

## Changing the Change Process



**Jerry Lanese**

By

**Jun 2, 2013 9:52 am EDT**

The following is a summary of the proceedings with editorial notes and commentary. Twelve speakers provided many common themes. Where there was a common message from more than one speaker, that thought is combined without reference to the contributors. Where a recommendation can be attributed to a specific speaker, that speaker is referenced, keyed to the Agenda in Figure 5. Since this meeting was organized by CDER, it focused on drug products. There was a troublesome exclusion of references to changes to biological products covered under 21 Code of Federal Regulations (CFR) 601.12,2 with the...

---

**Source URL:** <http://www.ivtnetwork.com/article/changing-change-process>