

# GMP veteran Carl Reynolds shares ‘483’ learnings

By Shane Starling, 05-May-2010

**The highly regarded good manufacturing practices (GMP) expert Carl Reynolds – recently re-hired by the FDA to help it manage GMP reporting – highlighted problems from stray rodent activity to lack of batch data to inappropriate identity testing.**

Reynolds, who is now a senior advisor in the Dietary Supplement Programs division at the Food and Drug Administration, last week told a packed house at the SupplySideEast trade show in New Jersey that he had not expected some of the transgressions and anomalies that have been picked up by [FDA GMP](#) inspectors so far.

*“It surprises me,”* he said, especially in the light of advance warning of the regulation’s requirements that had been clearly spelled out in several FDA GMP guidance documents.

Reynolds listed some of the key problems that had made their way into the completed 483s to date. These included:

- Insect and rodent activity in storage areas
- Insufficient documentation of procedures and failure to document procedural change
- Lack of batch data
- Lack of corrective action plans if GMP specifications are not met
- Formulations that do not meet label claims
- Lack of identity testing
- Inadequate quality control (QC) procedures and QC staff training
- Inappropriate sample collecting methods
- Non-documented procedural change
- Failure to qualify vendors

But the FDA is due to assist industry overcome these and other issues by producing a compliance program for dietary supplements that is in the *“clearance phase”* and is due to be published imminently, Reynolds said.

## Problems

*“Companies must have written documents of procedures,”* Reynolds said. *“The ones I have seen are not going far enough.”*

In regard to batch information he noted: *“Batches are faxes of the master and they must match the master records.”*

If GMP standards are not met for whatever reason and corrective action is required, Crawford noted corrective action plans must be in place. *“This is not well understood in the industry.”*

For identity testing, Reynolds noted test protocols were often selected without consideration of the usability. *“People say they took retained standards but there is no authenticity of standards used in the first place.”*

Reynolds said it was too early to point out any major trends from the 12 ‘483’ inspection reports completed in 2008 and 28 completed in 2009. That said he noted, *“a number of reviews were under way that may lead to regulatory action”*.