Amgen BLA 125518 DMPQ Manufacturing Site Inspection Teleconference

October 3, 2014
Date: 2:00pm to 3:00pm

Meeting Minutes:

- Production schedule at the manufacturing site located in Woburn, MA:
  -If we were to conduct pre- license inspection January 13th through January 20th, would your Woburn manufacturing site be available for inspection January 19th, which is a federal holiday.
  Amgen: Yes. Amgen will need a specific date to assist with preparation for the visit. FDA will give that before the visit.
  -Is the drug product production schedule included in the production schedule we received, such as for January 13th – January 20th inspection period?
  Amgen: Yes, It is included under the column indicating Day (b) (4) Fill/Freeze Day (b) (4))

- Medical requirements/medical questionnaire for inspectors:
  Do you have any medical questionnaires that you would need to file with FDA? Are there any testing requirements? Amgen: We have gowning and PPE requirements for entering the production facility. We do not allow anyone open lesions in the production facility. Other than these requirements, we do not have and specific vaccinations or testing requirements.

- Registration and FEI numbers for the following sites: -Woburn manufacturing site-UK testing facilities ((b) (4)) and Amgen Inc. (b) (4) site for drug product packaging, storage, and distribution

  We do have an inspection DUNS number / But not are aware of the guidance for registration FEI numbers. FDA: We are not sure if the FEI numbers will be discontinued, but the FDA will provide the guidance.
  Guidance: Per 21 CFR 207.21(a) and 21 CFR 207.3(a) (8), facilities need to be registered within 5 days of application and then FEI numbers need to be obtained. Procedures for how to register and obtain FEI numbers are described in FDA Guidance" Guidance for Industry: Providing Regulatory Submissions in Electronic Format-Drug Establishment Registration and Drug Listing"

- Name of tests performed at (b) (4)
  We will need names of tests performed at each of contract testing facilities in UK
  Amgen: Request for the names of tests were discussed during another teleconference and would be submitted soon as an amendment.

- You forwarded information on the recent facility changes via e-mail. There was not sufficient information provided to indicate the details and extent of the facility changes particularly relating to the filling area. We need more details including a comparison of changes in reference to the previous facility before these changes, in addition to information including requalification data that was performed to support these changes. Be sure to include the following information in your description as you prepare the amendment to the BLA submission:

  1-Clear detailed description of the changes made to the facilities
  2-Justification statement for the changes

3-Comparison of pre- and post- change facilities along with sufficient supporting documentation/data

The discussion points and comments above will be followed up as an information request that will be sending to you for you to respond and include this information as an amendment to BLA submission

We would also like to make a general comment: In your BLA submission, you provided very brief summaries of the validation/qualifications that were performed and reference pertinent regulations and guidance's; however your summaries did not provide enough details or supporting data. For example, the media fill studies performed to qualify aseptic processing were described, but related data are not included in the submission.

Amgen: We will address this when information request is received.

Amgen will provide follow-up information discussed at today's teleconference.

FDA will send the questions asked during the telecon as a part of the meeting minutes.
Amgen: We look forward to reviewing the email containing the additional requests discussed at today's meeting.

FDA: We would like to schedule monthly discussions for CMC issues that may come up during the review process. Mark Davidson will contact you with dates and times. Amgen agreed to monthly teleconference discussions.

FDA Attendees:

Nancy Waites
Rabia Ballica
Christine Harman
Ramjay Vatsan
Daniel Takefman
Richard Heath-Coats
Mark Davidson

Amgen Attendees:

Kathleen Sugrue-Richards
Anne Marie Woodland
Tara Reed
Mike Abernathy
Michelle Pernice
Amanda Kennedy
Steve Falcone
Parag Sane
Jose Watlington
Mike Schechter
Paul Bullock
Allan Gibson, Director
Colin Love