**FDA Opens the Door to ISO 13485 Acceptance**

The US Food and Drug Administration will launch a pilot program in June allowing medical device manufacturers to submit ISO 13485:2003 quality system audits in order to satisfy FDA 21 CFR Part 820 inspection requirements for one year.

Currently, the US regulator requires all domestic and foreign manufacturers to comply with 21 CFR Part 820 (also known as FDA Good Manufacturing Practice, or FDA GMP) quality system rules. By allowing firms the opportunity to avoid FDA inspection requirements for one year via ISO 13485 audit submissions, the agency seems to be aligning itself in this regard more closely to Global Harmonization Task Force (GHTF) guidelines.

Any domestic or foreign device manufacturer subject to both FDA GMP and ISO 13485 requirements is eligible to participate in the new program, provided they submit their ISO 13485 audit results within 90 days of receiving them. In addition, ISO 13485 auditors issuing manufacturers' reports must comply with GHTF founding member regulations. IF FDA reviewers find an ISO 13485 audit report submission acceptable, they will recommend that the manufacturer in question "be removed from the routine work load plan for one year from the last day of the most recent ISO 13485:2003 audit," according to new guidance issued on the pilot