GMP News
29/04/2013

Print News

New FDA Guidance for the Prevention of Cross Contamination of Beta-Lactam Antibiotics

Penicillin is also part of the Beta-Lactam antibiotics, a substance group that is know for its sensitizing effect. Article 21 CFR 211.42(d) already requires the separation of the manufacture, processing and packaging of Penicillin. Here the FDA does not necessarily mean separate buildings, but rather the isolation of the manufacturing area from that for other products. Paragraph 211.46(d) requests the separation of the ventilation system of the Penicillin manufacturing area, paragraph 211.176 asks for the testing of medicinal products for Penicillin if a cross contamination cannot be eliminated or if there is a risk of cross contamination.

In the now issued document the FDA describes how other (not-Penicillin) Beta-Lactam antibiotics are to be handled to prevent cross contamination. It explicitly mentions that these are recommendations. The document is applied to the manufacture of medicinal products, API synthesis and to (re-)packaging.

The biggest danger originates in the sensitizing effect and the possibility of a patient's allergic shock reaction. Here the FDA sees the same risk for Penicillin as for the other Beta-Lactam antibiotics and their precursor in the synthesis - as, e.g., the 6-Amino Penicillin Acid. The problem in this case is the determination of the minimal dose leading to a sensitizing effect and the measuring of this low concentrations with the analytical methods currently available. Another risk is the cross reactivity between the various Beta-Lactam antibiotic sub groups - meaning the sensitization by a medicinal product of the one sub group and an allergic reaction following a later Penicillin administration. The FDA differentiates the following groups: penicillins, cephalosporins, carbacephems, monobactams.

The FDA expects that manufacturers handle (not-Penicillin) Beta-Lactams like Penicillin. For that reason the authority recommends to establish a separation as well as respective controls to prevent two kinds of cross contamination:

1. The cross contamination between the groups
2. The cross contamination between medicinal products in general and a (not-Penicillin) Beta-Lactam

For manufacturers only manufacturing products within one group (e.g. various cephalosporins) it is not requested to separate the facility and ventilation if campaign operation and cleaning ensure sufficient control.

Please see the FDA Guidance Document "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination" for further information.

Conference Recommendations

No.	Date	Title	Location
7812	24-25 September 2013	Manufacture of highly potent Compounds	Berlin, Germany
7775	10-11 September 2013	Tableting - Equipment, Trouble Shooting & Compliance	Munich, Germany
7812	24-25 September 2013	Manufacture of highly potent Compounds	Berlin, Germany

Related GMP News

26/06/2013	USP expert answers questions regarding particulate matter testing
12/06/2013	Particles in Parenteralia - FDA's perspective
04/04/2013	FDA Warning Letter on Water Purification
12/03/2013	AQL testing in the visual inspection of parenterals (FAQs)
27/02/2013	FAQs concerning the visual inspection of Parenterals

0

RECOMMENDED EVENT

Manufacture of highly potent Compounds
24-25 September 2013, Berlin, Germany

GMP NEWS BY TOPICS

Analytical QC
APIs and Excipients
Computer Validation
Counterfeit Medicines
Good Distribution Practices
GMP Inspections/Audits
Pharma Technology
Quality Assurance
Sterile / Aseptic / Microbiology
Validation
Medical Devices
Pharmaceutical/Clinical Development
Regulatory Affairs