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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| Food and Drug Administration, CDER Inspection Assessment Branch<br>10903 New Hampshire Avenue Bldg. 51, Room 4316<br>Silver Spring, MD 20993 Phone: 1-301-796-3254<br>Industry Information: www.fda.gov/oc/industry | January 12-20, 2017 |
| | FEI NUMBER<br>3002806462 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Hubertus Hakert, Head of Supply Center Leverkusen

| FIRM NAME | STREET ADDRESS |
|---|---|
| Bayer Pharma AG | Kaiser-Wilhelm Allee |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| 51368 Leverkusen, Germany | Parenteral, solid oral dosage, and API drug manufacturer |

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

## OBSERVATION 1

Failure to ensure appropriate environmental conditions for filling parenteral products.

(b) (4) and (b) (4) are (b) (4) sterilized parenteral products filled in room (b) (4), classified as a Grade C area for the filling environment with laminar flow over the filling machine. The (b) (4) in which the products are filled contain an open port until (b) (4) This open port is exposed to the environment for an extended period of time from the time the (b) (4) are taken out of their packaging through the filling process, which could be (b) (4) or more. Control of environmental contaminants during the exposure of these open bags has not been thoroughly demonstrated with established procedures and monitoring. For example:

1. The operators manually handle the (b) (4) and were observed to lean over the (b) (4) with open ports while putting them on the filling line, disrupting laminar flow. The operator's gloves and gowns were observed to touch the (b) (4) ports. The operators handling the (b) (4) have exposed skin on their faces.

2. During interventions into the laminar flow area near the printing station, the (b) (4) with open ports are not removed after the operators work above them.

3. Non-viable particle monitoring is only conducted (b) (4) Filling can be conducted (b) (4) (b) (4) (b) (4) There is only (b) (4) sampling point inside of the laminar flow area. The sample volume is (b) (4) (b) (4) (b) (4) (b) (4). This does not ensure the environment remains in a state of control during routine operations or interventions. There is lack of scientific rationale for the sampling locations. For example, no sample is taken in the laminar flow area where the operators are manually handling the open bags.

4. Smoke studies to demonstrate laminar air flow are not representative of all operations. For example, use of particle and viable air samplers near the filling machine is not demonstrated. During smoke studies there were less stacks of (b) (4) waiting to be put on the line than what occurs in routine production.

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5. Environmental monitoring including active air, passive air, and surface monitoring only occurs (b) (4) Sampling locations have not been established based on a scientific assessment to identify the most critical locations and locations most relevant to the dynamic operations occurring in the filling area.

OBSERVATION 2

Procedures to ensure reliable detection of particulate matter in parenteral products have not been established.

1. During routine visual inspection, filled (b) (4) are visually inspected immediately after exiting the filling area. The filling process introduces (b) (4) bubbles that create cloudiness in the solution that takes a (b) (4) to subside. This cloudiness was observed to be present at the time of the visual inspection and could obscure particulate matter. This cloudiness would not be present during qualification of the visual inspection operators.

2. Routine visual inspection occurs on-line with operators (b) (4) in (b) (4) approximately (b) (4) from the (b) (4) to be inspected. During the qualification the operators work offline with (b) (4) they are holding in their hands.

3. During routine visual inspection (b) (4) move on a conveyor that does not turn or invert the bag to allow for full inspection. During qualification the operators manually hold the (b) (4) allowing it to be fully inspected.

4. Routine visual inspection of (b) (4) by the operator at the (b) (4) background station is occurring at up to (b) (4) (b) (4) per minute. During the qualification the operator is permitted up to (b) (4) minutes to inspect (b) (4) (b) (4)

OBSERVATION 3

Procedures for cleaning of the equipment and facility are not established and followed.

1. The (b) (4) building has (b) (4) (b) (4) They are not product dedicated, including (b) (4) (b) (4) that are shared use between (b) (4) products and non- (b) (4) products. Cleaning validation of the equipment failed to evaluate hard to clean and hard to visually inspect places, such as the (b) (4). Inspection of the (b) (4) (b) (4) evealed:



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a. The "clean" (b) (4) in room (b) (4) had unidentified white residues coating the surfaces of the (b) (4) valve facing the air flow and at the edges around an unused spray ball. This cleaning of the (b) (4) duct is not described in a procedure for the manual cleaning of this piece of equipment.

b. The "clean" (b) (4) (b) (4) 400 (b) (4) had white powder in the (b) (4) This cleaning of the (b) (4) is not described in a procedure for the manual cleaning of this piece of equipment.

c. The "clean" (b) (4) in room (b) (4) had white particles in the (b) (4) This area is cleaned with a spray ball. Validation of the cleaning process did not include sampling or inspection of this area.

2. In room (b) (4) in the (b) (4) department during ongoing production of (b) (4) on 19 January 2017, (b) (4) residues were observed on exterior surfaces of the equipment. The previous product, (b) (4), was (b) (4) in color.

3. On 19 January 2017, (b) (4) equipment BSF-632-1 was in use at the time of inspection. The equipment cleaning had not been inspected and the documentation was not signed as approved by a supervisor.

4. No clean hold times or dirty hold times have been established for equipment in the (b) (4) department.

5. Black, mold like material was observed on the wall of an office in the (b) (4) department.

6. For room (b) (4) used for filling of parenteral products:

a. Unidentified black material was observed on the ceiling of the room and on the grates of the HEPA filters in the laminar flow area. Unidentified (b) (4) material was observed on top of (b) (4) inside of the laminar flow area.

b. Cleaning activities observed on 13 January 2017 showed that wiping of all surfaces was not completed. For example, all of the (b) (4) that hold the open (b) (4) or (b) (4) inside of the laminar air flow barrier.



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c. Cleaning inside the laminar flow area was not done in a unidirectional, (b) (4) , and from (b) (4) manner.

d. A sporicidal is not used as part of the routine disinfection process.

OBSERVATION 4
A document control system has not been established.

1. There is no document control system to track issuance and use of GMP documents in the production area. Production personnel print or copy from the master copies and there is no process to reconcile the use of the forms. The following GMP documents were observed in a waste bin on 13 January 2017:

a. Partial batch record (b) (4) for (b) (4) Tablets. It was partially completed for the start of the (b) (4) process. The batch record reviewer did not note that this portion of the batch record was missing when the batch record was reviewed and approved. This portion was later discarded.

b. Two cleaning records related to (b) (4) FPL (b) (4) on 12 January 2017. It was reported a mistake was made on the form where the original data was recorded. The operator re-wrote the data onto a new form and discarded the original.

c. Numerous partially filled set-up forms for mounting of equipment associated with the start of (b) (4) campaigns were found in the waste bin. These included forms that were completely missing from batch records where the batch record reviewer did not detect the missing document and forms that were rewritten due to apparent incorrect information.

d. Numerous set-up parameter forms for setting tablet visual inspection parameters were observed in the waste bin. The original documents should have been maintained as part of the raw data for setting of parameters. Additionally, some of the discarded forms had been written using pencil.

e. Numerous original signed training records were found in the waste bin. The original records are required to be maintained per SOP 3-040-127.

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2. In the microbiology laboratory, duplicate sets of records containing raw data for the same personnel clean room qualification documentation were observed. The analyst stated the raw data from the copied sheets is later transferred to the official sheet and the forms with original raw data are discarded.

3. Non-viable particle monitoring data from room (b) (4) is recorded on laminated sheets of paper. The data recorded on the sheet can be erased.

4. Paper shredders are present in the QC laboratory and production area offices.



OBSERVATION 5
Failure to conduct thorough complaint investigations and extend the investigation to related batches.

1. Complaint 2015-015988 received 30 April 2015 and complaint 2015-016372 received 05 May 2015 documented leakage from (b) (4) bags where the (b) (4) connected to the bag on batch (b) (4) of (b) (4) Investigation determined a packaging material defect could be the root cause. The investigation failed to identify other batches which used the same packaging material. No retain samples of the affected batch were examined.

Follow-up with the (b) (4) supplier was made 08 June 2015 and the supplier confirmed a deviation related to (b) (4) parameters for the (b) (4) had occurred on one of the related (b) (4) batches. The complaint investigation failed to assess this information and make an evaluation of the product distributed to the market that used this lot of (b) (4)

A complaint for leakage at the same location was received for batch (b) (4) documented in complaint 2016-026147 received 31 May 2016. No retain samples were evaluated and no further action was taken.

2. The complaint handling procedure 3-020-082 does not describe evaluation of retain samples during complaint investigations. Retain samples were not evaluated when foreign matter was reported in the following complaints:

2015-009605 dark particles in solution for batch (b) (4) of (b) (4)
2016-020559 fiber in solution for batch (b) (4) of (b) (4).

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2016-007422 small fibers in batch (b) (4) f (b) (4)

3. The complaint handling procedure 3-020-082 does not describe when analytical testing of returned complaints samples will be conducted. Complaint 2015-024059 documented a cluster of four adverse events for rashes at the injection site for batch (b) (4) of (b) (4) The remaining portion of the shipment was returned, but analytical evaluation of the returned product was not included as part of the investigation.

OBSERVATION 6
Failure to establish separate areas to prevent cross contamination.

There is no process to analytically measure pressure differentials between production rooms and common corridors in the non-product dedicated (b) (4) production plant. (b) (4) are used to indicate the air flow between areas, but operators are not always present to ensure the proper flow of air during production activities.

On 19 January 2017, the (b) (4) between the (b) (4) room for ongoing (b) (4) (an (b) (4) product) production, and the change room did not appear to show significant pressure differential. Not all areas which manufacture (b) (4) products have dedicated change areas to enter and the production rooms open directly to the common corridors, including (b) (4) room (b) (4) and tableting rooms.

After entering production suites which contain dust from (b) (4) products, there is no gowning requirement to ensure operators do not transfer dust to other areas of their facilities on their shoes.

OBSERVATION 7
Failure to perform a thorough investigation into a discrepancy.

1. During environmental monitoring of the (b) (4) filling area, numerous alert and action level findings were not thoroughly investigated. From April-June 2015 there were 5 alert and 3 action level investigations opened for monitoring of the (b) (4) A thorough investigation with root cause evaluation and preventive actions was not performed. Trending analysis conclusions recommended increasing the cleaning frequency of this area, however this was never implemented.

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Additional alert and action results were observed at this point in September of 2015. The investigations were written as standalone reports that failed to evaluate other points in the same area that also had alert or action level findings during the same time period.

2. Investigation into the finding of Paneibacillus lactis during active air monitoring at the filling machine on 25 February 2016 failed to include thorough evaluation of the root cause and impact to product for endotoxin.

3. There is no process to ensure root cause evaluations of organisms detected that are not expected to be the normal microbial flora of the filling environment, such as Gram negative organisms, fungi, spore forming organisms.

4. Investigation into three OOS results during assay testing of (b) (4) during sample set (b) (4) (b) (4) nvalidated the OOS results due to shifts in retention time during the sequence. The standards passed system suitability and no limits had been established for retention time drift. No evaluation of previous analytical runs, which also showed retention time drifts, including sample set (b) (4) (b) (4) were performed. Additionally, no limits were established for acceptable retention time drift.



OBSERVATION 8
Facilities and equipment are not of a suitable design for their intended use.

1. The (b) (4) system has dead legs in the solution preparation department (point (b) (4) and in an equipment washing area (points (b) (4) of the (b) (4) plant.

2. Room (b) (4) s used to fill parenteral products. The floor and (b) (4) section of the wall are constructed of (b) (4) that does not create a smooth surface.

OBSERVATION 9
Failure to maintain and review all analytical data.

1. Until June 2016, analysts performed HPLC injections identified as "test" or other similar names and injections with no sample name at all. The content of these injections and their purpose were not documented and were

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never reviewed. For example, review of the 2015 project folder for assay and impurity testing of (b) (4) (b) (4) Tablet show that out of (b) (4) total injections, approximately 157 injections are identified with a name of "test" or similar and 6 were unnamed injections.

2. Repeat testing of IR was performed after abnormal results were generated. There was no documentation to explain what had occurred and the original data was not submitted for review. For example, sample (b) (4) was first tested on 12 January 2016 and was retested 14 January 2016.

3. The software used for performing in process weight checks is set to not report any data that is not plausible, defined as data with more than a (b) (4)% variation of expected results. The full set of data is not printed and evaluated by an operator to verify the reason for data that is not plausible. Review of audit trail entries for 19 January 2017 observed two non-conforming data points that were not reported and were not further evaluated.

OBSERVATION 10
Test procedures for analytical testing have not been established.

1. No procedures have been established to review audit trails for the laboratory software systems. Examples include, but are not limited to, Empower (Chromatography), Opus (IR Spectroscopy), and Disso Net (Dissolution by UV).

2. Manual integration of chromatograms is permitted. Procedures describing when manual integration can be performed, how it is to be performed, and how it will be reviewed have not been established.

OBSERVATION 11
Data is not recorded contemporaneously.

1. Production and laboratory personnel do not document contemporaneously. The practice of signing for multiple steps all at once is permitted.

2. Supervisors reviewing logs signed one page rather than each individual page requiring a signature.



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3. Microbiologists enter results into the electronic (b) (4) system for multiple samples all at one time during plate reading.

4. Microbiologists document in the (b) (4) system that all settle plates are exposed before starting to put out the settle plates.



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