

Gap Analysis Checklist for an Equipment/System/Facility Change Control Program

By **Miguel Montalvo** May 1, 2014 7:59 am PDT



Change Control is the implementation of, and adherence to, a formal process that documents any change to a (specified/qualified/validated/approved) piece of equipment, system, process or document that can affect the identity, strength, quality or purity of a drug product. The Gap Analysis is simply a comparison of the current system, its supporting documentation, and the people/resources qualifications/training against the defined requirements.

This checklist ensures that all change control items; including change control in facilities, computerized systems, documentation, training, and outsourcing; are thoroughly accounted for during a gap analysis.

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