing** is changing as a result of the overhaul of the distribution model. The traditional Healthcare Practitioner (HCP) channel is changing to focus more on D2C and ecommerce initiatives for non-prescription and lifestyle products. Firms are enabling a full spectrum impact view by liaising with the clinical and R&D function. For instance, for its CAR T-cell technology, Novartis had sales representatives act as resources to the physician, often sitting in on surgeries and providing education, training, and feeding patient/physician inputs back into the clinical and R&D functions.

- **Supply chain and distribution** is undergoing a shift to become responsive for niche therapies. Also, firms are increasingly applying new technologies to address age-old issues such as counterfeit drugs, with blockchain being explored as a means of ensuring drug authenticity and quality.

Driven by these changes, ecosystem interactions and quality orchestration are key imperatives driving life sciences firms.

“We’re making sure of the provenance of the product, guaranteeing it hasn’t been tampered with throughout the chain to the patient. Blockchain is such a natural fit for that kind of capability.”

*Dale Danilewitz, CIO, AmerisourceBergen*
The future of life sciences and implications for quality assurance

**Everest Group take**

The traditional QA function in life sciences has been characterized by a siloed approach built on disparate platforms, fragmented technology stacks, and varying value approaches. For life sciences firms to pivot to the B2C model and value-based care positioning, the QA function will have to change to support a leaner and more flexible approach based on:

- A proactive compliance posture based on continuous audit readiness, thereby enabling intrinsic linkages with business outcomes.
- End-to-end stakeholder (physicians, patients, payers, providers, patient advocacy groups, and NGOs) experience helping patients take control of care decisions through real-time data access.
- Data ecosystem orchestration, validation, and governance (providing real-time access to combined clinical, commercial, and Social Determinant of Health (SDOH) data).
- Accelerating time-to-value of initiatives through a platform-based approach.

**EXHIBIT 3**

The Four Es: Key imperatives of the new care business model and their impact on enterprise QA

Source: Everest Group (2019)

“**The pharma industry has been actively working on digitization of the quality and manufacturing areas. There is a huge expectation from regulators to strengthen data integrity with the use of technology. As far as possible, every data point should be directly captured into the system, and that data must not be available for manipulation.**”

Venkat Iyer, CIO, Wockhardt Ltd

- **Enabling** the data ecosystem by becoming the custodian of appropriate risk, outcomes, and pricing, by bringing together clinical and commercial data, along with other exogenous data such as social determinants of health and genomics. As coordination with payers and providers increases, life sciences also needs to reconcile clinical and commercial data for a 360-degree ecosystem view. Increasing collaboration will require coordinated quality/brand assurance. The QA stack needs to evolve to assure complex data across an extended ecosystem, and ensure continuous validation and protection of patient identity and data, especially Personally Identifiable Information (PII) and Protected Health Information (PHI).
Elevating R&D and clinical trials to improve spend efficacy. Focus on faster and intelligent decision-making to improve cycle times and process efficiency. As R&D and clinical trials embrace technology, QA will have to ensure the resilience of the validated good practices (or GxP) environment. Pervasive digitalization will necessitate end-to-end value chain assurance (e.g., the sales and marketing and clinical and R&D functions working together).

Engaging patient communities. Life sciences firms need to reimagine their engagement models with patients/consumers to regain trust. This change has to go beyond tactical/transactional communication to provide personalized recommendations and tailored guidance. Life sciences firms need to establish a dialogue by fostering communities, extending support to social groups/platforms, providing empathy-based advice, and supporting ecosystem initiatives. The future of patient-centricity requires customized QA services as life sciences firms try to ensure a consistent experience across a multitude of channels spanning different stages of the patient journey. QA services will need to act as the enabling layer to fuel these initiatives. Emerging AI adoption will need validation to address bias/ethics.

Enhancing drug quality and safety. For some time, safety and pharmacovigilance have been reactive. As incidents increase, life sciences firms will have to make the process more intelligent. QA services will need to help orchestrate the transformation of pharmacovigilance as it becomes more intelligent by acting at the intersection of patients, regulators, safety systems, and personalized therapies.

To orchestrate the quality of the care experience is a Herculean task, and life sciences firms need to work with a combination of channels and partners to enable it, including:

- **Partners:** HealthTech companies, regulators, commercial and clinical data providers, etc.
- **Channels:** Traditional channels (physicians, OOH, detailing) and partnered or third-party channels (e.g., healthcare platforms, consortia, communities, etc.)
- **Digital healthcare platforms:** Including start-ups and initiatives such as Apple’s ResearchKit and Alphabet’s Verily

For the QA function to evolve, it essentially needs to progress from a siloed structure to an orchestrator. The subsequent section explores what is needed to build this future model of QA with the help of a set of illustrative use cases within the life sciences industry.
Enabling data ecosystem: moving from real world data to real world evidence

Everest Group take
As the life sciences industry moves toward outcome-led business models, significant value can be unlocked by collapsing the silos between clinical and R&D and sales & marketing. By bringing together commercial, clinical, and R&D data, the life sciences industry can generate more meaningful insights into patient behavior and preferences as well as spark the discovery process for newer therapies and approaches. QA will need to act as the chief coordinator to help validate data, ensure veracity, and enable coordination through standards/protocols.

- **Industry context**: The clinical and R&D and sales & marketing processes have traditionally run in silos. Sales & marketing has been traditionally tasked with managing the physician and Key Opinion Leaders (KOL) ecosystems as the primary channels, leading to:
  - Difficulty in integrating real-time market data during discovery
  - Missed opportunities in therapies and care models
  - Limited progress in accelerating Real World Data (RWD) usage

- **Real world evidence of the future**: Effective use of real world evidence will be underpinned by the true unification of different data sources - clinical data, health data, patient-reported data, and data from other sources. Once these processes start talking to each other, a reverse feedback loop can be instituted to improve upstream processes in an iterative manner. This process will have to be enabled by tightly knit integration and validated data lakes, Business Intelligence (BI), and Data Warehousing (DW) initiatives to enable data reconciliation.

**EXHIBIT 4**

Orchestrating data across the life sciences ecosystem

Source: Everest Group (2019)
• QA for real world evidence of the future
  – **Data grid layer reconciliation**: Life science firms will have to reconcile multiple data sources for a range of niche and broad-based therapy areas in a secure validated environment. Enterprise QA will need to orchestrate this reconciliation through an effective data grid or hub that can both help to reconcile all of the data and ensure validation and resilience.
  – **Validating value chain coverage**: QA will have to bring best-of-breed capabilities in core R&D/clinical validation and also assure the efficacy of commercial data (with a focus on sales force effectiveness). Because cloud leverage varies across the life sciences value chain, straddling a multi-environment ecosystem will be crucial.
  – **Overall governance and risk management**: QA strategies will need to govern the broader integration of clinical, commercial, and health data, across enterprise networks extending traditional staff and managed services constructs to ensure consistency and compliance.
TransCelerate BioPharma Inc. is a non-profit organization with a mission to collaborate across the biopharmaceutical R&D community. The consortium comprises 19 leading companies working to identify solutions to common drug development issues and to drive efficiencies in the R&D process. Among other initiatives, TransCelerate operates a shared investigator platform that helps to streamline the clinical trial experience.

Elevating R&D and clinical trials: QA for next-generation cross-industry cloud collaboration

**Everest Group take**

There is a need for a single, intuitive scalable platform with common processes for clinical trials. A cloud-based digital platform can help pharma companies run clinical trials more efficiently and accelerate the development of new medicines. Such a platform will also help pharma firms collaborate with research labs for early stage drug discovery. Enterprise QA will enable end-to-end validation of clinical trial processes, multi-partner collaboration, data resilience and security, and governance.

- **Industry context**: Clinical trials technologies tend to be fragmented and are often point solutions, which causes issues with coordination, collaboration, and governance. The use of different platforms results in inconsistent standards between sites and sponsor companies and subsequent increased cost to maintain different platforms and processes. Finally, because R&D data is mostly hosted on the pharma’s in-house systems, providing external stakeholders access to internal systems becomes a challenge due to IP issues.

- **Clinical trials of the future**: The future of clinical trials is end-to-end validation of clinical trial processes on the cloud to enable a seamless flow of data across the entire clinical trial. This process includes orchestration of data from different sources (including healthcare indicators) while ensuring validated clinical data management and cloud-based collaboration/coordination of global clinical trials.

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**EXHIBIT 5**

Future of clinical trials data

*Source: Everest Group (2019)*

**As-is state of clinical data**

- Clinical notes
- Trial data
- Inputs from patients
- Data from other sources

**To-be state of clinical data**

- Clinical notes
- Trial data
- Inputs from patients
- Data from other sources

Unified clinical trials platform (common data format standardization and integration layer)

Unified view of the clinical record

**QA implications**

- QA hub to assure, orchestrate, and facilitate access to data
- End-to-end coverage
- Ecosystem orientation
- Platform-based approach
QA for clinical trials of the future

- **QA hub**: Firms will have to secure and orchestrate sharing of domain expertise and clinical data across collaborating partners on its research platform. QA can enable this through a hub of QA engineers, domain SMEs, validation SMEs, technology experts, and regulatory SMEs.

- **End-to-end coverage**: QA’s role will need to span across functional and non-functional QA, with a validation strategy aligned to cloud deployment. QA strategies will have to align with the Regulatory Assurance-as-a-Service (RAaaS) offering to provide compliance-related validation.

- **Ecosystem orientation**: QA needs to help life sciences firms coordinate a network of partners to streamline collaboration and provide a centralized point of access for trial sponsors, CROs, investigators, clinical researchers, etc. Enterprises need to measure performance of QA function by business outcomes (time to complete a study, time to set up a site, RoI on a drug discovery project, patient experience). The QA function itself will be driven by technology agnostic reusable test assets for optimal functional coverage.

- **Platform-based approach**: Enterprises would no longer require a separate module for each external partner; rather, a common integrated platform will ensure collaboration in a secure environment.
Engaging patient communities: QA for building trust with patients and consumers

**Everest Group take**

Life sciences needs to coordinate care for patients across a disparate range of touchpoints, from aiding discovery and education to monitoring care outcomes and potential adverse events. Enterprise QA will need to validate a unified view across the patient lifecycle and enable care coordination with other participants in the care experience journey (care givers and payers).

- **Industry context:** With the advent of e-commerce models for certain non-prescription products, evolving patient/consumer expectations, and closer coordination with payers/providers, pharma companies are grappling with an acceleration in DTC interactions. This change has broad implications, as it requires fostering trust with consumers and patients, who typically do not have direct relationships with pharma firms.

- **Patient engagement of the future:** Pharmaceutical companies need to establish a direct relationship with patients to engage them on their care journey, through medication adherence programs, assistance with scheduling appointments, mobile health monitoring, telehealth, and educational support. This process needs to be accelerated through a robust mobile channel supported by always-available, qualified clinical support (through certified professional and/or nursing staff on call/chat), which will help in coordinating care, monitoring medical lapses, and feeding information into the claims loop and the care loop to truly orchestrate healthcare. For full-spectrum impact, pharma firms must offer financial support through insurance verification, benefits investigation, claims appeals and re-coding, prior authorization, and co-pay assistance management.

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**EXHIBIT 6**

Patient engagement opportunities for pharmaceutical firms

Source: Everest Group (2019)
• QA for patient engagement of the future
  – Process orchestration: Given the wide range of market constituents involved – patients/consumers, payers, providers, regulators, channel partners – enterprise QA will need to orchestrate the workflow and process stack with focus on enhancing validation, reducing leakages, and full spectrum transparency and visibility
  – Data integrity: Data standards and interoperability tend to be significant problems in healthcare and life sciences. As it assumes this orchestrator role, enterprise QA will need to ensure end-to-end data verification and validation, while ensuring data traceability and integrity
  – Regulatory coordination: Pharma-to-patient interactions are highly regulated. To maintain the sanctity of these diverse touchpoints across the care continuum, enterprise QA will need to institute a strong, rules- and quality-based engine to flag regulatory input (such as adverse events) to coordinate trust across the ecosystem
Enhancing drug quality and safety: QA for reimagining pharmacovigilance

**Everest Group take**
Pharmacovigilance (PV) has always been viewed from a risk-avoidance and cost-of-doing-business perspective. Pharma firms realize that they need to move away from a compliance-mandated PV model to a patient-centric one. However, the current fragmented and reactive system does not enable such a shift. As they try to infuse more intelligence upfront to stem the rising number of cases, life sciences companies need end-to-end QA to support seamless verification and validation and to keep up with changing regulations.

- **Industry context**: As the number of drug recalls has increased tenfold over the past decade, drug safety performance has come under heavy regulatory scrutiny. Currently, pharma firms require significant manual effort to support case collection, processing, and risk management. Drug safety breaches continue to impact pharma companies with many of them losing billions to fines, lawsuits, and potential revenue.

- **Pharmacovigilance of the future**: End-to-end design verification and validation across digital information channels such as social media, patient blogs, and mobile apps now dominates the signal detection landscape. The challenge to separate real information from noise in the incoming datasets will be solved by advanced cognitive platforms; addressing the challenge will require instituting proactive pharmacovigilance with cognitive capabilities and automated case processing in a validated environment.

### EXHIBIT 7

**Current and future PV value chain**

**Source**: Everest Group (2019)

<table>
<thead>
<tr>
<th>Current state</th>
<th>Future state</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Signal detection</strong></td>
<td>The bulk of the signals come from digital channels such as social media, patient blogs, and mobile apps</td>
</tr>
<tr>
<td><strong>Case identification</strong></td>
<td>Advanced cognitive platforms to filter noise in massive incoming datasets</td>
</tr>
<tr>
<td><strong>Case processing</strong></td>
<td>Leveraging platforms to automate actions such as case intake, triage, medical coding, and narrative writing</td>
</tr>
<tr>
<td><strong>Regulatory reporting</strong></td>
<td>Electronic document management technologies to digitally manage each report using pre-defined templates</td>
</tr>
<tr>
<td><strong>Risk management</strong></td>
<td>Electronic document management technologies to digitally manage each report using pre-defined templates</td>
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</table>

**QA implications**
- Data protocol orchestration
- Platform-based approach
- Process efficiency
- Data interoperability
• QA for pharmacovigilance of the future
  – **Data protocol orchestration:** Developing systems to track adverse events from the world wide web will require stringent QA protocols that will ultimately result in fewer drug recalls
  – **Platform-based approach:** PV will be delivered as a utility (PV-as-a-Service) or a shared service platform among pharma firms, underpinned by a sound QA engine for validation and verification
  – **Process efficiency:** Help enable a superior user experience, increase application performance, and enhance overall productivity of case processing
  – **Data interoperability:** This platform should enable the interoperability of various data sources by building connectors and reconciliation tools
Characteristics of a best-in-class QA platform

**Everest Group take**
Combining the use cases highlighted and demand trends in life sciences, the need for a platform-based approach to QA is evident. Because the life sciences ecosystem comprises a fragmented solution landscape, success in this approach requires data standards, environment validation, process governance, system resilience, and scalability. This QA platform needs to be delivered in a flexible, consumption-linked platform that can operate across the technology-operations landscape to deliver business outcomes at speed and scale.

The trends highlighted in this analysis have specific implications for the future QA model. To support the shifts in the life sciences industry’s business model, the QA engagement model itself must shift to one that is:

- **Platform-led**: The life sciences business and technology landscape is littered with point solutions. As firms adopt platforms to streamline the solution portfolio – a common theme across the highlighted use cases – QA will also need to adopt a platform-based model to help enterprises scale the function

- **Consumption-linked**: QA needs to be “always on” in the new model. At the same time, rapid business and technology changes will require rapid QA scale-up and scale-down options, as well as the ability to offer easy integration options with data and technology stacks. To make this practical, the QA operating model has to be an as-a-service, platform-based model. The QA platform should be able to offer secure and agile integration with a multitude of technology elements including devices and the external ecosystem. A built-in repository of QA tools and solutions made available through as-a-service catalogues will be critical to enable easy consumption of services and offerings by ecosystem partner systems and consumption-linked commercial models

- **End-to-end**: QA needs to be focused on end-to-end process and data coverage for a patient care journey spanning the entire ecosystem

- **Linked to business outcomes**: The efficacy of the QA function needs to be measured in terms of speed and agility and improvements in detection and accuracy of compliance reporting, as opposed to traditional cost metrics

- **Open**: The enterprise QA platform needs to be loosely coupled - with the ability to stitch modular components of tools and solutions from the ecosystem (internal, shared, and external). Seamless integration through APIs and modularity allows the platform to stitch together both tools and services (e.g., crowdsourced QA) delivered through ecosystem

- **Secure**: The platform should enable secured and compliant operations with several built-in security components as well as the ability to use best-of-breed, third-party security solutions

- **AI-enabled**: The QA platform should have built-in intelligent components to learn QA activities as the platform produces data and eventually automate operations

A future-proof life sciences QA platform should exhibit these characteristics to help enterprises meet evolving demands. These changes will also lead to an evolution of QA’s role in the enterprise ecosystem.
Conclusion

The evolving role of QA in the future of life sciences

As life sciences firms pivot to this new reality, QA will also have to assume greater ownership of outcomes. The change will take place in stages:

- **Stage 1: Assurer of processes** has been the traditional function of QA, which is largely tactical. The focus in this stage is managing a global estate, process excellence, cost optimization, and tackling product quality – largely risk-avoidance.

- **Stage 2: Custodian of quality systems** is the role that QA is moving into. In this stage, QA helps life sciences firms maintain system resilience in a converging healthcare ecosystem. The key value drivers are seamless system maintenance, CX coordination, and pervasive value chain digitalization.

- **Stage 3: Orchestrator of audit readiness** is the future state, the goal of which is to elevate QA’s role to assume end-to-end ownership and ensure audit readiness at all times. The key value drivers include enabling a proactive compliance posture, care coordination, and safeguarding the overall brand experience.

**EXHIBIT 8**
Evolution of QA’s role in life sciences

Source: Everest Group (2019)
Life sciences is changing in terms of its positioning within the broader healthcare ecosystem and establishing a direct relationship with patients/consumers. This change places QA in an vital position to act as the caretaker-in-chief. The success of the revised QA role will be measured in new ways:

- Supporting the digital innovation agenda for life sciences
- Orchestrating the ecosystem to drive improvements in care
- Driving incremental and continual quality improvements
- Validating data to enable real-time insights
- Advancing a trust-based relationship with consumers
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