WHITE PAPER

Realigning Life Sciences Regulatory Compliance for the AI-Driven Era

Balancing Productivity and Privacy

Abstract

For some years now, Artificial Intelligence (AI) has been providing an opportunity for a fundamental transformation to the way businesses operate. However, it also poses unique challenges to the life sciences industry, which is a highly regulated space. As pharma companies use AI technologies for performing diagnostics and accelerating drug development and clinical research, it is important to consider the impact of the technology on the regulatory compliance function and what must be done to maintain compliance. Life sciences organizations that understand the regulatory implications and prepare themselves will be better positioned to use AI for driving maximum benefits for all stakeholders.

AI – An Evolving Technique

RTraditionally, life sciences organizations have struggled to remain compliant by satisfying the requirements of regulators. To be fair, they never had it easy given the evolving regulations, strict privacy, cybersecurity controls, huge fines for non-compliance, integrated systems across multiple geographies each under the purview of local regulations, and M&As, that always presented the need to harmonize disparate quality systems. Adding AI to the mix must not be viewed as a magic silver bullet. In fact, as much as AI helps pharmaceutical companies accelerate drug development, lower the cost of drugs and devices, and navigate the intense and always-changing regulatory environment, the obscurity of its workings sometimes raises regulatory flags.

Consider a use case - AI solution that assigns risk-rating scores to patients for a certain disease based on their lifestyle and provides recommendations for pre-emptive steps. As per the General Data Protection Regulation (GDPR), the subject has the right to understand how his personal data is being used and receive meaningful explanation for arriving at a certain treatment decision. This applies to AI and ML algorithms that depend on the growing volumes of data to operate efficiently and evolve continuously. A black box makes an AI solution less auditable and non-transparent and this does not sit well with the regulators. Therefore, an organization will need to ensure that the outcome of the AI solution meets the expectations and is not trespassing on the principles of privacy, equality, and non-discrimination. It all boils down to how effectively specifications are documented for a technique that is designed to learn and grow autonomously while ensuring continued patient safety and technical control over such solutions.

Making the existing IT regulatory universe AI-ready

Do we need a complete overhaul of the risk management framework? The answer is - No. A rational evaluation of the current practices and policies, accurate risk-profiling, and plugging of the necessary gaps with robust technical and procedural controls will serve the purpose of retrofitting AI. However, while prepping the IT framework, organizations need to consider the following:

Strategy and Governance: Strategy is the fuel driving the engine of change. Like with any new initiative, it is essential for the organization to have a clear strategy around the introduction and adoption of AI technologies. Endorsement of the leadership for AI adoption is a must.

AI needs large sets of data to make a meaningful impact and hence data management forms a core component of AI strategy. Data hygiene must be identified as a strategic objective, and with well-placed but typically considerable investment, heterogeneous data sources can be consolidated into an enterprise data lake as a single source.

Also, not all risks associated with AI will be known at the outset and some of them may manifest during implementation. Therefore, the overall strategy should be evaluated and reassessed frequently to verify its continued alignment with the organization's risk management policy.

Risk Management Framework: A methodology for identifying AI implementation risks, risk classification, acceptance criteria, and remediation processes must be designed. Also, an up-to-date common repository of applicable laws, rules, regulations, and effective corporate policies should be created to drive a robust risk management program.

Due to the evolving nature of AI algorithms, it is essential to establish continuous testing and operational monitoring to verify controls are effective and residual risks, if any, are in line with expectations. For successful uptake and confidence, end-users including professionals and patients must be able to understand and trust AI outcomes.

At a minimum, the existing framework must be revised to include guidance on aspects like:

- For a continually learning system, how and when an AI-based solution must be re-validated[1]
- Should re-validation be based on the 'level of autonomy' a solution enjoys
- Scenarios where scrutiny by a human is required
- The ways to maintain the quality of data inputs - Training and validation of data sets needs to be carefully curated to ensure it satisfies business use-cases and regulators, and avoid introducing bias or error[2]

[1] *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback https://www.fda.gov/media/122535/download*

[2] *The emergence of artificial intelligence and machine learning algorithms in healthcare: Recommendations to support governance and regulation https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bsi/nsb/innovation/mhra-ai-paper-2019.pdf*

- Metrics needed to examine and validate if the models are operating as expected
- Evaluation criteria for assessing data protection and equality (fairness)
- Principles of fairness, transparency, and algorithm accountability

Talent Management: In a global survey[3] , 68% of executives reported moderate to extreme AI skill gap and more than a quarter (27%) rated their AI skill gap as major or extreme. While organizations across the globe are investing heavily in intelligent technologies, it is imperative that sufficient investment is earmarked for reskilling people to work with these technologies. AI is a big-ticket transformation item, hence it is vital to evaluate and mitigate any adverse effect it has on the existing talent pool. Identified gaps need to be addressed with a robust and innovative learning & development model.

AI systems in regional markets may have a significant impact on local regulations, hence due diligence should be done to assess training needs at the local level.

Organizations should invest in capacity-building across the regulatory universe through knowledge-sharing platforms and forums focusing on AI/data science-related trends and applications. This learning needs to be supplemented with cross-functional expertise around key areas like privacy, cybersecurity, supplier management, ethical marketing, legal, etc.

Monitoring and Reporting: With AI adoption increasing and use cases maturing, it will be essential to monitor if the AI component is working as intended. As AI penetration in patient health and safety increases, the organization's risk exposure may also increase, and therefore, it is essential for the company to have a 360-degree view of its risk universe. Monitoring should include updating standard operating procedures (SOPs) in reaction to regulatory and legal changes occurring across markets of interest.

[3] *https://www2.deloitte.com/content/dam/insights/us/articles/6546_talent-and-workforce-effects-in-the-age-of-ai/DI_Talent-and-workforce-effects-in-the-age-of-AI.pdf*

The following additional pointers should be considered while designing a monitoring and reporting framework:

- Target KPIs
- Acceptable levels of accuracy and bias
- Exception handling
- Specific requirements for static Vs continuous learning AI solutions
- How learnings will be incorporated back into the model
- Frequency and triggers for alerts and user communication

Conclusion

In the near future, AI will arguably be the greatest opportunity of transformation for the life sciences industry with its ability to unlock innovations for maximum health impact. It promises to improve patient experience by enabling faster disease detection, developing precision medicine tailored to individual needs, and expediting new drug development process. AI when used in the pharmacovigilance space can reduce case processing costs and facilitate timely identification/reporting of Adverse Events (AEs) of pharmaceutical products.

However, the path to success is rarely straight – on one hand, AI holds big potential, while, on the other, there are justified concerns over data protection and quality, accountability, transparency, ethics, privacy, and bias. Pharma AI use cases are advancing at a rapid pace and each day adds new opportunities and risks to the mix. Regulatory compliance function will play a crucial role in this transformation with the development of policies, procedures, and practices that will allow the organization to provide services in an ethical and compliant manner while being effective and efficient in their pursuit of strategic goals.

About The Author

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Manish Malik is a IT regulatory compliance professional with the Life Sciences unit. He has over 10 years of experience delivering digital risk management & validation services for pharmaceutical clients. He also has experience handling other roles in management consulting, project management, business analysis, training planning and execution.

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