Deloitte.

Digital Quality & Compliance services for life sciences

Keeping pace with an evolving technology and regulatory ecosystem

Digital transformation in life sciences

Digital transformation in life sciences is a new competitive imperative. And as organizations move from doing digital to being digital, the ever-changing regulatory landscape shouldn't be seen as a roadblock.

Could our Digital Quality & Compliance services help remove some of the obstacles you might be facing? Consider these questions.

ADVISE

- Are you struggling to lower your cost of compliance? Is your process too cumbersome?
- Is your software development life cycle (SDLC) not giving you sufficient value while bogging you down?
- Are you struggling to digitize your IT quality (ITQ) delivery?
- Are you looking into adopting automation or an ITQ automation road map?
- Are you struggling with cloud migration adoptions?
- Are you struggling to enable a digital health compliance strategy?
- Are you struggling with artificial intelligence (AI) validation? AI framework?
- Are you struggling to enable Continuous Integration and Continuous Delivery (CCID) in Good Practices (GxP)?

IMPLEMENT

- Are you looking for an experienced service provider to help you deploy a regulated system?
- Are you looking to implement and modernize your quality management system (QMS)?
- Are you looking to implement next-gen reliability, IT QMS metrics for your company?

OPERATE

- Are you looking to find a service provider who can help maintain the validated state of your GxP systems in a cost-effective compliant manner?
- Are you looking to outsource your IT audits or third-party audits, knowing they will be managed efficiently?

Now, imagine if you could strengthen compliance and elevate ITQ with a risk-intelligent approach, harness insights and analytics to drive smarter decision-making, and set the stage for innovation with emerging digital technologies to achieve business objectives beyond compliance. From strategy to implementation, our Digital Quality & Compliance services help you do just that—all while moving at the speed of business.

Introducing Deloitte's Digital Quality & Compliance services

Strategic services

Analyze and define a digital strategy that aligns to business objectives and drives efficiency beyond basic compliance

Digital health solutions

Set up a consistent approach for managing and conveying the quality and compliance of your digital health solutions

Enterprise platform solutions

Move forward with data analytics capabilities while helping to mitigate the privacy, security, and compliance risks of a cloud-first IT strategy

Mergers and acquisitions (M&A)

Strengthen M&A by integrating the right quality system elements from due diligence, carve-outs to post-transaction activities

Deloitte's Digital Quality & Compliance services provide an enterprisewide set of solutions and services designed to help life sciences organizations achieve their strategic imperatives. They also help you **evolve over the digital quality maturity curve faster** while potentially **reducing the investment and time it takes** to do so.

Strategic services

Life sciences companies are facing increasing pressures in how they serve patients, how they embrace the future of medicine (e.g., personalized medicine, virtual health), how they manage costs, and how they stay ahead of an evolving regulatory landscape. To help address these pressures, more and more organizations are accelerating their digital strategies and ways of working.

To stay at pace with this acceleration, traditional ways of driving quality and compliance simply won't work. ITQ functions are being forced to take a close look at how they can become an enabler of the business versus being perceived as slowing down innovation. The challenge is how to accomplish this vision without cutting corners on risk management and compliance.

Our Digital Quality & Compliance practice has developed a formula to help you move your organization forward and not only keep pace with the business and IT but become an accelerator to their strategy.

Assessment and road map — **Transformation** — **Organization change management**

Service overview
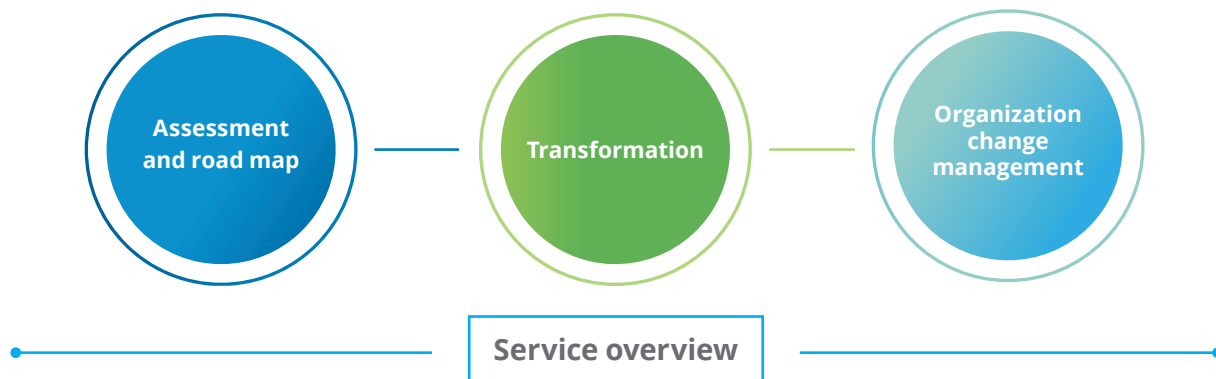
1 Establish a baseline of your current-state capabilities and services, ways of working, and tech enablement; understand where you are compared to your peers; and assist in establishing an action-oriented road map and business case to help you modernize and transform your Quality/Compliance function.

2 Put the plan into action through implementation of agreed-upon initiatives to help you refine the services you provide, how they are delivered, and how value is measured and communicated to the organization.

3 Transform in a way that retains the leading talent and creates a potential opportunity for your team to uplift how they engage with key stakeholders; also establish a change strategy that helps prepare the organization for what is new and drives adoption.

Digital health solutions

Today, the digital health market is booming with solutions ranging from software as a medical device to clinical decision support software to general wellness apps. Each aims to lower costs, boost convenience, or improve patients' health. That's making it harder for customers to evaluate the quality of the options available to them. It's also raising the bar for digital health providers who aim to stand out from the crowd.

We can help you set up a consistent approach for managing—and conveying to stakeholders—the quality and compliance of your digital health solutions.

Assessment — Implementation — Remediation — Base business assistance
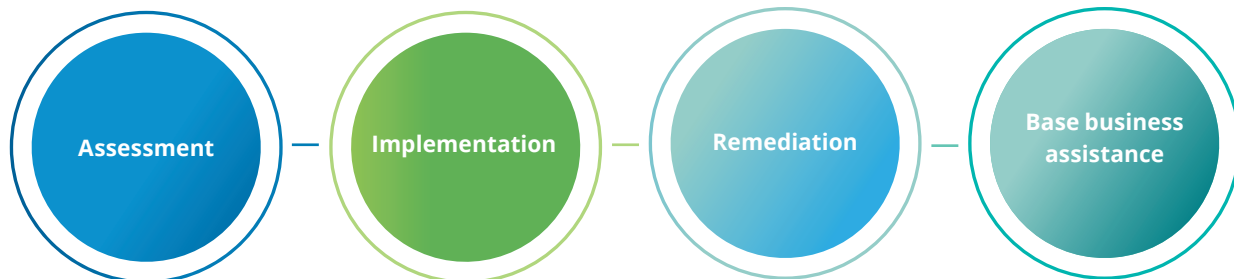
Service overview

1 Identify existing QMS and/or related capabilities for digital health products, evaluate them against industry standards and practices, then develop a plan for potential improvement.

2 Build the capabilities—think QMS, digital product development, and more—necessary to help launch high-quality health tech products in a timely and agile manner.

3 Align affected business systems and products with global digital health requirements for clinical evaluation, cybersecurity, and QMS.

4 Maintain validated* digital health products via periodic reviews, supplier and vendor audits, corrective and preventive actions (CAPA) management assistance, and digital health regulations training.

*As used in this document, "validated" refers to control activities performed to understand and evaluate data and does not intend to be an attestation.

Enterprise platform solutions

As enterprise resource planning (ERP) systems move to the cloud, life sciences companies gain access to an entirely new set of capabilities. Goodbye, upfront costs and fixed hardware infrastructure. Hello, pay-as-you-go services that scale up or down on demand.

In a regulated environment, cloud-based ERP systems can bring an entirely new set of issues around compliance, especially as they relate to GxP quality guidelines. A key reason is that once ERP systems go external, they can become that much more vulnerable to quality issues.

Deloitte can help you assess a vendor's controls related to your cloud-based ERP.

Mitigating controls — **Maintenance and upgrades, BCP & SLA** — **Record retrieval and termination of services**

Service overview

1 Take the quality by design (QbD) approach to compliance with patient safety and product quality protocols.

2 Develop the required controls procedures that facilitate patches and periodic releases, backup, disaster recovery, business continuity plans.

3 Establish a plan to help protect data access, retrieval, and retention of records during transitional times.
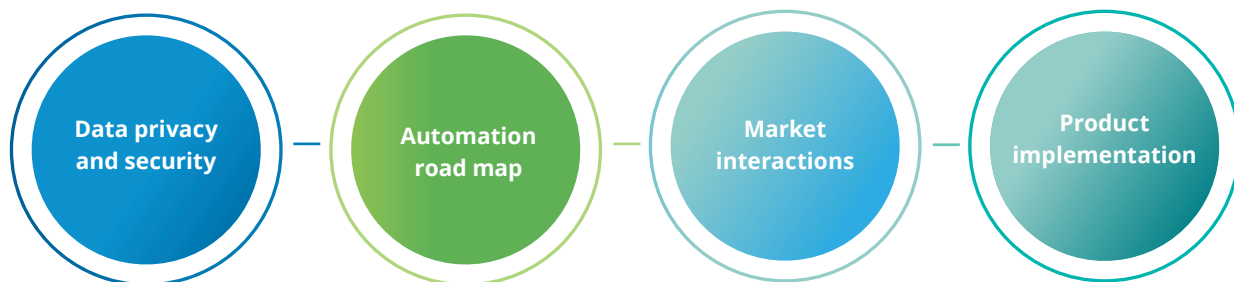
Enterprise platform solutions (cont.)

Enterprise analytics platforms in life sciences organizations are using modern analytics capabilities to extract insights from a broad range of data—patient health records, images, genomics, and more.

As organizations are getting to be more data-driven and dependent, a "Quality Data View" is key to driving accurate decisions. Thus, defining

the source as well as the intended use of the data is critical in establishing a robust Quality Data View.

Deloitte can help you to identify potential risks associated with privacy, security, vendor's controls, and compliance capabilities based on leading practices on data management platforms.

Data privacy and security — **Automation road map** — **Market interactions** — **Product implementation**

Service overview

1 Model threats, lay out privacy and security requirements, and assist in implementing a secure software development life cycle (SDLC) in collaboration with legal and data security stakeholders.

2 Define the strategy, key activities, and deliverables to help increase automation.

3 Review potential partnerships and other collaborations for potential conflicts of interest, fair market value, contracting, and other standards.

4 Assess vendors being considered to implement, host, and maintain systems, against client-defined criteria

Mergers and acquisitions (M&A)

Consolidation is an ongoing trend in life sciences as companies look to fill product pipelines and expand into new markets. Although high-profile M&A deals tend to be the ones that grab headlines, a significant number involve acquisitions of smaller companies with an innovative therapy. Transactions like these can help acquiring companies address a range of market shifts, from lower reimbursements to competition from generic manufacturers.

But some acquirees may lack the resources for sophisticated digital quality control. Others could have systems and processes that are redundant or misaligned. And both sides of the transaction may be without a cost-effective way to spin up digital quality resources to meet integration execution demand.

From pre-transaction readiness to post-merger integration, we can help you address M&A-related quality system issues while potentially strengthening data integrity program controls along the way.
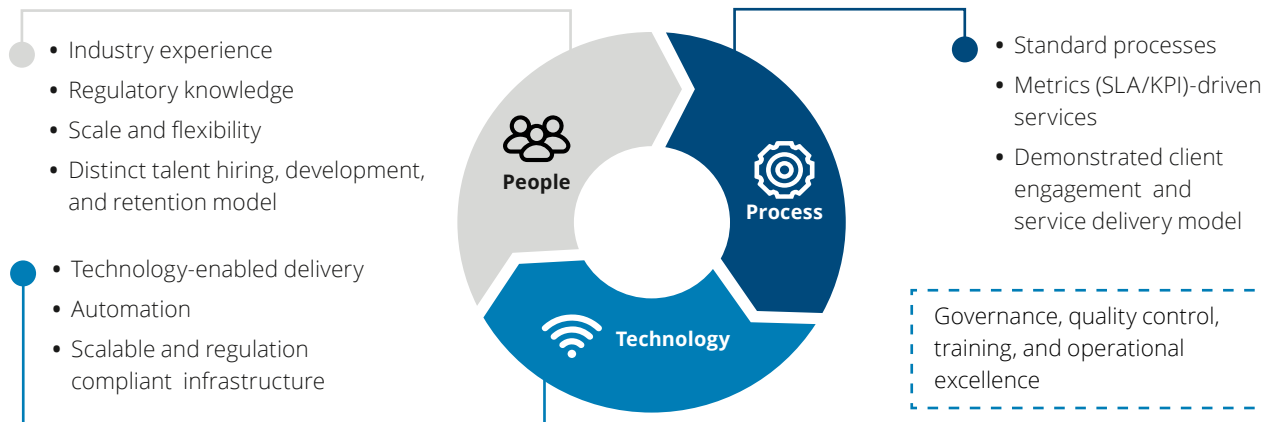
Strategy — Due diligence — Remediation and integration — Divestiture
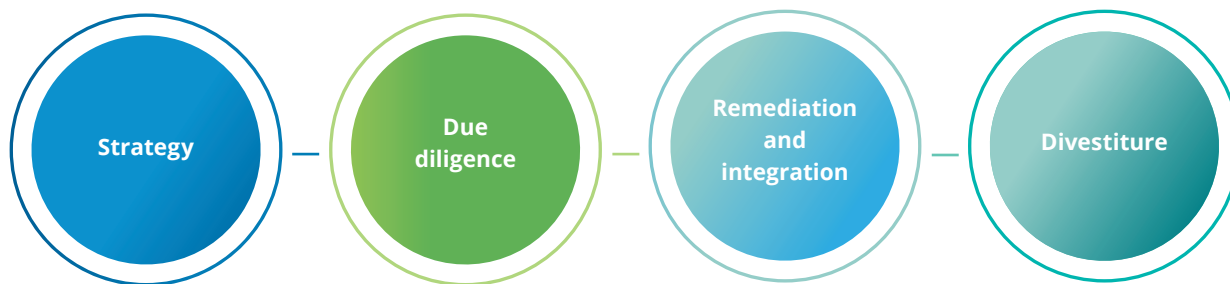
Service overview

1 Assist in creating a framework to consistently evaluate IT quality and compliance risks, then define mitigating controls across the M&A transaction life cycle.

2 Assess a target company's QMS and other quality and compliance applications against the acquiring organization's standards and industry leading practices.

3 Help close any IT quality and control gaps that come to light during due diligence, with an eye toward complete and accurate integration of data, application, processes, and technology.

4 Help migrate and remove applications along with associated quality systems elements as part of a divestiture while potentially alleviating the potential impact on the divesting company's digital quality capabilities.
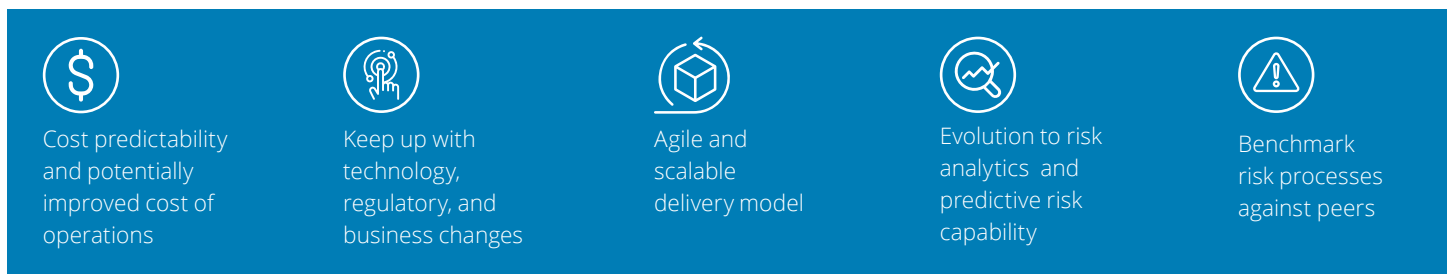
Managed services

Our Digital Quality & Compliance managed services assist organizations to take a strategic approach to digital quality and compliance operations activities. Our services can help you to transform the 'ways of working' by balancing between ongoing digital quality and compliance, operational efficiency, and technology-enabled delivery integration to enable a continuously changing business, regulatory, or technology environment.
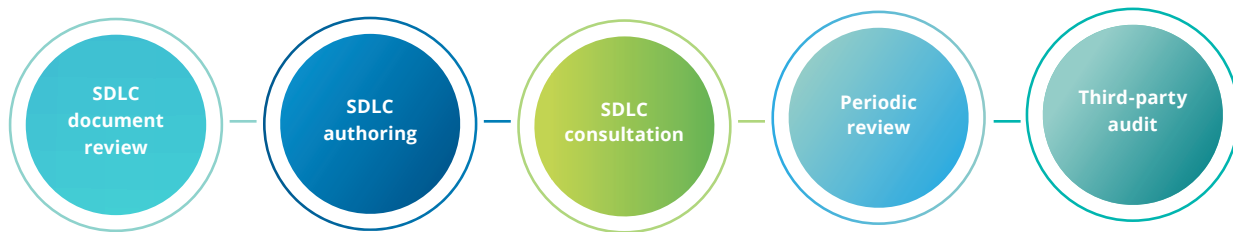
Digital Quality & Compliance computer system validation (CSV) capabilities

- Industry experience
- Regulatory knowledge
- Scale and flexibility
- Distinct talent hiring, development, and retention model

- Technology-enabled delivery
- Automation
- Scalable and regulation compliant infrastructure

People

Process

Technology

- Standard processes
- Metrics (SLA/KPI)-driven services
- Demonstrated client engagement and service delivery model

Governance, quality control, training, and operational excellence

Future-focused digital quality and compliance management programs

| Cost predictability and potentially improved cost of operations | Keep up with technology, regulatory, and business changes | Agile and scalable delivery model | Evolution to risk analytics and predictive risk capability | Benchmark risk processes against peers |

Digital Quality managed services features

SDLC document review → SDLC authoring → SDLC consultation → Periodic review → Third-party audit

Service overview

1 Review and approval of SDLC documentation required to support CSV activities.

2 Document authoring of select SDLC documents to support CSV activities (e.g., validation plan and validation summary report).

3 Assist with system risk classification consultation and SDLC governance oversight.

4 Planning, execution, and documentation of the required periodic review process within the client's IT governance procedures.

5 Planning, execution, and reporting of IT vendor audits.

Why Deloitte?

Quality and insights
Get results through leading-edge processes that include enabling technology, taking the guesswork out of managing an effective service. Our extensive data analytics capabilities helps bring the IT organization to a more strategic and robust state.

Global capability
Gain access to the skills globally on a just-in-time basis, along with specialized knowledge, cost savings, and continuity of service across the enterprise.

Technology
Deloitte's digital quality services are enabled through our proprietary technology platform and automation, bringing consistency, standardization, and optimization to digital quality processes.
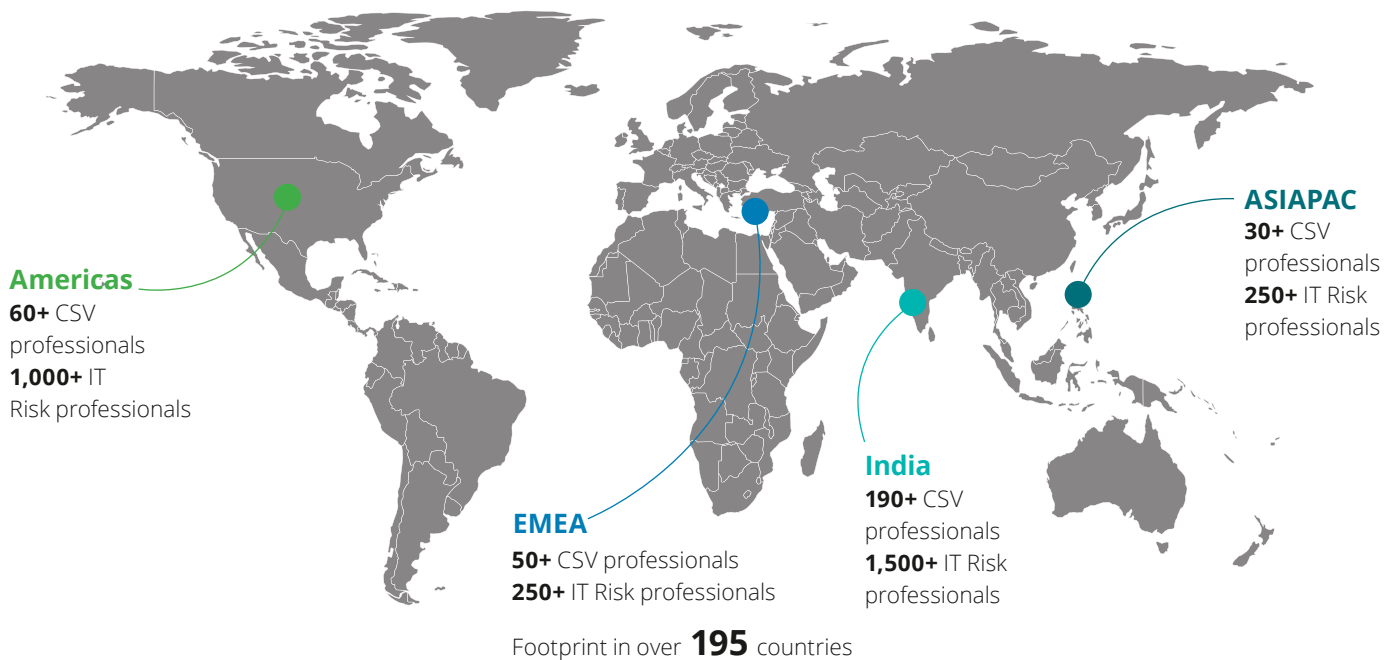
Experience
Our dedicated data quality professionals offer global regulatory experience, including cGxPs, Part 11, and EMEA – Annex 11, as well as other global regulatory requirements.

Leading-class processes
With experience across industries, Deloitte brings industry-leading processes to our clients. A harmonized approach with a customizable service delivery model can help drive continuous improvement.

Capabilities spanning the globe through the Deloitte Touche Tohmatsu Limited (DTTL) network of member firms

Americas
60+ CSV professionals
1,000+ IT Risk professionals

EMEA
50+ CSV professionals
250+ IT Risk professionals

India
190+ CSV professionals
1,500+ IT Risk professionals

ASIAPAC
30+ CSV professionals
250+ IT Risk professionals

Footprint in over **195** countries

Serving **8 of the 10** largest biotech companies (S&P Capital IQ)

Serving **10 of the 10** largest global pharma manufacturers (imshealth)

Serving more than **90%** of the US Fortune 500 life sciences/ health care companies

Source: https://www2.deloitte.com/content/dam/Deloitte/us/Documents/audit/us-audit-lshc-brochure.pdf

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