

A bold future for life sciences regulation

Predictions 2025

November 2018

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Deloitte Centre *for* Health Solutions

The Deloitte Centre for Health Solutions is the research arm of Deloitte LLP's Life Sciences and Health Care practices. Our goal is to identify emerging trends, challenges, opportunities and examples of good practice, based on primary and secondary research and rigorous analysis.

The UK Centre's team of researchers seeks to be a trusted source of relevant, timely and reliable insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, patients and suppliers. Our aim is to bring you unique perspectives to support you in the role you play in driving better health outcomes, sustaining a strong health economy and enhancing the reputation of our industry.

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Foreword

The life sciences industry operates in an increasingly complex regulatory landscape. Over the past few years, the industry has seen a proliferation of regulatory changes, with a plethora of new regulations due to come into force over the next few years. At the same time, regulators face the challenge of continuing to protect patients and enhance public health, while fostering innovation by responding quickly and effectively to the exponential pace of change in medicine, science and technology.

Deloitte's Centre for Health Solutions and Centre of Regulatory Excellence for Life Sciences have published numerous reports on these challenges, with insights drawn from primary research, literature reviews and our experience working with relevant stakeholders across our global network. This new report draws on our combined expertise and insights to take a novel view of the Future of Regulation in 2025.

In this report we imagine a new paradigm, where life sciences companies and regulators work collaboratively, stable and predictable regulations are seen as an enabler rather than a barrier, and disruptive technologies and new generation treatments are used more effectively to improve outcomes for patients. While there is of course a range of alternative scenarios, including a world where there is little collaboration and an antagonistic, restrictive and punitive approach to regulation, the evidence available today suggests that the more positive and optimistic outlook is what regulators and industry are striving to achieve.

However, achieving this more positive vision of the future and delivering better outcomes for patients will require regulators and the industry to: develop more efficient and effective systems and processes; acquire new skills and talent; and deploy new generation technologies more effectively. Indeed, the skill set and engagement strategies of regulators will look quite different from today, and life science companies will need to re-programme their regulation mind-set to create a new, more collaborative environment that drives a culture change across the industry. This is a future in which patients are fully engaged in designing regulations, companies are truly patient-centric and the regulatory function of each life science company has moved from being a back-office enabler to a strategic business partner.

Today, our industry finds itself facing a regulatory gap, where regulators struggle to keep pace with technological and other innovations. Drawing on our combined expertise in working with regulators and the regulatory functions across industries, we have developed four bold and optimistic predictions of what regulation in the life sciences industry might look like in 2025. Each prediction, brought to life by imagining how regulators, industry and patients might behave in this new world, is underpinned by trends, events and examples in 2018 that, if adopted more widely, paint a picture of a regulatory system that is very different from today.

We hope this report stimulates rich dialogue and prompts a move to action.

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Regulation today

The role of regulators

The regulation of medical drugs and devices is aimed at assuring the safety and efficacy of products, while also facilitating the movement of innovative therapies through the investigative and regulatory processes as quickly as possible.

The exponential advance of developments in science and technology, alongside the blurring of traditional barriers between existing and new health care providers, is increasing the need for new regulatory frameworks and greater clarity about how the changes will impact the relationships between regulators and industry, patients and other stakeholders.

The ultimate goal of regulators, to safeguard and enhance public health, remains their foremost concern, but the tools at their disposal now include adoption of AI, machine learning and robotic process automation (RPA).

Key challenges for regulators

- Ensuring that regulations keep pace with technological and scientific breakthroughs.
- Developing new approaches to evaluate the growing number of complex products, such as new molecular entities, orphan breakthrough products and fast track designations, digital pills and connected medical devices. These technologies have the potential to create value to society by generating improvements in patient health (net of treatment risks) that were previously unattainable.
- Engaging more effectively with patients in evaluating and monitoring new products.
- Obtaining new skills and talent to collaborate more effectively with other regulators, health technology assessment agencies (HTAs), and both traditional and new non-traditional industry incumbents.

Impact of regulation on the life science industry

Regulatory compliance is an enabling component of the highly regulated life science industry. It is a cornerstone of both product development and commercialisation, giving the business a framework in which commercial objectives and patient access can be optimised.

Interpreting the growing volume of regulatory legislation accurately and implementing any necessary changes in a co-ordinated, cost-efficient and timely manner, across a number of business functions, is testing the capabilities of the industry.

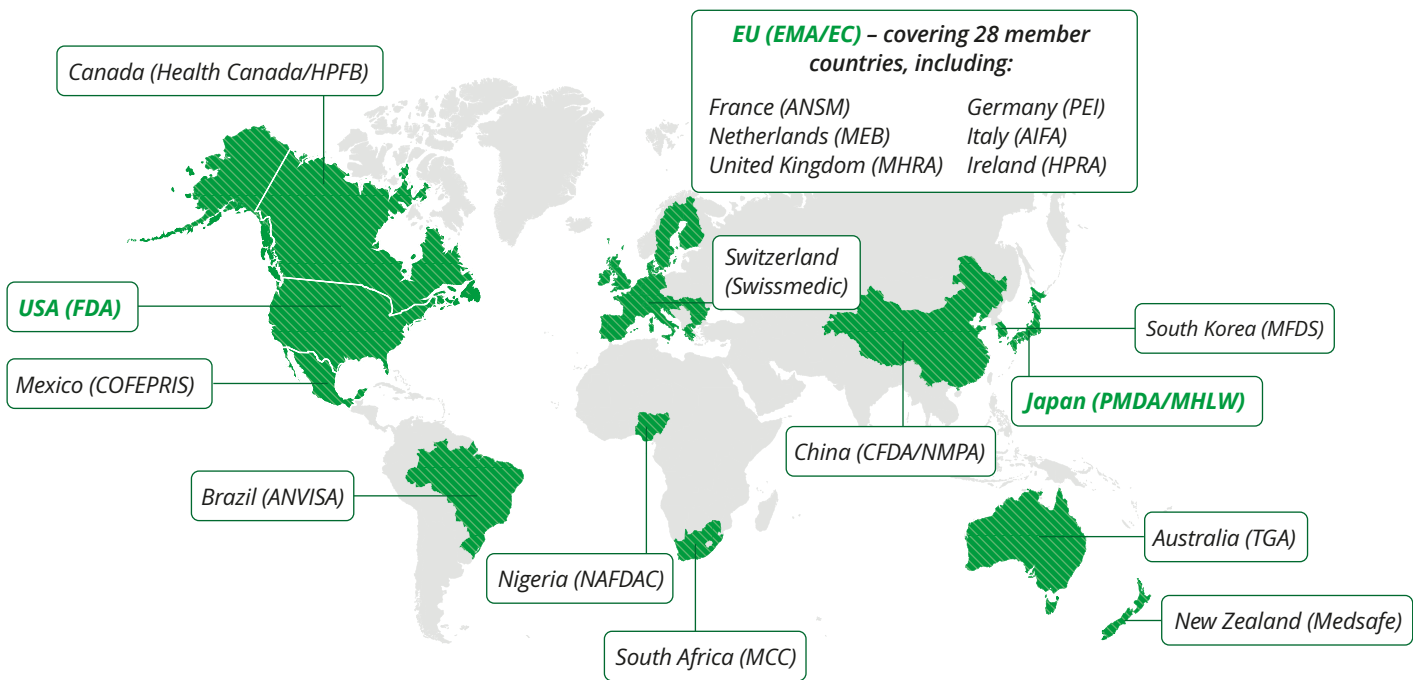
Effective compliance management is seen as a source of competitive advantage, with compliance officers required to demonstrate the value of their function to the organisation. Compliance using technology, with a focus on efficiency and value creation, is shaping the regulatory function and is demonstrating increasingly a positive ROI for the industry. For example, by improving speed to market, rather than being seen simply as a cost of doing business.

In the face of fast-paced regulatory change and the continued expansion of regulatory requirements, the industry has recognised the need to develop new skills and talent, improve the use of technology solutions and adopt new business and operating models. The aim is to capture sufficient, reliable data to provide a consolidated, holistic view of compliance, in the knowledge that failure to respond adequately will raise the prospect of increased reputational risk.

Key challenges for the industry:

- Drug development continues to be a complex, time-consuming and costly business. Increasing regulatory requirements and a more complex understanding of science are leading to year-on-year increases in costs and declines in average peak sales per asset.
- The adoption of emerging technologies is influencing the future of R&D. Real-world evidence (RWE) and RPA are impacting the whole R&D value chain from study design, physician and patient recruitment and in-trial decision making, to automating repetitive tasks such as regulatory filing.
- Information from social media, mHealth, wearables, connected medical devices and telemedicine are transforming how physicians and patients are engaged and retained in clinical trials. This includes how they report positive and negative outcomes.

Figure 1. A snapshot of some of the main regional and local life science regulators across the world

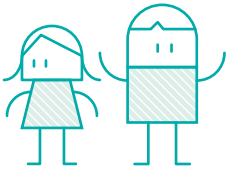


Australia (TGA)	Therapeutic Goods Administration	South Korea (MFDS)	Ministry of Food and Drug Safety
Brazil (ANVISA)	Agência Nacional de Vigilância Sanitária	Mexico (COFEPRIS)	Comisión Federal para la Protección contra Riesgos Sanitarios
Canada (Health Canada/HPFB)	Health Canada/ Health Products and Food Branch	Netherlands (MEB)	Medicines Evaluation Board
China (CFDA/NMPA)	China Food and Drug Administration / National Medical Products Administration	New Zealand (Medsafe)	New Zealand Medicines and Medical Devices Safety Authority
European Union (EMA and EC)	European Medicines Agency / European Commission	Nigeria (NAFDAC)	National Agency for Food and Drug Administration and Control
France (ANSM)	Agence Nationale de Sécurité du Médicament et des Produits de Santé	South Africa (MCC)	Medicines Control Council
Germany (PEI)	Paul Ehrlich Institute	Switzerland (Swissmedic)	Swiss Agency for Therapeutic Products
Ireland (HPRA)	Health Products Regulatory Authority	United Kingdom (MHRA)	Medicines and Healthcare products Regulatory Agency
Italy (AIFA)	Agenzia Italiana del Farmaco	United States (FDA)	Food and Drug Administration
Japan (PMDA/MHLW)	Pharmaceuticals and Medical Devices Agency / Ministry of Health, Labour and Welfare		

Source: Deloitte research, 2018

Key drivers of regulatory change

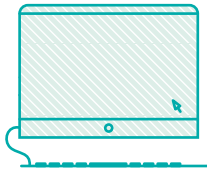
The four key drivers



Better patient safety and outcomes based on P4 medicine (predictive, preventative, personalised and participatory)



New treatments, such as combination therapies, immunotherapies, nutrigenomics, gene editing and digital therapeutics

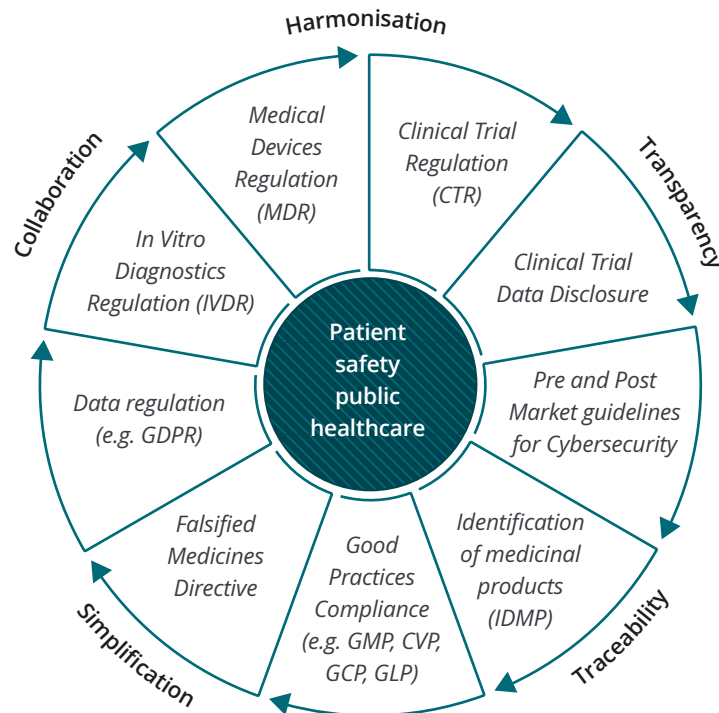


Access to real-time information and data

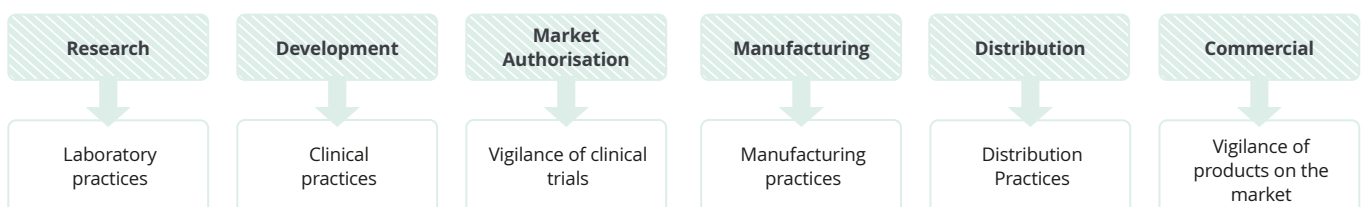


New technology such as machine learning, RPA, robotic surgery, 3D printing, the Internet of Medical Things and virtual reality

The emerging and evolving regulatory framework



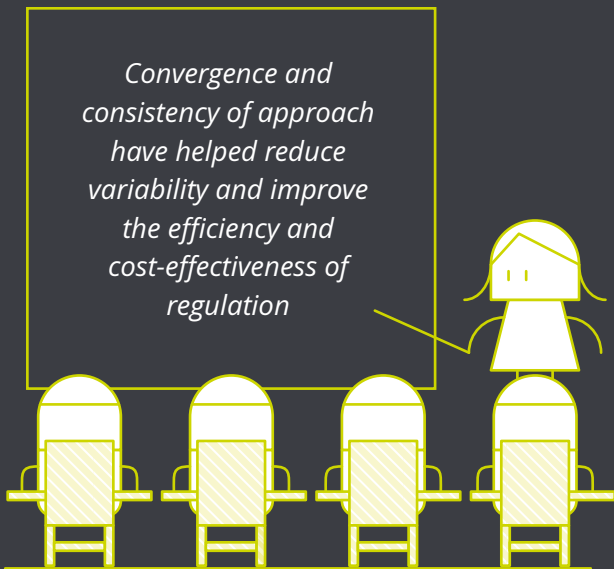
Impact across the life sciences value chain



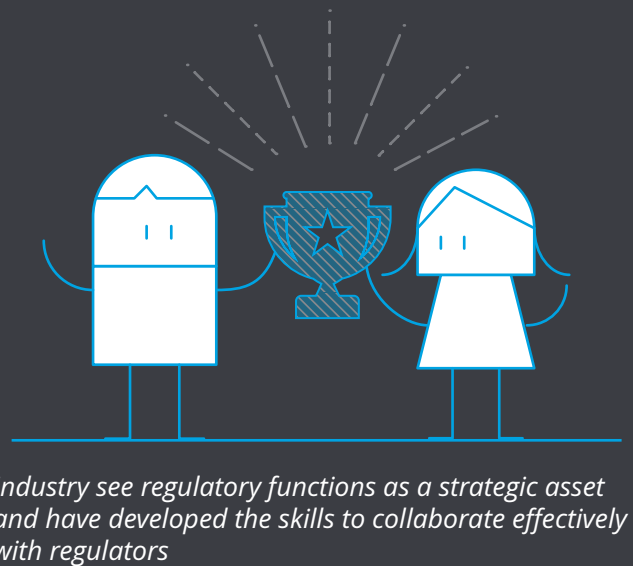
The future of life sciences regulation: four predictions for 2025

In 2025, digital transformation meets 'Regulation 4.0', where:

1. Regulators are globally aligned and coordinated



2. Regulatory relationships are based on a 'win-win' approach

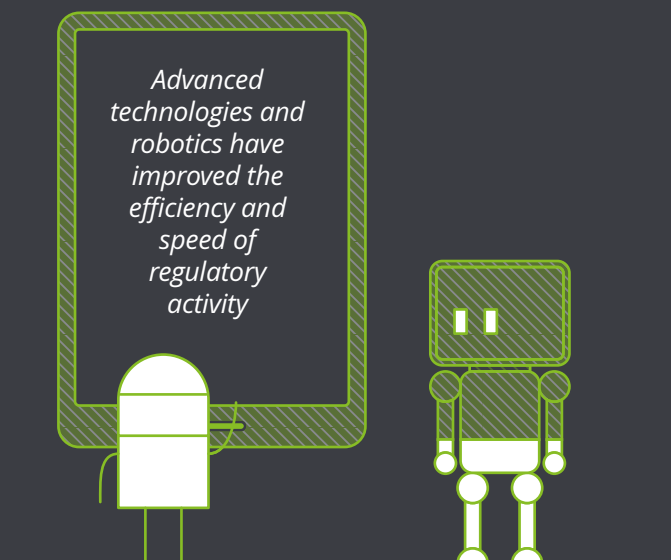


3. Regulators successfully balance rapid assessment of innovation with real-time regulation



New data-driven approaches enable faster regulatory approvals, better sharing of risk and value to patients

4. A technology-enabled approach is driving the productivity and quality of regulation



2025

1 Regulators are globally aligned and coordinated

Convergence and consistency have reduced variability and improved the efficiency and cost-effectiveness of regulation.



Prediction Regulation has been aligned at both a national and international level, with regulators around the world benefiting from more collaborative approaches such as co-regulation, self-regulation, and international co-ordination. This approach has encouraged innovation while protecting consumers from potential fraud or safety concerns. Regulators have also agreed robust data sharing arrangements. As life sciences companies have continued to expand into multiple jurisdictions, increasing the number of multinational trials, regulators have acknowledged the benefits of regulatory convergence in speeding up the process of getting products to market around the world. In 2018 regulatory harmonisation was an ambition, but by 2025 harmonisation and convergence are a reality.



Key features of the world in 2025

- International agreements on rapid data sharing and harmonised standards have enabled disparate databases to talk to each other and improved signal detection.
- Regulatory harmonisation has helped speed up the process of getting drugs and medtech products to market sooner, as regulation convergence has enabled all aspects of the product lifecycle to benefit from increasing globalisation.
- The lowest class of medical devices now has a single, substantially simplified regulatory process.
- Ad hoc requests from local regulators have been vastly reduced in number as confidence in regional and international approaches has increased.
- The cumulative time taken to evaluate and approve new drugs has been reduced substantially by regulatory convergence.
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has been instrumental in spearheading interoperability, to promote public health and reduce duplication of animal and human testing.
- Regulatory approval of technology-enabled clinical trial recruitment processes has enabled increasing numbers of patients across multiple geographies to sign up for global clinical trials, enhancing recruitment (especially for patients with rarer diseases etc).



Key enablers

- A new International Medicines Organisation, facilitating global cooperation between the different Drug Regulatory Agencies, has helped harmonise regulatory oversight.
- Collaboration with regional agencies and investment in partnerships with academia to develop a series of e-learning modules helped tackle the shortages in skills and talent that were becoming increasingly evident in 2018.
- All regulators have signed up to the Global Medical Device Nomenclature (GMDN) system as a way of harmonising the global system.
- Use of cloud and digital technology has enabled different regulators to share inspection schedules and use Common Electronic Submission Gateways as a platform for sharing information.
- The widespread adoption of a new set of international data security standards has led to reduced risks and increased confidence in sharing data and a significant improvement in transparency of completeness of clinical trials data.
- Regulators have leveraged blockchain to enable regulators to exchange data securely and quickly. Blockchain is also providing assurance about the safety and security of the complex global supply chain.

Note: All elements on this page are Deloitte's view of regulation in 2025



Portrait of a regulator in 2025

The local Drug Regulatory Authority (DRA-A) had struggled to recruit enough people with skills and talent to be able to respond effectively to the pace of innovation across the pharma industry, especially since the launch of a new government-backed industrial strategy supporting the development of innovation. Not wishing to be seen as a barrier to progress, DRA-A adopted blockchain technology to enable it to share and exchange data quickly and securely with the regional regulator. Regional harmonisation in the adoption of RPA for evaluation of dossier submissions and compliance with agreed safety and quality end points has helped drive efficiencies within DRA-A so that the cumulative time taken to review a submission has been reduced by 24 per cent in the past three years. Market monitoring has also been transformed using AI technology to interrogate the multiple sources of unstructured data pertaining to each drug, including data sharing with other regulators.



Portrait of the industry in 2025

The regulatory affairs team at Pharmaco B was pleased to be nominated for a company award for its contribution to driving improvements in the company's culture of compliance. The global company had adopted a proactive approach to building trust and effective relationships with both the local and regional regulators. This has sped up the time to market, helped ensure that any regulatory issues or uncertainties are addressed in a collaborative and timely manner, and improved the reputation of the industry amongst patients. A combination of the skills and talent of the regulatory affairs team (including data scientists) and direct patient and payer involvement in innovative drug trial designs has enhanced the efficiency and productivity of drug development. The compliance function has become increasingly accountable for managing risks relating to R&D operations, with greater attention being given to expanded access programmes and health care economic information. Pharmaco B has also been able to pass cost savings from simpler submission processes to patients in the form of cheaper medicines. Regulatory convergence has lessened the compliance burden on industry functions, who have re-assigned staff to ensuring higher quality products.



Portrait of a patient in 2025

Ruth was diagnosed with a neurological condition and with the support of her consultant was accepted on to a global clinical trial. Following a simple registration process, Ruth was equipped with a smart band for tracking her vital signs, including an attachment that enabled a new mini-brain scan to help track changes in her brain patterns. Her medication was delivered by a drone in monthly batches, and her vital signs were monitored remotely. Through an app on her smart phone, Ruth was able to input comments on how she was feeling in general and about the impact of the drugs on her mental and physical health. She had teleconferences each month with her consultant and the lead clinician for the clinical trial, but she was also encouraged to seek advice whenever needed. Once every six months Ruth visited the local tertiary hospital for a full body scan. The ease of participating in the clinical trial and the minimal disruption to her normal lifestyle meant that Ruth maintained her compliance with the trial protocols.

Regulation has been aligned at both a national and international level, with regulators around the world benefiting from more collaborative approaches such as co-regulation, self-regulation, and international co-ordination. This approach has encouraged innovation while protecting consumers from potential fraud or safety concerns.

Evidence in **2018**

The current harmonisation between regulatory agencies

Across the world, the three most influential life science regulators are the FDA, EMA and PDMA. However, most other countries have local regulatory agencies. As the regulation of the life sciences industry has evolved, there has been growing acknowledgment of the need for a consolidated global view on life science regulation. As a result, today's system is characterised by increasing levels of harmonisation – from collaboration on selected topics and Mutual Recognition Agreements (MRAs), all the way to full integration (as in the European Union). Indeed, the European Medicines Agency (EMA) and the European Commission for regulation of medical devices are an exercise in collaboration between EU member countries. Europe consequently has a much more complex regulatory structure than the US FDA.

Furthermore, a number of global bodies have been established in recent years to improve collaboration and harmonisation among the more established regulatory agencies such as the ICH. Additionally, the ICH and the World Health Organisation (WHO) are working to achieve a global scientific consensus for the development of regulatory guidelines to improve access to medicines in the developing world. Nevertheless, in 2018 pharmaceutical standards and regulatory systems in many countries across the developing world remain fragile, of uneven quality, and highly dependent on aid and technical support from international donors.^{1,2}

How the Pharmaceutical Product Working Group (PPWG) is attempting to harmonise life science regulation across the ASEAN region

ASEAN consists of 10 member states that have come together to promote economic, social and security cooperation. As an element in this partnership, the PPWG was created in 1999 to harmonise life science regulation schemes, technical documents and other requirements for the region. The group has worked closely with the ICH and WHO to harmonise the regulatory landscape, including an ASEAN CTD. In 2018 the group developed two new standards on the quality, safety and efficacy requirements for biological products including vaccines. However, challenges remain. There was a two-year delay in getting unanimous agreement for the ASEAN CTD. Furthermore, despite harmonisation of key requirements, products currently need to be registered individually in each country, and market access is hindered frequently by local differences in administrative data and labelling requirements, such as additional country-specific requirements and local language translations of the inserts. As regulatory convergence increases further, the industry expects to see greater incentives to enter harmonised markets, and patients in the region stand to benefit from quicker drug commercialisation, meaning quicker access to new drugs and therapies.^{4,5}

How regulation has been streamlined between Canada and the US

In 2011, the Canada-United States Regulatory Co-operation Council was announced, aimed at streamlining regulation. As a result, both countries share inspection schedules and use the Common Electronic Submission Gateway as a platform for the industry to send information to both the FDA and Health Canada at the same time. In addition, both agencies participate in the Medical Devices Regulators Forum to improve harmonisation in this field.³

How Australia's Therapeutic Goods Administration (TGA) is expanding public access to medical devices by recognising registrations and certifications from other international and regional regulators

In 2018, the TGA announced plans to accept certifications and approvals of market applicants from foreign medical device regulators in addition to European CE Marking. TGA will recognise registrations and certifications from the US FDA, Health Canada, the Japanese PMDA and Medical Device Single Audit Program (MDSAP) auditing organisations. Australian market applicants may leverage approvals and registrations from these agencies for expedited TGA pre-market reviews in a bid to expand public access to more medical devices and technologies.⁶

Evidence in 2018

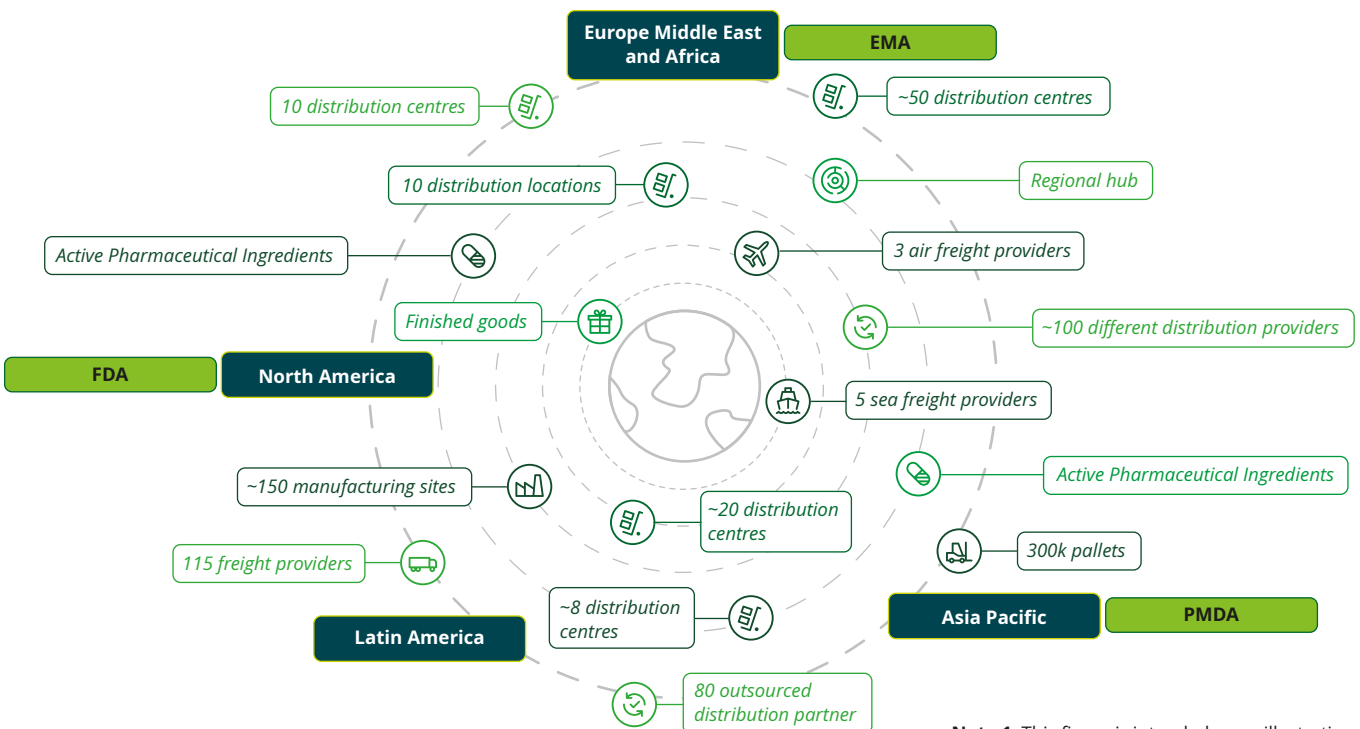
How APACMed is aiming to harmonise the regulatory landscape in Asia Pacific

Founded in 2014, APACMed brings together local industry associations, multinational, pan-Asian and local corporations, and innovative start-up companies to address the specific challenges of a heterogeneous health care landscape in Asia Pacific. It provides a unified voice and champion for advancing the industry to address the significant unmet needs of patients in the region and serve patients best. Its aim is to foster collaboration between all participants in the MedTech system, and to give them a voice and a role in shaping the future of health care. As disruptive medical innovations – from AI to augmented reality, mobile health and big data – exact a profound transformation in health care across the value chain, its role is to support industry's ongoing needs.⁷

The African Medicines Registration and Harmonisation programme

Kenya, Rwanda, South Sudan, Tanzania and Uganda are currently implementing the African Medicines Registration Harmonisation (MRH) programme. The MRH programme, supported by the World Bank, aims to improve public health by increasing rapid access to good quality, safe and effective medicines by reducing the time taken to register medicines. This includes joint product evaluation and registration and GMP inspections. The region is also working towards cooperation and collaboration in GCP inspections, clinical trial control oversight and information sharing. Furthermore, at the end of 2017 a delegation of Heads of Agencies from the East African Community (EAC) met with the EMA to learn more about how the EMA operates, to assess whether the same model could be adopted in East Africa through the creation of a regional medicines agency.^{8,9}

Figure 2. Illustration of the complexity of a global life sciences manufacturing which crosses geographical and regulatory boundaries



Note 1. This figure is intended as an illustration of the complexity of regulating a life sciences supply chain and does not include all of the components

2025

2 Regulatory relationships are based on a 'win-win' data driven approach

Industry sees regulatory functions as a strategic asset and has developed the skills to collaborate effectively with regulators.



Prediction Regulators, patients and industry (including non-traditional health care players) work closely together, sharing 'real-time' data to enable faster review and feedback. Regulators have created a digital platform for more 'self-regulation' moving management of risk closer to those affected by it. Regulation is outcome-based, data-driven and segmented, using advanced analytics to detect new patterns and trends, to ensure that products are safe, effective and personalised. This iterative approach enables products to get to market sooner. Industry has responded by creating its own regulatory pathways (as the creation of innovative products continues to outpace the ability of regulators to classify them). Industry has also invested in acquiring the skills and talent needed to improve its collaboration and negotiations with regulators.



Key features of the world in 2025

- As pharma and medical device companies endeavour to keep up with market demand, they have formed trusted partnerships to help them comply with the maze of complex regulations, and have optimised the use of new technology, especially automation and data management solutions, to ensure more effective compliance.
- Regulators are fostering innovation using accelerators (partnerships with private companies, academic institutions, and other experts) and 'sandboxes' (controlled environments that allow innovators to test products, services or new business models without having to follow all the standard regulations (see Figure 3).
- The regulatory functions use unified Regulatory Information Management (RIM) technologies and have adopted a common RIM model.
- Companies have aligned their Compliance Risk Management strategy with their business strategy, seeing compliance as an enabling function.
- Regulatory functions have become an agile and integrated part of their company, helping to bring products to market faster, and to manage and maintain compliance with increasing regulatory complexity.
- Automation has become a game changer for regulatory functions: a significant proportion of reporting is automated.
- Compliance professionals have moved their focus from hindsight to foresight and insight, to support business growth. Compliance is seen as a positive return on investment rather than a cost of doing business.



Key enablers

- A shared set of objectives among regulators, payers and patients has had a critical impact, increasing the success of drug development and speed of market access.
- Engagement among diverse stakeholders using digital 'omni' channels has helped build trust and emphasised the importance of collaboration.
- The regulated functions within industry have acquired new cognitive, analytical and data science skills and talent to match the expectations of regulators, providing real-time data for regulators, creating alerts, and predicting adverse events.
- The cyber security team within the regulatory function is now more closely involved with product development, procurement and sales.
- In order to tackle the skills and capacity gap, regulatory functions use a combination of outsourcing and a return to in-sourcing and automation, to undertake compliance activities in the most efficient and cost-effective way.
- Master Data Management (MDM) has been universally adopted, providing a cleaner path to regulatory compliance and end-to-end business oversight.
- Both regulators and the regulatory functions use AI, neuro-linguistic programming (NLP) and behavioural analytics to: interrogate high volumes of data and unstructured information to drive risk identification and process enhancement; enhance compliance monitoring, detection and response; and enable effective evidence-based collaboration.



Portrait of a regulator in 2025

The regional regulator, Reg X, has introduced a more adaptive regulatory framework to keep up with the pace of innovation and enable fast approval for ground-breaking products. This includes adopting a risk-based approach to regulating novel products to assess the degree of granularity required to monitor them. It has also created separate divisions for more specialist products, to ensure appropriate approval while safeguarding against threats to patient safety. By recruiting data scientists and behavioural analysts, Reg X has been able to increase the speed of regulatory approval and encourage a more predictable approach to the development of breakthrough therapies. In establishing platforms for self-regulation, Reg X has improved the quality of innovative products and the speed in reaching the market, and at the same time is working with other regulators to develop a co-ordinated response for handling products from non-traditional players that have entered the life sciences market.



Portrait of the industry in 2025

Two years ago, Meditech and PharmaC merged to form the loMT companion diagnostic and pharma company – Digipharm. This enabled the more traditional PharmaC to utilise the skills and expertise that had played such a large part in the growth of Meditech. Digipharm now takes a more digitally-enabled participative approach to compliance and is helping to speed up R&D. Digipharm has established effective collaboration with regulators to implement its framework for developing innovative products. Digipharm has also entered into a partnership with a large tech company to leverage its brand, engineering and customer service skills, to improve the understanding of patient behaviour and expectations in relation to participating in clinical trials. This improved approach to patient centricity has increased the willingness of patients to share real-time data, enabling the company to drive innovation in 4P medicine. This in turn has improved Digipharm's relationship with Health Technology Assessment bodies and enabled it to obtain quick approval on reimbursement of new products.



Portrait of a patient in 2025

Jake has been diagnosed with heart failure and has been fitted with an implantable cardiac device. This new recently-authorised SaMD is powered by AI-enabled algorithms, and is used to augment clinical decision-making by providing real-time data to his clinicians and also greater assurance to the patient around his diagnosis, the management of his condition and his response to treatment. Jake also uses a behavioural health app to help him adjust his lifestyle and improve his health outcomes. Jake shares the data from his connected medical devices with regulators and industry more securely, efficiently and effectively to help the cardiac device maker develop enhancements to the product, which will hopefully help maintain his care should his condition deteriorate. Jake also takes part in a regulator-run patient advisory group, providing input to the approval process for new medtech products.

Evidence in **2018**

How the FDA's new regulatory framework for the Software Pre-certification pilot programme could enable a degree of self-regulation

Initiated in July 2017, the aim of the Precertification programme is to develop a regulatory framework, based on collaboration between industry and regulators, which assesses the safety and effectiveness of software technologies without inhibiting patient access to these technologies. The ultimate goal is for industry to lead the charge and 'self-regulate'. As part of the pilot scheme, the FDA selected nine companies (out of 100 that applied) to participate in the Precertification programme, ranging from Apple Inc. and Fitbit to more traditional health care players such as Roche and Johnson & Johnson. The selection criteria required companies to demonstrate a culture of quality, organisational excellence and performance monitoring for their software-based medical products. The end goal is that 'Pre-certified' companies should then either market their lower-risk devices without additional FDA review or follow a faster marketing submission process. Companies in the pilot programme are expected to provide feedback to help the FDA refine the proposed regulatory model and influence new regulations, iron out problems and ensure that new regulations and guidelines are fit for purpose.¹⁰

How the EMA's single gateway for parallel consultations with HTAs is helping to improve re-imburement decisions

In July 2017, the EMA introduced a single gateway for parallel consultations between the EMA, the European Network for Health Technology Assessment (EUnetHTA) and health technology assessment (HTA) bodies. The aim is to help developers generate optimal and robust evidence that satisfies the needs of both regulators and HTA bodies, by providing developers with simultaneous feedback on their plans for generating evidence to support decisions on marketing authorisation and reimbursement of new medicines. These consultations can take place before or after the product is made available on the market. The procedure has four stages: simultaneous submission (of letter of intent to EMA and EUnetHTA), pre-submission, evaluation and advice/outcome. This initiative replaces the parallel scientific advice procedure for EMA and HTA bodies which required medicine developers to contact the HTA bodies of member states individually. Patient representatives and health care professionals also participate in the parallel consultation procedure on a routine basis, so that their views and experiences are incorporated into discussions.¹¹

How the US Medical Devices Innovation Consortium's process is improving assessment and review

In 2012, the US established the Medical Devices Innovation Consortium (MDIC) with representatives from the FDA, NIH, CMS, industry and not-for-profit and patient organisations to improve processes for the assessment and review of new medical technologies. The FDA has partnered with the MDIC, and they have used their joint expertise to overcome capability and capacity hurdles while also fostering a better working relationship with industry. A key accomplishment of this partnership has been the publication of the Patient Preference Framework Report in 2015, which informed subsequent FDA guidance. In Europe, a similar shift is apparent with the SPOR task force, made up of industry representatives, regulators and third party SMEs, which has contributed to the development and implementation of the ISO IDMP standards in the EU.¹²

How the FDA's Medical Device Safety Action framework is recalibrating its evaluation of benefit and risk

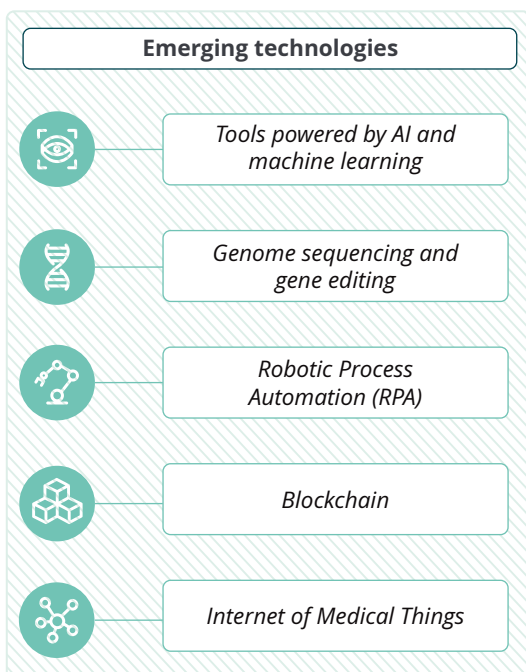
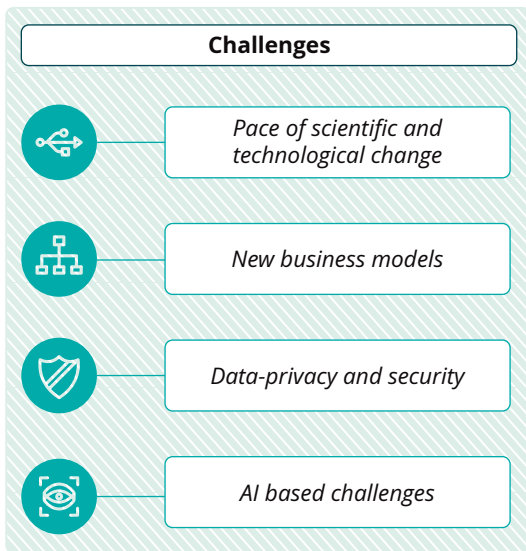
Released in April 2018, the FDA's Medical Device Safety Action Plan recognises that safety regulation is not just about how the use of a device could harm patients, but also how lack of access to a device could also be harmful. The new framework therefore recalibrates the FDA's evaluation of the benefit-risk balance in its regulatory decision-making and outlines how the FDA aims to encourage innovation to improve safety, detect safety risks earlier and keep doctors and patients better informed. It incorporates initiatives to encourage device companies to improve their products continuously and move quickly to implement controls in response to benefit-risk changes. It also tightens further the oversight of device cybersecurity. Central to the new plan is expansion of the National Evaluation System for Health Technology (NEST) to improve surveillance, signal management and post-market studies. In addition, it also proposes:

- an alternative 510(k) clearance route to expand the current requirement for data to show that a new device meets or exceeds the level of performance of appropriate predicate device(s).
- a new 'total product lifecycle' (TPLC) office within the device centre.
- a Unique Device Identification (UDI) programme promoting use of real-world evidence to support product approvals.^{13,14}

Evidence in 2018

Figure 3. Current disruptors and five principles for rethinking regulation in an era of rapid technological change

Disruptors



Future of Regulation



Source: Deloitte Center for Government Insights analysis.¹⁵

2025

3 Regulators successfully balance rapid innovation with real-time regulation

New data-driven approaches enable faster regulatory approvals, better sharing of risk and value to patients.



Prediction Regulators now expect real-world evidence (RWE) to support decisions for approving new drug applications (NDAs), label expansions and revisions. The increasing reliance on data collected outside the controlled environment of clinical trials has led to the creation of new evidence frameworks and the

development of new skillsets and capabilities within regulatory bodies. RWE has provided industry with opportunities to address evidence gaps, resolving a number of issues that had previously proved difficult, unethical or cost-prohibitive to address in randomised control trials (RCTS) and post-launch surveillance. This, together with significant advances in biological data and computing power, has resulted in the regulatory approval of treatments for numerous rare diseases and conditions that had previously proved elusive, like dementia and other neurological diseases.



Key features of the world in 2025

- Pharma companies have incorporated patient genetic and genomic information into clinical development programmes, to drive a better understanding of diseases.
- Complex precision oncology trials now harness massive computing power with comprehensive information and advanced analytics to design and execute complex, data-driven clinical studies. Using these data has increased clinical trial efficiency, bringing therapies to market faster.
- New sensors, software, and automation have enabled pharma companies to track, monitor, and verify products throughout the supply chain in line with their serialisation requirements.
- The Unique Device Identification (UDI) requirements have made it possible to apply new class-based regulations to medical devices, clarifying the mandatory changes needed for development, testing, reporting, and marketing.
- The use of adaptive trial designs and innovative endpoints (like minimal residual disease in hematologic cancers) are now commonplace, as a way to evaluate drug efficacy in dementia instead of using improvements in cognition and function.
- Schemes that enable regulators to foster innovation and speed up regulatory approval have been implemented universally, enabling them to divert their attention to other critical areas of the regulatory process.



Key enablers

- Regulators have upgraded their skill sets and created data infrastructures based on intense global collaboration.
- Regulators have clarified which kind of data can be used for the different kinds of regulatory decision-making.
- Blockchain technology is used to verify the origin and veracity of data submissions and ensure an audit trail of the data.
- While challenging regulators initially, industry's innovative development of new medicines, new treatment modalities, advanced therapies, connected medical devices, and point of care diagnostics has encouraged them to develop a new and more open regulatory mind-set.
- Collection of vast amounts of data, often from disparate sources, has made possible the transformation of treatment in many therapeutic areas. Data is now stored on cloud platforms allowing different authorised parties to access the data.
- New guidelines have streamlined and modernised oncology trials, fostering a more patient-focused approach, including extending the ages of patients eligible for clinical trials, more flexibility in designing studies, and clarification of when placebo controls should be used.



Portrait of a regulator in 2025

The regional Drug Regulator Authority (DRA-B) has adopted technological advances for evaluating clinical research and development submissions. As a result it is now pioneering approval of precision medicines that produce improved patient outcomes in targeted populations. DRA-B is using predictive data analytics and tools to identify appropriate governance approaches, and it is using AI programmes to spot abnormal patterns very quickly, target suspicious activity and provide insights into the scale and size of the activity. DRA-B has also improved its approach to protecting intellectual property and patient data when establishing regulations to promote innovation and prevent misuse of data. Moreover, technology-based solutions for the management of small data sets have enabled the development of therapies for rare/orphan diseases. Additionally, in working with payers and industry to shape an adaptive real world trial DRA-B were able to bring to market a therapy for a rare cancer which would otherwise not have been economically viable to develop treatment for in the previous regulatory environment.



Portrait of the industry in 2025

PharmaZ has recently received early approval for a new gene therapy oncology drug that was developed using new technologies and strategies that have revolutionised innovative drug development and approval. For example, most pre-testing was done using an organ on a chip model: this was significantly faster and less expensive than animal testing. Phase 2 testing was also sped up using computational models and a virtual population, reducing costs and development time. Both elements of development were approved by the regulator. The use of RWE throughout the drug development phase gave insights into how the drug might work and how patients might be expected to respond. Overall, PharmaZ was able to shorten development time, allowing the drug to reach the market sooner. R&D costs were also around two-thirds of the average cost across the industry. Industry professionals with extensive regulatory experience have been instrumental in creating realistic protocols while satisfying complex and evolving regulatory requirements.



Portrait of a patient in 2025

Amal was diagnosed with epithelial lung cancer in 2020 and underwent surgery and radiotherapy in an attempt to remove all the cancer. Unfortunately, Amal's cancer returned, with further tumours appearing in late 2022. Following two courses of chemotherapy over the following months the cancer was judged to be terminal. In 2023, Amal was offered the opportunity to participate in the latest immunotherapy trial. Researchers use naturally-occurring tumour-infiltrating lymphocytes (TILs) to treat a group of cancers termed 'common epithelial cancers', which together account for a significant percentage of all deaths due to cancer, mostly from metastatic disease. The first step in this approach to treatment, first pioneered in breast cancer, was to DNA sequence the tumour. In Amal's case the researchers identified numerous mutations in the lung tumour cells. The second step was to isolate TILs, which are present naturally in 80 per cent of epithelial cell tumours, but in tiny amounts not substantial enough to attack the tumour. The tumour cells were grown outside of Amal's body to boost their numbers, and then injected back into the tumour to tackle the cancer. After the treatment, all Amal's tumours disappeared, and 12 months later he is still in remission.

Evidence in **2018**

How a new approach to the evaluation of trial outcomes could benefit the treatment of Alzheimer's disease

Alzheimer's disease is extremely complex. Between 1998 and 2017, there were 146 unsuccessful attempts to develop medicines to treat and potentially prevent Alzheimer's. In that same timeframe, only four new medicines were approved to treat the symptoms of the disease. Alzheimer's nevertheless remains an extremely active area of research even though the failure rate in clinical trials over the past decade exceeds 99.6%. Meeting regulatory requirements is a key challenge. In recognition of this, the FDA announced in January 2018 that it would use biomarkers to approve medicines before patients show any signs of the illness (instead of requiring evidence that a drug alleviates symptoms). Its new draft guidelines outline four categories for the design and evaluation of clinical trials of Alzheimer's, recognising advances in understanding of the disease. The FDA noted that while biomarkers may not "reasonably" predict an actual benefit, its aim is to support innovation by providing encouragement to researchers and patients. As of April 2018, America's biopharmaceutical research companies were investigating or developing 92 potential treatments (18 were in phase III and another 36 wherein phase II).¹⁶

Why the FDA has approved the use of modelling and simulation

In June 2018, the FDA announced the introduction of new scientific domains into the development and review process, including the more widespread use of modelling and simulation, greater use of RWE in the pre- and post-market setting, and the adoption of better tools for collecting and evaluating real-time safety information after products are approved. The initiative also includes engaging sponsors earlier in the development process to ensure that trial designs are efficient and structured in the most effective way for identifying risks and measuring benefit. Equally important is ability to engage external stakeholders, such as disease specialists, academic researchers and regulatory partners at other agencies. In addition, ongoing relationships and interactions with patient groups are becoming an important part of FDA regulatory practices.¹⁷

How the FDA's guidelines are aiming to modernise and expedite clinical trials

During 2018, the FDA issued a number of new guidelines aimed at streamlining and modernising oncology clinical trials. The guidelines aim to foster a more patient-focused approach, extending the ages of cancer patients eligible for clinical trials, allowing more flexibility in designing studies, and providing clarification about when placebo controls should be used. The FDA has also issued guidance on master clinical trial protocols and efficient trial design strategies to help expedite the development of oncology drugs and devices. Other new guidance has also been issued on the use of adaptive trial designs, and innovative endpoints like minimal residual disease in hematologic cancers.¹⁸

How the FDA is encouraging the use of novel medication-assisted treatments for opioid users

In August 2018, the FDA issued new scientific recommendations to encourage more widespread innovation and development of novel medication-assisted treatments (MAT) for opioid use disorder (OUD). Draft guidance outlines new ways for drug developers to measure and demonstrate the effectiveness and benefits of new or existing MAT products. Regular adherence to MAT helps patients gain control over their use of opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse. MAT, combined with relevant social, medical and psychological services, is a highly effective treatment for OUD. Additionally, patients receiving MAT reduce by half their risk of death from all causes. The FDA is championing efforts to identify new ways to gauge success beyond simply whether a patient in recovery has stopped using opioids, such as reducing relapse overdoses and infectious disease transmission. This new guidance shows how innovators can use these clinically relevant measures as part of new drug development programmes. The new draft guidance also identifies several additional potential clinical endpoints and other measured outcomes that drug developers may consider.¹⁹

Evidence in 2018



Why the EMA is creating specialist divisions

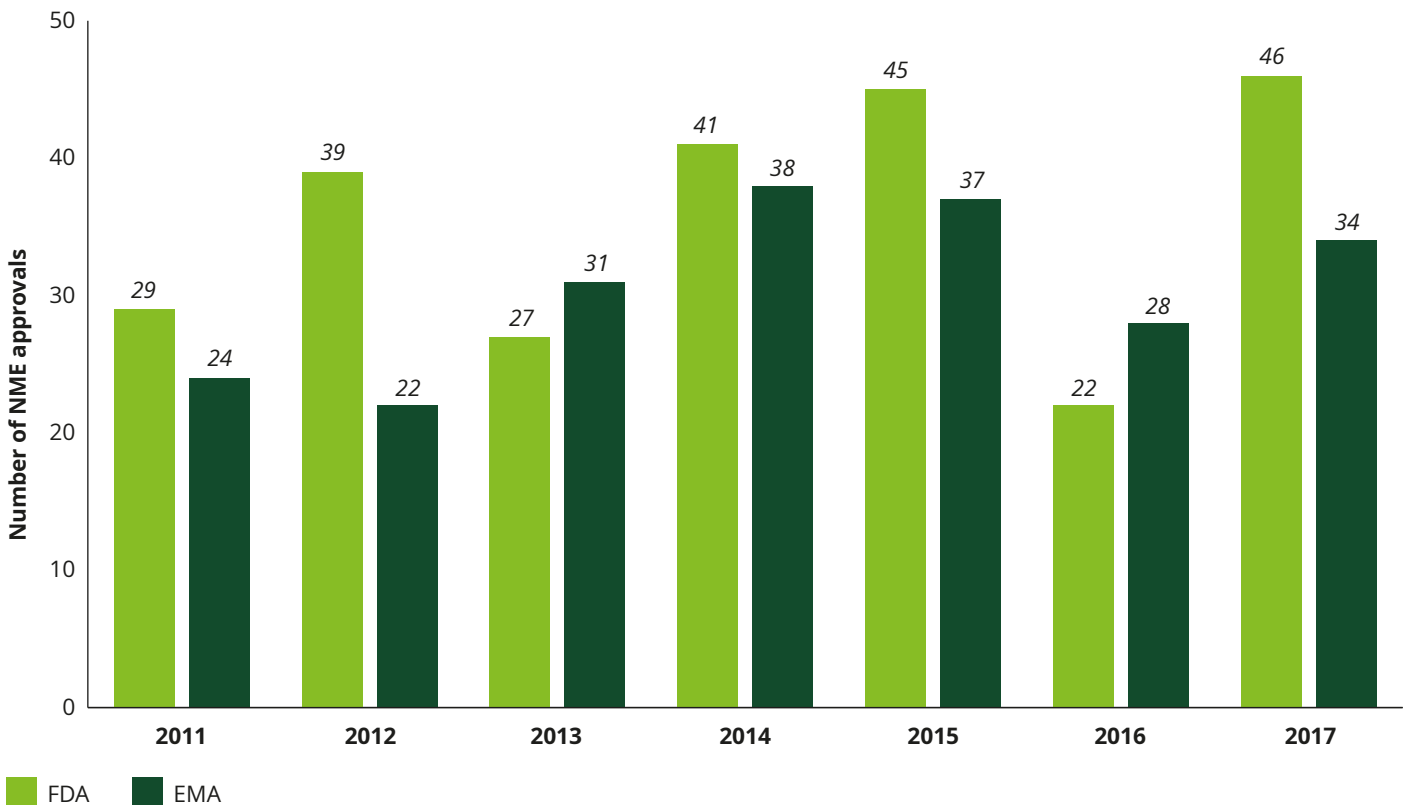
Due to the increasing complexity of medicinal products on the market, regulators are now creating specialist divisions to assess and monitor these products. To support the authorisation of advanced therapy medicinal products, the EMA's Committee for Advanced Therapies (CAT) assesses the quality, efficacy and safety of products and then submits an opinion to the Committee for Medicinal Products for Human Use, to inform its decision about market authorisation.²⁰ In March 2018, the EMA granted central marketing authorisation to Alofisel (developed by Takeda), the first allogeneic stem cell therapy to be centrally approved in Europe, following endorsement by CAT. The product was seen to provide an alternative and less invasive treatment for patients with complex perianal fistulas in Crohn's disease who were not responding well to existing treatments.²¹



How 2017 represents a new high for drug approvals

In 2017 the FDA approved 46 new drugs. Of these, 36 were considered specialty therapies; and 15 were first-in-class (see Figure 3). These new drugs marked significant advances in the treatment of cancer, inflammatory diseases, multiple sclerosis, and rare (or orphan) diseases, with almost 40% of the novel drugs being designated as orphan drugs. In addition, 2017 saw the first of three gene therapy approvals. The FDA Commissioner noted that these approvals represented "a whole new scientific paradigm for the treatment of serious diseases."²²

Figure 4. Number of new molecular entity approvals as a measure of product innovation



Source: FDA, 2018; EMA, 2018

2025

4 A technology-enabled approach is driving the productivity and quality of regulation

Advanced technologies and robotics have improved the efficiency and speed of regulatory activity.



Prediction Regulators and industry have both adopted next generation ('4th industrial revolution') technologies to automate processes and help improve the speed and quality of regulatory oversight.

Technology is enabling regulators to process the large amounts of data available to them to make faster, better decisions and take regulatory action where there is a perceived issue with product safety or efficacy. Regulators and industry are working together more closely via the sharing of 'real-time' data, enabling faster review and feedback on clinical trials using real world data.



Key features of the world in 2025

- Regulators have successfully balanced assessment of rapid innovations with real-time regulation. MHealth apps, wearables and artificial intelligence (AI) technologies are used as standard in clinical trials, to streamline processes, enhance data capture, produce real-time data, improve patient experience, and reduce costs.
- Digital platforms for sharing data and working together between industry and regulators are fully established, creating a new age of transparency and trust. Companies have streamlined their systems and clinical, regulatory, and quality processes to eliminate functional siloes and improve compliance efficiency across the product development lifecycle.
- Organisations benefit from streamlining processes across global sites, suppliers, contract manufacturers and other partners, and have leveraged cloud technology to drive greater efficiency and visibility across quality processes.
- Companies use workflow management technology and automated processes to enable expert engagement, improve compliance controls and provide more efficient operations.



Key enablers

- Regulatory processes have been standardised and automated, giving new clarity to the regulation of new technology-enabled interventions and the pre-certification and breakthrough approvals of products.
- New software tools are driving productivity improvements in regulatory filings.
- Digitisation of the supply chain has helped industry improve the post-authorisation track and trace of products with digital supply networks, using machine learning and blockchain to remove risks associated with product security (e.g. tampering).
- Acceleration of connectivity and cognitive technology has improved the productivity and nature of compliance work, with jobs in the compliance functions re-invented or automated, and new roles created.
- AI applied to social media and connected medical devices, automatically monitors reports of adverse events and compliance with therapies.



Portrait of a regulator in 2025

DRA-C has alleviated resourcing pressures using RPA to improve the productivity of repetitive processes. Digital technology is used to monitor both structured and unstructured data from multiple sources: this alerts DRA-C to any discrepancies or adverse events in a timely way. DRA-C uses AI to monitor progression through clinical trials, enabling faster approvals; and advanced cognitive analytics are now an integral feature of monitoring and inspections, identifying patterns of non-compliance and enabling regulators to target their efforts cost-effectively. DRA-C has put in place blockchain mechanisms to use with data sources from regulators across the globe. The use of blockchain has helped provide assurance over data submissions in clinical trials, the quality and safety of supply chains, and have helped detect falsified medicines. Modelling and simulations are used as standard to evaluate trials, using biomarker-enriched populations. DRA-C has secured access to cloud-based data from Software as a Medical Device (SaMD) companies.



Portrait of the industry in 2025

PharmaK has made the regulatory affairs lead accountable directly to the Board for the use of next gen technologies. PharmaK now uses automation of dossier compilation to reduce the time and cost of the marketing authorisation applications process. It also uses AI to identify any anomalies in dossiers and rectify them before submission and NLP to translate dossiers for multiple applications. Automation has been implemented across the supply chain, improving the speed, accuracy and quality of regulated activities. Blockchain's custody and serialisation capabilities have enabled real-time tracking of the control, transfer, management and distribution of medicines. Automation has also made it easier to create an audit trail, improving compliance and decision-making. Data obtained by way of advanced search and contextualising capabilities has improved knowledge management. Overall, PharmaK has mastered pre- and post-authorisation information management leveraging AI and business intelligence capabilities.



Portrait of a patient in 2025

Mari has a rare progressive disease and has been equipped with a SaMD to enable her to communicate more effectively with her clinician, improve her compliance with her medication instructions, and help her to manage her health. By registering with an online patient portal that recruits people with rare diseases, Mari has been enrolled into a new clinical trial. Her membership of an online community of people with similar diseases has also helped her understand the role of regulators, which in turn has helped improve her confidence in the safety and effectiveness of the technologies that she comes into contact with. Perhaps more importantly, the support she receives has given Mari confidence to agree to receive her regular blood infusions in the safety of her own home, cutting the number of visits she has to make to hospital. Her experience in using the SaMD and her on-line community have helped improve both her digital and health literacy, and she has recently agreed to participate in her local regulator's patient panel.

Evidence in **2018**

How the use of electronic pre-market submissions is intended to speed up approvals

In September 2018, the FDA announced a new pilot programme to simplify pre-market reviews. The FDA's Quality in 510(k) (Quik) Review Program pilot is intended to establish a standard form for 510(k) applications using the agency's eSubmitter software for pre-market submissions: eSubmitter formats the applicant's submission into a zip file, which should be copied to a CD, DVD or USB. Quik Review Program pilot participants are asked to include a cover letter with their submissions clearly stating that they are participants in the programme and so are not required to provide paper copies of their submissions.²³

How collaboration between regulators and the medtech industry is promoting the development of medical devices to manage pain effectively

Regulators are collaborating with industry in order to promote innovation. The FDA's Center for Devices and Radiological Health has initiated a challenge for companies to develop new medical devices for managing pain, in order to tackle the opioid epidemic in the US. Selected developers will engage more frequently with the Agency throughout development and evaluation of their product, and the product will receive breakthrough device designation if it meets the necessary criteria. As well as tackling the opioid crisis directly, this will quicken the process for developing innovative products, by engaging regulators actively throughout the development of the new devices.²⁵

How the automation of adverse event follow-up by AstraZeneca has improved response rates

AstraZeneca's Patient Safety Teams (AZPST) currently manage approximately 100,000 adverse event reports annually. Legally, pharmaceutical companies are responsible for following up with health care professionals to gather further information on the event and to form their benefit-risk evaluation, which is then reviewed by regulators. In 2016, AZPSTs adverse event follow-up process involved writing letters and emails to patients and physicians, and documenting this information. However, Deloitte partnered with AstraZeneca over six weeks to develop a fully validated, industry-first RPA solution for automating adverse event follow-up. As a result, valuable resources were freed up to focus on value-adding activities, and job satisfaction was improved within the Patient Safety Teams. In addition, the RPA solution has an improved response rate from health care professionals, and AstraZeneca are now able to manage an increased workload without threatening quality or compliance, or increasing costs.²⁴

How the use of blockchain is being used to track and trace the security of drugs in the supply chain

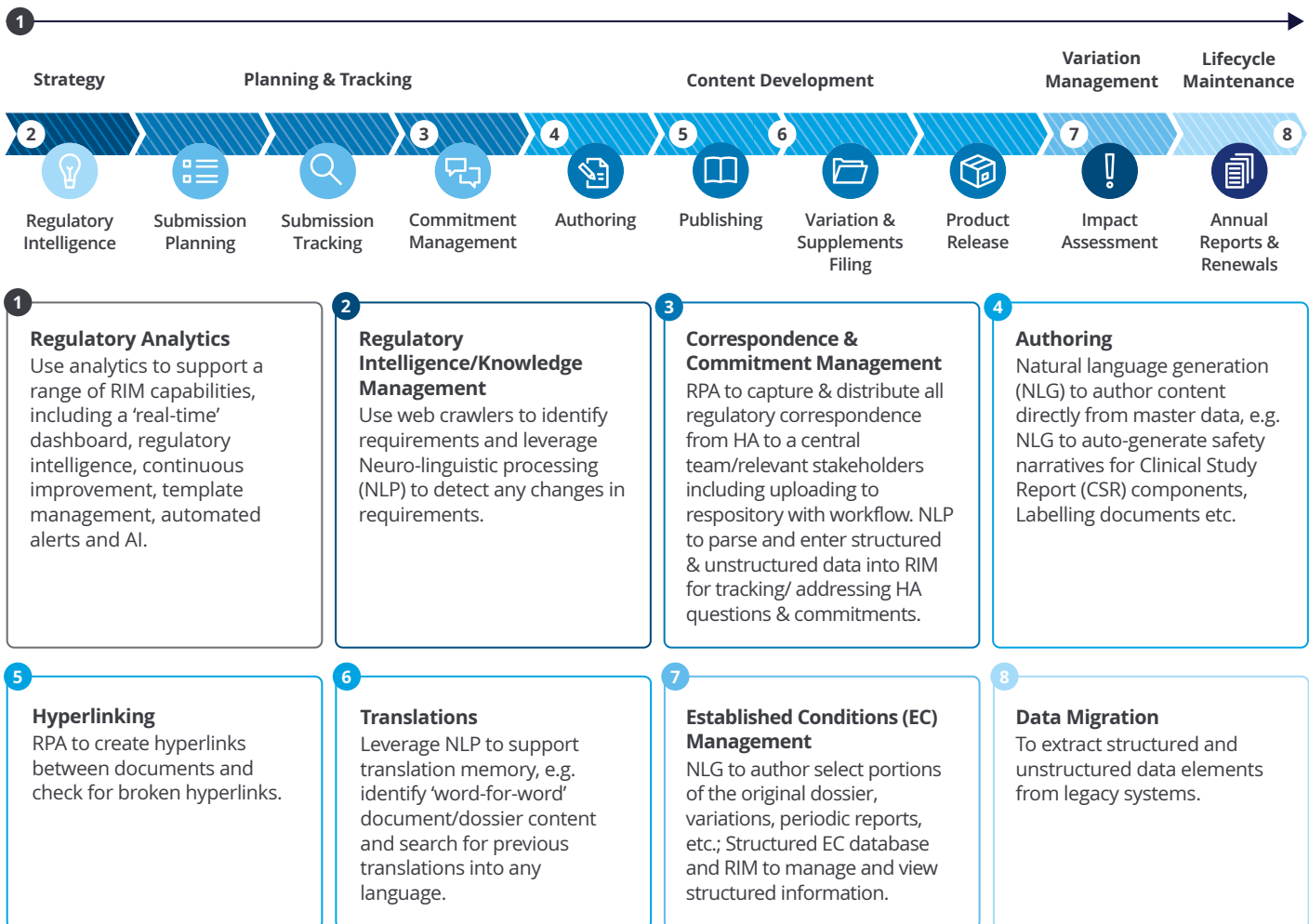
Intel Corp. has partnered with a number of life sciences companies, including Johnson & Johnson, to use blockchain to track and trace where drugs are falling out of the supply chain. Intel is also looking to use blockchain to tackle the opioid epidemic, by identifying when a patient takes out multiple prescriptions from various physicians, a practice known as 'double doctoring'. This would work by means of a pharmacy scanning a drug when it is issued to the patient and uploading the prescription on to the blockchain register. If this were to be universally adopted in the US, it would be possible to detect individuals obtaining multiple prescriptions for opioids.²⁶

Evidence in 2018

How the use of tools to monitor the completeness of clinical trial submissions is improving transparency

A key concern around the lack of data transparency is the failure to disclose fully or in a timely manner the results of clinical trials. AllTrials is a campaign, set up in 2013 and run by the charity Sense about Science, to lobby for all data around clinical trials to be published. To help promote this, they set up a tool that identifies which trials have not fully submitted all their data on to the US registry (ClinicalTrials.gov), to assist the FDA in issuing fines. The tracker, which went live in February 2018, identified fines of \$578,450 within five days. In addition, AllTrials has set up a Transparency Index, ranking pharmaceutical companies on their clinical trial policies. The Index has been applied to pharma companies, and there are plans to expand its use to non-industry players that perform clinical trials. There is an equivalent EU site called the EU Trials Tracker that monitors which companies are compliant with posting summary results of clinical trials to EMA's EudraCT database. This could assist regulators in streamlining their investigations around clinical trials (see Figure 5).

Figure 5. Opportunities across the regulatory end-to-end value chain for improving the speed, accuracy and quality of regulatory activities



Source: Deloitte LLP, 2018

Conclusion

Our four predictions draw on insights provided by our Global Centre of Regulatory Excellence, supplemented by an in-depth review of relevant literature and discussions and debate across our global life sciences business. We also drew on research by the Deloitte Center for Government Insights.²⁹

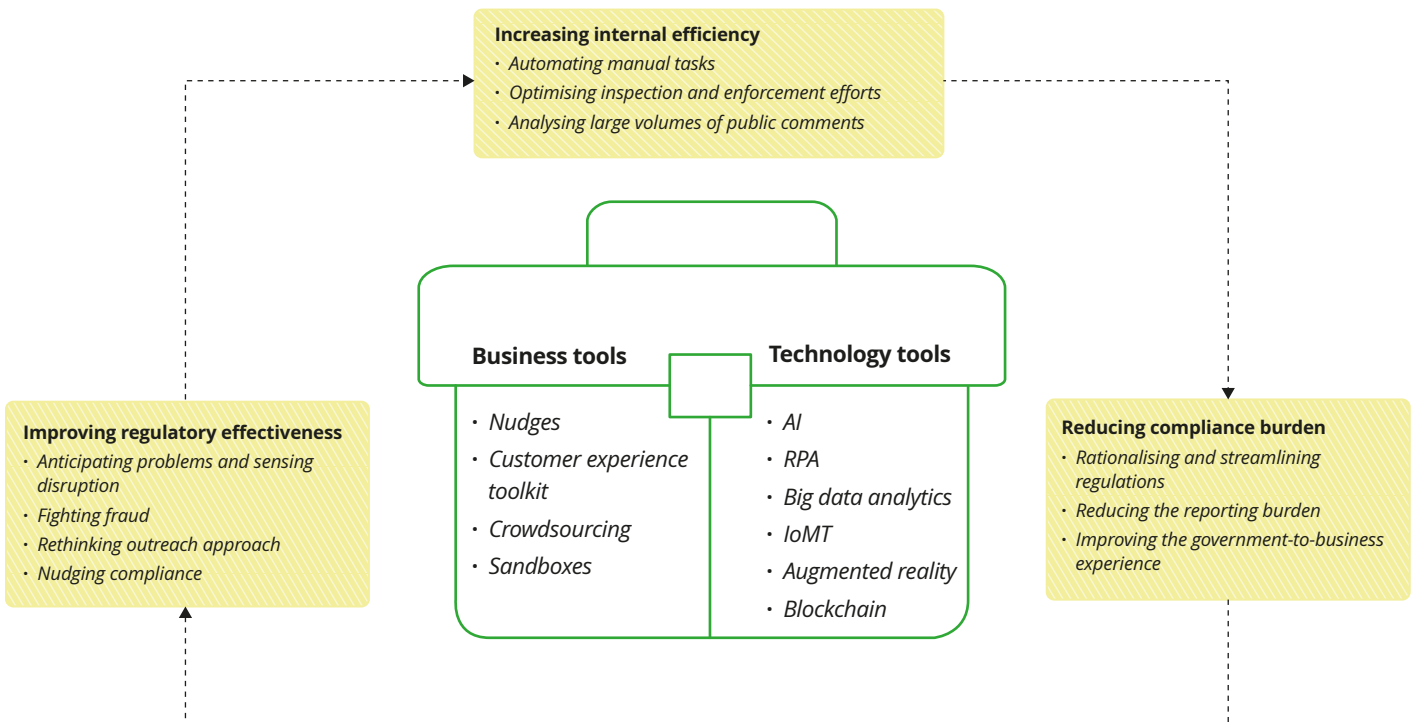
Today's regulatory environment is changing rapidly. This poses significant challenges for life sciences regulators who are striving to maintain a balance between fostering innovation, protecting patients and addressing the consequences of innovation.

There are three operational challenges policymakers and regulators need to address to deliver an effective approach to life sciences Regulation 4.0. These include:

- increasing internal efficiency of regulators
- reducing the compliance burden
- keeping pace with scientific and technological advancements
- improving the effectiveness of the regulatory process.

Adopting appropriate technologies can also help regulators automate and speed up their processes, improve their effectiveness and deliver a more streamlined approach that meets the needs of patients and industry (See Figure 6).

Figure 6. How technology based tools drive the economy, efficiency, and effectiveness of regulatory operations



Source: Deloitte Centre for Government Insights analysis

By 2025, we foresee that regulators are likely to adopt a more collaborative and consistent approach to regulation globally. As well as alliances between regulators, it is likely that regulators will take more of a partnership approach with industry leaders to drive quality and transparency. In order to take advantage of this, industry should:

- take steps to standardise global operations to facilitate regulatory convergence
- increase transparency of operations and data to showcase to regulators the benefits of partnerships, as well as improve public trust in the organisation
- transform culture, processes and operating models to embrace the newfound interconnectivity of the regulation.

This will put industry in a strong position to implement a regulatory intelligence solution, to not only improve regulatory self-assessment and third party assessment, but also act as a major source of improvement and innovation.

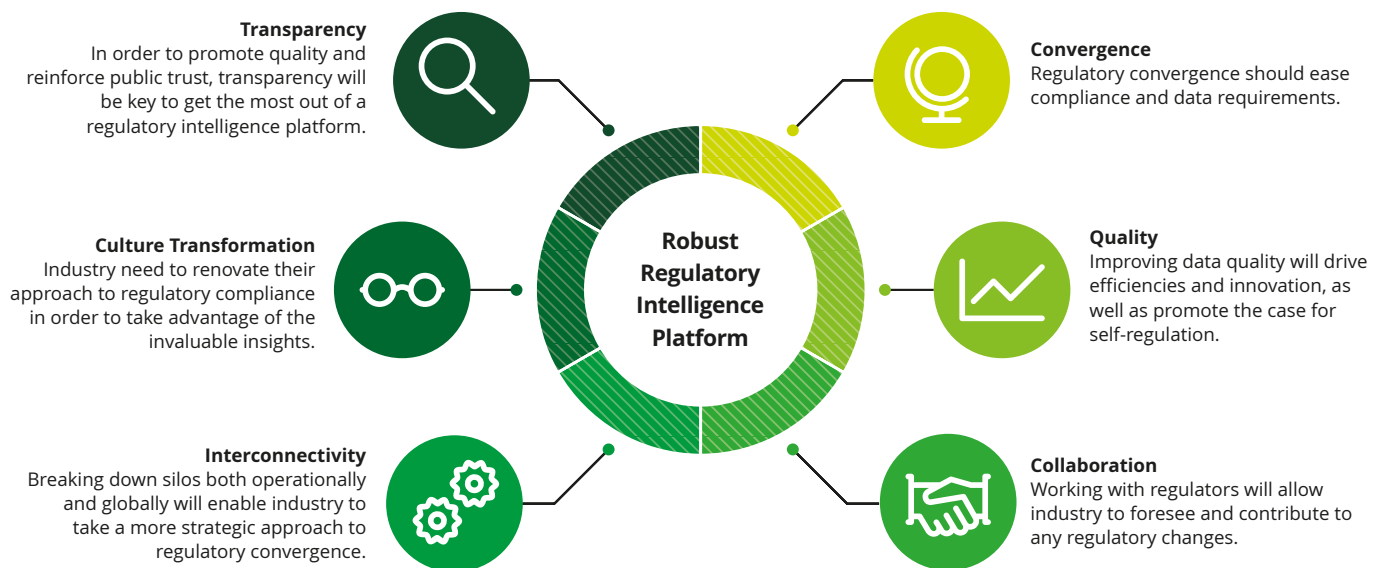
A strong foundation for regulatory compliance will drive both efficiencies and quality, and improve the reputation of the industry with all stakeholders. Figure 7 demonstrates the key factors necessary to implement a robust regulatory intelligence platform.

Although we recognise that our four predictions are an optimistic view of what the life sciences regulatory landscape might look like in 2025, we contend that the vision it presents, while ambitious, is achievable. However, this will require regulators and industry to embrace the following three key enablers:

- wide-scale adoption of new digital and cognitive technologies
- recruitment and retention of new skills and talent
- streamlined and agile regulatory systems and processes.

These enablers are critical for realising each of our predictions, and the speed of adoption will inevitably impact the pace of change.

Figure 7: Key factors for a robust regulatory intelligence platform



Source: Deloitte LLP, 2018

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