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Innovation in regulatory

Accelerating drugs to market with AI

Innovation in regulatory

Regulatory processes in pharmaceutical are crucial to the safe and effective use of medicine but are costly and can delay the launch of new and improved treatments to market. Here we describe some of the challenges in regulatory and show how artificial intelligence (AI) can enhance and accelerate these processes with real examples.

Paul Walsh and Linda Ringnalda

Accelerating treatments to market with automation and AI

The COVID-19 pandemic has highlighted the urgency of bringing new medications to market. However, the development of new treatments must be carried out in compliance with stringent regulatory checks and balances, in order to ensure that new medications are developed and administered in a safe and effective manner. This places a huge workload and cost on the pharmaceutical industry, which is one of the most regulated manufacturing sectors [1]. Stringent regulation can also delay the launch of new treatments to the market.

- **Innovation is in the DNA of the pharmaceutical industry, which has transformed human health, well-being and longevity.**
- **Yet the pharmaceutical industry is burdened with complex regulatory compliance obligations.**
- **Innovation is now being applied to ease the regulatory process using AI.**

Here we discuss how innovation can be used to alleviate this load while maintaining safety and compliance. We highlight that, while innovation in other regulatory industries is gaining traction, there are barriers to innovation in the pharmaceutical sector. We show how these barriers can be overcome and demonstrate how Accenture can address pharmaceutical regulatory challenges with innovative and transformative automation and AI.

Researching innovation in pharmaceutical regulatory

A team of analytics experts, software engineers, researchers and Fjord designers at The Dock—Accenture's flagship Research and Development (R&D) and global innovation center in Ireland—spent over six weeks investigating this topic with our pharmaceutical industry clients.

We compiled this study on the current state of regulatory in pharmaceutical from the perspective of stakeholders in regulatory affairs, drug labeling, promotion and CMC (chemistry, manufacturing and controls).

The findings were tested in a series of innovation sessions with a wide panel of healthcare experts and numerous clients at The Dock, and we presented the work to a series of international pharmaceutical clients during a series of sessions at The Dock from September 2019 to February 2020.

Their feedback was used to validate and refine the findings that are presented in this document.

Background

New Year's Eve is, for many, a time of hope and optimism. However, on December 31, 2019, prospects for the coming year were frustrated when health authorities in China first reported an outbreak of viral pneumonia cases of unknown cause in Wuhan China. As of August 10, 2021, more than 108 million cases of COVID-19 have been reported in more than 192 countries and territories, resulting in more than 4,306,398 deaths [2].

COVID-19 has pulled into sharp focus the ever-present need for humanity to develop safe and effective treatments, not only for viral infection, but also for a wide range of health conditions. Throughout history, researchers in the pharmaceutical sector have discovered and developed numerous wonder treatments, ranging from penicillin to AZT[1]. Scientific innovation drives the industry, and as science has changed, so has the way we innovate. New Science, a dynamic combination of the best in science and health technology that is filling unmet needs with more precise and effective treatments, is driving rapid change [3]. Our research has found that New Science is projected to drive 81% of biopharma revenue growth and 61% of all revenues between 2021 and 2026.

Yet developing new treatments can be fraught with danger, as past lessons have shown. As a result, government agencies around the world have put in place many regulations that must be strictly complied with to ensure the development of safe and effective treatments.

Such regulations are critically important; however, they have the side effect of slowing the delivery of new treatments to market while simultaneously contributing to the enormous cost.

The regulatory process typically starts at the R&D and pre-clinical development phase, where regulatory teams determine not only the need for a submission to the relevant regulatory authorities, but also the type of submission, timelines and the content required for the submission. Dedicated teams focus on keeping up to date with the health authority's requirements, which are constantly changing, and interpreting and applying these requirements to their regulatory process.

During the clinical development phase, regulatory teams receive the required documents by the research teams. They check these documents for submission readiness, identifying missing components, page orders, structure and content issues.

This is a complex and manual process, and the role of regulatory teams is to make sure the clinical trial application and the subsequent generated data meet the needs of the health authorities and that there are continuous conversations with health authorities to communicate any changes on safety, protocols and investigators.

The marketing application phase is perhaps one of the key phases in the drug approval process, where regulatory teams compile a drug application in the form of a submission dossier. The authors of the source documents approve the submission content, and final versions are locked down and internally published for quality control.

In most cases, an electronic common technical document (eCTD) is populated and submitted to the health authority. The eCTD is a structure and specification for the transfer of regulatory information developed by the International Council for Harmonization (ICH). If necessary, documents are translated into other languages.

Finally, the regulatory department keeps track of any changes made to the submission document during the health authority review period, as well as categorizing the correspondence and maintaining, updating and managing subsequent filed submissions in a regulatory information management system after the initial health authority approval has been received.

Failure to comply with these regulations can have direct and indirect impacts. Direct costs, such as fines and other quantifiable costs, can be significant for pharmaceutical companies, while indirect costs, such as reputational damage, can have long-term consequences [4]. Indeed, the internal regulatory processes at large pharmaceutical companies are complex, with constant and continuous iterations.

Many pharmaceutical companies are outsourcing this complete process, leading to an 11.5% increase of the regulatory outsourcing market from 2014 to 2023 to an enormous $5.7 billion [5].

We therefore consider if innovation within the regulatory sector can bring about a reduction of both cost and time to market, while maintaining accountability, traceability and patient safety.

Azidothymidine (AZT), is an antiretroviral medication used to prevent and treat HIV/AIDS.

Regulatory technology

Regulatory technology

Key questions

- What are the barriers to innovation in pharmaceuticals?
- How can pharmaceuticals overcome barriers to innovation?
- What areas of regulatory are most open to innovation?

Many heavily regulated industries are embracing regulatory innovation, most notably in the financial sector. This is driven in part by the financial crisis of 2008 and by the increased focus on fighting financial crimes, such as fraud and money laundering.

Emerging technologies such as AI, machine learning, cloud computing and robotic process automation (RPA) provide new ways of enforcing compliance, and the financial industry is rapidly leveraging these technologies.

"The confluence of significant regulatory and technological changes over the past few years has created incentives for firms to rethink how compliance functions operate."

Financial Industry Regulatory Authority

https://www.finra.org/sites/default/files/2018_RegTech_Report.pdf

Financial institutions have also increased their focus on developing end-to-end solutions for regulatory management over the past years, with top-tier global banks integrating artificial intelligence to detect actionable components in new and updated regulations. This new industry, combining regulatory and technology, is called RegTech, which focusses on using information technologies for regulatory monitoring, reporting and compliance [6], [7], [8]. However, up to now, it has been mainly focused on financial compliance, whereas its application for compliance in the pharmaceutical space is less developed.

This raises the question: If technology and innovation are having an impact in the financial world, how can we realize similar benefits in the pharmaceutical sector? While progress is taking place in the financial industry, what barriers to innovation does the pharmaceutical industry face, when similar incentives are applicable?

"RegTech has two aims: increasing the effectiveness and the efficiency of compliance. Both are critical."

Tom Graham
Managing Director – Accenture, Banking, UK & Ireland

https://bankingblog.accenture.com/regtech-what-is-it-what-are-benefits

Barriers to RegTech innovation in pharmaceuticals

While the pharmaceutical industry has similar drivers to the financial services industry in terms of effectiveness and efficiency, there are significant underlying differences between them, and they face different issues when adopting new technologies. The finance sector is essentially focused on the management of virtual assets, whereas the pharmaceutical sector has to deal with physical constraints and would suffer greater impact due to production downtime. The following are some of the issues faced by those attempting to bring innovation to the pharmaceutical industry:

Four factors that impede innovation

1. **Complexity**
2. **Resistance**
3. **Risk**
4. **Scarcity**

1. Complexity: The timeframes and processes within pharmaceuticals are known to be complex. In-house complexity and specificity of processes are significant obstacles for bringing about change in any regulated industry. Due to silos in the pharmaceutical industry, organizations have fragmented data, making it difficult to create fully integrated, data-driven solutions [9]. However, the emergence of integration technologies is now starting to have an impact on these problems. Accenture is recognized as the world leader in systems integration (SI) [10]. At The Dock, we work closely with our clients to integrate new solutions to existing processes and IT infrastructure to ensure a seamless experience for users.

2. Resistance to change: Change management in any corporate situation is fragile and costly. The pharmaceutical industry is facing a curious dichotomy of forward-thinking leaders working in a world of legacy systems and processes. Moreover, in recent years, the pharmaceutical industry has faced a lot of challenges, and employees are weary of change. Over the past few years, the industry has experienced budget pressures, increasingly complex stakeholder environments, greater difficulties in securing market access, expiring patents, closer scrutiny, more stringent regulatory requirements, changing communication methods and a great amount of M&A activity. It is therefore no surprise that employees experience something called “change fatigue.” People become saturated with change and experience a sense of helplessness and lack of direction [11].

Therefore, low-impact, step-by-step changes are often preferred over highly disruptive systemic change. So, when change brings about new technologies, this should be done in a manner that is inclusive with all stakeholders. In the Dock, we include all stakeholders affected by new technologies early in the ideation and development process, identifying their specific pain points so that new technologies

3. Risk: Pharmaceutical leaders fear that implementing new and, sometimes untested, technologies could cause an increase in compliance and consumer safety issues compared to legacy systems. This includes the costs for remediation, product recalls and the possibility of not getting new approvals. Together, these costs can easily be over $100 million [12]. Another important factor of being non-compliant is the consequent audits and controls, where the investigation of batch records, control reviews and certifications can easily lead to another $100 million in costs. Penalties by regulators can be as high as $500 million and can cost $15,000 per day for non-compliance [4].

Litigation is another non-compliance risk, where costs can be as high as $1 billion should a typical fault be observed in a newly automated process [12]. Consumer backlash would also be significantly damaging to both revenue and brand [4].

The goal of any AI or automation initiative should be to eliminate and mitigate such risk by carefully enhancing existing processes to protect consumer safety. In The Dock, we carefully map out the existing "as-is" process and examine each step carefully to gauge how new technologies could enhance the process. This allows us to focus on key points that can be improved using technology while at the same time preserving tried-and-trusted stages. We also pilot new innovations with key stakeholders, ensuring that the proposed innovation has maximum and welcome impact. The overall effect of this approach is to eliminate risk from the process, not to increase it.

Tapping the brakes:

Risk-aversion is an impediment to progress.

As noted, 72% of companies believe digital will drive success in achieving strategic imperatives...

Two-thirds of respondents believe an aversion to risk is preventing them from fully embracing digitalization.

Yet only 36% of companies are adopting digital as a key strategy in R&D.

In companies with market caps about $10B, that number jumps to 75%.

Accenture survey of 250 global pharmaceutical and biotechnology leaders to understand the state of digitalization in biopharmaceutical R&D
https://www.accenture.com/us-en/insights/life-sciences/driving-digital-biopharma-rd

4. Talent scarcity: As the industry innovates, new talent is needed to transform and maintain regulatory processes. This is not only true for traditional pharmaceutical roles, but also for new skills such as artificial intelligence, machine learning, data analytics and cloud computing. The pharmaceutical industry is not only facing change fatigue amongst its employees, but also a talent shortage across all facets of its industry, both old and new. There simply aren't enough skilled people available to fill this talent gap, and pharmaceutical companies struggle to attract talent with new technological skills, as they are competing with other industries to attract this talent.

Moreover, in a complex and siloed industry like pharmaceuticals, losing talented employees can be absolutely devastating due to the knowledge that is lost when they leave. Many of the complex processes in pharmaceuticals are only fully understood by those who have been there for long periods of time due to a scarcity of detailed operating procedures and historical documentation. However, these issues can be mediated using technology such as knowledge management and AI-based information retrieval systems, where current and future knowledge can be stored safely. For example, in chemistry, manufacturing and controls (CMC), we use innovative AI to allow regulatory affairs teams to mine CMC knowledge to rapidly answer queries from regulators.

All these issues can be distilled down into four factors that stifle innovation: complexity of processes across siloed functions, resistance to change by stakeholders, the perception of risk and the scarcity of talent and know-how to bring about innovation. While these factors can impede innovation, we have shown that they are surmountable through the considered design of inclusive AI-based systems. Next, we will call out some of the drivers that are pushing for regulatory innovation.

Drivers for change

While there are barriers to innovation, there are also many forces that are acting as accelerators of innovation.

Since the financial crisis of 2008, regulators in that sector have brought about more complex regulations. In the years after the financial crisis, the fastest and easiest way to keep up with all the regulations was to put more people on it. However, as we now have a talent shortage, automation and digitalization is the only viable way to automate regulatory workflows. Consequently, the financial industry has been keen to innovate due to the regulatory restrictions put on them as a result of the 2008 financial crisis. For these reasons, the financial services industry is ahead of the pharmaceutical industry when it comes to innovation in their regulatory processes [13]. Perhaps the current COVID-19 pandemic and rising healthcare costs will provide a similar impetus, driving the appetite for innovation in the pharmaceutical sector.

Fortunately, there has been a shift in the relationship between regulation and innovation in the pharmaceutical space. Where regulation and regulators used to be seen as a barrier to innovation, new types of practice and new ways of thinking are helping to demonstrate the important role regulators and regulation play in enabling socially, environmentally and economically valuable innovation. Regulators are starting to explore how business-led innovation can help them achieve their objectives by delivering regulatory interventions that support or even stimulate innovation.

Indeed, both the EMA and FDA are innovating the way they regulate the pharmaceutical industry. The FDA recognized the need for internal change in response to increasing expectations from the pharmaceutical industry, public demands and technological advancements to keep pace in the 21st century. The current text-driven regulatory submission approach makes it difficult for the FDA to assess quality and risk. As a solution, the FDA is developing the KASA system, which will be data driven and aimed to modernize the quality assessment of drug applications. This new system will be a huge step forward in the way regulatory submissions to the FDA are conducted. Instead of piles and piles of documents, data can be taken straight from pre-clinical trials and other steps in the drug-development processes.

In the European Union, the way clinical trials are conducted will undergo a major change when the Clinical Trial Regulation—Regulation (EU) No 536/2014—comes into application. This harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System (CTIS). CTIS will contain a centralized EU portal and database for clinical trials. The European Medicines Agency (EMA) will set up and maintain CTIS in collaboration with the Member States and the European Commission. All these innovative steps taken by the regulator means that the pharmaceutical industry must innovate at a similar pace to the health authority for these new measures to be beneficial to them. This way, regulations have a positive effect on the innovative process in the industry [14], [15].

"We've had to modernize our overall approach to regulation to effectively advance the kinds of innovations that are becoming available. This includes modernizing how we organize our medical product review programs. These initiatives are part of our comprehensive Medical Innovation Access Plan."

Scott Gottlieb, M.D., FDA Voices

https://www.fda.gov/news-events/fda-voices/fdas-comprehensive-effort-advance-new-innovations-initiatives-modernize-innovation

Not only do regulations affect innovation in the industry, but technical innovation can also have a major impact on regulation, as is the case when technological advances render certain regulations obsolete or outdated [16].

Regulators seem to be aware of this, and the EMA announced that one of their key goals for 2025 is to catalyze the integration of science and technology in medicines development. This includes facilitating the implementation of novel manufacturing technologies in the drug development process. For the regulator, this would require the recruitment of talent with fitting skills to allow for the assessment of these novel technologies.

"The regulatory science strategy to 2025 aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine."

Guido Rasi, EMA's Executive Director

https://www.ema.europa.eu/en/news/regulatory-science-2025-launch-six-month-public-consultation

Cost driver

Of course, cost is a major driver of innovation. In 2008, it cost $802 million to put a new drug on the market. These costs increased by 145% to $2.6 billion in only 10 years, the same amount of time it takes to get a new drug to the market, on average [17]. This rise in costs echoes the increasingly stringent regulatory requirements, such as the length, complexity and volume of clinical trials per marketing application. These regulations ensure the safety, efficacy and quality of treatments and are required by health authorities, such as the FDA. As a result, the regulatory process and the related cost play a central role in driving innovation [18].

AI solution

One potential approach to enhancing and streamlining regulatory processes is by innovating new approaches that exploit technologies, such as AI. Recent studies show that the use of AI in the pharmaceutical industry is increasing, with a projected market volume reaching $10B by 2024 [19].

> **"Accenture conducted a large enterprise systems study in 2019, showing a high correlation between technology adoption and revenue growth. Leaders in the Life Sciences industry have an AI adoption rate of 96%, compared to the bottom 25% of the industry."**
>
> https://www.accenture.com/us-en/insights/future-systems/future-ready-enterprise-systems

In the next section, we will illustrate how AI is already transforming a number of processes within the regulatory space in the pharmaceutical sector.

Innovating AI

Despite the many challenges, real innovation in regulatory is already happening through the use of automation and artificial intelligence (AI) [20], with further studies identifying regulatory intelligence as a major use of AI in the pharmaceutical industry [21]. A 2018 report from the Artificial Intelligence Consortium, which consists of health authorities, NGOs and industry regulatory professionals, calls out opportunities for the use of AI in the regulatory space. They highlight the use of AI based on natural language processing (NLP) for extracting complex information on regulatory intelligence from unstructured text. For product characteristics, summaries and CMC (chemistry, manufacturing and controls) documents, AI can assist regulatory and health authorities in their decision-making processes and would allow the pharmaceutical industry to prepare submissions more rapidly. NLP has also been recognized as providing an opportunity for automatically importing information from health authority guidelines into regulatory intelligence systems. AI tools will allow regulatory specialists to assess the compliance of material across marketing authorizations [22].

AI techniques have also been shown to have potential for processing and managing drug-related information, including the extraction of terms related to adverse drug reactions (ADRs), which are unwanted effects caused by the administration of a drug [23]. ADRs are in the top 10 leading causes of death and cost approximately $75 billion annually in the United States [24].

AI innovation case studies

AI innovation case studies

Key points

- Analytics and AI can positively impact the regulatory process
- AI can support submission to regulatory authorities
- AI can aid review and audit of regulatory material
- The art of the possible: Identification of Medicinal Product (IDMP)

At Accenture, we have real-world experience in innovating AI solutions for regulatory challenges. These solutions were brought about through extensive consultation with our clients culminating in workshops where we carefully analyzed their regulatory processes. This was done with a wide range of client stakeholders, including C-suite, regulatory, business and technology teams. This allowed us to assess the effectiveness of existing processes and the identification of client pain points, which led to an extensive list of features where AI could positively impact the process both in terms of efficiency and reliability. A program of research and development was carried out in our global innovation center, The Dock, where prototyping, experimentation and validation with clients was carried out to refine and optimize the solutions. These include solutions for drug labeling, promotional materials and CMC (chemistry, manufacturing and controls).

AI for drug labeling

The production of drug safety information is carried out in a labeling process, where teams of medical, legal and regulatory specialists track the latest data on medicinal products, so that accurate material relating to the indications, directions, dosage, side effects and other safety information is presented on consumer packaging and information leaflets. The safety information associated with these leaflets and packaging are known as drug labels, and serious health issues can arise for consumers if the information on drug labels is not accurate or if it is not up to date.

Regulators, such as the FDA, enforce rules to ensure that drug labels contain a summary of essential scientific information needed for safe and effective use of the human prescription drug or biological product, which must not be inaccurate or misleading and must contain up-to-date information [25].

While adherence to these rules takes considerable effort, the cost of non-compliance includes fines, penalties and seizure of product [26].

In addition, once a medicine is in the market, it must undergo constant surveillance through clinical trials and the monitoring of potential adverse drug reactions. This can result in label changes several times each year across multiple markets, and these changes must be designed, reviewed, approved and implemented, which are time-consuming processes [27].Therefore, drug product labels often lag behind emerging drug knowledge, as it may be a number of years since the drug was first released to the market [28].

This can lead to real issues, for example an analysis of 9,105 drug product labels found that significant numbers of multi-manufacturer treatments and generic treatments had discrepancies in the adverse drug reaction (ADR) sections of the labels due to missing and outdated information and formatting issues [29]. ADRs are among the leading causes of mortality, and such drug-related morbidity is estimated to cost approximately $136 billion annually [30].

Studies have also found that drug product labels failed to keep up to date with the latest findings from scientific research and clinical trials. Issues included deficits in the pharmacokinetic data listed in product labels [31], omissions in age-related product label information in antidepressants [32], quantitative information missing in 92% of 50 renal drug products [33] and deficits in drug-drug interaction information in 15% of the product labels for treatments that interact with warfarin [34].

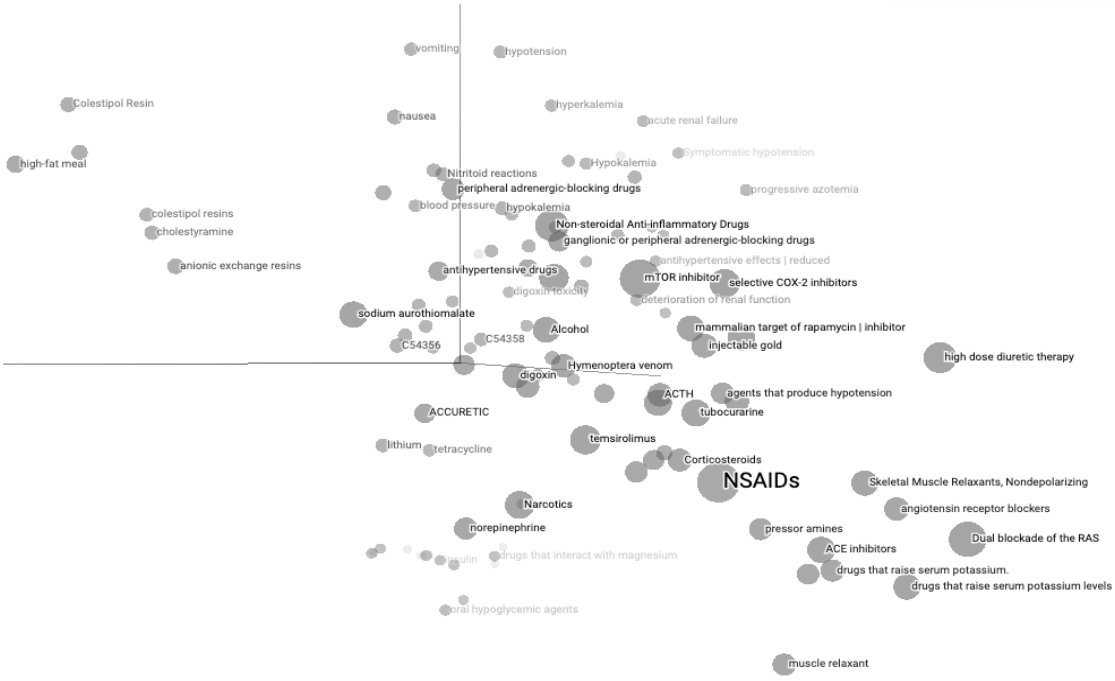
Software integration and structured document authoring plays a role in addressing these issues by maintaining the integrity of information across the labeling process; however, there is still an enormous level of manual effort involved. Therefore, human and system failures can still lead to inaccurate safety information.

Our natural language processing techniques offer a solution for processing and managing drug-related information, including the extraction of relevant clinical terms. For example, regulators, such as the FDA, mandate that label information for approved treatments should include observed and predicted, clinically significant drug-drug interactions (DDIs) [35]. Our platform can analyze and extract DDIs from unstructured drug label text, identifying treatments and detecting the relationships between them—essentially putting meaningful structure on unstructured text. We then use this structured output to build a knowledge graph of interacting substances using Ampligraph, a machine learning tool developed by Accenture's Tech Labs that creates deep learning graphs. These graphs aggregate related drug label knowledge into a data structure that serves as a basis for detecting missing drug information and recommending suitable drug interactions. For example, the following text is taken from an open-source data set of drug labels:

Do not co-administer quinapril hydrochloride with aliskiren in patients with diabetes. Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors or aliskiren is associated with increased risks of hypotension, hyperkalemia and changes in renal function (including acute renal failure) compared to monotherapy…

Our deep learning technology scans this text and automatically classifies it into the appropriate category, classifying treatments, drug classes and the relationships between them. The creation of structured knowledge from unstructured text allows us to use Accenture's Ampligraph technology to build knowledge graphs, augmented by medical dictionaries, which can then be used to run complex queries that can reason over this data. For example, we can assess the relevance of phrases to a given drug by computing a similarity score, which can be interpreted geometrically as to how related a term is to the drug of interest.

Driven by our machine learning algorithms, the system can automatically suggest the relevance and accuracy of generic phrases, such as "treatments that raise serum potassium levels" for given drug labels.



AI in chemistry, manufacturing and controls

Bringing a new medication to market also involves the submission of documentation relating to its chemistry, manufacturing and controls (CMC). However, pharmaceutical manufacturers face an ever-expanding diversification of their organization and are encountering new levels of complexity and speed across R&D. It's a priority for them to transform their CMC knowledge processes to become digitally enabled, globally connected powerhouses capable of breakthrough innovation at scale.

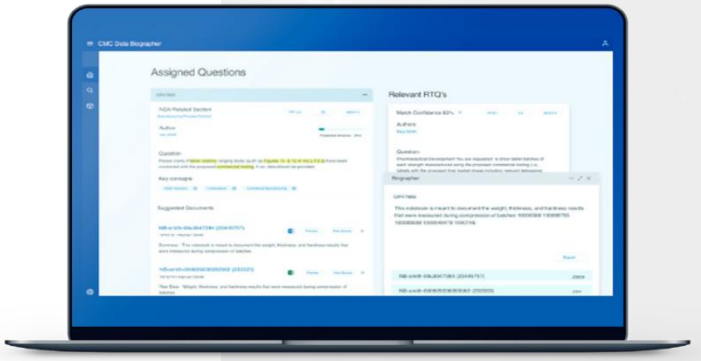
Legacy processes can create divisional disconnects between research and manufacturing organizations. This results in archaic knowledge sharing practices and laborious ways of working for scientists across the drug development process.

A primary example exists in the regulatory authoring process, where challenges with knowledge sharing can limit the ability to get a product to market as quickly as possible and in the hands of patients that need them. Regulatory documentation is based on diverse information sources across a wide range of development process steps. Submitting documentation to health authorities can also result in repetitive cycles of review, feedback and response between pharmaceutical companies and regulators.

To increase the efficiency of this process, enablers such as structured content management systems for collecting, distributing and assessing regulatory information are being developed. However, much of the data currently within CMC processes is in the form of unstructured text along with diverse sources of semi-structured information. At Accenture, we are bringing innovation to this space using AI that can structure and query such data.

To address these challenges in CMC, our global innovation team at The Dock engaged closely with our pharmaceutical stakeholders who are working on the frontline of regulatory compliance, through a series of innovation workshop sessions. The Dock team worked with experts from regulatory, research and manufacturing to understand CMC regulatory work processes and uncover key pain points and root causes. We then co-created with the client on a prioritized set of future state features that can address pain points and create new value. Semantic search across databases, the ability to match past response to queries (RTQs) with suggested relevant documents were among the key features prioritized.

We designed a future-state experience, including AI-assisted workflows to empower scientists and regulatory affairs specialists when formulating responses to health authority questions. We developed innovative AI techniques that retrieve information highly relevant to an RTQ, including the extraction of tables and figures pertinent to the questions asked by regulators. This type of intelligent semantic search allows regulatory affairs teams to quickly find the relevant information needed to respond to regulators' questions and supplement these responses with important quantitative data. The prioritization and planning of RTQ responses are also facilitated by our algorithms, which provide estimates on the effort required, in person hours, to answer questions from regulators.



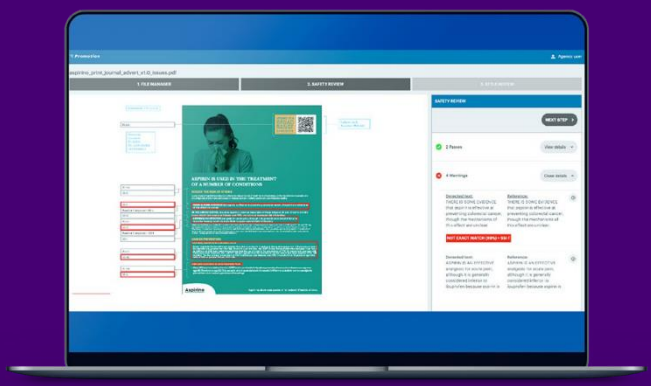
AI for promotional materials

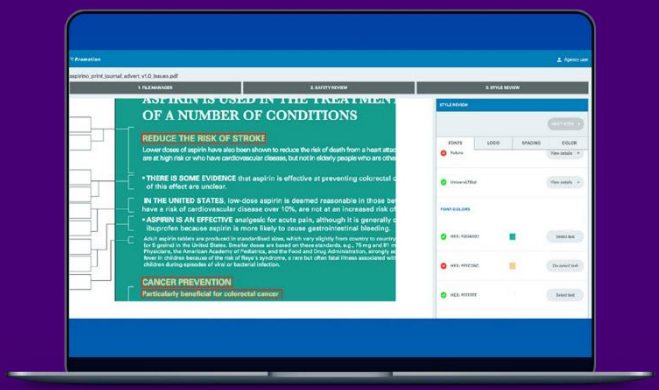
Regulators also strive to guard public safety by ensuring that drug marketing material is accurate through comprehensive surveillance and compliance activities. Pharmaceutical companies are also highly protective of their reputation and brand. Damage due to misleading information on promotional material can include injury to patient safety, costly fines, withdrawal of product and irreparable reputational damage. To safeguard against these risks, industry and health authority regulatory professionals invest enormous effort in complex, labor-intensive processes. Moreover, the volume of information that must be processed and the rate of progress in drug development means that both industry and regulators are faced with increasing workloads.

The volume of information is even higher in the case of “blockbuster” treatments, which have approval to go to market but are still technically in the final phase of clinical trials. This is already happening with advanced treatments, such as immunotherapies, and will likely be the situation with any high-impact treatments such as a COVID-19 vaccine. Stakeholders wish to bring such treatments to market quickly and effectively, so pre-approval is likely in such situations. This means that follow-up clinical trials will be ongoing, and new findings will need to be rapidly propagated to drug labels and promotional materials. AI can now assist in achieving compliance for drug labels and promotional materials in such challenging environments. At Accenture, we are working with clients to streamline their processes by using AI to automatically review promotional material against drug product core data sheets and brand guidelines.

For example, the screen capture (below left) from our promotion software demonstrates how marketing promotional material can automatically be reviewed against core product safety information, highlighting any discrepancies that could be inaccurate or misleading. Natural language processing is used to extract and analyze text from PDF marketing materials, and the veracity of this unstructured text is checked against a ground-truth database of core product characteristics and safety information. Any potential infringements are highlighted with detailed feedback to the user, whereby they can address and correct any inaccuracies in the text using links provided with the core product information.

The screen capture (below right) demonstrates how marketing material can also be reviewed against brand guidelines, where business rules for each product and marketing channel are stored by the system. Normally, this work needs to be laboriously carried out by regulatory promotional material specialists, who must forensically analyze all aspects of the promotion material against core information and brand guidelines. Promotional material aspects such as font, color, logo, white space, text kerning and spacing are all scanned and evaluated by our technology. For example, in the screen capture below right, the highlighted text uses a font that has not been approved in the brand guidelines for this particular product. Industry experts have confirmed that this use of AI technology can save enormous amounts of time, which would be freed up for them to work on higher value aspects of promotional material review such as medical, legal and regulatory assessment.





The art of the possible: AI for IDMP Compliance

In addition to building case studies through extensive client workshops, we also composed a theoretical case study around health authorities driving innovation in regulatory by transforming their data standards.

The intentions of various health authorities to shift towards a data-driven regulatory paradigm has never been clearer. Take the FDA's Center for Drug Evaluation and Research (CDER's) Data Standards Program, for example, that looks to support, maintain, promote and optimize data standards within the landscape [36]. Similarly, in the EU, the EMA's telematics strategy is in the works to maintain common technological services to support and bolster pharmaceutical policy and legislation [37]. The Identification of Medicinal Product (IDMP) is a new regulation that forms an integral part of the EMA's telematics strategy to facilitate the reliable exchange of medicinal product information in a robust and consistent manner through data standards. A key challenge to this is that data is often stored in many fragmented archaic systems that have unaligned formats and poor integrity. Additionally, the data may be found in unstructured formats, where extraction has proven to be a manual, cumbersome and time-consuming process [38]. It is clear that this pursuit of interoperability requires pharmaceutical organizations to adopt a proactive approach in ensuring their data is complete and reliable, and to focus on data governance and master data management not just within the regulatory function, but also across the organization [39], [40].

At Accenture, we believe AI innovation, such as robotic process automation (RPA), natural language processing (NLP) and virtual agents, have capabilities that can support data cleansing, transformation and the application of data standards such as IDMP [41]. Synergizing our deep domain expertise in the regulatory landscape and technology, we are developing a tool that leverages intelligent automation to support organizations in their journey to IDMP compliance. The solution aims to support clients in three key areas: data analysis, data extraction and data enrichment.

For example, IDMP data might be stored in a regulatory information management (RIM) system, or alternatively within a manufacturing system. Beyond identifying where the data is stored, organizations must also ensure that the specific IDMP data element is found in that system. Our solution could effectively assess data availability across various systems and categorize the data element based on subject area. How? By incorporating IDMP's data model straight into the solution. This enables the tool to quickly and accurately carry out an assessment based on the specific data source provided. What if the data is held in an unstructured source? As previously mentioned, extracting data for IDMP this way can prove to be tedious for regulatory functions. The solution is further empowered by natural language processing (NLP) to analyze regulatory documents (e.g., cover letters and summaries of product characteristics) to extract the required data for IDMP compliance, thereby creating greater efficiency. The result? Alleviating regulatory resources from manual, time-consuming activities, enabling organizations to focus on more strategic activities. Furthermore, machine learning ensures the solution evolves over time through the data it receives, improving not only its accuracy of data extraction, but also its ability to work on even more complex document types. Finally, once the relevant data is identified and extracted, the solution not only transforms the data for compliance, but also conducts an analysis and provides confidence levels for each automated output to help prioritize any remaining manual quality control efforts.

While master data management and governance are pivotal for IDMP compliance, we believe that having high quality authoritative data goes beyond simple adherence. This philosophy pivots the regulatory function from a back-end function to a highly valuable strategic asset empowered by future-state technologies to harness global innovation and reduce unmet patient needs.

Conclusion

The pharmaceutical industry has transformed healthcare; however, strict regulatory guidelines must be followed to ensure patient safety and effective treatment. This places a burden on the industry, whereby regulatory teams must ensure that information is accurately managed throughout the drug development and post-marketing process. Enhancing the regulatory process through innovation is challenging and must be done in such a way that minimizes costs while reducing risk of non-compliance. By engaging closely with the pharmaceutical industry, we have shown a number of cases where innovative AI solutions can enhance processes in a highly regulated environment.

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