Life Sciences Regulators Must Write Cloud-Specific Guidance

By **Nate Brown and Marlee Gallant** (November 1, 2023)

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Cloud services have revolutionized the way businesses and governments operate, offering scalability, flexibility, cost-efficiency and security.

This is especially the case in the life sciences industry, where the cloud has already been incorporated into medical devices and pharmaceutical manufacturing. Life science entities can use the cloud to store and manage great volumes of sensitive data, make them more easily accessible, improve traceability, and support research and development for innovative medical products.

As one of the most highly regulated industries, compliance systems, including maintenance of records, are critical to life sciences entities and entities in this space are increasingly looking to cloud services to support their regulated activities.

Although the U.S. Food and Drug Administration and other government bodies have indicated support for the use of cloud services, and many of them leverage the cloud themselves, some government written policies are out of date or otherwise create confusion about cloud use.

The FDA and other government bodies have the opportunity to support regulated industries and technological advancement by providing greater clarity and certainty.

A review of U.S. and international policies demonstrates the need for cloud-specific guidance on the national and international stages. There are a wide variety of policy documents that address data management and storage for regulated entities.

While a select few documents that have been issued recently expressly permit the use of cloud, many government policies, particularly those that were issued more than 10 years ago, have not been updated to reflect technological advances. Especially in a highly regulated area like life sciences, the failure to update these policies leads to ambiguity that can slow the adoption of innovative tools.

Government Bodies Recognize the Benefits of Cloud Services

The FDA and other government bodies recognize the advantages of the cloud in managing large volumes of data and have made utilizing the cloud an internal priority.

In the FDA's latest Prescription Drug User Fee Act reauthorization letter, the agency announced that it aims to leverage cloud technology to progress digital transformation because "[c]loud and cloud-based technology offer significant advantages over traditional on-premise data repositories and analytics."[1]

The agency plans to explore cloud services as part of various initiatives, including modernizing its own technical infrastructure,[2] and applicant-FDA regulatory interactions for pharmaceutical products.[3]

The PDUFA letter represents the goals that result from the FDA's discussions with the regulated industry and public stakeholders, and in this provision, the FDA likewise encourages the industry to adopt the cloud.

The FDA has decided to utilize the cloud environment to meet review needs across the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research because secure cloud technology will enable the FDA to effectively receive, aggregate, store and process large volumes of highly sensitive data.[4]

Inconsistency and Confusion on Cloud Policy

Government bodies have taken steps in the right direction by acknowledging whether cloud services may be used in specific situations.

For example, the FDA issued guidance that explicitly states that cloud services may be used to support record-keeping requirements under Title 21 of the Code of Federal Regulations, Part 11, for electronic records, signatures and systems generated or used as part of clinical trials.[5]

The guidance states that "[t]here are various ways to retain electronic records, including in durable electronic storage devices and using cloud computing services;"[6] and that "[s]ponsors and other regulated entities can contract with vendors to provide IT services for a clinical investigation (e.g., data hosting, cloud computing software, platform and infrastructure services)."[7]

Despite the FDA's recognition that cloud services can enhance traditional data retention and utilization practices, some FDA policies inadvertently undermine cloud adoption.

For example, the agency recently issued guidance that may inadvertently prohibit use of the cloud in the same scenario. Specifically, in its draft guidance on decentralized clinical trials for drugs, biological products and devices, the FDA states that there should be a physical location where all clinical trial-related records for participants under the investigator's case are accessible.[8]

Just two months earlier, the FDA issued guidance providing that all clinical trial-related records could be stored in the cloud — not a physical location.[9] It is unlikely that the FDA intended to preclude the use of cloud storage in this case, and cloud users and FDA inspectors would benefit from the agency clarifying this matter.

In other instances, regulations and policies that predate cloud technology are crafted in a manner that calls into question whether cloud services can satisfy FDA expectations.

For example, the generally applicable guidance that the FDA released in 2003 regarding meeting the record-keeping requirements of Part 11 references some forms of electronic media in use at the time, e.g., PDFs,[10] but would need to be updated to reference cloud.

In another guidance from 2012, the FDA notes that regulated entities must establish and maintain records "at the location where the covered activities described in the records occurred, or at a reasonably accessible location."[11]

Although cloud storage could arguably serve as a reasonably accessible location, this policy approach is ambiguous and leads to confusion for FDA inspectors and regulated entities.

The FDA should issue a policy statement to: (1) make clear that entities may use the cloud to support compliance activities throughout the product lifecycle, not just documents related to clinical trials; and (2) address nuances specific to the cloud, such as that a precise physical location does not need to be on premises or even known to the regulated entity. Often, cloud service providers make known the general location of their data centers but not specific addresses.

Other agencies, such as the National Institute of Standards and Technology, have taken this approach successfully.[12]

Global Policymaking Is Necessary

Clarity is also needed on a global scale, and a clear, unified position from the FDA would be a powerful signal to other governments.

Differences in regulation worldwide decrease entities' agility and capacity to innovate. Like the FDA, several other government bodies use cloud services for their own operations, indicating trust for the cloud's storage, maintenance and security capabilities.[13] In fact, several regulatory bodies worldwide instruct government organizations to consider cloud solutions before alternatives[14] and have issued policies intended to encourage the use of cloud technology.[15]

For example, the U.K. instructs public sector organizations to consider and fully evaluate "potential cloud solutions first before considering any other option" — an approach that is mandatory for central government and strongly recommended to the wider public sector.[16]

The European Medicines Agency has developed a strategy to transition fully to the cloud by 2025 because cloud technologies will make it easier for the EMA to meet "its needs for secure and regulated exchange of data at a European and global level."[17]

Despite widespread acknowledgment of the advantages of cloud services, some policies suggest that using the cloud entails additional risk in comparison to on-premises infrastructure, when that is not necessarily the case.

Moreover, in some cases, a seemingly neutral approach to ensuring that any technology, including cloud, can support compliance obligations is interpreted by regulators to place a greater burden on cloud users, again due to lack of clear standards issued by these authorities.

On its face, these policies may appear neutral, but as a practical matter, they implicate greater scrutiny from regulators and customers. For example, the EMA's guideline on computerized systems and electronic data in clinical trials recognizes that cloud services may be used to manage data from clinical trials, but warns that responsible parties are at a certain risk when using the cloud because services may be managed less visibly by the cloud provider.

The guidance notes, appropriately, that these risks may be managed through validation of computerized systems and contractual relationships. The guidance, however, implies that these risks are specific to use of the cloud, but the cloud does not present additional risks as compared to on-premises infrastructure.

Likewise, in Japan, the Pharmaceuticals and Medical Devices Agency states that using the cloud is permissible to support compliance activities, but indicates that inspectors take special considerations into account for use of the cloud.[18]

Regulators Should Issue Coordinated, Clear Policy on Cloud to Encourage Uptake

Entities that use cloud to support regulated activities are ultimately responsible for ensuring that they meet applicable requirements — and this is no different for other electronic platforms or even paper systems.

Regulated entities are expected to validate and understand the systems they use to meet compliance standards, and have contractual relationships with vendors, regardless of the technology.

Although regulators are generally enthusiastic about the promises of cloud technology, guidance has been sporadic and, at times, inconsistent, potentially leaving entities and their employees confused.

Regulators should make consistent, coordinated policy to allow entities to employ cloud technology with confidence. Specifically, the FDA should:

- Clarify that cloud may be used to meet Part 11 record-keeping requirements;
- Commit to updating antiquated policies to explicitly include cloud technology;
- Educate its staff on the use of cloud to meet existing regulatory requirements; and
- Collaborate with other regulators to develop a harmonized perspective on the use of cloud to support regulated activities.

In developing these policies, the FDA and other government bodies should consider adopting existing governance mechanisms, such as alignment with industry standards, frameworks and certifications.

The FDA already references industry standards in its guidance documents relating to record-keeping, and should ensure that those reflect standards specifically applicable to cloud providers.

Industry-recognized third-party attestations are vital as they help establish cloud service provider accountability and ensure that appropriate controls are in place to address potential risks.

Moreover, industry standard reports and certifications obtained by cloud service providers play a crucial role in mitigating foundational risks by health care and life science organizations.

These certifications demonstrate that the providers have undergone independent audits and assessments, instilling confidence in the security and privacy assurance of their services.

These steps would mark significant progress toward the FDA's goal to advance the use of the cloud and allow life sciences entities to move forward with their use of the cloud with confidence, enabling secure and efficient support for regulated activities.

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[3] See, e.g., FDA, Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, (Jan. 26, 2023), https://www.fda.gov/media/152279/download; Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, (Aug. 23, 2022), https://www.federalregister.gov/documents/2022/08/23/2022-18087/pharmaceutical-science-and-clinical-pharmacology-advisory-committee-notice-of-meeting-establishment.

[4] FDA, Framework for the Use of Digital Health Technologies in Drug and Biological Product Development (March 2023), https://www.fda.gov/media/166396/download.

[5] FDA, Draft Guidance, Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers (Rev. March 2023), https://www.fda.gov/media/166215/download.

[6] Id. at 6.

[7] Id. at 15.

[8] FDA, Draft Guidance, Decentralized Clinical Trials for Drugs, Biological Products, and Devices 3 (May 2023), https://www.fda.gov/media/167696/download.

[9] FDA, Draft Guidance, Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers (Rev. March 2023), https://www.fda.gov/media/166215/download.

[10] FDA, Guidance, Part 11, Electronic Records; Electronic Signatures – Scope and Application (Aug. 2003), https://www.fda.gov/media/75414/download.

[11] FDA, Guidance for Industry – Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5) (Feb. 2012), https://www.fda.gov/media/83073/download.

[12] See NIST, General Access Control Guidance for Cloud Systems, NIST SP 800-210 (July 2020), https://csrc.nist.gov/pubs/sp/800/210/final.

[13] Shared Services Canada, Cloud Services, https://www.canada.ca/en/shared-services/corporate/cloud-services.html (last updated Dec. 14, 2021).

[14] See, e.g., Central Digital and Data Office, Government Cloud First policy – Guidance, https://www.gov.uk/guidance/government-cloud-first-policy (last updated Jul. 21, 2022); Central Digital and Data Office, Use Cloud First – Guidance, https://www.gov.uk/guidance/use-cloud-first (last updated Jul. 21, 2022); Treasury Board of Canada Secretariat, Cloud Adoption Strategy: 2023 Update, https://www.canada.ca/en/government/system/digital-government/digital-government-innovations/cloud-services/cloud-adoption-strategy-2023-update.html (last updated Jan. 19, 2023).

[15] See, e.g., EMA, Final Programming Document 2023-2025 (2023), https://www.ema.europa.eu/en/documents/report/final-programming-document-2023-2025_en.pdf; Health Canada, 2023-24 Departmental Plan: Health Canada, https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2023-2024-departmental-plan.html (last updated Mar. 10, 2023).

[16] Central Digital and Data Office, Government Cloud First policy – Guidance, https://www.gov.uk/guidance/government-cloud-first-policy (last updated Jul. 21, 2022).

[17] EMA, Information Management, https://www.ema.europa.eu/en/about-us/how-we-work/information-management# (last updated Jul. 15, 2022).

[18] PMDA, Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products (May 25, 2022), https://www.pmda.go.jp/files/000247966.pdf.