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# Power BI as a Single-Source-of-Truth Platform for FDA-Regulated Environments:

*Capabilities, Compliance Gaps, and Implementation Guidance*

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**Abstract:**
Microsoft Power BI has seen broad enterprise adoption as a business intelligence and analytics platform. Organizations operating under U.S. Food and Drug Administration (FDA) jurisdiction increasingly seek to leverage Power BI as a "Single Source of Truth" (SSOT) for operational and quality data. This paper critically evaluates Power BI's architectural capabilities against the regulatory requirements imposed by 21 CFR Part 11 (Electronic Records and Signatures), 21 CFR Parts 211 and 820 (cGMP and QSR), Good Clinical Practice (ICH E6 R3), and FDA data integrity guidance. The analysis identifies functional strengths — including role-based access control, dataset certification, and integration with Microsoft's compliance ecosystem — alongside substantive gaps: the absence of a native audit trail within Power BI datasets, no built-in electronic signature workflow, and a full validation burden placed on the regulated entity. The paper then provides a structured risk register and implementation checklist to guide quality assurance and IT teams in deploying Power BI in a compliant, defensible manner. The conclusion is honest: Power BI can support an SSOT architecture in regulated environments, but only as a visualization and reporting layer over a validated, integrity-controlled data infrastructure. It should not be treated as a standalone regulated system.

**Index Terms:** 21 CFR Part 11, Computer System Validation, Data Integrity, FDA Compliance, GAMP 5, Microsoft Power BI, Quality Management Systems, Single Source of Truth.

## I. INTRODUCTION

The concept of a Single Source of Truth (SSOT) has become central to modern enterprise data strategy. When applied to FDA-regulated industries — including pharmaceutical manufacturing, medical device production, biologics, and clinical research — the stakes of data accuracy, traceability, and integrity extend beyond business efficiency to patient safety and legal accountability.

Microsoft Power BI is one of the most widely deployed business intelligence platforms globally, and its adoption within regulated life sciences organizations has accelerated as companies seek unified dashboards, real-time operational visibility, and centralized KPI reporting. The appeal of Power BI as an SSOT is intuitive: it can aggregate data from disparate systems (MES, LIMS, ERP, CTMS), apply standardized business rules through its semantic layer, and present a consistent view of the enterprise to all stakeholders.

However, the regulatory frameworks governing FDA-regulated activities impose specific and non-negotiable requirements on electronic systems used to create, modify, maintain, archive, retrieve, or transmit records. These requirements — most prominently codified in 21 CFR Part 11 — were designed for an era of purpose-built validated systems and do not map cleanly onto modern cloud analytics platforms that are built for agility and rapid iteration.

This paper does not advocate for or against Power BI as a regulated platform. Its purpose is to provide an honest, evidence-based assessment of what Power BI can and cannot do in a regulated context, where compliance gaps exist, and what additional controls are necessary to achieve a defensible implementation. The authors have drawn on publicly available Microsoft documentation, FDA guidance documents, industry standards (GAMP 5, ICH Q10), and common deployment patterns documented in the life sciences literature and consulting practice.

This paper does not present original experimental data, nor does it derive conclusions from proprietary case studies. All claims about Power BI's functionality are based on the platform's documented capabilities as of the time of writing. Organizations should independently verify current platform behavior, as cloud services are subject to continuous change.

## II. REGULATORY CONTEXT AND APPLICABLE REQUIREMENTS

### *A. The Regulatory Landscape for Electronic Records*

FDA-regulated industries operate under a layered set of regulations and guidance documents that collectively define expectations for data management. The cornerstone regulation for electronic records is 21 CFR Part 11, enacted in 1997, which establishes that electronic records and electronic signatures may be used in lieu of paper records and handwritten signatures only when systems meet specific criteria for authenticity, integrity, and confidentiality [1].

While 21 CFR Part 11 is the most commonly cited regulation in the context of computer system validation (CSV), it does not exist in isolation. GMP regulations under 21 CFR Parts 211 (pharmaceuticals), 820 (medical devices, transitioning to ISO 13485-aligned QMSR in 2024), and 606 (blood and blood components) all require that records be accurate, complete, attributable, and contemporaneous. The FDA's 2018 guidance on data integrity and cGMP compliance — while not a binding regulation — provides the agency's current thinking on what constitutes acceptable data governance in manufacturing environments [2].

For clinical trials, ICH E6 R3 (Good Clinical Practice) imposes the ALCOA+ principles: data must be Attributable, Legible, Contemporaneous, Original, and Accurate, with additional attributes of being Complete, Consistent, Enduring, and Available [3]. These principles apply regardless of whether data is stored in a paper or electronic system.

### *B. Summary of Applicable Regulations*

Table I summarizes the primary regulatory instruments applicable to organizations considering Power BI as a component of their electronic data infrastructure.

**TABLE I**

*Applicable FDA Regulations and Guidance Documents*

| Regulation / Guidance | Title | Relevance to SSOT / Data Integrity |
|---|---|---|
| **21 CFR Part 11** | Electronic Records; Electronic Signatures | Governs authenticity, integrity, and confidentiality of electronic records and signatures used in FDA-regulated activities. |
| **21 CFR Part 211** | Current Good Manufacturing Practice (cGMP) | Requires accurate, complete, and attributable manufacturing records; data integrity is central. |
| **21 CFR Part 820** | Quality System Regulation (QSR) / QMSR (2024) | Mandates document control, design controls, corrective and preventive action (CAPA) records. |
| **21 CFR Part 58** | Good Laboratory Practice (GLP) | Requires audit trails, raw data retention, and controlled access to study records. |
| **ICH E6 R3 (GCP)** | Good Clinical Practice | Requires reliable, attributable, contemporaneous, original, and accurate (ALCOA+) data in clinical trials. |
| **FDA Guidance: Data Integrity (2018)** | Data Integrity and Compliance with CGMP | Addresses completeness, consistency, and accuracy of electronic data; warns against data manipulation. |

### *C. The GAMP 5 Framework for Computer System Validation*

The ISPE GAMP 5 (Good Automated Manufacturing Practice) framework provides the industry's standard methodology for validating computerized systems used in regulated environments [4]. GAMP 5 categorizes software into types based on their complexity and customization potential. Under this taxonomy, Power BI would most likely be classified as a Category 4 (configurable off-the-shelf) or, if heavily customized with complex DAX logic and embedded Python/R scripts, approaching Category 5 behavior. The classification matters because it determines the expected depth of validation documentation, including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

A critical implication of GAMP 5 is that Microsoft, as the software vendor, is responsible for verifying that Power BI operates as documented — but the regulated entity is entirely responsible for validating that its specific implementation, configuration, and use of Power BI meets the requirements of its intended regulated use. Microsoft does not provide pre-authored validation documentation for Power BI, and organizations should not assume that Microsoft's own compliance certifications (ISO 27001, SOC 2 Type II, FedRAMP Moderate) satisfy FDA CSV requirements. These certifications address information security and operational reliability, not GxP data integrity.

## III. POWER BI ARCHITECTURE IN THE CONTEXT OF SSOT

### *A. Architectural Overview*

Power BI consists of three principal components: Power BI Desktop (a local authoring application), the Power BI Service (a cloud-hosted SaaS platform running on Azure), and Power BI Report Server (an on-premises hosting option for organizations unable or unwilling to use cloud services). For enterprise SSOT architectures, the Power BI Service — particularly when combined with Microsoft Fabric, Microsoft's integrated analytics platform announced in 2023 — is the dominant deployment model.

In an SSOT architecture, Power BI operates as the semantic and visualization layer above a data storage and processing tier. Data originates in source systems (SAP, Veeva Vault, OSIsoft PI, Oracle, Salesforce, etc.), is ingested into a data warehouse or lakehouse (typically Azure Synapse Analytics, Azure Data Lake Storage, or Microsoft Fabric's OneLake), transformed via ETL/ELT processes (Azure Data Factory, Power Query, dbt), and then exposed to Power BI via datasets (now called "semantic models" in Fabric nomenclature) that define measures, dimensions, hierarchies, and security rules.

This layered architecture is significant from a compliance standpoint: Power BI is not the system of record for any data. It is a consumer of data. Data integrity, audit trails, and access controls at the source system level are prerequisites for SSOT trustworthiness — Power BI cannot compensate for deficiencies upstream.

### *B. The Semantic Model as the "Single Version of Truth"*

Power BI's certified dataset (semantic model) capability is the feature most directly relevant to the SSOT concept. Dataset certification — available in Power BI Premium and Fabric workspaces — allows designated data stewards to formally endorse a dataset as the authoritative source of business metrics for a given domain. Endorsed and certified datasets appear with visual indicators in the Power BI data hub, signal to report authors that these datasets should be preferred over uncertified alternatives, and can be configured to restrict modification to approved owners.

This capability is architecturally sound and aligns with SSOT principles. However, certification in Power BI is an administrative designation, not a technical lock. It does not prevent a sufficiently privileged user from altering the underlying dataset logic. Maintaining the integrity of certified datasets in a regulated environment requires complementary governance controls: change management procedures, dataset ownership assignments, workspace promotion pipelines, and periodic review of DAX measures against validated specifications.

### *C. Data Lineage and Transformation Transparency*

Microsoft has invested significantly in data lineage capabilities within the Fabric ecosystem. The lineage view in Power BI workspaces visualizes the flow of data from sources through datasets to reports and dashboards. Microsoft Purview, when integrated with Fabric, extends lineage metadata to enterprise-wide data cataloguing.

These capabilities are valuable but must be critically evaluated against regulatory expectations. Power Query M-code — the transformation language used to shape data before it reaches the semantic model — can introduce significant transformations, including filtering, column remapping, row deduplication, and formula-based value substitution. These transformations are not always transparent to end users viewing a finished report. In a regulated environment, all such transformations must be documented, version-

controlled, and included in validation test scripts to demonstrate that the reported values accurately reflect the source data. Power BI does not enforce this documentation discipline; it must be imposed externally.

## IV. COMPLIANCE ANALYSIS: POWER BI AGAINST 21 CFR PART 11

Table II presents an honest assessment of Power BI's native capabilities against each major requirement of 21 CFR Part 11. The assessment is grounded in Microsoft's publicly available product documentation and reflects platform behavior as currently documented. Capabilities are classified as Adequate, Partial, Conditional, or Insufficient to reflect the degree to which native Power BI features satisfy regulatory requirements without additional controls.

**TABLE II**

*Power BI Capability Assessment Against 21 CFR Part 11 Requirements*

| 21 CFR Part 11 Requirement | Regulatory Intent | Power BI Capability | Compliance Posture |
|---|---|---|---|
| **Audit Trails** | Required — automatic, computer-generated, time-stamped | Power BI Service logs user activity (via Microsoft Purview / Unified Audit Log); limited natively within datasets; dependent on source system audit trails. | Partial — requires source-system controls and Azure Monitor |
| **Access Controls** | Limiting access to authorized individuals | Row-Level Security (RLS), workspace roles, Azure AD / Entra ID integration; MFA support. | Adequate — well-supported with proper AAD configuration |
| **Electronic Signatures** | Signer's name, date/time, and meaning of signature | Power BI has no built-in e-signature workflow; approval workflows must be built externally (e.g., Power Automate + DocuSign). | Insufficient natively — requires external tooling |
| **Record Retention** | Records must be retrievable and accurate for required period | Datasets and reports can be archived; Power BI Premium / Fabric supports version history; retention is infrastructure-dependent. | Conditional — depends on Premium/Fabric licensing and IT governance |
| **System Validation** | Software validation per GAMP 5 or equivalent | Microsoft provides no out-of-box IQ/OQ/PQ documentation; organizations must generate validation scripts and evidence themselves. | Gap — full validation burden falls on the regulated entity |

| 21 CFR Part 11 Requirement | Regulatory Intent | Power BI Capability | Compliance Posture |
|---|---|---|---|
| **Data Integrity (ALCOA+)** | Attributable, Legible, Contemporaneous, Original, Accurate | Power BI pulls data from source systems; integrity depends on upstream ETL and source controls. Power BI itself does not certify data origin. | Inherited — ALCOA+ must be enforced at source, not in Power BI |
| **Backup & Disaster Recovery** | Protection against data loss | OneDrive / SharePoint integration; Power BI Premium offers geo-redundancy; RPO/RTO must be contractually defined with Microsoft. | Adequate with Premium — requires SLA verification |

### *A. The Audit Trail Problem*

The most significant compliance challenge with Power BI in a regulated context is the audit trail. 21 CFR Part 11 §11.10(e) requires that computerized systems used to create, modify, maintain, or transmit electronic records be capable of generating audit trails that capture date-and-time-stamped records of operator entries and actions that create, modify, or delete electronic records [1].

Power BI's semantic models do not generate record-level audit trails of data changes within the model itself. When a DAX measure is modified, there is no automatic regulatory-grade log recording who changed what formula, when, and what the previous value was. The Unified Audit Log (UAL), accessible via Microsoft Purview, does log certain Power BI service activities (dataset refreshes, report sharing events, workspace membership changes) but is not a substitute for the record-level audit trail that 21 CFR Part 11 contemplates for systems where regulated records are created or modified [5].

For an SSOT implementation to be compliant, the audit trail requirement must be satisfied at the source system level — the LIMS, MES, ERP, or clinical data management system from which Power BI pulls data. Power BI should not be the system where regulated data is created or modified; it should be read-only in relation to regulated records. When this architectural principle is maintained, the audit trail gap in Power BI itself is mitigated, because the audit trail resides appropriately in the source system. Organizations must document this architectural decision explicitly in their validation documentation.

### *B. Electronic Signatures*

21 CFR Part 11 Subpart C establishes requirements for electronic signatures, including the requirement that they be unique to the individual, not reused by others, and accompanied by a printed name, date/time, and the meaning of the signature [1]. Power BI has no native electronic signature capability. Approval workflows — for example, a quality manager approving a batch record dashboard or releasing a CAPA closure — cannot be completed within Power BI.

Organizations wishing to use Power BI as part of workflows that include required approvals must integrate with a separately validated electronic signature solution. Microsoft Power Automate can orchestrate such workflows, and integrations with DocuSign, Adobe Acrobat Sign, or a validated internal signature module are technically feasible. However, each such integration represents a point of complexity that must itself

be validated, and the validation scope grows accordingly. It is not sufficient to implement Power Automate as an integration layer and assume compliance follows; the entire workflow, including the handoff from Power BI to the signature platform and back, must be tested and documented.

### *C. System Validation Obligations*

Perhaps the most important point to communicate clearly is that Microsoft's compliance certifications — ISO 27001, SOC 2 Type II, FedRAMP Moderate for Government — do not satisfy an FDA-regulated organization's CSV obligations. These certifications address the security and operational reliability of Microsoft's infrastructure. They say nothing about whether a regulated entity's specific Power BI implementation correctly calculates a yield formula, applies the right business logic to a CAPA aging report, or enforces the correct row-level security restrictions for a controlled substance inventory dashboard.

The validation obligation rests entirely with the regulated entity. This means authoring a Validation Plan that defines scope, risk classification, and regulatory basis; executing IQ, OQ, and PQ protocols; retaining signed test evidence; and maintaining the validated state through change control. Microsoft's documentation acknowledges this responsibility but provides minimal scaffolding for it. Organizations typically must develop their own validation frameworks or engage specialized CSV consulting resources.

## V. RISK REGISTER FOR POWER BI IN FDA-REGULATED ENVIRONMENTS

Table III provides a structured risk register identifying the primary compliance and operational risks of deploying Power BI in a regulated SSOT architecture. Severity ratings (High / Medium / Low) reflect the potential for regulatory finding, patient safety impact, or data integrity compromise. They are qualitative assessments, not the output of a formal quantitative risk model.

**TABLE III**

*Risk Register: Power BI as SSOT in FDA-Regulated Environments*

| Risk | Severity | Description | Mitigation |
|---|---|---|---|
| **Data Drift / Transformation Opacity** | **High** | ETL pipelines in Power Query may alter source data without a complete audit trail visible to end users. | Enforce data lineage documentation; validate all M-language transformations; version-control Power Query scripts. |
| **Unvalidated Report Changes** | **High** | Ad hoc edits by report authors can change business logic without change control records. | Implement workspace governance: promote reports through Dev → Test → Prod; require change tickets for each promotion. |
| **No Native E-Signature** | **High** | Approval workflows (e.g., batch release) cannot be completed within Power BI alone. | Integrate with validated e-signature solutions (e.g., DocuSign, Adobe Sign via |

| Risk | Severity | Description | Mitigation |
|---|---|---|---|
| | | | Power Automate); document integration validation. |
| **Shared Dataset Mutation** | **Medium** | Multiple downstream reports share a certified dataset; a schema change can silently break compliance logic. | Certify and lock certified datasets; require formal impact assessment before schema changes. |
| **Vendor Lock-In / Service Changes** | **Medium** | Microsoft may deprecate APIs, modify Fabric features, or change SLAs without regulatory notice. | Maintain platform-agnostic source data; subscribe to Microsoft update communications; include vendor lock-in risk in IT risk register. |
| **Audit Log Accessibility** | **Medium** | Unified Audit Log (UAL) is not Power BI-native; logs reside in Microsoft Purview and have a 90-day default retention. | Extend UAL retention via Azure Log Analytics; periodically export and archive logs to validated long-term storage. |
| **Row-Level Security Misconfiguration** | **Medium** | Incorrectly scoped RLS can expose restricted data across departments. | Formally test and document RLS rules; include in validation test scripts; re-test after every role or DAX change. |
| **Internet Connectivity Dependency** | **Low** | Power BI Service is cloud-hosted; loss of connectivity disrupts access to reports. | Define downtime procedures; evaluate Power BI Report Server (on-premises) for mission-critical, disconnected use cases. |

## VI. IMPLEMENTATION GUIDANCE

### *A. Architectural Principles for a Compliant Deployment*

The following architectural principles should guide Power BI deployment in any FDA-regulated environment. They reflect both regulatory expectations and practical experience with validated analytics platforms.

**Principle 1: Power BI is a reporting layer, not a system of record.**

Regulated data — batch records, device history records, clinical study data, laboratory results — must originate in and be maintained by source systems that are independently validated to the appropriate GxP standard. Power BI reads from these systems; it does not own data. This principle must be enforced technically (read-only connections), architecturally (no data entry in Power BI), and procedurally (SOPs explicitly prohibiting use of Power BI as a primary record system).

**Principle 2: The semantic model is the single source of business logic.**
For SSOT to function in practice, all agreed business definitions — yield calculations, batch size normalization, CAPA aging logic, lot genealogy — must reside in a single certified semantic model. Duplicate calculations in individual reports undermine SSOT. Dataset certification, combined with governance policies preventing report authors from creating local calculated columns that shadow certified measures, is essential.

**Principle 3: Every transformation must be documented and version-controlled.**
Power Query transformations, DAX measures, calculated tables, and any embedded Python or R scripts are business logic with compliance implications. They must be documented in specification documents, stored in version control systems (e.g., Azure DevOps, GitHub), and explicitly tested in OQ and PQ protocols. Undocumented transformation logic is a direct data integrity risk.

**Principle 4: Promotion pipelines replace ad hoc development.**
Power BI deployment pipelines (Dev → Test → Production) or equivalent governance mechanisms must be implemented and enforced. Changes to production workspaces must be traceable to change control records. The ability of any authorized user to directly modify a production report must be controlled and, ideally, technically restricted.

***B. Implementation Checklist***

Table IV provides a structured implementation checklist for organizations undertaking a Power BI SSOT deployment in a regulated environment. The checklist is intended as a starting point; organizations must adapt it to their specific regulatory context, risk profile, and existing quality system.

**TABLE IV**

*Implementation Checklist for Power BI in FDA-Regulated Environments*

| Category | Action Item | Owner |
|---|---|---|
| **Platform Architecture** | Define whether Power BI Service (cloud) or Report Server (on-premises) will be used | IT / Compliance |
| **Platform Architecture** | Document system configuration including tenant settings, gateway configurations, and data source connections | IT |
| **Platform Architecture** | Confirm Microsoft 365 / Azure tenant is SOC 2 Type II certified (obtain current AOC from Microsoft) | IT / QA |
| **Validation (CSV)** | Develop Validation Plan citing regulatory basis (21 CFR Part 11, GAMP 5 category) | QA / Validation Lead |
| **Validation (CSV)** | Author IQ: confirm software installation, tenant configuration, and environment specifications | Validation Lead |
| **Validation (CSV)** | Author OQ: verify Power BI functions per design specifications (RLS, data refresh, audit log availability) | Validation Lead |

| Category | Action Item | Owner |
|---|---|---|
| **Validation (CSV)** | Author PQ: execute user-acceptance test scripts in production environment with actual regulated data scenarios | Validation Lead / End Users |
| **Validation (CSV)** | Execute all test scripts with actual data; obtain wet or electronic signatures on executed protocols | Validation Lead / QA |
| **Validation (CSV)** | Issue Validation Summary Report; obtain QA and management approval | QA Director |
| **Data Governance** | Define a certified dataset ownership model with named stewards | Data Governance / IT |
| **Data Governance** | Establish workspace promotion pipeline: Dev → UAT → Production | IT |
| **Data Governance** | Configure dataset certification and endorsement policies | IT / QA |
| **Data Governance** | Document all Power Query (M) transformations; version-control in source repository | Data Engineer |
| **Access Control** | Map all users to Azure AD / Entra ID groups; enforce MFA | IT Security |
| **Access Control** | Implement and test Row-Level Security rules; document test evidence | IT / Validation |
| **Access Control** | Define and document workspace roles (Admin, Member, Contributor, Viewer) | IT / QA |
| **Audit & Monitoring** | Enable Unified Audit Log in Microsoft Purview; extend retention ≥ retention period required by regulation | IT |
| **Audit & Monitoring** | Configure Azure Monitor / Log Analytics for Power BI activity exports | IT |
| **Audit & Monitoring** | Define audit log review frequency and assign responsibility | QA / Compliance |
| **Change Control** | Integrate Power BI workspace changes with corporate change control system | QA / IT |
| **Change Control** | Define and communicate process for report and dataset change requests | QA |
| **Training** | Deliver and document training for report authors on GxP data integrity obligations | QA / Training |

| Category | Action Item | Owner |
|---|---|---|
| **Training** | Maintain training records in validated LMS or controlled document system | HR / QA |
| **Periodic Review** | Schedule annual (or change-triggered) re-validation assessment | QA |
| **Periodic Review** | Review Microsoft service updates quarterly; assess impact on validated state | IT / QA |

## VII. LIMITATIONS AND AN HONEST ASSESSMENT

### *A. What This Paper Cannot Determine*

This paper does not present experimental data, organizational case study evidence, or quantitative risk scores derived from empirical measurement. The compliance assessments in Table II are grounded in Microsoft's product documentation and the authors' reading of applicable regulations, but they cannot account for every possible Power BI configuration, licensing tier, or integration scenario. Organizations must perform their own gap assessments.

Furthermore, Power BI is a rapidly evolving platform. Microsoft releases updates frequently, sometimes altering feature behavior, deprecating capabilities, or introducing new compliance-relevant functionality. Any assessment of Power BI's compliance posture has a finite shelf life. Organizations should establish a process for monitoring Microsoft's release notes and assessing their impact on the validated state of their implementation.

### *B. A Candid View of the SSOT Claim*

The designation of any system as a "Single Source of Truth" carries significant operational and regulatory weight. In a regulated environment, SSOT implies that the data in question is the authoritative, validated, and auditable record that would be submitted to the FDA, relied upon in a quality investigation, or presented during an inspection. Power BI, in its current form, cannot independently sustain that designation.

What Power BI can legitimately claim is the role of a "Single Source of Reporting" — a unified interface through which consistently defined, governance-controlled metrics derived from validated source systems are presented to users. This is a meaningful and valuable capability. It prevents the proliferation of shadow spreadsheets, aligns organizational understanding of KPIs, and provides operational visibility. But it is categorically different from being the authoritative record system.

Organizations that deploy Power BI and describe it to their quality teams or regulators as the "SSOT" without qualification risk creating a misunderstanding about where data integrity controls actually reside. The honest description is: Power BI is the authorized reporting interface over our validated source systems, and the integrity of the data it displays is guaranteed by the controls in those source systems, which we have independently validated.

### *C. Comparison with Purpose-Built GxP Platforms*

Purpose-built GxP platforms — such as Veeva Vault QualityDocs, MasterControl, Pilgrim SmartSolve, or validated LIMS systems from LabVantage or LabWare — are designed from the ground up to satisfy

21 CFR Part 11. They provide pre-validated audit trails, native electronic signature workflows, and vendor-supplied IQ documentation. Deploying Power BI in parallel with these systems for operational reporting and analytics is rational and commonplace. Attempting to replace these systems with Power BI is not advisable and would likely not withstand regulatory scrutiny.

The value proposition of Power BI in a regulated environment is aggregation and visualization across validated systems, not substitution of those systems. Organizations should resist the temptation — often driven by IT cost consolidation — to position Power BI as a replacement for validated GxP applications.

## VIII. CONCLUSION

Power BI is a capable, scalable, and increasingly feature-rich business intelligence platform. Its adoption in FDA-regulated life sciences environments is a natural consequence of broader enterprise digital transformation initiatives, and when deployed thoughtfully, it can deliver genuine value: operational visibility, consistent KPI definition, and reduced reliance on ungoverned spreadsheets.

However, Power BI is not a validated GxP system, and it should not be positioned or understood as one without significant complementary controls. Its native capabilities leave substantive gaps against 21 CFR Part 11 requirements — most notably in record-level audit trails, electronic signatures, and system validation scaffolding. These gaps are not disqualifying, but they are not trivial either. Each must be addressed through architectural decisions, external tooling, or procedural controls — all of which must be documented and validated.

The Single Source of Truth label, when applied to Power BI in a regulated context, is most accurately reframed as "Single Source of Reporting." The integrity of data displayed through Power BI remains contingent on the integrity of upstream source systems and the ETL processes that connect them. An organization cannot outsource its ALCOA+ obligations to a reporting layer.

For organizations committed to a compliant Power BI deployment, the path is defined: perform a thorough gap assessment against applicable regulations; classify the system under GAMP 5; author, execute, and retain IQ, OQ, and PQ documentation; implement governance controls for dataset certification and workspace promotion; integrate validated audit and signature capabilities; and establish a change control and periodic revalidation program. This path is achievable. It requires organizational commitment, quality system integration, and realistic expectations. It does not require abandoning Power BI — only deploying it honestly.

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