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AI in Life Sciences: The Key to Tangible Transformation?

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Biography

Elvis Paćelat is the Executive Vice President, Life Sciences at AMPLEXOR (www.amplexor.com).

Elvis is a business and technology executive with more than two decades of international experience in the Life Sciences market. With detailed technical understanding and expertise in compliance and regulatory content management solutions for Life Sciences, Elvis is a specialist in business impact analysis.

At AMPLEXOR he is responsible for driving the corporate strategy and market success of the AMPLEXOR Life Sciences business. Elvis is committed to delivering benefit for clients, partners and shareholders, whilst supporting client-centric strategies and spearheading ground-breaking innovations.

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Paper type Research

Abstract

For all the talk of the need to improve organizational agility, the pharmaceutical industry hasn't found this easy because there are so many practical barriers in the way. But what if artificial intelligence and machine learning could light and lead the way, starting with simple but powerful improvements to the way companies manage regulatory information?

Introduction

It is easy for life sciences organizations to think the more adventurous end of technological innovation belongs to markets less encumbered by red tape, such as retail, hospitality and travel. But this is a risky assumption: ignoring the potential could put pharmaceutical firms on the back foot as their own market succumbs to disruption.

Artificial intelligence (AI) and machine learning are good examples. Rich in potential for accelerating and transforming patient diagnoses in healthcare, while in life sciences start-ups are already using machine learning algorithms to reduce drug discovery times. In an age of data overload, AI offers a way to find and keep teams focused on what's important – from what's being said in the market, to how routine processes are managed.

What exactly is AI?

AI takes automation and makes it smart. So whereas robots in factories excelled at doing repetitive, mundane tasks efficiently and tirelessly, with precision, AI can be programmed to carry out more complex tasks.

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Machine learning improves upon that, allowing AI-based systems to find better ways of doing things. Rather than humans having to foresee every possibility and programme a system for every eventuality, AI-based systems can learn and adapt from what they know to create effective and powerful shortcuts.

If they are faced with a deluge and range of data that would tie up a human team for days or months, machine learning systems can perform analyses and distil subtle trends that humans might overlook. In the context of pharmacovigilance they can help scour the internet for relevant patient feedback about life sciences products, or identify unmet needs or gaps in the market. Operationally, such tools can help companies navigate routine processes more promptly, thoroughly and economically, freeing up teams to use their skills where they will add greater value.

Addressing the mundanity of regulation

An obvious area where AI and machine learning can help here is in managing matters of regulatory compliance – where requirements are multiplying and changing all the time. Not only does this increase the burden on regulatory affairs and quality teams; it also potentially slows companies' time to market. Moves towards international standards, and deployment of sophisticated content management systems, go a long way towards alleviating the additional work involved and maintaining data quality. Yet, with each new regulatory initiative or submissions hoop that companies need to jump through, the business agility and creativity they are aiming for appears to become further out of reach.

The ideal for Regulatory Affairs teams is that their product lifecycle content systems will make it more intuitive to manage data changes, document authoring and reviews, quality control, and submission. Currently much of this is managed via comprehensive rules, templates and workflow which help to streamline processes and ensure that the right data is used in support of the given requirement.

But what if AI and machine learning could promote reliable shortcuts, and issue red flags or suggestions if rogue actions are taken, the wrong master data is used, or someone tries to alter approved ISO IDMP-compliant source content?

As well as freeing up skilled people's time to do more satisfying and productive work, AI could also reduce the risk of dependence on a single person's knowledge of how things are done. (If a highly skilled team member moves on, there is usually a productivity gap as their replacement gets up to speed.)

Making regulatory information management more intuitive

Life sciences firms are already harnessing more automation to streamline regulatory information processes: annual surveys[1] by Gens & Associates repeatedly show increasing sophistication in the industry's approach to regulatory information management.

We can speculate about a number of ways AI could transform regulatory information and submissions management transformation – improving the process of planning, structuring, authoring, publishing and archiving content.

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Example scenarios might include using AI to monitor and determine which content elements of a submission are routinely included, so that they become a structural component in their architecture. AI could also help ensure referential integrity, so that the correct, approved master content is reliably drawn on every time, and that protected sources (for example, ISO IDMP data) cannot be tampered without a formal change request.

Document and dossier authoring and reviews could be streamlined as AI capabilities learn to spot content that has been changed frequently in the past. Drawing on this knowledge the system could propose changes as a document is being put together, saving rounds of redrafting. An intuitive user-friendly interface combined with smart, machine-based deductions could save a lot of clicks, system navigation and time.

AI could reinforce compliance and content quality along the supply chain, too, helping to restrict what country affiliate representatives are able to do with content. Where there have been quality violations, AI could provide the analysis and insight so teams can act and prevent repeated issues. Related to this, the technology could help identify and avoid common submission queries, to prevent delays in getting products approved.

New opportunities … and issues to be aware of

As organizations start to make the connection and understand the role artificial intelligence could have in transforming their operations, new opportunities may begin to present themselves – for example, the potential to improve R&D by sharing 'learning' back along the product lifecycle.

In the meantime, there are associated issues companies will need to consider. For example, how might AI use affect the compliance processes, especially if checks have previously relied on conditions remaining static? If the AI capability is becoming an additional reviewer or actor in the workflow associated with creating regulated or regulatory content, how does this change the auditing requirements and where does responsibility lie?

None of these details are a reason to dismiss AI's potential; they merely need to be factored into the design plan. It's all part of understanding the technology's potential in the context of the challenges life sciences organizations are trying to overcome and at this stage nothing should be ruled out

Reference	
1	http://gens-associates.com/2018-world-class-rim-survey/