From: Oates, Mary [redacted]

To: Havey, Adam
Sent: 2/16/2021 9:22:27 AM
Subject: FW: [External] Fwd: Emergent Event

Confidential

Adam I need your advice on how to proceed with this. Please let me know when we can talk.

Regards,
Mary

From: [redacted] <[redacted]@lachmanconsultants.com>
Sent: Tuesday, February 16, 2021 8:26 AM
To: Oates, Mary <[redacted]@ebsi.com>
Subject: [External] Fwd: Emergent Event

I received this from [redacted], spoke to him and then indicated I would pass this on to you. [redacted] voiced concerned about this and wants to be certain he addresses this appropriately as well as escalate it to me. I confirmed that he did speak within the Emergent organization, "Chain of Command" and we both felt this should be brought to your attention. You may have been made aware from the local team, but we wanted to be sure you received the information from us ,and you could then provide [redacted] with direction as to how he should respond to this if questioned again as well as any documentation he should provide in his QA support role.

Thanks Mary and hope all is well,

[redacted]

Begin forwarded message:

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From: [redacted]<[redacted]@lachmanconsultants.com>
Date: February 15, 2021 at 8:15:45 PM MST
To: [redacted]<[redacted]@lachmanconsultants.com>
Subject: Emergent Event
Hi [redacted]

I was made aware of an event at Emergent Bayview last Thursday, February 11th, that I want to bring to your attention.

February 11th was the third and final day of the FDA site visit focusing on the Janssen Covid-19 vaccine, although some topics regarding other Emergent clients were also discussed. In addition to the typical document reviews and subject matter expert interviews, the FDA inspectors went on several tours during their three days on site. On Thursday February 11th the inspectors were scheduled to view the filling process of one of the Janssen batches. The batch that was scheduled to be filled was "GMP 7" for Janssen (the actual batch number is not readily accessible to me as I type this, but it is also commonly known within the facility as GMP 7).

On Wednesday February 10th, I was in meetings discussing the sub-lotting of GMP 7 because there had been a potential quality issue with a portion of the batch. Approximately 1/3 of the batch was placed on Hold by QA and was segregated from the remainder of the batch. At some point after physical segregation, the affected portion of the batch was tagged with QA Hold tags by a QA Manager. I do not know the timing of the placement of the tags. The affected portion of the batch was in two containers and I assume the remainder of the batch was in four other containers.

The filling of GMP 7 was to begin late afternoon on Thursday February 11th, but it was delayed for reasons of which I am unaware. The FDA inspectors were given a tour of the area even without the filling operation in progress. While the tour was in progress, one of the QA Managers from Manufacturing mentioned to me and others supporting the inspection backroom that he was made aware that the QA Hold tags had been removed from the two containers of GMP 7 that were under QA Hold. This same QA Manager had placed the QA Hold tags on the two containers of bulk drug substance so that they were clearly marked.

The following information was verbally conveyed to the Sr. Manager of Quality Systems and me by the QA Manager:

- The tags were yellow and conspicuous. There were two tags on each container – one on the side and one on the bottom.
- A Senior Manager in Operations had informed this QA Manager that he was going to remove the QA Hold tags so that they would not draw attention to the two subject containers.
- The QA Manager asked his on-floor QA team to check the containers; at 4:00pm they were still tagged and by 5:00pm the tags had been removed. The tour with the FDA inspectors started at about 5:00pm.
- While the tour was in progress, the Senior Director of Manufacturing Operations was notified by the QA Manager about the removal of the QA Hold tags. The Senior Director of Manufacturing Operations indicated that he was aware of the activity and was in agreement.
- While the tour was in progress, the VP of Manufacturing Operations (acting site head) was notified by the QA Manager about the removal of the QA Hold tags. I do not know how he responded.

The discussion among the Quality System team members in the inspection backroom centered around how and when to inform the Senior Director of Quality (site Quality head) that the QA Hold tags had been removed. Once the tour ended, there was a short break so that the inspectors could prepare for the final daily wrap-up meeting. The Sr. Manager in Quality Systems informed me that he had spoken with the site Quality head about the removal of the tags during that break. The final wrap-up occurred and then a debrief of the day was provided by the site Quality head to the Emergent senior level team and some of the team supporting the inspection. During the debrief, the site Quality head mentioned the removal of the tags, indicating that they were aware and had been in

agreement with the decision to remove the tags. I do not know if this was conducted by their direction, but they were in support of removal. There was a request to the floor QA personnel to make sure the containers were re-tagged with QA Hold tags before the end of the evening. Upon questioning from one of the backroom support team members, the site Quality head indicated that they did not want to have the sub-lotting conversation with the FDA.

On Friday February 12th, I asked the site Quality head about the circumstances surrounding the tag removal and replacement. I mentioned that several Quality Systems team members were aware of the situation and I wanted to know how to explain it to them. The site Quality head indicated that prior to giving permission to do so, they had confirmed that a sub-lot number had been assigned to the two subject containers and the sub-lot was on hold in SAP. There was no SOP in place that required visual QA hold tags. Material status is tracked in SAP. The site Quality head had confirmed that the two subject containers were re-tagged before the end of the evening.

Since the tags were deemed necessary before and after the FDA's visit, it is my understanding, based on the entirety of what I observed and was told, that the purpose of removing the QA hold tags was to avoid drawing attention to the two subject containers during the tour by the FDA inspectors.

If you have questions, please let me know as I am sure that this will be discussed on site and as I am aware of this situation, I wanted to be sure that I escalated this appropriately.

Best regards,
[redacted]

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