WHITE PAPER

Regulatory 2025

Developing an effective 10-year strategy for technology-enabled regulatory transformation

ArisGlobal

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Executive Summary and Key Takeaways

As we approach the year 2021 with its dynamically evolving regulatory and commercial demands, we need to take a progressive, future-proof approach towards any transformational investment. Life sciences companies must respond to emerging regulatory drivers in a holistic way: how will R&D, pricing, supply chain and other pressures impact on their strategies?

The pressure to bring drugs to market more rapidly, to proactively respond to quality metrics demands from regulators and to prepare for a period of hyper-innovation – with the huge surge in document submissions that entails-can lead companies to think short-term. The emphasis should instead be on going beyond immediate demands to developing solutions that meet these requirements and more – providing intelligence to the organization, ensuring a platform of quality metrics that the entire organization can use, and looking to automation to ease processes and improve outcomes.

To succeed, companies will need to assess current and emerging technologies and determine what, when and how to leverage capabilities to the benefit of the broader organization. These span embracing mobile solutions and moving to the cloud to tapping into important digital disruptions, including social media, big data technologies, and blockchain.

The future holds huge potential for regulatory organizations that think beyond 2021 and reach for transformative business processes into 2025.

Introduction

Regulatory departments at most life sciences companies are currently investing in regulatory information management capabilities as they gear up for what has been dubbed the “2021 vision” and assess what regulatory investments are needed to successfully navigate the regulatory framework in the coming decade.

As regulatory departments establish their 2021 vision, their primary objectives are to address five overarching challenges:

- Lack of centralization of approved product data, which is particularly a concern where approved information deviates from the corporate-proposed specs, potentially putting compliance at risk
- Poor collaboration with affiliates and other resources, resulting in delayed or low-quality submissions
- Inefficient, manual ways of sharing or extracting information from other departments
- New standards compliance (such as xEVMPD, IDMP, and UDI) requiring data to be extracted from unstructured documents, which typically have been handled manually
- Costly, time-consuming upgrades to avoid technology obsolescence with changing regulations

To address these challenges, regulatory departments are investing in both business infrastructure and capabilities – people, skills and business processes-as well as IT infrastructure such as technology architecture, IT processes and data. They are looking at how to converge disparate regulatory information management (RIM) capabilities; implement best practices for data governance roles and responsibilities; and create formal information architecture aligned to data standards for effective documentation, storage and sharing of regulatory information. They are also looking to build start-to-end process ownership; collaborate more effectively with partners; and establish a global regulatory organizational structure with centers of excellence.

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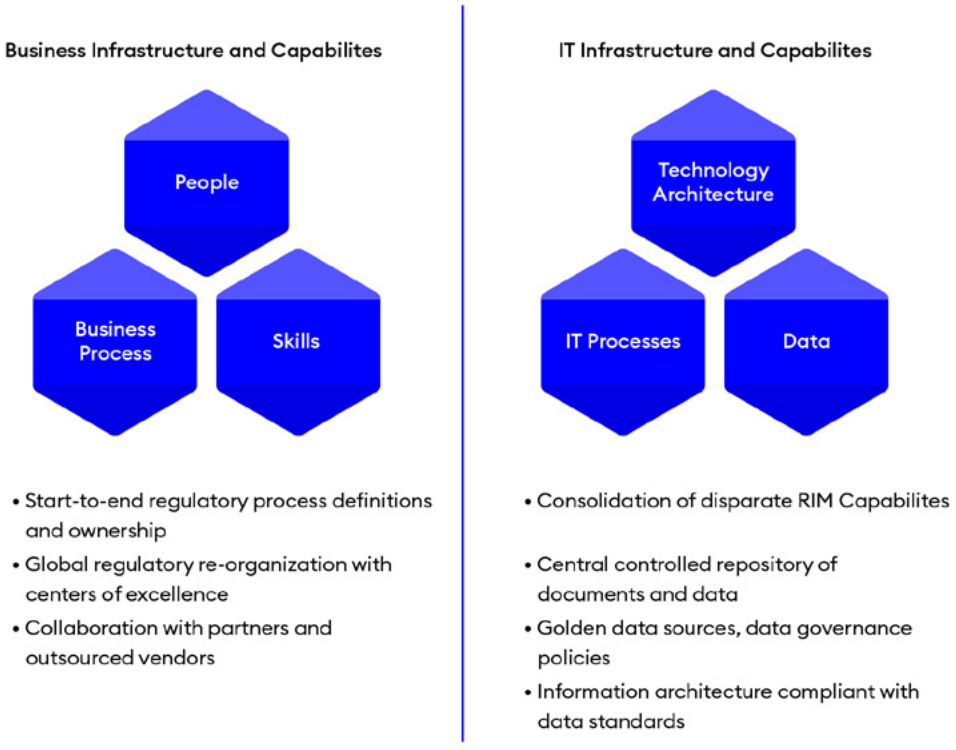


Reflecting on Investments towards the 2021 Vision

A common theme across all projects that regulatory is investing in today is to improve the efficiency and productivity of the global regulatory organization and key touchpoints – such as safety, medical information, manufacturing and marketing-while reducing compliance risk and the total cost of ownership (TCO).

The question to be asked before embarking on large-scale projects is whether a company's vision – and hence the programs planned to be implemented – is truly transformational and strategic, or whether it is being pulled in a siloed, one-dimensional and purely operational direction. If the latter, it's likely the short-term goals won't be aligned with the broader business objectives and vision. Such an approach can result only in incremental change that may not support the "2021 business transformation vision," and will certainly fail to deliver a platform that takes a company beyond 2025. The reason a transformational and strategic vision is so important is two-fold.

On one hand, we have the outside-in wave of change, in which the rapidly evolving clinical, regulatory and business landscape is challenging companies to rethink their approaches to research and development (R&D), pricing, supply chain and business and commercial models. "The Emerging Business Drivers and Impact on the Regulatory Department" section of this white paper will explore some of these external business drivers and their impact on regulatory department.

On the other hand, an inside-out wave of change is being led by life sciences and technology companies proactively partnering to explore how new technology can help identify fresh business models and associated value proposition for patients, payers, providers and shareholders. This in turn presents an opportunity for regulatory departments to leverage technology investments to enable company wide-transformation. The "New Disruptive Technologies and Impact on RIMS Landscape" will focus on emerging disruptive technologies and how regulatory departments can leverage them.

In the "Path to Self-Assessment and Transformation for a Successful 2025" section, we will explore how a self-assessment should be conducted to ensure that your current investments are not just getting you ready for the next decade, but also helping to future-proof you for 2025 and beyond.

Emerging Business Drivers and Impact on the Regulatory Department

From an innovation perspective, two overarching models have emerged: the traditional big pharma model of hyper innovation resulting in around two drugs a year; and the specialty biopharma model of divesting low-performing assets and focusing on specialty therapeutic areas. Other approaches are proving unsuccessful for most companies, forcing the industry to consolidate around the hyper innovation or specialty pharma model. These models and a sharp rise in submission volumes have a knock-on effect on regulatory departments, which is further compounded by multiple emerging drivers – from pricing pressures, to heightened demands from the regulators for quality metrics. Furthermore, a complex global environment demands knowledge and expertise on how to respond to political, clinical, regulatory and commercial developments. Such drivers affect how regulatory departments need to work, innovate, invest and strategize to prepare for 2021 and beyond.

The following sections explore some of the most pressing demands and changes affecting regulatory capabilities.

Increasing regulatory agency demand for quality metrics data Submission

Can regulatory look beyond data submission compliance as the end goal?

The emphasis that regulatory authorities place on quality systems creates important considerations for the regulatory department, not just in the intermediate term, but for a progressive 2025 strategy. With so many inspections to manage, agencies are taking a quantitative approach to determine which companies to inspect first. To do this, they are proposing that companies send them raw manufacturing data, which agencies can use to calculate quality metrics to determine the state and quality of the product and facility. Some of the metrics proposed by agencies such as the U.S. Food and Drug Administration (FDA) are lot acceptance rate (LAR), product quality compliant rate (PQCR) or invalidated out-of-specification rate (IOOSR). Based on these metrics, the agency plans to prioritize sites that are deemed risky.

Since regulatory departments have historically been the gateway for sharing data in a structured format with the agencies, the responsibility to share quality metrics data will most likely fall on them.

To meet the data requirements, it's imperative that they have efficient processes and tools in place to facilitate communication with other departments that provide the raw data, so that it can be compiled in a structured messaging format, reviewed, and submitted electronically to the agencies. This is similar to what will be required by 2021 to meet IDMP standards.

A 2021 approach requires harmonized processes and a central technology platform for data collection, workflow collaboration and electronic gateway communication to meet health authority structured data exchange objectives. A more progressive 2025 approach means all that and more; it means going beyond compliance by establishing a platform from which the rest of the organization can consolidate data and proactively measure metrics internally. With this approach, regulatory departments can provide the rest of the organization with the insights they need to determine which manufacturing sites are not meeting the quality metrics cut-off and are therefore potentially at risk of an inspection.

In the long-term, by proactively monitoring manufacturing sites' quality systems, regulatory can help the organization to quickly rectify any problems before they catch the eye of the agency for a potential inspection notice. And since every inspection places burdens on regulatory, fewer inspections reduces workload.

To summarize, regulatory should view the agency demands for more and more structured data not as a compliance overload, but as a means to proactively achieve higher product quality and innovation in internal operations.

Pressure from business to get drugs approved faster than even before

Could operational KPIs be used to assess where delays are happening and why?

Delays in product approval are extremely costly for companies – often up to $1 million in lost sales revenue each day for innovator companies. As a result, the business places extraordinary pressure on the regulatory department to ensure that drugs are approved in the shortest possible time. But to speed up the submission process, regulatory needs to be able to determine where hurdles and gaps lie; they need to be able to measure and benchmark their activities to assess where improvements are being made and where more needs to be done. These measurements aren't possible without appropriate metrics and tracking tools.

Metrics and tracking tools are especially important when managing affiliates to ensure timely initial and review response submission to regulators. Even if affiliates do meet their timelines, they may not record such actions in a timely fashion due to a low local adoption rate of a global Regulatory Information Management System (RIMS). As a result, regulatory headquarters (HQ) struggle to gain visibility into the current submission and approval status. While regulatory departments are working toward an easy-to-use technology and harmonized process landscape to improve oversight, there are opportunities to take a 2025 approach and gain deep, comprehensive insight.

By building a regulatory data warehouse connected with the RIMS, regulatory will significantly boost intelligence capabilities without being burdened by time-consuming manual report extraction processes. Unlike a transactional RIMS system, a data warehouse makes it possible to get near real-time metrics with drill-down capabilities that allow regulatory HQ to perform Root Cause Analysis (RCA) on each delayed step of the process, thereby gaining region-specific insights as to where the problems lie. These might include identifying and finalizing a high-quality dossier Table of Contents (TOC) aligned to regulatory filing requirements, compiling and dispatching the core dossier, completing a high-quality final submission dossier or in getting internal responses in time to health authority review questions. The warehouse will also allow HQ to drill down on a negative metric along several dimensions such as product line, therapeutic area, outsourced contractors, etc. Based on the insights gained, appropriate remedies can be put in place.

The next step would be to continuously monitor if the remedies are indeed effective. For this, the regulatory data warehouse will allow regulatory HQ to conduct temporal trend analysis to compare performance over similar periods – the previous quarter, the previous year – and determine whether performance is improving or regressing, and what the potential root causes might be. Service level agreements (SLAs) can be agreed upon with affiliates and those with positive trends can be appropriately rewarded, creating a measurable, fair and globally transparent cycle of RIMS adoption and change.

In summary, a progressive approach to RIM should go beyond simply gathering data about when a dossier was submitted to include metrics and key performance indicators (KPIs) enabled through a regulatory data warehouse. In so doing, regulatory will realize better outcomes and reduced approval cycle times.

Emergence of new complex therapies and evolving regulatory Guidance

How can regulatory intelligence be effectively applied to determine successful approval pathways?

Tracking operational KPIs is an important corrective approach to problems with the submission process, but a 2025 vision requires a more proactive way to minimize risk and delays from the outset. This becomes extremely important if the products that need to be placed on the market are in new therapeutic areas, involve research domains that have not been completely explored through extensive clinical trials and where there is limited or evolving regulatory agency guidance on scientific approaches for product safety and efficacy.

Regulatory intelligence is playing a more prominent role in determining the regulatory approval pathways for such products by gathering and analyzing publicly available regulatory information from multiple sources to develop an informed regulatory strategy.

To determine future outcomes, regulatory intelligence teams often use historic decisions by regulatory agencies as a lens for potential future decisions. However, often regulatory intelligence personnel have to read between the lines because the agency's expectations and requirements are not always clear. Further slowing their progress is the fact that data gathering is manual since past decisions, including analysis and steps to address regulatory questions, often aren't properly maintained in systems.

The same applies to assessing the likelihood of reimbursement: by drawing on intelligence from past actions by the health authorities, companies can determine which trials to conduct to receive better reimbursement.

When considering investments for success beyond 2021, regulatory departments should consider regulatory intelligence technology capabilities to boost productivity of personnel and enhance analysis effectiveness. Priorities when assessing a tool should include:

- The ability to automatically take RSS feeds from agencies' regulations updates
- An open architecture with application programming interfaces (APIs) to load other sources of
- regulatory intelligence data

- A well-structured repository of regulatory intelligence elements covering both formal guidance from agencies-submission requirements, filing document checklists, expected timelines, obligatory commitments, approval pathways, etc. – as well as experiential learning gathered by affiliates while working with agencies
- Fuzzy logic search across the repository to allow analysis to be inferred and then recorded in hierarchical manner

A progressive technology platform will enable the global, regional and local regulatory managers, as well as clinical leaders, to effectively share information and be more informed on expectations from and experiences with agencies. This in turn will help them to produce high-quality submissions that will be subject to fewer changes, thereby improving overall regulatory efficiency and productivity – a key goal of any regulatory 2021 vision and beyond.

The new normal of hyper innovation and growth

Can regulatory marry data and documents to reduce dossier anagement workload?

Perhaps the most pervasive problem when it comes to productivity is the creation and management of documents. Regulatory departments remain document-heavy. And as the industry, in general, enters into a new phase of hyper innovation – driven by increased life expectancy, chronic and communicable diseases, recent patent expiries, scientific and technology advances – regulatory affairs and regulatory operations, labeling and artwork teams face an increased document burden from a huge surge in new application submission volumes, as well as a growing number of approved product licenses to maintain. Regulatory must, therefore, find a way to tackle the increasing workload of manual document authoring and collection.

The key to tackling this challenge lies in marrying the concepts of documents and data to create a single source of truth as opposed to just extracting data from documents. By using existing data that resides in systems of clinical, R&D, manufacturing and regulatory departments, regulatory departments can create a unified underlying source of product and process information – a central data hub that is data-standard agnostic and yet can cater to multiple submission requirements. From this underlying source, regulatory can digitally and automatically author dossier documents using natural language generation technologies. The same underlying data can also be used to cater to multiple data submission requirements (such as XEVMPD, IDMP, SPL and UDI).

Having the underlying data instead of approved dossier documents as the golden source of approved product information enables other avenues of automation for cross-functional processes such as automatic MedDRA coding of clinical particulars for IDMP submissions and safety case reporting, batch release control in the supply chain, etc.

In so doing, regulatory can not only reduce the total time and cost of preparing for numerous

submissions, but also ensure consistency between document content and submitted information and enable faster and trusted mechanisms of inter-departmental digital exchange of approved product information.

Constantly evolving regulatory guidelines as a moving target

Can regulatory leverage the cloud not just for reduced TCO but also improved agility?

Life science companies are increasingly adopting the cloud to reduce TCO by cutting back on infrastructure costs. But there are more benefits of cloud adoption. Cloud makes it easier to collaborate with payers and patients for personalized medicine delivery, it helps R&D to securely exchange data with external laboratories and innovators, and it supports reorganization from M&As – an absolute necessity given the complexity involved in trying to bring together data, processes and operating models from two different organizations.

There are strong reasons for regulatory to follow the route that other functions are already taking. Cloud adoption not only creates opportunities for regulatory departments to cut down on the costs of maintaining on-premise RIM solutions, but it also addresses the challenge of technology obsolescence in the face of rapidly changing regulations. Other benefits of cloud, such as improved collaboration, more secure exchange of data and a harmonized way to integrate different sets of regulatory information, are as important for regulatory as for other functions.

By investing in a cloud-based RIM solution, regulatory can both reduce their TCO and build a platform for integrating with emerging innovative cloud-based technologies that enable distributed computing, collaboration mashups and big data analytics. Having a cloud-based solution as a central extensible and agile platform will be key to a successful 2021-and-beyond approach to business and regulatory transformation.

And many more...

There are many factors pushing regulatory departments to assess the way they currently operate and consider progressive technologies and processes. Among the other key drivers that a_ect the way regulatory works are issues such as:

- The move toward low-cost clinical trial launch pads in newer emerging markets such Latin America and Asia Pacific
- Pressure from governments, agencies, payers and patients to justify drug prices, paving the way toward real-world, evidence-based value pricing and end-to-end evidence management strategies
- The potential ramification of o_-label product promotion

These and many other drivers require regulatory departments to think carefully about their current investments for building their 2021 landscape, and to ensure their investments take them beyond 2021 and toward 2025 to tackle these and other pressing requirements, while aligning with broader business objectives.

New Disruptive Technologies and Impact on RIMS Landscape

The drivers and solutions discussed in the previous section combine to create a perfect storm for life sciences in general and regulatory in particular. In this environment, there is a need for rapid change in operating models and the technologies that support them. Underlying the organization-wide move to assess systems and processes is the omnipresent shift to digital. Disruptive new technologies offer a significant opportunity for life sciences companies to unlock new business value through new business models that were earlier not possible.

As per the theory of Diffusion of Innovation by Everett Rogers, the Innovators and Early Adopters are already exploring the benefits of these disruptive technologies. This, in turn may, completely change the way the life sciences industry does business in the next decade, leaving little time for the Late Majorities and Laggards to catch up.

Hence it is imperative that regulatory departments consider these new technologies to assess their wider impact on the regulatory landscape in the new decade.

Interweaving the new collaboration tools with RIMS

Enhanced regulatory information sharing and RIM adoption by the next-gen

The regulatory organization is no longer a simple structure. Some organizations adopt a centralized model, with all product lines and geographies supported from the headquarters. Other companies are more decentralized, with a global regulatory affairs team working from headquarters with regional and country-specific regulatory teams. Additionally, with the increase in outsourcing many processes and capabilities, regulatory needs to work with external consultants and partners. These complex and often-changing geographical, organizational and technological structures underscore the need for a scalable platform for operational collaboration, regulatory intelligence/knowledge sharing and improved global adoption of RIMS by infrequent users such as affiliates.

Moreover, the new generation of regulatory managers, many of whom are millennials, are accustomed to using new technological tools to share and collaborate and are unwilling to use traditional, discrete point-collaboration capabilities such as emails, fax and calendar-based task reminders. Furthermore, many companies are embracing the bring-your-own-device policy, and users expect to be able to leverage the same collaboration capabilities that they use in their personal life for work collaboration.

This creates problems for tracing and auditing in regulatory: how do you track operational metrics such as time to submission when data exchange, reminders, task completions, information/document hand over and intelligence sharing is happening via social media and other collaboration apps such as Yammer, Slack, Confluence, Smartsheet, Quip, Podio, Glip, Trello, Bloomfire, Cisco Spark, etc.? How do you ensure that next-generation managers are encouraged to use RIMS for reporting and sharing documents and data?

A 2025 approach involves a RIM platform that can integrate with the new collaboration tools so that communication exchange taking place in such tools, for example around the status of submissions, is automatically updated in the RIM solution. This would minimize the risk of double and possibly inconsistent data entry – a main cause of low RIM adoption among infrequent users. Equally important, information generated from the RIM solution about upcoming submissions, assigned workflow tasks or product approval notification needs to be fed into collaborative tools to make

sure all users receive important alerts through the channels they are accustomed to.

Mobile apps for regulatory

Bring regulatory data closer to point of consumption

There's no doubt that an increasingly mobile workforce and demands for real-time information requires an appropriate and scalable response. In this context, mobile applications are becoming a key focus in life sciences, whether for the conduct of clinical trials, real-time reporting of adverse events or to assist medical information with providing information. The emphasis in most cases is on bringing the point of data capture closer to the source of data to ensure no data is lost and that it is immediately available in the system.

As part of the 2021 vison, some regulatory departments may consider adoption of regulatory mobile apps to bring the point of data capture closer to the source of data, for example by encouraging affiliates to use such apps to report when a product is approved. But practically, even if complex regulatory data sets -- such as the product composition and packaging structure of an approved combination kit -- could be easily captured using a mobile app, the reality is that regulatory events like product approval don't happen multiple times each day. This makes it difficult to justify adoption of a mobile app that allows for instant regulatory approval status and specifications recording on the go as soon as the person sees an agency approval email notification flash on his mobile.

A more pressing use case for mobile apps in regulatory is where the data source is brought closer to the point of information consumption, shifting the focus of such regulatory apps to data sharing, while leaving the more complex data update steps to the full RIMS web application. For example, it would be more effective to have a RIM app for quickly sharing reports with manufacturing on approved product specifications, or dispatching a notification to product supply indicating expected approval is now delayed. Prompt sharing of product specification and regulatory status are crucial since manufacturing depends on these to prepare products and ensure the supply chain is up to date.

To further improve collaboration and process integration, the central regulatory team could use their RIM app to send alerts or reminders to the label artwork team to deliver an updated Package Insert template they have requested. Local affiliates could use the RIM app to get an alert on product approval in a reference country or to check the status of their request for reference approval certification. These apps encourage infrequent RIMS web application users to collaborate more effectively.

As part of the future-proof vision for 2025 and beyond, regulatory departments should look at specific data sharing, request tracking and notification use cases and build focused RIM mobile apps that deliver definitive but high-impact results, instead of trying to build a comprehensive mobile version of a web application.

Going beyond the media hype on artificial intelligence

Cognitive technologies for submission success prediction

While social media and mobile are here and now, artificial intelligence is often thought of as a future technology. And while there has been a lot of media hype about AI, it is already being used in the life sciences industry; indeed, companies will continue to invest extensively in AI. It is expected that by 2021, life sciences will invest around $6 billion in AI to enhance many areas of the business, such as R&D decision making or patient targeting for personalized medicine delivery.

In fact, certain AI technologies such as text analytics, natural language processing (NLP) and machine learning platforms have become technologically mature for commercial deployment and also have high potential for delivering value to regulatory.

One such use case is the application of a sub-set of AI technologies related to cognitive computing to predict the success rate of product approval. The first step is to gather past submission data -- applications, agency objections and queries and actual agency decisions – and use NLP to decipher meaning, intention and sentiment of each agency decision. Next, deep learning platforms are used to identify patterns across multiple submissions. These patterns are compared against the submission in question. For example, the FDA always asks for additional data if certain excipients are used in a product. Such patterns aid the next step, where rule-based decision-making systems are used to make statistical recommendations based on probability. These recommendations will tell you, based on what's happened in the past, what the likely success rate will be. If, based on this analysis, regulatory determines that the likelihood of success is only 20%, they might recommend failing early rather than investing more in ongoing agency reviews. Alternatively, using cause analysis, it might be possible to determine what the past barriers have been and improve the chances of a future submission's success.

While these capabilities have yet to be realized, regulatory departments need to spend time now organizing data in a platform that is built to enable machine learning and be ready for

2025 opportunities.

Leveraging regulatory big data

While AI taps into data to correlate patterns and analyze potential outcomes, big data itself – gathered from sources such as social media – presents exciting opportunities for various parts of the life sciences business. For example, safety departments have been successfully using signal detection tools that seek out safety signals in social media. R&D has recently joined safety departments in leveraging big data analytics for evidence-based and targeted personalized medicine.

But big data is not just about social media; rather it's about the massive amounts of largely untapped data that exists internally and externally. It's an area that holds huge potential for regulatory, which needs to find a seamless way to leverage the vast amounts of data that reside in different forms: unstructured internal document repositories, traditional transactional data systems holding approved product specifications and applications tracking data, product promotions on social media and blogs and public data available from regulatory agencies.

Regulatory departments need to determine how best to leverage big data investments of other departments to transform their own processes. One use case would be predictive regulatory correspondence management using past responses to determine what the authorities are likely to ask. For example, will you get a warning letter or a recall? To predict outcomes, regulatory intelligence teams can draw upon a variety of big data.

First is RSS feeds on regulatory guidance, which provides updates on what companies need todo to improve the quality of their products. NLP tools can be used to extract patterns, themes or sentiments.

Another big data source that regulatory needs to pay attention to is product promotion on social media. Is the manufacturer promoting your product in line with the approved product specifications, or does the promotion veer into off-label territory, potentially putting the company at risk of an unfavorable agency ruling?

A recall announcement of competitor products is another valuable source of big data. By analyzing

data using spatial and contextual-meaning analysis tools, regulatory teams can learn from these mistakes and determine whether their product is potentially also at risk.

All above inferences on regulatory big data can be corroborated with patterns from your own past correspondences with the agency to anticipate possible concerns that can result in a deficiency letter or issues in the dossier assessment report from the agency. This will help companies be better prepared to respond effectively, or better yet, preempt problems with higher quality initial submissions.

A first step in getting regulatory to a point where it can embrace emerging technologies to analyze big data would be to with the adoption of a data warehouse, as discussed earlier in the paper. This would help to put regulatory departments on the road to transforming how they gather, manage, assess and make use of big data.

Blockchain era beyond Bitcoin and financial industry

An intermediary-free, secure value exchange portal for regulatory

Social media, AI and big data, and even the Internet of Things are well-understood – if not yet fully appreciated and adopted – in life sciences today. But there is one other emerging technology that holds significant promise for life sciences companies and regulatory departments that few in the industry understand as yet. That is blockchain. This new technology is currently primarily used in the financial sector, with the best example being the digital currency, Bitcoin.

Blockchain is a distributed ledger that can be used to hold something of value – money, deeds, contracts, scientific discoveries, intellectual property and so on. Multiple parties can log into this ledger and securely view the content there and exchange information or value (such as money and deeds) in a secure way. Security and trust is established through a distributed environment, mass collaboration and clever code, completely bypassing intermediaries.

For the life sciences industry, blockchain holds potential in several ways: to create a secure, interoperable repository of patient health information that can be used by care providers and researchers; to safeguard the supply chain, ensuring the drug and raw materials move through securely while reducing documentary burden; or to ensure greater visibility between the pharmaceutical company and its partners and patients.

For regulatory, blockchain has potential in two important areas: reporting and improved collaboration. Regulatory's chief responsibility is to ensure that every action they take, from responses to the agency to working with other departments, is auditable. Recording actions on a blockchain that is transparently accessible by the agencies at any point without added audit burden lets regulatory quickly demonstrate to the authorities that it is in compliance and allows regulators to quickly check what actions have been taken. In so doing, regulatory could drastically cut back on the documentation and records it must maintain to demonstrate compliance.

Another use case for blockchain in a regulatory context is to improve and secure collaboration between the marketing authorization holder (MAH) and the drug master file (DMF) holder. Confidential drug substance information that the DMF holder doesn't want the MAH to access but does need the regulators to see can be made available on a blockchain that is transparently but securely available to the right parties.

As these and other new disruptive technologies start to gain traction across the life sciences industry, regulatory departments must assess how to take advantage of capabilities that could transform the way they operate. They need to think carefully about how they build their platforms, determine if and how each emerging technology might work best for them, and consider how they will prepare for current and future regulatory demands.

Path to self-assessment and transformation for a successful 2025

A prescriptive approach to regulatory will never succeed. Every organization needs to determine what, how and when to adopt current and future technologies. It's never wise to adopt technologies simply because they're the new big thing. Nevertheless, progress is needed to meet current and future pressures and business drivers, both internal and external. Regulatory departments must assess their current investments to determine whether these will help them to succeed beyond 2021 and into 2025.

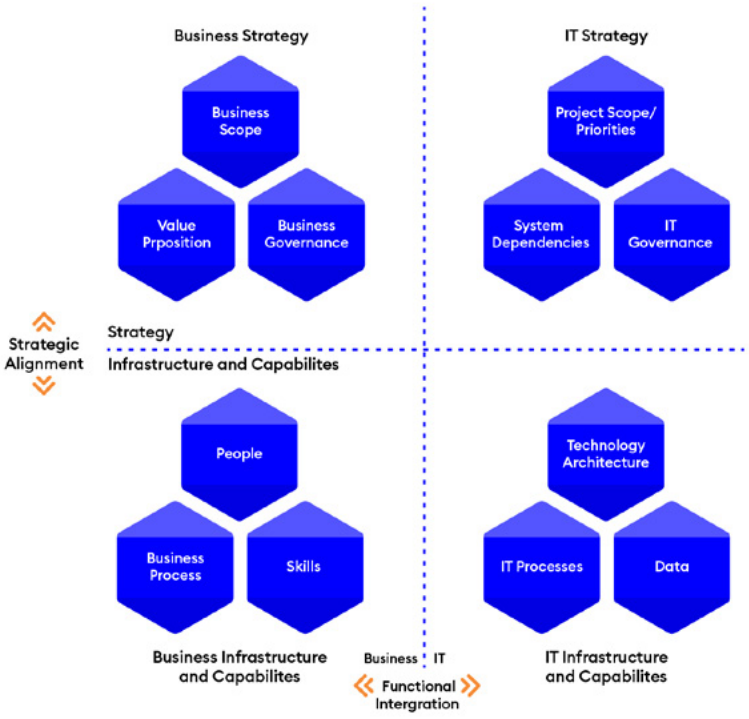
Regulatory is already investing in business and IT infrastructure– such as RIM. But RA leaders, and other decision makers, including CIOs, need to look at their current investments and ask hard questions about whether their direction is future-proof.

They need to ask whether they are investing in individual, discrete projects or whether the projects are harmonized in an overarching program aimed at addressing the many issues regulatory and the overall business face.

Decision makers must also determine what impact these individual projects will have on organizational culture, including roles and responsibilities. If emerging technologies are adopted in a haphazard or poorly-planned way, they might negatively impact how people work, creating chaos and conflicts rather that structural benefit.

Most importantly, whatever investment is made to develop business and IT infrastructure needs to align with the overall business and IT strategy. If desired capabilities are not aligned to proposed strategy, investments may end up being operational. This might help regulatory meet some 2021 objectives, but they won't future-proof the organization and prepare it for 2025 and beyond.

To meet 2021 and 2025 business and IT objectives with planned projects and investments, organizations need to perform a self-assessment. One successful way to do this is to use the Strategic Alignment Model [Henderson and Venkataraman, 1999], a framework for aligning IT



strategy with business strategy and leveraging IT infrastructure on a continuous basis to develop new business infrastructure that delivers sustainable competitive advantage. The Strategic Alignment Model is composed of four quadrants: two business quadrants, namely business strategy and business infrastructure; and two IT quadrants, namely IT strategy and IT infrastructure. These quadrants work together to determine the extent of strategic fit and functional alignment.A company with a strong 2025 regulatory vision must strive toward alignment between the business and IT, with IT supporting the business capability and potentially even helping the business to build new strategy and models. In order to achieve this alignment, regulatory departments should at the minimum consider the following two of the many alignment perspectives available on the Strategic Alignment Model.

The Strategic Execution perspective of the Strategic Alignment Model guides regulatory to consider the emerging external drivers and business trends that impact the overall business strategy of the company. These market forces lead to new business infrastructure, namely new R&D avenues, advanced technology-driven manufacturing processes, dynamic supply chain models and aggressive marketing and commercial goals. Regulatory needs to ensure that their current investments in regulatory strategy and RIMS infrastructure are in alignment with the evolving business strategy for 2025 and beyond.

Emerging Business Drivers

- Pressure on high prices
- Approval and Reimbursement Convergence
- Off-label promotion
- Quality metrics reporting
- Political uncertainty
- Cost pressures
- Hyper innovation driven growth
- Increasing regulatory requirements

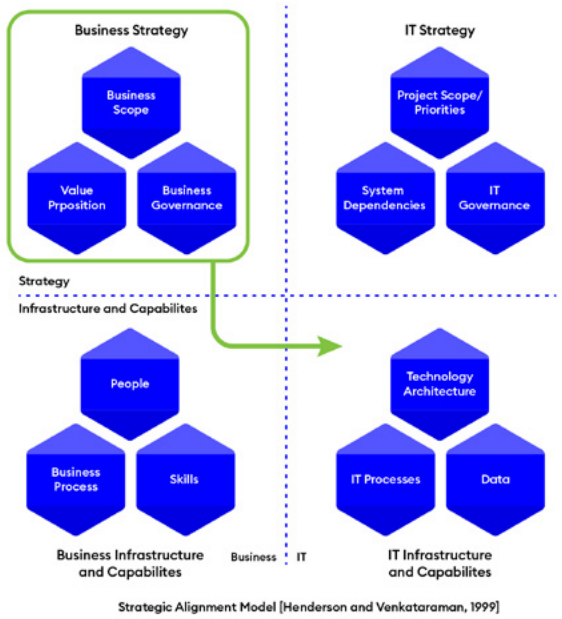


Figure 3: Using the Strategic Execution perspective for analyzing emerging business drivers

The Technology Potential perspective of the Strategic Alignment Model asks regulatory to look at new disruptive technologies, which are already being explored by some of the leading innovator companies. Regulatory should consider these disruptive technologies to build an IT regulatory strategy that can deliver new competitive advantage supported with the right regulatory infrastructure and capabilities. These capabilities lay the foundation for a truly transformed regulatory landscape of 2025

New Disruptive Technologies

- Collaboration Platforms
- Big Data
- Internet of Things
- BPM Platforms
- Artificial Intelligence
- Block Chain
- Mobile Apps

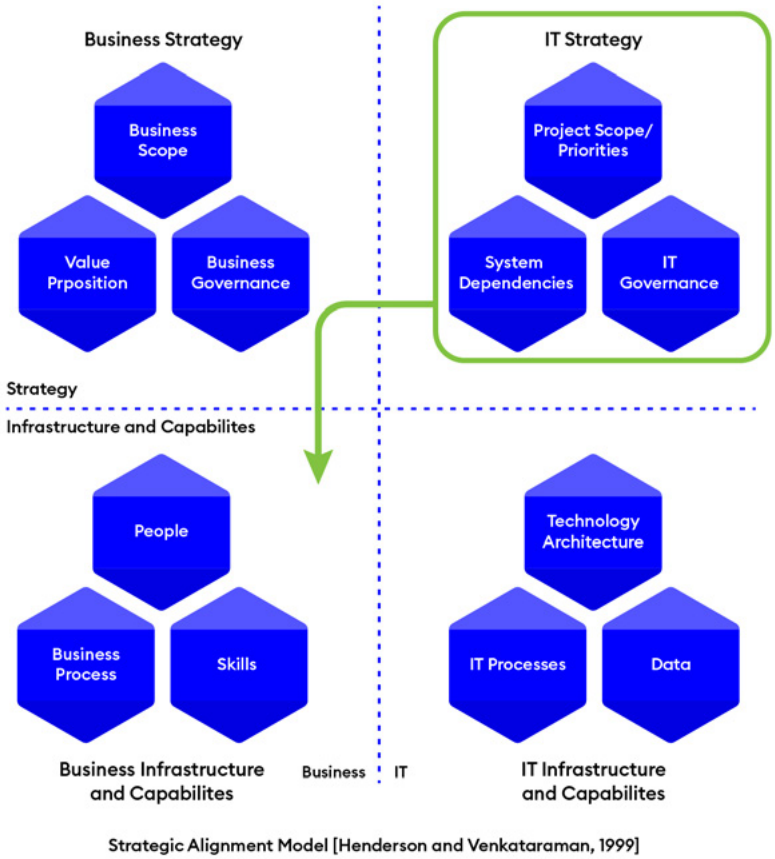


Figure 4: Using the Technology Potential perspective for analyzing new disruptive technologies

Conclusion

Achieving regulatory transformation involves far more than simply analyzing the latest technology and business trends. It's imperative to have an overall strategy in place, otherwise regulatory departments will end up investing in incremental and poorly constructed projects and a few years later will be forced to go through the whole process again.

As the regulatory department prepares for 2021 and the rest of the decade it must address transformative technologies that take it beyond increased productivity, compliance or TCO to also target improvements in innovation and decision-making and, ultimately, transform how the business works.

By aligning strategy and capabilities for a successful 2021, progressive regulatory leaders can also prepare to meet the 2025 regulatory landscape.

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ABOUT ARISGLOBAL

ArisGlobal is transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. Our end-to-end drug development technology platform, LifeSphere®, integrates our proprietary Nava® cognitive computing engine to automate all core functions of the drug development life cycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, LifeSphere® is a unified platform that boosts efficiency, ensures compliance, delivers actionable insights, and lowers total cost of ownership through multitenant SaaS architecture.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India, Japan, and China.

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