

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax: (410)779-5707	DATE(S) OF INSPECTION 4/9/2020-4/20/2020*
	FEI NUMBER 3015448605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph A. Rogalewicz, Site Quality Head

FIRM NAME EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC.	STREET ADDRESS 5901 E Lombard St
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CITY, STATE, ZIP CODE, COUNTRY Baltimore, MD 21224-6824	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory
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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

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

- A. The Quality Unit failed to ensure that electronically held data generated during analytical testing of Drug Substance, Drug Product, and stability samples, was protected from deletion or manipulation, and/or reviewed for accuracy and completeness. The Quality Unit also failed to review audit trails of various Data Acquisition Software platforms, in support of generated analytical results. At the time of this inspection, no investigations had been performed to assess the impact of the data deletions, modifications or the failure to review system audit trails on drug substance and drug product analyzed until approximately, December 2019.

For example, (b) (4), data acquisition software, was used for analytical testing of drug substance and drug product from approximately (b) (4) to (b) (4). An audit trail review identified (b) (4) deletions, and (b) (4) reprocessed files. No investigation to the nature of the deletions or reprocessed files, or assessment of the impact to reported drug substance and drug product analysis, was performed.

- B. Analytical Balances used in the analysis of drug substance and drug product, sample receipt, and sample preparation, have no mechanism by which to prevent users from changing the date and time

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present on printed records.

C. The Windows Operating System installed on the firm's computers, do not fully prevent users from changing the system date and time. During the biochemistry laboratory walk-through, it was observed that the preset time-zone and subsequently, the date and time was able to be modified.

OBSERVATION 2

Established specifications, test procedures and laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

A. Sample Identification numbers are inconsistent and were observed to be manually corrected, multiple days after data acquisition. No investigation was performed, nor was any documented justification provided for the changes to sample identification numbers. For example,

Analysis Number (b) (4),
Test Method (b) (4), Step 6.8.6 directs the analyst to "(b) (4)", the following manual edits to the sample ID numbers (b) (4) were observed.

- (b) (4) #QC19-0549A, acquired on (b) (4), was changed to QC19-0549B on 11/18/2019.
- (b) (4) #QC19-0352A, acquired on (b) (4), was changed to QC19-0553A then QC19-0552A, on 11/19/219.
- (b) (4) #QC19-0352B, acquired on (b) (4), was changed to QC19-0552B on 11/19/2019.

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- (b) (4) #QC19-0353A, acquired on (b) (4) was changed to QC19-0553A on 11/19/2019.
- #QC19-0553B, acquired on (b) (4) was changed to QC19-0553B on 11/19/2019.
- #QC19-0354A, acquired on (b) (4) was changed to QC19-0554A on 11/19/2019.
- #QC19-0354B, acquired on (b) (4) was changed to QC19-0554V on 11/19/2019.
- #QC19-0355A, acquired on (b) (4) was changed to QC19-0555A on 11/19/2019.
- #QC19-0355B, acquired on (b) (4) was changed to QC19-0555B on 11/19/2019.

The print out of the sequence, however, was not manually corrected to align with the change in the sample (b) (4), noted on the printed (b) (4). No supporting data or documented justification for the change in sample (b) (4) on the (b) (4) was provided, and no investigation into the (b) (4) discrepancies was performed by the Quality Control Unit.

B. Deviations from test methods are not investigated, and are manually corrected, days after performance, with no supporting data or documented justification for the changes. For example,

(b) (4), the sample incubation (b) (4) was originally documented as performed on (b) (4) at (b) (4) °C from (b) (4) to (b) (4), with (b) (4) incubation (b) (4) Treatment) performed at (b) (4) °C, from (b) (4) to (b) (4). Per Test Method (b) (4), analysts shall "(b) (4)". On 15AUG2019, the incubation temperature and times for the (b) (4) were manually corrected and exchanged with the incubation temperature and times of the (b) (4) treatment, without any documented evidence, or justification supporting the change, or investigation into the apparent deviation from the test method.

C. Documentation of Stability Sample Analyses documentation for appearance, (b) (4) determination and

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(b) (4), Per (b) (4), "Visual Inspection (Appearance) of (b) (4) using the (b) (4) Method" are deficient; the lot number of the (b) (4) glass tubes used in analysis are not recorded, glass tubes are (b) (4) with (b) (4) which is not filtered for residue, particulates or oil, and after determination of (b) (4), the sample (b) (4) does not have to be immediately used, however there is no documentation regarding the sample storage between analyses. For example,

(b) (4), (b) (4) determination of samples was performed on (b) (4), and (b) (4) analysis was performed on (b) (4). However, no records could be provided, documenting where the samples were stored between analyses, despite the required (b) (4) °C sample storage condition.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- A. SOP042317, "QC Investigations and Invalid Events", does not preclude the analyst who performed the analysis which generated an invalid event, from performing an independent investigation into the invalid event. (b) (4) of (b) (4) invalid events since January 21, 2020 were investigated by the same analyst who performed the original analysis. The written procedure states that "verbal approval can be used in order to move forward with a repeat test". As such, sample retest, per the written procedure, is possible prior to a documented secondary review and approval of the accuracy and completeness of the invalid event investigation.
- B. Data generated from laboratory analyses is not reviewed in a timely manner, or in accordance to the written procedure. SOP000299, "Review of Quality Control (QC) Data", Step 6.1.2.1, establishes that QC data shall

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be reviewed within (b) (4) days. However, it was repeatedly observed that data is routinely reviewed outside of the (b) (4) day window, without comment, justification or investigation

OBSERVATION 4

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically,

On 04/09/2020 during a walkthrough of the biochemistry laboratory, (b) (4) storage solutions, (b) (4), were observed connected to an HPLC. Upon request, it was determined that the preparer did not document preparation of the (b) (4) solutions, per the firm's written procedure, SOP002191, "Solution Preparation". Additional request for the preparer's training record resulted in determination that traceability of the preparer to training records was not possible, as the preparer was not present on the firm's employee signature log. There is no documented evidence the preparer has been trained on that relevant procedure(s). Additional inquiry identified (b) (4) other people who participate in analysis or perform actions in the firm's analytical laboratories, are similarly not identified on the employee signature log, preventing traceability to their relative training and qualifications. At the time of this inspection, no assessment had been made to the impact on analysis performed, or impacted, by personnel who do not have documented evidence of training on the firm's written procedures or test methods.

OBSERVATION 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected components before disposition.

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(b) (4) of (b) (4), Lot No. (b) (4) and (b) (4) containing a (b) (4). Lot No. (b) (4), were observed in the reject cage. Upon inquiry, it was determined that there was no associated non-conforming material report initiated for the (b) (4), indicating the rationale for rejection, as per written procedure, SOP001965, "Non-Conforming Material Process". Additionally, it was determined that, the (b) (4), Lot No. (b) (4), was previously rejected and disposed for disposal within (b) (4), on (b) (4). Neither material was labeled with reject labels as per SOP001965.

***DATES OF INSPECTION**
4/09/2020(Thu), 4/10/2020(Fri), 4/14/2020(Tue), 4/15/2020(Wed), 4/16/2020(Thu), 4/17/2020(Fri), 4/20/2020(Mon)

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