Teleconference Minutes

December 3, 2014 Wednesday

FDA Attendees: Rabia Ballica and Ramjay Vatsan

The purpose of this teleconference was to confirm that there were no changes to the filling process as a result of the facility modifications (*for details of the facility changes/modifications refer to Amendment dated November 26th*). The firm confirmed that there had been no changes to the filling process, including filling speed, filling temperature and actual filling duration and other durations before and after actual filling, which would have impacted the product stability. However, the actual filling duration became about (b) (4) longer because of more interventions challenged for the newly installed (b) (4) in the drug product filling area. The firm indicated upon a question (*has the product stability been impacted?*) that the new validated filling duration ((b) (4)) for the filling of the drug product was within the total validated period (*which was indicated as* (b) (4) *during the teleconference*).

The written responses to FDA questions discussed during the teleconference were forwarded via an e-mail dated December 5th (*refer to the attachment*). The following questions were dicussed:

Question 1:
Confirm that there were no changes to the fill process as a result of the facility modifications.

Question 2:
Clarification of the filling duration discussed in table 3 in section 3.2.P.3.5 Process Validation of the BLA and its relation to exposure time duration for the Drug Product (b) (4) in table 3 in section 3.2.P.3.3. (b) (4), Filling, and Freezing of the BLA.

Question 3:
Why is there a difference in media fill duration between Table 3 in section 3.2.P.3.5 Process Validation of the BLA and Table 6 in response # 3 filed 26 November 2014.

Question 4:
Explain why there is a range for the vial fill line speed.