INTELLIGENT RCQ AS A VALUE ACCELERATOR

Leveraging data and digital to advance core regulatory, compliance and quality capabilities and foster closer relationships with health authorities

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BECOMING DATA-DRIVEN IS CRITICAL FOR FUTURE-PROOFING LIFE SCIENCES RESEARCH – BUT MANY COMPANIES ARE STRUGGLING TO ACHIEVE IT

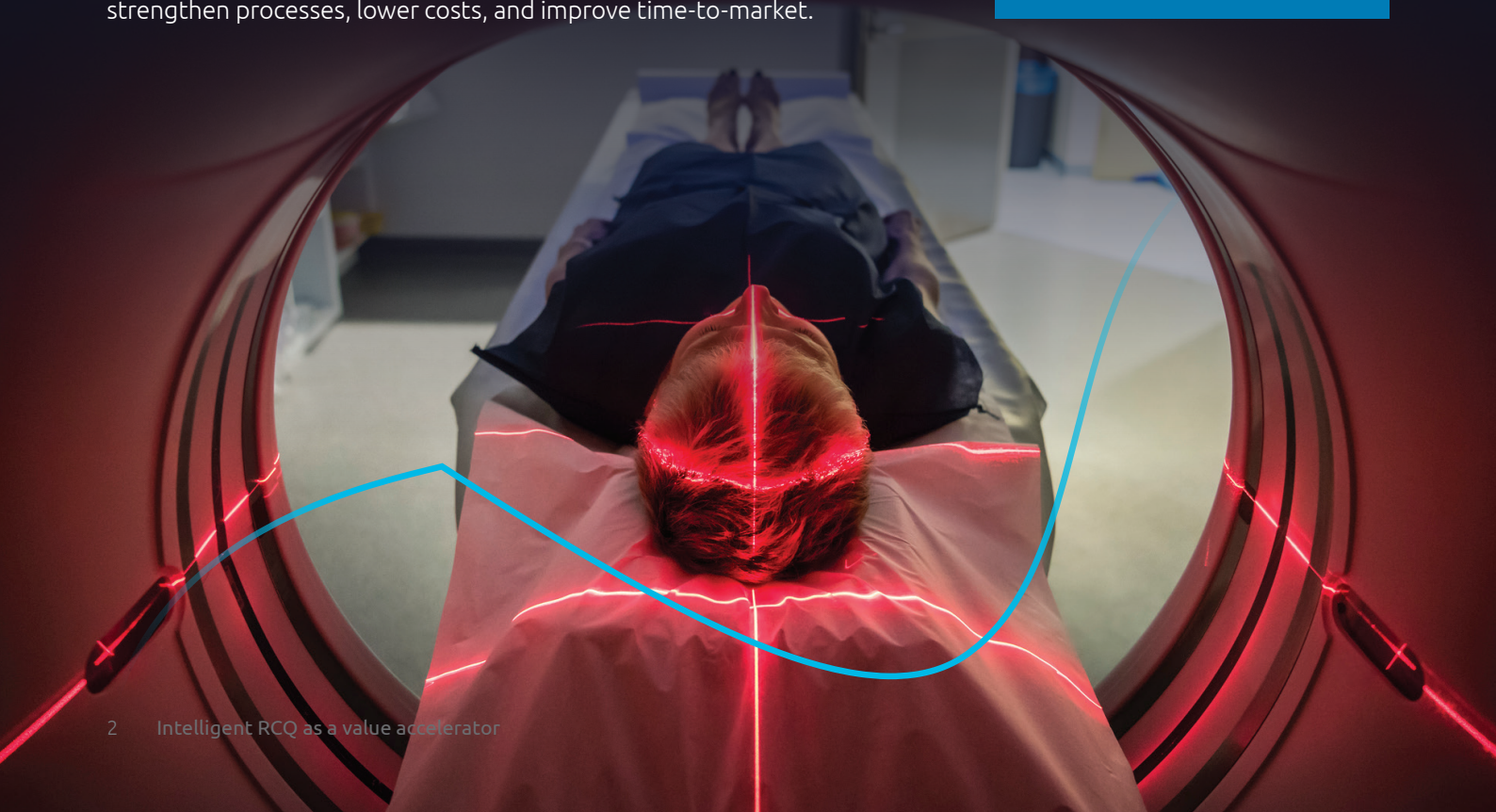
As health authorities deepen their commitment to regulatory sciences, life sciences organizations must do their part to support regulators in assessing the safety, efficacy, and quality of new and existing therapies. At the same time, companies are under mounting pressure to accelerate the pace and decrease the cost of bringing new therapies to market. However, these two issues are not mutually exclusive if approached in the right way.

Infusing advanced digital and data capabilities within core regulatory, compliance and quality (RCQ) functions, and integrating those capabilities across the research and development lifecycle is the key to streamlining regulatory and compliance processes and, in turn, improving time-to-value.

In this paper, we explore how organizations can leverage data and digital technology to advance their regulatory, compliance and quality capabilities to create a true Intelligent RCQ function – helping the organization strengthen processes, lower costs, and improve time-to-market.

What is Intelligent RCQ?

Intelligent RCQ is a new approach to traditional RCQ that leverages data and digitization to develop new tools, standards and approaches that help regulators assess the safety, compliance, quality, and performance of all regulated products' development, manufacturing, and distribution



WHY DO COMPANIES NEED TO ADVANCE THEIR RCQ MATURITY?

Over the past several years, the life sciences landscape has seen significant growth in the development of new and complex product types, as well as shorter lifecycles. Adapting processes to remain compliant with legislation requires the organization and its supply chain to work in a coordinated and transparent manner.

Companies that rely on legacy systems and complex, manual processes are at a disadvantage, adding weeks and months to timelines and potentially losing revenue due to delays caused by the need to collect data needed for the submission. Further, this traditional approach does not enable the close partnership and engagement that organizations and health authorities are striving for as part of the regulatory science model.

The role of digital continuity in Intelligent RCQ

One fundamental capability and critical enabler within Intelligent RCQ is **digital continuity** – a state in which all relevant stakeholders, including regulatory officials, have shared and real-time access to RCQ data. Digital continuity is one way to accelerate critical parts of the compliance lifecycle, including dossier authoring, application submission, and health authority review. This can not only help shorten the regulatory approval process, but also allow regulatory agencies and applicants to work more closely, enhancing safety, efficacy, and quality.

Achieving digital continuity

Achieving digital continuity requires organizations to structure data and related processes in a way that ensures that data is well-managed, trusted, accurate, traceable, and legible – a set of attributes often referred to collectively as data integrity. Our related paper, *Unlocking digital transformation in life sciences R&D through data management*, explores this topic in greater detail. Download

EXPLORING THE VALUE OF INTELLIGENT RCQ

Intelligent RCQ is an important growth lever.

Intelligent RCQ grants organizations the ability to automate regulatory documentation authoring, as well as compliance and quality business processes and documentation automation, which can potentially shave months or weeks off the standard review timeline. A faster regulatory review process enables quicker time-to-market, which means therapies can reach people sooner and companies can begin earning revenue faster.

Intelligent RCQ also streamlines document management after a submission is made, which further optimizes processes and unlocks new growth opportunities for the business. The combined effects of time saved during and after submissions and during lifecycle changes allows leaders and staff to reinvest that time in higher value activities.

Intelligent RCQ enables organizational agility.

Regulations change and companies need to be able to respond to those evolving requirements.

For example, in 2022, the U.S. Food & Drug Administration (FDA) published its final guidance for principles for premarket review of combination products, which outlined three distinct approval pathways for device-led

combination products, drug-led combination products, and biologic-led combination products. For companies that rely on processes that are manual and rigid, it can be nearly impossible to adapt them quickly to meet these changing needs – let alone integrate those changes seamlessly within the rest of the development process.

Intelligent RCQ processes and systems are built on the principles of digital continuity, linking R&D to production, as well as the application process to regulatory bodies. This is a business facet that takes advantage of the lifecycle and collaboration mechanisms of digital continuity, such as impact analysis, change management, configuration, and others.

Intelligent RCQ allows for continuous innovation.

Once a drug is launched, many companies hesitate to make any modifications to the processes or systems that were approved by the regulatory bodies – even if such a change could unlock valuable cost savings or time efficiencies. This is because any updates would require resubmission for approval with regulators in any country or region where the drug is available, which requires the time and attention of regulatory staff and can introduce risk.

Intelligent RCQ streamlines and accelerates market product changes, making it possible for the organization to evolve over time and take advantage of new capabilities and insights that could benefit the business. It also allows the company to determine the expected impact of regulatory change on the business within the context of local markets, such as by assessing and anticipating the impact of new or upcoming regulations, identifying regulatory actions to be made, and measuring impact to the business – all of which substantially lower the risk of making changes.

Intelligent RCQ is a way to cut costs and timelines by improving organizational efficiency.

Intelligent RCQ replaces highly repetitive and time-consuming processes with automated workflows. In this model, scattered and siloed IT systems are integrated – and processes are designed with compliance in mind at the outset, so no time is wasted looking for data or recasting it to satisfy regulatory needs later in the process. These efficiencies translate into reduced costs and shortened timelines for the business, while assuring the highest standards of safety and quality.

Intelligent RCQ enables better decision-making.

Companies that lack visibility across the entire product development lifecycle and supply chain or that do not have access to relevant and timely data are not able to make optimal decisions. Intelligent RCQ not only puts data in the hands of the people who need it, but also provides additional landscape context and the ability to consider multiple scenarios more quickly to help them make better, more informed decisions.

Intelligent RCQ unlocks new levels of collaboration and partnership across the life sciences ecosystem.

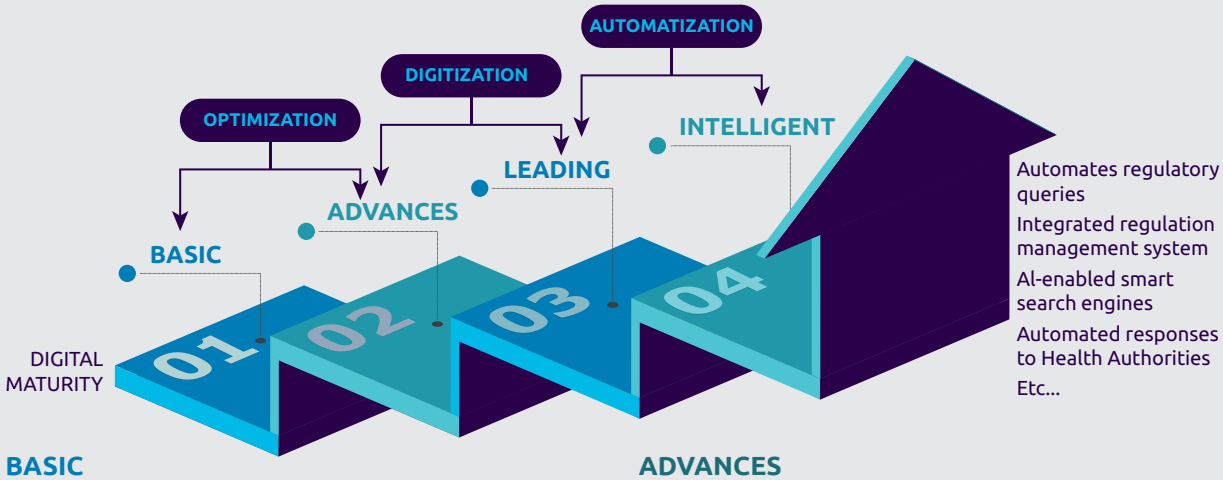
When companies have a high level of digital maturity, it is possible to extract and share data across the ecosystem. The industry saw the value of this capability recently with the development of COVID-19 vaccines, which involved cross-company collaboration and close coordination with regulatory bodies. This same collaboration allows more fluid cross site development within firms, improved technical and method transfer, and a safer, more efficient movement of on market therapies to generic producers at patent expiry.

EMBRACING THE OPPORTUNITY OF INTELLIGENT RCQ

Intelligent RCQ is not a single solution to be deployed or a definitive destination to be reached. It is a connected and evolving system of tools, standards and approaches that improve the safety, efficacy, quality, and performance of all regulated products' development, manufacturing, and distribution. These capabilities will constantly adapt and advance in time with technology.

For that reason, organizations must embrace the idea of constantly advancing their Intelligent RCQ capabilities, as opposed to embarking on an internal transformation program to establish them. In this way, we advise that companies evaluate their current state and mark progress towards becoming intelligent.

It is important to note that there is incremental value to be gained by advancing from one level of maturity to the next. Organizations need not reach the most advanced level of intelligence to reap the benefits of having an Intelligent RCQ function.



BASIC

- Siloed working
- Duplication of certain activities
- Limited data, non-standardized sources
- Manual activities
- Disparate &local systems

ADVANCES

- Cross functional collaboration
- Harmonized practices &processes
- High volumes of data, standardized sources,
- Semi-digitized processes
- Connected systems

LEADING

- Globally integrated teams
- Lean processes, technologies enables approaches
- Data driven analysis &insights
- Fully digitized, semi-automated processes
- Interoperability, transparence &control

INTELLIGENT

- Regulatory functions becoming "strategic assets"
- Data driven approached, real-time view
- AI-enabled solutions &analysis
- Right level of automation &digitization
- Cloud based systems

5 hallmarks of an Intelligent RCQ system

Manual vs automated

- Leveraging robotic process automation (RPA) and artificial intelligence (AI) to accelerate the pace of cause-and-effect understanding and replace manual processes to allow people to refocus efforts on higher-value tasks
- Harmonizing and standardizing processes, templates, and documentations to ensure a robust dossier

Reactive vs proactive

- Anticipating regulatory changes through an automated regulatory watch and modelling their impact on cost of license maintenance globally (including supply, stock, complement, and variations)
- Designing systems and processes to be able to evolve over time to meet changing regulatory needs

Disconnected vs connected

- Connecting systems and processes to enable data continuity and data interoperability
- Leveraging aggregated cloud solutions and regulatory information management (RIM) to maintain interdependence between various systems

Stagnant vs agile

- Enabling continuous innovation
- Supporting real-time monitoring and documentation

Isolated vs collaborative

- Establishing a multi-vendor ecosystem and federated vendor partnerships through RIM and standardized quality management systems (QMS), as well as standard frameworks, processes, and accelerators
- Creating opportunities for partnership with regulatory bodies

CREATING AN INTELLIGENT RCQ PRACTICE

CASE STUDY

How a global healthcare company reduced authoring time by 90% and created efficiency savings of ~20 FTEs per year with Capgemini

Challenge

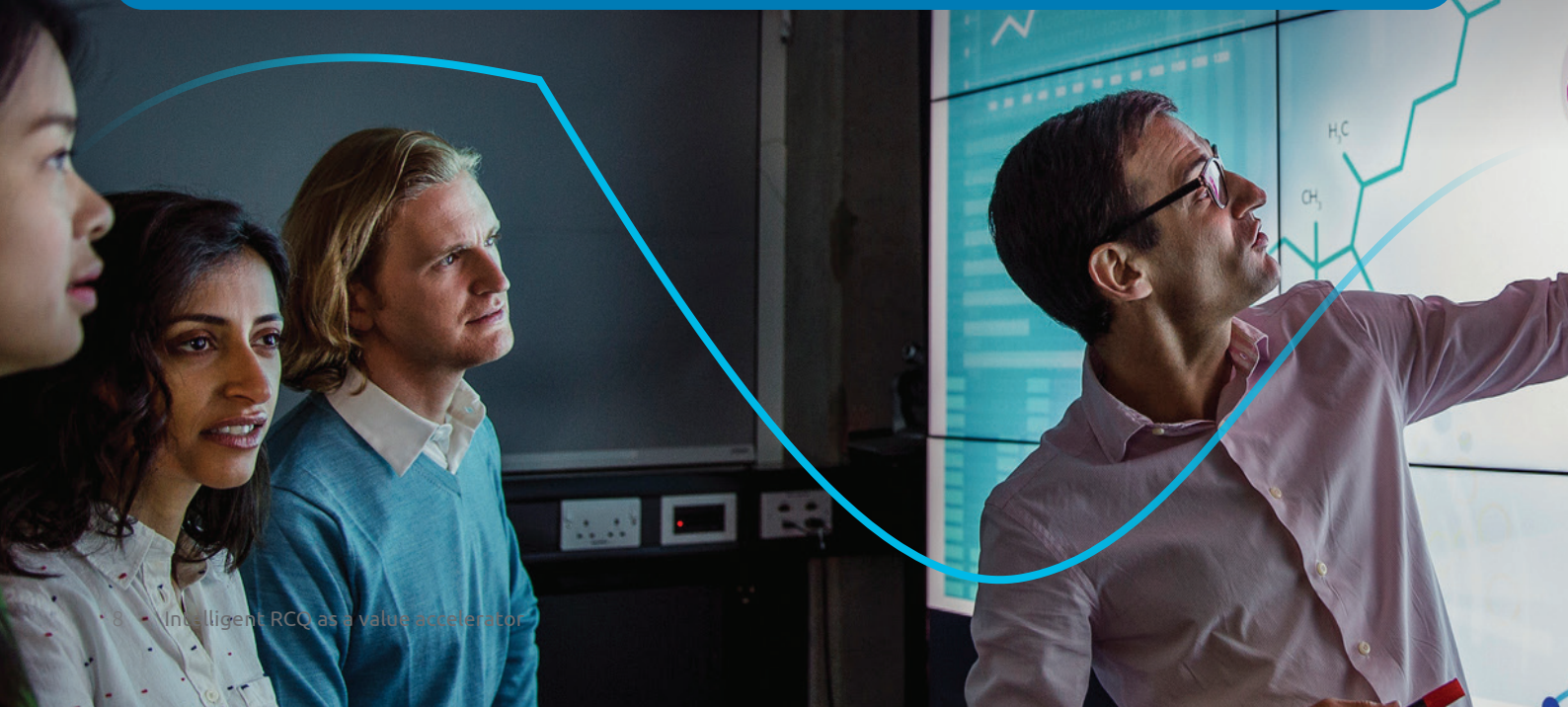
Regulatory reporting is a critical but notoriously time-consuming task that typically requires a significant amount of manual, low-value work, including formatting, copying/pasting or creating tables and graphs. To reduce manual work and improve time to market, one global pharmaceutical company wanted to automatically generate process validation reports to enable research teams to more rapidly submit filings used in initial market applications.

Solution

The company partnered with Capgemini to develop a digital transformation roadmap and implement a cloud-based platform to enable automated and accurate reporting. The automated solution enables authors to populate, edit and update tables and statistical graphs dynamically within each document.

Results

- Eased the authoring effort of scientists and reduced manual authoring time by more than 90%
- Created efficiency savings of between 15 and 25 full time employees (FTEs) per year
- Avoided non-compliance fines
- Reduced time-to-market



CONCLUSION

The complex nature of today's regulatory landscape and the need for closer partnership and streamlined interaction between health authorities and life sciences organizations requires companies to modernize and advance core RCQ functions. This is necessary not only to expedite reviews from government agencies, but also meet internal goals to bring new therapies to market more quickly and cost-effectively.

In building a true Intelligent RCQ function, life sciences organizations can take a critical step towards helping the health care system operate more safely, efficiently and cost effectively for all stakeholders. To learn more about how your company can leverage Intelligent RCQ as a value accelerator, please contact our expert team and learn more about our market-leading capabilities in this emerging field.

About Capgemini

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