Corrective and Preventive Action

The Context
Device manufacturers encounter problems (actual nonconformances) which they investigate to determine the cause. Subsequently, the corrective action process identifies actions to prevent recurrence of the nonconformance.

The device manufacturer "establishes" procedures to meet the QSR requirements. Establish means to define, document, and implement. §820.100(a)(5) requires that the corrective and preventive action procedures include implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

The idea is that while identifying the actions is necessary, they don't prevent the nonconformity's recurrence unless the manufacturer implements them. As always, keep records.

FDA Investigators check conformance to the regulations using the Quality System Inspection Technique, QSIT. To check the documentation and implementation of changes, QSIT tells the Investigator, "it may be necessary to view actual processes, equipment, facilities, or documentation".

The Warning Letter
FDA sent an August 22, 2012 Warning Letter to Hospira Incorporated concerning the results of an inspection the facility in Costa Rica that manufactures infusion pumps and intravascular administration sets.

The Issue Cited
The Warning Letter cites a failure to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR §820.100(a)(5).

The citation says, "Your firm initiated a recall (Z-3284-2011) in September 2011 to correct an unrestricted free-flow condition on Plum branded infusion pumps. An investigation was conducted and corrective actions were implemented by Hospira to ensure that proper installation of the regulator closure (source of the failure) was completed during manufacturing." It goes on to say, "One of the corrective actions implemented for recall Z-3284-2011 was to perform a visual inspection after installation of the regulator closure. The Mechanism Assembly Instructions PLUM A+ procedure, 502-95004-006, requires a visual inspection of the assembly after installation of the regulator enclosure. During the observation of the regulator closure installation, the investigator noted that the visual inspection did not occur."

It appears the Investigator went to the production area to observe the visual check, but the operators were not doing it. The Investigator wrote a 483 observation to which the company responded. The FDA escalated this observation to a Warning Letter citing an inadequate response, "Your firm also provided training documentation for the visual inspection required during regulator closure installation. However, your firm did not provide documented evidence that the visual inspection is being performed in the manufacturing process."

The Requirement
The Quality System Regulation requires, in §820.100(a)(5), implementing and recording changes in methods and procedures.

Recommendations
Ensure the implementation of your actions. A check usually occurs shortly after implementation because the actions call for revised documents, trained operators, and verification. One problem, however, is ensure the long-term implementation.

One easy way is to include verification as part of internal quality audits. This would be especially important in this case, because the problem resulted in a recall.

In addition, the recurrence of the problem might show up in failures at an acceptance activity or an increase in complaints. Analysis of this data can help determine if the corrective actions remain effective.