**Challenges in Implementing EU Regulation 910/2014: A Comparative Analysis with 21 CFR Part 11 and Japanese ERES**

*This paper explores the reasons why the European Union (EU) Regulation 910/2014, commonly known as the eIDAS Regulation, presents significant challenges for businesses during implementation and fails to achieve full integration, unlike its counterparts, the 21 CFR Part 11 in the United States and the Japanese ERES (Electronic Records and Electronic Signatures). This paper analyzes the key provisions of each regulation, their intended purposes, and the unique complexities that businesses face when attempting to comply with each one. It also explores the cultural, legal, and technological factors that contribute to the differing degrees of adoption and integration in the respective regions.*

## Introduction

The digital transformation of business processes has become a global imperative, prompting governments worldwide to enact regulations that facilitate secure electronic interactions and promote trust in the digital environment. The EU eIDAS Regulation, 21 CFR Part 11 in the US, and Japanese ERES are exemplary attempts to address these concerns. While the US and Japanese regulations have seen substantial integration and compliance, the eIDAS Regulation has faced several hurdles. This paper examines the underlying reasons for this discrepancy and provides a comparative analysis of the challenges that businesses encounter in implementing these regulations.

## Overview of Regulations

### EU Regulation 910/2014 (eIDAS (electronic Identification, Authentication and trust Services) Regulation)

The eIDAS Regulation was established to create a harmonized legal framework for electronic identification, electronic signatures, and trust services within the EU. Its overarching goal is to facilitate cross-border recognition and acceptance of digital signatures and to promote the adoption of secure electronic transactions.

eIDAS is an EU regulation on electronic identification and trust services for electronic transactions in the European Single Market. It was established in EU Regulation 910/2014 of 23 July 2014 on electronic identification and repeals 1999/93/EC from 13 December 1999.

It became effective on 17 September 2014 and applies since 01 July 2016 except for certain articles, which are listed in its Article 52. All organizations delivering public digital services in an EU member state were to recognize electronic identification from all EU member states from September 29, 2018.

### 21 CFR Part 11

21 CFR Part 11 is a regulation which became effective 20 March 1997 by the United States Food and Drug Administration (FDA) that governs the use of electronic records and electronic signatures in the pharmaceutical and medical device industries. Its primary objective is to ensure the integrity, authenticity, and confidentiality of electronic data used in regulatory compliance.

Part 11 didn't start well. Many software and device service providers released Part 11 "compliant" updates of their product which initially were not complete or insufficient to fully comply with the rule. Confusion and complaints resulted in the release of:

*FDA Guidance for Industry Part 11, Electronic Records: Electronic Signatures – Scope and Application (2003).* This document was intended to clarify how Part 11 should be implemented and would be enforced and its current thinking at the time; and

*Guidance for Industry Computerized Systems Used in Clinical Investigations.* This final version of their guidance on computerized systems in clinical investigations was issued in May 2007. This guidance superseded the guidance of the same name dated April 1999; and supplemented the guidance for industry on Part 11, Electronic Records; Electronic Signatures — Scope and Application and the FDA's efforts to apply these guidelines to source data generated at clinical study sites.

FDA had previously announced that a new Part 11 would be released late 2006. However that has not been the case as yet.

**Japanese ERES (Electronic Records and Electronic Signatures)**

The Japanese MHLW (Ministry of Health, Labor and Welfare) ERES Notification 0401022 dd 01 April 2005 Japan's regulatory framework that provides legal guidelines for the use of electronic records and signatures in various sectors. Its main focus is to enhance the efficiency and reliability of electronic transactions while ensuring the protection of sensitive information. Besides registry requirements, registry responsibilities and storage requirements, a sponsor is required to maintain a QMS which should include security, system's monitoring, QA, backup and recovery, privacy protection, confidentiality management, transparency, CSV, data collection and handling. This legal guideline reflects a more holistic approach to ERES management.

**Complexity of EU Regulation 910/2014 Implementation**

**Key Challenges**

One of the significant challenges faced by businesses implementing the eIDAS Regulation is the existence of diverse legal frameworks across EU member states. The Regulation provides a harmonized set of rules, but individual countries can apply their interpretations, leading to potential inconsistencies in enforcement and compliance.

The eIDAS Regulation's successful implementation requires businesses to invest in robust and sophisticated technological infrastructure. This can be a daunting task for small and medium-sized enterprises (SMEs) with limited resources, hindering their ability to adopt eIDAS-compliant practices.

The EU is a region rich in cultural and linguistic diversity. This diversity presents challenges in implementing eIDAS-compliant solutions that cater to varying user preferences and requirements across member states.

**Comparative Analysis**

The integration of 21 CFR Part 11 in the US and Japanese ERES has been relatively smooth due to various factors. The US regulatory environment fosters innovation and technological advancements, which has enabled businesses to more readily embrace electronic records and signatures. In Japan, a

culture of efficiency and a strong focus on technological progress have contributed to the successful implementation of ERES and internationally as most requirements were already in place.

Both 21 CFR Part 11 and Japanese ERES offer more straightforward and clearer guidelines compared to the eIDAS Regulation. The lack of ambiguity in these regulations has expedited compliance efforts for businesses in the respective regions.

21 CFR Part 11 and Japanese ERES cater to specific industries, primarily pharmaceuticals and medical devices in the US and various sectors in Japan. This focused approach has allowed for a deeper understanding of industry-specific challenges, resulting in more targeted solutions.

**Implications and Recommendations**

The EU should consider streamlining the eIDAS Regulation to make it more accessible and understandable for businesses across the member states. A harmonized approach to its implementation, with clear guidelines and unified enforcement, would facilitate compliance.

To aid businesses in adopting eIDAS-compliant practices, the EU should invest in promoting technological advancements and providing support to SMEs in upgrading their infrastructure.

Collaboration and knowledge sharing among EU member states can foster best practices and experiences in implementing the eIDAS Regulation, leading to a smoother transition and integration.

Consent and User Awareness: Auditing the explicit consent obtained from users for electronic transactions demands careful documentation and transparency. Ensuring user awareness of the implications of ERES usage is vital for a compliant EU landscape.

**An auditors perspective:**

Cross-Border Recognition and Acceptance:

The eIDAS Regulation aims to promote cross-border recognition and acceptance of electronic signatures. For a pharmaceutical service provider operating across multiple EU member states, verifying the legal validity and recognition of electronic signatures used in different countries can be challenging during audits. Ensuring that the signatures comply with both the eIDAS Regulation and the specific laws of each member state requires a thorough understanding of the legal landscape and verification mechanisms. Limiting the scope within EU, whilst the 21 CFR Part 11 and MHLW ERES applies to data which will be submitted in either region/country making those regulations global by definition.

Identification and Authentication Methods:

The eIDAS Regulation encourages the use of secure and reliable electronic identification and authentication methods. For pharmaceutical service providers handling sensitive data, ensuring the appropriateness and effectiveness of the chosen identification and authentication methods can be complex. Auditors need to evaluate the adequacy of the implemented authentication measures and

assess whether they meet the Regulation's requirements, such as being secure, traceable, and capable of mitigating fraud risks.

Technological Infrastructure and Integrity of Trust Services:

The eIDAS Regulation emphasizes the importance of maintaining the integrity and security of trust services, such as electronic signatures, seals, time stamps, and registered delivery services. During audits, the pharmaceutical service provider must demonstrate the effectiveness and resilience of its technological infrastructure in safeguarding these trust services against potential cyber threats and unauthorized access. As not many service providers and pharmaceutical sponsor are audited to this regulation more experience will be required as some aspects would be new to auditors e.g auditing of seals.

Compliance with Member State-specific Requirements:

As mentioned earlier, the eIDAS Regulation provides a harmonized framework, but individual member states can have their additional requirements and interpretations. Auditors must ensure that the pharmaceutical service provider is aware of and adheres to any country-specific obligations related to electronic signatures and trust services when operating in multiple EU jurisdictions. This will be a challenge to audit as contract auditors in general only get 2 to 3 days to cover complex multiple platforms and system.

Recordkeeping and Audit Trails:

The eIDAS Regulation requires maintaining accurate and complete records of electronic transactions and audit trails to facilitate traceability and accountability. For a pharmaceutical service provider dealing with critical data and sensitive processes, demonstrating the integrity of these records and the ability to produce audit trails during inspections can be challenging. The audit trails must effectively capture and retain relevant information to support the verification of electronic signatures and the authenticity of electronic documents. This would add additional auditing expertise needed to reviewing of audit trails to comply with eIDAS.

However, with the introduction of the recent draft FDA Guideline Computer Software Assurance for Production and Quality System Software 13 September 2022 which will apply to regular review of audit trails operationally, this would assist auditors to ensure internal frequency of review of audit trails of the various platforms used in devices and clinical trials and ensuring Global ERES requirements are complied with in my opinion.

Consent and User Awareness:

The eIDAS Regulation emphasizes obtaining explicit consent from users for the use of electronic signatures and trust services. During audits, pharmaceutical service providers must demonstrate that users are fully aware of the implications of their electronic transactions and have given informed consent. Ensuring that the consent process is adequately documented and transparent can be challenging to verify during audits.

Cultural and Language Considerations:

For multinational pharmaceutical service providers, ensuring consistent implementation and understanding of the eIDAS Regulation across different cultures and languages can be difficult. Auditors need to assess whether the organization has effectively communicated the relevant requirements to all relevant stakeholders and that there is a consistent understanding of the Regulation's provisions.

In summary, audits in a pharmaceutical, devices, CRO etc and service provider or systems setting regarding eIDAS implementation may encounter challenges in verifying cross-border compliance, evaluating the adequacy of identification and authentication methods, assessing the integrity of trust services and technological infrastructure, addressing member state-specific requirements, ensuring robust recordkeeping and audit trails, and documenting user consent and awareness. Overcoming these challenges requires a comprehensive approach, deep knowledge of the eIDAS Regulation, and collaboration between the organization and auditors to ensure compliance with the Regulation's provisions.

Future Technologies and Advances in ERES Requirements:

Blockchain Technology: The implementation of blockchain in ERES systems can enhance data immutability and traceability, significantly reducing the risk of data tampering and ensuring long-term document integrity.

Advanced Encryption: Employing quantum-resistant encryption protocols safeguards electronic records from future threats posed by quantum computing, providing greater security assurance.

Biometric Authentication: Integrating biometric authentication mechanisms strengthens user identification, rendering electronic signatures more reliable and resistant to fraudulent activities.

Artificial Intelligence (AI) Compliance Tools: AI-powered compliance tools can streamline the auditing process by automating data analysis, risk assessment, and compliance monitoring.

**Conclusion**

Auditing and legally complying with ERES regulations present multifaceted challenges that require a unified effort from auditors, legal practitioners, and regulators. Addressing the complexities demands a harmonized implementation approach, transparent guidelines, and the incorporation of future technologies and advances. As we envision a secure digital future, ERES regulations must continuously adapt to foster trust, efficiency, and innovation, empowering businesses across sectors to embrace the opportunities presented by the digital era. By embracing advancements in technology and fostering international collaboration, we can pave the way for a robust ERES landscape that inspires confidence in electronic transactions globally.

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