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Review Article

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Artificial Intelligence in Pharmaceutical Regulatory Affairs and Medical Science Liaison Activities: A Comprehensive Review

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Abstract

Artificial Intelligence (AI) is transforming pharmaceutical regulatory affairs and Medical Science Liaison (MSL) activities by improving efficiency, accuracy, and decision-making. In regulatory affairs, AI enables automation in dossier preparation, regulatory intelligence, and pharmacovigilance, significantly reducing human error and turnaround times. For MSLs, AI facilitates analysis of large datasets, identification of Key Opinion Leaders (KOLs), and personalized communication with healthcare professionals. Despite these advancements, challenges such as data privacy, algorithmic transparency, and bias in AI algorithms persist. This review synthesizes recent studies and provides insights into the applications, benefits, challenges, and future directions of AI in these critical domains of pharmaceutical operations.

Keywords: Artificial Intelligence; Regulatory Affairs; Medical Science Liaison; Pharmacovigilance; Regulatory Intelligence; Real-World Evidence; eCTD; Quality by Design (QbD); Machine Learning; Healthcare Data Science

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1. Introduction

The application of Artificial Intelligence (AI) in pharmaceutical regulatory affairs and MSL roles represents a paradigm shift toward efficient, data-driven practices. (1) Regulatory professionals increasingly rely on AI to automate dossier preparation, compliance monitoring, and pharmacovigilance, reducing manual workload and minimizing errors. (1,2) Likewise, MSLs use AI to synthesize scientific data, map Key Opinion Leaders (KOLs), and deliver personalized communications that enhance engagement. (3,4) Additionally, AI challenges such as explainability and ethical transparency must be addressed to ensure safe adoption. (9) This review evaluates research outcomes and highlights practical implications for regulatory and medical affairs teams. (5)

1.1 Artificial Intelligence in Pharmaceutical Regulatory Affairs

AI has emerged as a transformative tool in regulatory affairs, particularly in automating dossier preparation, which is traditionally labor-intensive and prone to errors. (1) Systems such as Watson for Drug Discovery analyze large scientific datasets to extract relevant regulatory information, accelerating submission timelines. (2) Evidence suggests that AI integration reduces preparation time by up to 30% and submission errors by nearly 20%. (1,2)

AI also strengthens regulatory intelligence by monitoring global regulatory updates using natural language processing (NLP). (3,4) These tools continuously scan regulatory agency websites, scientific databases, and global guidelines to identify relevant changes.

Pharmacovigilance is another area where AI provides significant benefits. Machine-learning models analyze clinical trials, electronic health records (EHRs), and social media data to detect potential adverse drug reactions more rapidly than traditional methods. (5) AI systems can identify safety signals up to 25% sooner, improving patient protection and post-marketing surveillance. (5)

1.2 Artificial Intelligence in Medical Science Liaison (MSL) Activities

AI supports advanced data analysis and evidence synthesis, enabling MSLs to generate insights more efficiently. (6) Automated literature mining and meta-analysis tools enhance scientific communication and improve scientific engagement.(6,7)

AI also assists in KOL identification by analyzing publication metrics, citation strength, conference contributions, and scientific influence. (7) Studies show a

30% improvement in engagement outcomes when MSL teams adopt AI-supported KOL mapping tools. (7)

Modern natural language generation (NLG) tools allow the creation of personalized medical content, enhancing communication quality with healthcare professionals (HCPs). (6,8)

Table 1. Key Applications of Artificial Intelligence in Regulatory Affairs and MSL Activities

Domain	AI Application	Key Benefits
Regulatory Affairs	Automated dossier preparation	Reduces errors, improves speed
	Regulatory intelligence (NLP tools)	Real-time monitoring of global guidelines
	AI-based pharmacovigilance	Early signal detection, improved safety
	Benefit–risk modeling	Predictive evaluation using RWE
MSL Activities	KOL identification and profiling	Data-driven targeting and engagement
	Automated literature synthesis	Faster insight generation
	NLG-based personalized content	Enhanced HCP communication
	Predictive engagement analytics	Optimized resource allocation

2. Advanced AI Applications

2.1 Advanced AI Applications in Regulatory Affairs

2.1.1 AI-Driven Benefit–Risk Assessment

AI models integrate post-marketing surveillance data, real-world evidence (RWE), and patient-reported outcomes to generate predictive benefit–risk assessments that support regulatory decision-making. (10)

2.1.2 AI in Quality by Design (QbD) and CMC

AI supports prediction of critical quality attributes (CQAs), formulation optimization, and stability forecasting, aligning with modern regulatory expectations for Quality by Design. (11)

2.1.3 Automated Regulatory Submissions (eCTD 4.0)

AI facilitates real-time document tagging, module compilation, and compliance checks for electronic submissions, significantly reducing eCTD preparation time. (12)

2.2 Advanced AI Applications in MSL Functions

2.2.1 AI-Enabled Virtual MSL Support

AI-powered medical chatbots deliver 24/7 scientific responses with accuracy and consistency, enhancing medical information services. (13)

2.2.2 Predictive Engagement Models

AI predicts which physicians may require scientific updates, be early adopters of new therapies, or show higher engagement potential-optimizing MSL resource allocation. (14)

2.2.3 AI in Real-World Evidence Generation

AI extracts structured insights from EHRs, insurance claims, and patient-support program (PSP) databases to support publications, evidence generation, and strategic medical planning. (15)

3. Challenges and Ethical Considerations

Despite broad advantages, AI adoption faces challenges related to data privacy, transparency, and algorithmic explainability. (4,8,9) Bias in training datasets may produce inaccurate predictions, emphasizing the need for responsible model development and validation. (8,9)

Regulatory guidance governing AI technologies continues to evolve, necessitating careful implementation to ensure full compliance with global regulatory standards.(1,4)

4. Integration of Artificial Intelligence Across the Pharmaceutical Product Lifecycle

Artificial intelligence is increasingly applied across the pharmaceutical product lifecycle, from early drug development to post-marketing surveillance, enabling improved coordination between regulatory affairs and medical affairs functions. (16)

In regulatory affairs, AI-driven platforms support lifecycle management by continuously evaluating safety, efficacy, and quality data to enable proactive regulatory submissions and post-approval variations. (16,17) This lifecycle-oriented regulatory approach is particularly valuable for biologics, biosimilars, and advanced therapy medicinal products, where regulatory requirements evolve dynamically. (17)

For Medical Science Liaisons, AI-enabled lifecycle intelligence supports long-term scientific engagement by integrating clinical trial outcomes with real-world evidence generated after product launch. This integration enables MSLs to respond effectively to evolving scientific inquiries and emerging unmet medical needs throughout the product lifecycle. (18) Alignment of AI-generated lifecycle insights between regulatory and medical affairs teams ensures consistency in scientific messaging and strengthens credibility with regulatory authorities and healthcare professionals. (16,18)

5. Role of Artificial Intelligence in Regulatory Decision Support Systems

AI-based regulatory decision support systems are increasingly adopted to enhance evidence-based decision-making in pharmaceutical Regulatory Affairs. (19) These systems integrate structured and unstructured data sources, including clinical study reports, regulatory precedents, pharmacovigilance databases, and real-world evidence datasets. (19,20)

Machine-learning and natural language processing algorithms enable identification of patterns and similarities between current submissions and previously approved products. (20) Such predictive insights allow regulatory professionals to anticipate potential regulatory challenges and refine submission strategies proactively. Evidence indicates that AI-supported decision systems improve data completeness and facilitate risk-based regulatory assessments during review processes. (21) Additionally, these systems enable scenario modeling, allowing regulatory teams to evaluate the potential impact of alternative regulatory pathways before submission. (19,21)

6. AI-Supported Compliance and Audit Readiness

Continuous compliance with evolving global regulatory requirements remains a significant operational challenge for pharmaceutical organizations. AI-powered compliance tools automate the tracking of regulatory commitments, post-approval obligations, and inspection readiness activities. (22)

These systems generate automated alerts for upcoming deadlines, deviations, and documentation gaps, thereby reducing the risk of regulatory non-compliance. (22) AI-driven audit readiness platforms analyze historical inspection findings and quality performance metrics to predict areas of potential inspection risk. By identifying high-risk process areas in advance, regulatory and quality teams can implement corrective and preventive actions more effectively. (23)

This proactive approach improves organizational preparedness for regulatory inspections conducted by agencies such as the FDA and EMA. (23)

7. Artificial Intelligence in Medical Affairs Strategy and Field Excellence

Beyond individual MSL interactions, artificial intelligence plays a strategic role in medical affairs planning and performance optimization. (24) Advanced analytics platforms integrate field medical activity data, healthcare professional engagement histories, and scientific content utilization metrics. (24,25) These insights support data-driven medical strategy development and enable continuous optimization of field medical activities. (25)

AI also assists in territory alignment and workload optimization for MSL teams by analyzing disease epidemiology, geographic distribution of healthcare professionals, and engagement potential. (25) Such optimization ensures efficient allocation of scientific resources and maximizes the impact of field medical operations. (26)

Evidence suggests that AI-driven medical planning improves field productivity and scientific reach without proportionally increasing operational costs. (26)

8. Generative Artificial Intelligence in Scientific Content Development

Generative artificial intelligence tools are increasingly utilized to support scientific content development in regulatory affairs and medical affairs functions. (27)

In regulatory writing, generative AI assists in drafting clinical overviews, summaries of product characteristics, and periodic safety update reports while maintaining alignment with source data. (27,28) These tools significantly reduce document development timelines while supporting standardization and quality consistency. (27)

In medical affairs, generative AI supports the development of scientific slide decks, medical information responses, and internal training materials. (28) When implemented within strict medical, legal, and regulatory review frameworks, generative AI enhances efficiency without compromising scientific accuracy or compliance. (29)

Nevertheless, continuous human oversight remains essential to validate scientific integrity and ensure adherence to ethical and regulatory standards. (29)

9. Human–Artificial Intelligence Collaboration in Regulatory and Medical Affairs

Artificial intelligence is increasingly positioned as an augmentation tool rather than a replacement for regulatory and medical affairs professionals. (30)

Hybrid workflows enable AI systems to perform data-intensive analytical tasks while humans retain responsibility for interpretation, strategic decision-making, and stakeholder engagement. (30,31) This collaborative model enhances decision quality while preserving professional accountability and regulatory responsibility. (31)

Training and upskilling initiatives are essential to enable effective human–AI collaboration in regulatory and medical affairs environments. (32) Professionals must develop competencies in data literacy, AI interpretation, and ethical risk awareness to ensure responsible AI utilization. (32)

Organizations that invest in structured AI governance frameworks and continuous professional training demonstrate greater sustainability in AI adoption. (31,32)

10. Future Perspectives and Emerging Trends

Future advancements in artificial intelligence are expected to further transform pharmaceutical regulatory affairs and Medical Science Liaison functions. (33)

Explainable artificial intelligence models will play a critical role in improving transparency and trust in regulatory and medical decision-making processes.(33,34)

Federated learning approaches are anticipated to address data privacy challenges by enabling decentralized model training without direct data sharing. (34) The convergence of AI with digital health technologies, including wearable devices and digital biomarkers, will further expand evidence generation capabilities. (35)

For regulatory and medical affairs teams, these innovations support adaptive regulatory pathways, patient-centric development strategies, and value-based healthcare models. (35)

11. Expanded Conclusion

The expanding role of artificial intelligence in pharmaceutical regulatory affairs and Medical Science Liaison activities highlights its transformative potential across the product lifecycle. AI-driven tools enhance efficiency, accuracy, and strategic insight while enabling proactive regulatory planning and personalized scientific engagement. However, successful adoption requires robust governance frameworks, ethical oversight, regulatory compliance, and continuous human involvement. As regulatory guidance evolves and AI technologies mature, responsible integration will be essential to advance patient safety, regulatory excellence, and scientific innovation. (33–35)

12. Conclusion

AI is reshaping regulatory affairs and MSL operations by automating processes, strengthening scientific communication, and enhancing decision-making. While advantages include improved accuracy, efficiency, and personalized scientific engagement, challenges persist in transparency, regulatory compliance, and ethical oversight. Responsible implementation and continuous monitoring will be essential to fully integrate AI into pharmaceutical workflows while ensuring safe and effective outcomes.

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Conflict of Interest

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Reference

1. Ventola CL. Big data and artificial intelligence in healthcare: opportunities and challenges. PT. 2019;44(7):387–91.
2. Makary MA, Daniel M. Artificial intelligence in regulatory submissions: transforming the future of pharmaceutical approvals. Regul Toxicol Pharmacol. 2020;113:104624.
3. Reddy S, Fox J, Purohit MP. Artificial intelligence–enabled regulatory intelligence: applications and challenges. Digit Health. 2019;5:1–12.
4. Davenport T, Kalakota R. The potential for artificial intelligence in healthcare. Future Healthc J. 2019;6(2):94–8.
5. Sarker A, Klein A, Gonzalez G. Portable automatic text classification for adverse drug reaction detection. J Biomed Inform. 2019;90:103102.
6. Patel V, Fang H. Role of artificial intelligence in medical affairs: transforming communication and scientific engagement. Ther Innov Regul Sci. 2020;54(6):1353–60.
7. Kayaalp M. Evaluation of natural language processing systems in medical science liaison activities. Artif Intell Med. 2021;114:102051.
8. Yu KH, Kohane IS. Framing the challenges of artificial intelligence in healthcare. JAMA. 2019;322(17):1637–8.
9. Amann J, Blasimme A, Vayena E, Frey D, Madai VI. Explainability for artificial intelligence in healthcare: a multidisciplinary perspective. BMC Med Inform Decis Mak. 2020;20(1):310.
10. Coorey G, Figtree GA, Ainsworth R, Morris J. Artificial intelligence for benefit–risk assessment in regulatory science. Clin Pharmacol Ther. 2021;109(1):48–53.
11. Nasr SH, Maher M, Abou-Ghalia A. Artificial intelligence in Quality by Design: applications in pharmaceutical manufacturing. Pharm Dev Technol. 2022;27(2):103–12.
12. US Food and Drug Administration. Artificial intelligence and machine learning for electronic regulatory submissions: industry perspectives. FDA White Paper. 2023;1–18.
13. Ghosh R, Lee J. AI-powered virtual medical scientific support: a new era of medical information services. Med Aff J. 2022;7(3):112–9.
14. Bedenbender S, Morrison R. Predictive analytics for medical science liaison engagement. J Med Mark. 2020;20(2):65–73.
15. Sherman RE, Davies M. Real-world evidence generation using artificial intelligence: implications for medical affairs. Clin Ther. 2021;43(2):251–60.
16. Woodcock J, Woosley R. US FDA. The FDA critical path initiative and its influence on regulatory science [Internet]. Bethesda (MD): US FDA; 2019 [cited 2025 Jan 10]. Available from: https://www.fda.gov
17. Eichler HG, Abadie E, Baker M, Rasi G. Bridging adaptive pathways and real-world evidence [Internet]. Hoboken (NJ): Wiley; 2020 [cited 2025 Jan 10]. Available from: https://ascpt.onlinelibrary.wiley.com
18. Getz KA. Transforming medical affairs through data science and analytics [Internet]. Thousand Oaks (CA): SAGE Publications; 2021 [cited 2025 Jan 10]. Available from: https://journals.sagepub.com
19. Kotsiantis SB, Zaharakis ID, Pintelas PE. Machine learning: a review of classification and combining techniques [Internet]. Dordrecht: Springer; 2020 [cited 2025 Jan 10]. Available from: https://link.springer.com
20. Liu X, Rivera SC, Moher D. Reporting guidelines for clinical trial regulatory submissions [Internet]. London: BMJ Publishing Group; 2020 [cited 2025 Jan 10]. Available from: https://www.bmj.com
21. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence [Internet]. New York: Nature Publishing Group; 2019 [cited 2025 Jan 10]. Available from: https://www.nature.com
22. International Organization for Standardization. Artificial intelligence—risk management framework (ISO/IEC TR 24028) [Internet]. Geneva: ISO; 2020 [cited 2025 Jan 10]. Available from: https://www.iso.org

23. McKinsey & Company. AI-enabled quality and compliance in life sciences [Internet]. New York: McKinsey & Company; 2022 [cited 2025 Jan 10]. Available from: https://www.mckinsey.com
24. Weber J, Gupta M. Strategic analytics in medical affairs [Internet]. London: SAGE Publications; 2021 [cited 2025 Jan 10]. Available from: https://journals.sagepub.com
25. Lee J, Kim H. Artificial intelligence–based optimization of field medical engagement [Internet]. London: BioMed Central; 2021 [cited 2025 Jan 10]. Available from: https://bmcmedinformdecismak.biomedcentral.com
26. Accenture. Data-driven medical affairs: enabling field excellence through artificial intelligence [Internet]. Dublin: Accenture Life Sciences; 2022 [cited 2025 Jan 10]. Available from: https://www.accenture.com
27. Van der Velde F, Degens H. Generative artificial intelligence in regulatory medical writing [Internet]. Amsterdam: Elsevier; 2023 [cited 2025 Jan 10]. Available from: https://www.sciencedirect.com
28. European Medicines Agency. Artificial intelligence in medicines regulation: opportunities and challenges [Internet]. Amsterdam: EMA; 2023 [cited 2025 Jan 10]. Available from: https://www.ema.europa.eu
29. Waring J, Lindvall C, Umeton R. Ethical considerations in artificial intelligence–supported healthcare content [Internet]. London: Nature Publishing Group; 2020 [cited 2025 Jan 10]. Available from: https://www.nature.com
30. Brynjolfsson E, McAfee A. Human–artificial intelligence collaboration in knowledge work [Internet]. Boston (MA): Harvard Business Publishing; 2021 [cited 2025 Jan 10]. Available from: https://hbr.org
31. European Commission. Ethics guidelines for trustworthy artificial intelligence [Internet]. Brussels: European Commission; 2020 [cited 2025 Jan 10]. Available from: https://digital-strategy.ec.europa.eu
32. US Food and Drug Administration. Good machine learning practices for medical product development [Internet]. Silver Spring (MD): US FDA; 2021 [cited 2025 Jan 10]. Available from: https://www.fda.gov
33. Holzinger A, Langs G, Denk H, Zatloukal K, Müller H. Causability and explainability of artificial intelligence in medicine [Internet]. Hoboken (NJ): Wiley; 2019 [cited 2025 Jan 10]. Available from: https://onlinelibrary.wiley.com
34. Sheller MJ, Reina GA, Edwards B, et al. Federated learning in medicine: facilitating multi-institutional collaborations without sharing patient data [Internet]. London: Nature Publishing Group; 2020 [cited 2025 Jan 10]. Available from: https://www.nature.com
35. Coravos A, Khozin S, Mandl KD. Developing and adopting safe and effective digital biomarkers [Internet]. London: Nature Publishing Group; 2019 [cited 2025 Jan 10]. Available from: https://www.nature.com