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FDA issues guidance on cross-contamination prevention

By Nick Taylor, 06-Apr-2011

The FDA has released draft guidance on using separate facilities to prevent cross-contamination with non-penicillin beta lactam antibiotics.

Both penicillin and non-penicillin beta lactam antibiotics can cause hypersensitive reactions. To minimise the risk of cross-contamination at plants manufacturing multiple products the US Food and Drug Administration (FDA) recommends separating production areas.

“The section of a facility dedicated to manufacturing a sensitising non-penicillin beta lactam should be structurally isolated from areas in the facility in which other products are manufactured”, says the draft guidance .

Structural isolation is defined in the guidance as *“completely and comprehensively separated”*. In a clarification of cGMP (current good manufacturing practice) penicillin guidance the FDA said options other than completely separate buildings are viable.

If production occurs in the same building the penicillin area must be structurally isolated and use completely separate air handling systems. Manufacturers must test non-penicillin products for cross-contaminants where the possibility of exposure exists.

The non-penicillin beta lactam draft guidance highlights the similarity with penicillin: *“Just as FDA considers the separation of production facilities for penicillins to be cGMP, FDA expects manufacturers to treat sensitising non-penicillin beta lactam-based products similarly.”*

Application of these recommendations covers separation of areas manufacturing different classes of non-penicillin beta lactams, as well as sections producing unrelated products, such as aspirin.

In plants producing a specific class of beta lactam compound, such as the cephalosporin family, production campaigning and cleaning could be sufficient. Separate facilities and air handling systems are unlikely to be required in these cases.

Guidance applies to production of active pharmaceutical ingredients (APIs) and finished products. APIs can be sensitising compounds capable of causing anaphylactic shock and as such cross-contamination has a similar risk in ingredients as in finished products.

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