DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	4/7/2026-4/10/2026
	FEI NUMBER 1000548922

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bruce K Lee, Vice President of Operations

FIRM NAME	STREET ADDRESS
All Quality & Services, Inc.	401 Kato Ter
CITY, STATE, ZIP CODE, COUNTRY Fremont, CA 94539-8333	TYPE ESTABLISHMENT INSPECTED Contract 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 WE OBSERVED:

OBSERVATION 1

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically,

Your firm's procedure, QMSP-830-001 Control of Nonconformance Procedure, Revision M, Effective Date 09/30/2023, fails to meet established requirements. For example,

a. Physical segregation requirements or controls to prevent unintended use of nonconforming material are not adequately defined.

b. Criteria are not defined for when investigations are required, scope of investigation activities, root cause analysis requirements, or evaluation criteria for determining the need to notify external parties responsible for the nonconformity.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Brittany D Mccracken, Investigator
Sasha L Eckstein, Investigator

X Brittany D Mccracken Investigator Signed By: BRITTANY D. MCCRACKEN -S Date Signed: 04-10-2026 10:27:59

DATE ISSUED
4/10/2026

c. The procedure requires (b) (4) for Part Verification and (b) (4) for NCMRs but fails to define specific roles, qualifications, authority levels for different disposition types, or criteria for determining appropriate dispositions.

d. Whether rework procedures undergo the same review and approval as original procedures is not discussed.

e. Handling nonconforming products detected after delivery is not addressed.

f. Criteria are not defined for when customer notification is required, notification timeframes, content requirements, documentation of customer acceptance, or regulatory authority notification requirements.

OBSERVATION 2

Corrective action procedures defining the requirements for reviewing nonconformities, determining the causes of nonconformities, 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 firm's procedure, QMSP-852-001 Corrective Action Procedure, Revision J, Effective Date 03/17/2022, fails to meet established requirements. For example,

a.It is unclear what documentation is required for corrective actions including investigation results, root cause analysis, action plans, timelines, responsibilities, or verification of effectiveness.

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b. Requirements are not addressed to verify that corrective actions do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.

c. Criteria for effectiveness, timeframes for review, methods for verification, or responsibilities for conducting effectiveness reviews have not been defined.

d. The procedure does not define what constitutes "timely" or establish timeframes for corrective action completion.

e. Record requirements for corrective actions including results of investigations, actions taken, verification of effectiveness, or rationale for decisions are not adequately defined.

OBSERVATION 3

Records from management review were not adequately maintained.

Specifically,

a. The records do not adequately document review of monitoring and measurement of all QMS processes.

b. Zero of the four management review records reviewed during the inspection include review of preventive actions as a distinct input, despite your firm having a Preventive Action procedure.

c. The management review records do not adequately document decisions and actions related to improvement of products related to customer requirements.

d. Multiple positions are listed as "Need" without documented decisions or timelines. Multiple action items show extended delays.

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e. The management review records show inconsistent treatment of required inputs across different review periods, suggesting the firm does not have a systematic approach to ensuring all inputs are addressed.

OBSERVATION 4

Process(es) for establishing competence, providing needed training and ensuring personnel awareness have not been adequately documented.

Specifically,

Your firm fails to have an established procedure that defines competence, awareness, and training needs. While a training matrix was maintained, no written procedure was available to define the process for identifying training needs, providing training, or evaluating training effectiveness.

OBSERVATION 5

Written MDR procedures have not been developed.

Specifically,

Your firm failed to establish written procedures for medical device reporting.

X Sasha L Eckstein
Investigator
Signed By: SASHA L. ECKSTEIN -S
Date Signed: 04-10-2026 10:28:53

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

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X Brittany D Mccracken
Investigator
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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."