DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/9/2026-2/12/2026 FEI NUMBER 3010539401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Thomas K. Spain, Chief Operating Officer	
FIRM NAME Gobiquity, Inc	STREET ADDRESS 1321 Murfreesboro Pike Ste 202
CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37217-2672	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.

Specifically,

Your firm failed to apply a risk-based approach to the control of appropriate processes needed for the quality management system. Your firm's failure to apply risk-based controls to complaint handling, nonconforming product control, corrective action, and data analysis limits your firm's ability to identify, assess, and mitigate risks (including cybersecurity vulnerabilities) that could adversely affect patients including but not limited to personal health information breach and clinical risk factors remain undetected and patient is not referred for further evaluation (HA-21 and HA-46).

For example,

A. **Complaint Handling:** Appendix A of your firm's Corrective and Preventive Action (CAPA) Interim Protocol (QMS-PR-16-001 Rev 03, effective 7/8/2024) does not establish criteria for determining risk associated with complaints. The procedure does not define the terms "negligible" or "N/A," yet your firm has classified all complaints received since at least 2024 with these undefined risk levels. Additionally, your firm has failed to adequately investigate complaints in a timely manner or evaluate whether complaints represent cybersecurity issues that could impact patient safety or data security. For example,

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	Jamie P Webb, Investigator X Jamie P Webb Investigator Signed By: 2003424907 Date Signed: 02-12-2026 10:22:29	2/12/2026

a) System-wide outage not adequately investigated. On February 19, 2025 (one day after recall documents were signed), your firm experienced a system-wide outage affecting the GoCheck Kids App and Portal, resulting in approximately 113 customer complaints logged on the same day. Your firm classified all complaints as "Negligible" or "N/A" risk and did not initiate a CAPA or document an investigation of the root cause, despite the scale of the outage. Your firm did not document an evaluation of whether the outage was related to Design Change DC-2024-SA-02 or the recall corrections, or whether the outage indicated the recall corrections were ineffective.

B. **Control of Nonconforming Product**, Your firm has failed to apply risk-based controls to the evaluation and disposition of nonconforming product, resulting in nonconforming devices remaining in quarantine without proper disposition since at least July 2024. These devices require critical software updates, including cybersecurity patches, but cannot be released until properly dispositioned.

C. **Corrective Action**, Your firm has failed to apply adequate risk-based controls to corrective action processes, resulting in inadequate investigation of root causes (including whether issues impact the cybersecurity of your devices) and delayed implementation of corrective actions. For example,

a) Inadequate root cause analysis for software-related CAPA. CAPA-00077 (opened 10/9/2024) identified that an EHR web application release was not handled as a design change, resulting in inadequate testing and "out-of-box" device failures. However, The corrective actions address only the immediate technical fix (updating the EHR procedure and developing unit tests for the specific code block) but do not address the systemic failure to identify software changes as design changes requiring change control per your Design and Development procedure. Additionally, your firm did not assess whether this software defect could have introduced cybersecurity vulnerabilities.

b) Recall effectiveness not verified. Your firm initiated CAPA-00078 in January 2025 to address functional failures caused by Design Change DC-2024-SA-02. In February 2025, your firm determined a recall was necessary and signed recall documents (Health Hazard Evaluation and Correction and Removal Summary Form, QS-008-F1 Rev C) on February 18, 2025. The

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Correction and Removal Summary Form states that effectiveness checks would be conducted and documented. However, your firm did not document effectiveness checks to verify that the recall successfully reached affected customers or that the corrective actions were effective. Additionally, on February 19, 2025 (one day after the recall documents were signed), your firm experienced a system-wide outage resulting in approximately 113 customer complaints, which your firm did not evaluate for potential relationship to the recall corrections or as an indicator that the recall corrections may have been ineffective.

D. **Analysis of Data and Management Review**, Your firm has failed to apply risk-based controls to the analysis of quality data and management review processes, limiting management's ability to identify systemic issues (including cybersecurity risks) and ensure QMS effectiveness. For example,

a) Cybersecurity vulnerabilities are not adequately integrated into your firm's QMS processes. Your firm does not have documented procedures for how cybersecurity vulnerabilities are identified through [redacted] testing or other security assessments.

Your firm's [redacted] testing performed in [redacted] identified a Critical cybersecurity vulnerability [redacted]. Your firm corrected this vulnerability. However, your firm did not adequately document the risk assessment (including whether the vulnerability represented Controlled or Uncontrolled risk), the rationale for why the compensating controls were adequate to mitigate the risk, or the evaluation of whether the vulnerability required reporting under 21 CFR Parts 803 or 806.

b) Nonconformances are not included in Management Review. Section 6.1.3.4 of your Management Responsibilities and Controls procedure (QS-SOP-003 Rev F, effective 12/12/2019) requires management review input to include "Monitoring and measurement of products, including supplier management" and "Monitoring and measurement of processes, including supplier management." However, Nonconforming product data was not included as input to FY 2023 or FY 2024 Management Reviews, despite nonconformances accumulating without adequate disposition since at least July 2024.

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c) Supplier approval and monitoring requirements not followed. Your firm's (b)(4) testing vendor (Level 3 supplier) was added to the Approved Supplier List (ASL) in August 2025 without completing the required Supplier Approval Form (QS-005-F2). Section 6.1.2 of QS-SOP-005 Rev G requires a Supplier Approval Form, QS-005-F2, for each Level of supplier (Levels 1-3) and for any supplier added to the approved supplier list (ASL). Instead, your firm used a memo dated August 25, 2025 to approve (b)(4) suppliers simultaneously, stating "No additional Supplier approval form was necessary due to this documented review." When requested during the inspection, your firm confirmed no Supplier Approval Form exists for your firm's (b)(4) Testing supplier.

d) Management acknowledged systemic failures but did not implement adequate controls. During the inspection, your Chief Operating Officer stated that the previous Quality personnel ~~were terminated~~ **[resigned]** in August 2025 ~~due to~~ **[following]** inadequate handling of complaints and nonconformances. However, as of February 2026 (6 months later), the same systemic issues persist.

OBSERVATION 2

Design and development changes were not adequately reviewed, verified, validated, and approved before implementation.

Your firm did not adequately control design changes made to correct cybersecurity vulnerabilities identified through (b)(4) testing, resulting in a recall due to functional issues and the subsequent identification of a Critical cybersecurity vulnerability. For example:

A. **Design Change DC-2024-SA-02 (January 2025):** Initiated to correct cybersecurity vulnerabilities identified in 2023 and 2024 (b)(4) testing, including (b)(4), (b)(4)' and (b)(4) Your firm did not

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adequately verify and validate the design change prior to release, resulting in a recall due to functional failures [redacted] caused by the security fixes.

B. **Recall corrections not evaluated for cybersecurity impact:** After correcting the functional issues caused by DC-2024-SA-02, your firm did not document an evaluation of whether the corrections could introduce or exacerbate cybersecurity vulnerabilities. Nine months later [redacted] testing identified a [redacted] in the same vulnerability category [redacted] as the vulnerabilities DC-2024-SA-02 was intended to correct. This vulnerability **[could have allowed]** allowed [redacted] user accounts across all clinics. Your firm did not document an evaluation of whether the Critical vulnerability was related to the design changes made in DC-2024-SA-02 or the subsequent recall corrections.

C. **Inadequate design change control**:

- 2023-2024 [redacted] Testing: Your firm failed to correct identified [redacted] vulnerabilities in a timely manner (2023 vulnerability still present in 2024 testing)
- Risk management not updated: Hazard Analysis (RMF-05-02 Rev 07) does not include hazards related to design change errors or inadequate verification/validation of design changes

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Under consideration

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."