Navigating the Unique Challenges of AI and Automation in Pharmacovigilance: The Vital Role of Computer System Validation (CSV)

Artificial Intelligence, Machine Learning, Automation, Cost Reduction: all the buzzwords in pharmacovigilance! Everyone seems to be implementing Automation and AI in pharmacovigilance to reduce manual work and reduce costs of safety monitoring. However, compared to all other fields where Automation and AI is being implemented, pharma as an industry is facing a unique set of challenges in implementing these systems.

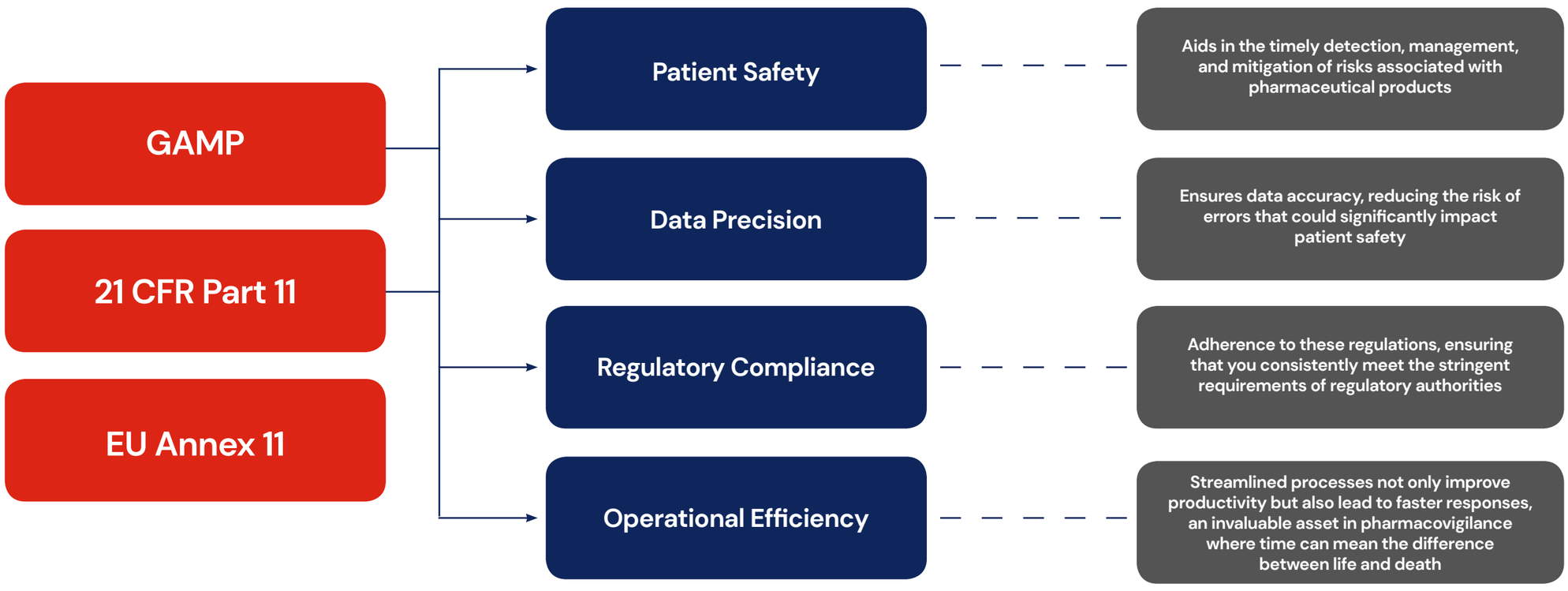
Regulators such the USFDA and EMA require that computerized systems should be fit for intended use and meet current regulatory requirements. 'Fit for intended use' is a broad term that encompasses detailed testing, documentation, qualification and validation activities to demonstrate that the 'use' and 'fitness for such use' of a system is demonstrated effectively and is available for review during audits and inspections.

The method for achieving this is Computer System Validation, which is rooted in the principles of Good Automated Manufacturing Practice (GAMP), Title 21 CFR Part 11, and EU Annex 11. In the pharma space, the requirements become all the more critical, since it is no longer just about compliance; it's about safeguarding lives.

The Indispensable role of CSV in Pharmacovigilance

End Point	Regulation	Requirement	How CSV helps to achieve the requirement
Patient Safety	EU Annex 11	Patient Safety	Aids in the timely detection, management, and mitigation of risks associated with pharmaceutical products
Data Precision	GAMP	Precise Reporting	Ensures data accuracy, reducing the risk of errors that could significantly impact patient safety
Regulatory Compliance	Title 21 CFR Part 11, EU Annex 11	Robust compliance standards for electronic records and signatures in FDA-regulated industries, guidelines for computerized systems in the European Union	Adherence to these regulations, ensuring that you consistently meet the stringent requirements of regulatory authorities
Operational Efficiency	GAMP, Title 21 CFR, and EU Annex 11	Importance of efficient systems	Streamlined processes not only improve productivity but also lead to faster responses, an invaluable asset in pharmacovigilance where time can mean the difference between life and death

In the next few parts of this series, I will be discussing some approaches that we have followed in implementing CSV procedures for software systems developed for the pharmacovigilance space, what we have learned in the process, how CSV can be applied by harmonizing international regulatory requirements and how it can be applied to the agile development. Stay tuned for more updates and reach out to me if you would like to see any other topics covered as part of the series.



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Tanvi is a pharma professional with more than 10 years of experience in pharmacovigilance. She has expertise in pharmacovigilance and clinical safety processes, including pre-approval, postmarketing and late phase safety requirements and has managed end-to-end project setup for EU and US based projects that include process development, safety database and medical information database setup with data migration and validation, transition of overall PV services, team selection and mentoring, and troubleshooting across PV verticals. Has experience across various domains like ICSR processing in safety databases, literature management, aggregate reporting, signal management, regulatory intelligence, EudraVigilance systems, system automation, process development and transition, and pharmacovigilance quality assurance. She is eligible to provide Responsible Person for EudraVigilance (RPEV) services to Sponsors of Clinical Trials in the EU.

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We support companies from the initial development stage of a drug/vaccine to the approval and ultimate marketing of the therapy, supporting ongoing operations and regulatory commitments globally.