DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	3/23/2026-3/30/2026* FEI NUMBER 1825740

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eric A. Bonderman, Director and Owner

FIRM NAME	STREET ADDRESS
Analytical Control Systems, Inc	9058 Technology Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fishers, IN 46038-4511	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

One or more processes for risk management in product realization have not been adequately documented.

Specifically, your procedure QSP 7.3-3 Risk Management, Rev A, effective 07/11/2014 states in section 6.1 Overview that a Risk Management Plan is used to describe and identify the medical device being analyzed, identify the intended use and purpose of the device, identify the personnel who will execute the risk analysis and define the risk analyses that are to be conducted, Additionally, the procedure state a risk evaluation/analysis shall be documented for each product/product family, as applicable, with the risk assessment summarized in the Risk Management Summary.

However, your firm provided an incomplete Risk Management Plan for the Hemoglobin Controls Product and an incomplete Risk Management Plan and Summary for the Serum Based Products. For example, both risk management files did not have the required risk mitigation strategies nor the residual risk analysis following mitigation strategies.

OBSERVATION 2

Procedures for validation of processes were not adequately documented.

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Specifically, your procedure QSP 7.5-6 Process Validation Procedure, Rev A.01, effective 10/10/2016 states in the Purpose-Scope that validation is required when the results of a process cannot be fully verified by documented inspection and testing. The procedure states a validation will include a Validation Protocol and a Validation Report and be included in the Master Validation List Form 7.5-6-1.

However, your firm could not provide a Master Validation List Form 7.5-6-1 nor the Validation Protocol and Validation Report for the (b) (4) process.

OBSERVATION 3

Infrastructure requirements needed to achieve conformity to product requirements have not been adequately documented.

Specifically, your firm installed two new (b) (4) with serial number (b) (4) and (b) (4) during December 2022 and February 2023. Your procedure QSP 6.3.2 Equipment Installation Qualification, Rev A, effective 06/27/2014 requires that new equipment complete an Equipment Installation Checklist Form 6.3-2-2. This checklist described the requirements for establishing calibration requirements, maintenance requirements, installation qualification, process validation, performance qualification, and other requirements.

However, your firm did not complete the Equipment Installation Checklist and its prescribed activities for the new (b) (4) to ensure that equipment used in the manufacturing process meets specified requirements. For example:

- The (b) (4) have not been assessed to determine if a new process validation or performance qualification is required for the (b) (4) process that is used to (b) (4) the product.
- The (b) (4) are not on the Equipment Master List Form 6.3-2-1 that tracks calibration requirements and have not undergone calibration at the recommended (b) (4) intervals stated in the operations manual.
- The (b) (4) are not on the Preventive Maintenance Schedule Form 6.3-4-1 which tracks

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equipment that requires maintenance and have not undergone their manufacturer's recommended preventive maintenance of (b) (4) and (b) (4) tasks.

OBSERVATION 4

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

Specifically, your procedure QSP 7.4-1 Supplier Evaluation and Monitoring, Rev A, effective 07/11/2014 does not apply a risk-based approach to the evaluation and monitoring of suppliers critical to the quality of the finished product. For example:

- Suppliers are not categorized based on risk to the finished product.
- Unique blood doners that provide raw material product for finished goods not considered suppliers.
- There is no objective criteria for what is acceptable and not acceptable performance for a supplier.
- Suppliers currently on the Approved Supplier List do not have the required Supplier Initial Evaluation Form 7.4-1-1 for initial qualification nor the Ongoing Supplier Evaluation Form 7.4-1-4 to monitor ongoing performance.

OBSERVATION 5

Corrective action procedures defining the requirements for evaluating the need for action to ensure that nonconformities do not recur, planning and documenting action needed and implementing such action, verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically, your procedure QSP 8.5-1 Corrective and Preventive Action, Rev A, effective 06/20/2014 states in the Purpose-Scope that the controls exercised over the corrective action and preventive action

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programs at your firm include analysis, investigation of root cause, identify corrections and on-going corrective actions required to correct or prevent any deficiencies or potential deficiencies related to products, processes or the quality management system, and to verify and validate the CAPA was effective and does not adversely affect the finished device.

However, 7 of the 7 CAPA records reviewed were incomplete and did not include implementation of corrective actions or verification of effectiveness.

OBSERVATION 6

Justification for not investigating a complaint(s) was not adequately documented.

Specifically, your procedure QSP 8.2-1 Customer Inquiries and Complaints, Rev A, effective 10/22/2014 states in section 6.13.2 if a complaint product is not available for evaluation, the following will be noted in the Complaint section of the Form as appropriate for the situation:

- Previous number of complaints related to the defect noted
- Evaluation of available product or samples
- Review of appropriate Device History Records to provide component traceability and assure that the required tests have been completed.

Your firm received two complaints in 2022 for the same lot (b) (4) within a one-month time frame alleging invalid values or out or range values, Complaint 2022-01 and 2022-02. However, your firm chose not to investigate the issue and did not conduct a review of previous complaints, evaluation of samples, or review of device history records.

OBSERVATION 7

Procedures to describe the responsibilities and requirements for planning and conducting internal audits and recording and reporting audit results were not adequately documented.

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Specifically, your procedure QSP 8.2-2 Internal Audits, Rev A, effective 10/22/2014 states in section 6.1.4 all elements and processes of the Quality System and associated procedures shall be audited on a (b) (4) basis. Additionally, section 6.1.1 states an Internal Audit Plan will be developed for the (b) (4) and section 6.10 described utilizing the Internal Audit Report Form 8.2-2-4 to record the pertinent audit information.

However, your firm did not have records for internal audits for 2024 and 2023. Additionally, internal audit for 2025 and 2022 contained only the plan and no final report. The 2025 and 2022 internal audit plans only contained portions of the quality system and not the whole quality system. Thus, the whole quality system has not been audited on (b) (4) basis as required.

OBSERVATION 8
Procedures for management review have not been adequately documented.

Specifically, your procedure QSP 5.6-1 Management Review, Rev B, effective 10/2/2022 states in section 6.1 that there must be scheduled management review meetings with informal meetings occurring at any frequency and formal management review meetings conducted at least (b) (4) Your firm stated that informal meetings currently occur (b) (4)

However, your firm was only able to provide management review meeting records for January 2026 and Oct 2022 of which the records were not completed according to your procedure requirements.

***DATES OF INSPECTION**
3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/30/2026(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

Observation 8: Promised to correct

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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."