

## **What is the relationship between FDA's Quality System Regulation for Devices, Part 820, and ISO 9001:2000?**

FDA's Quality System Regulation Part 820, is harmonized with ISO 13485:1996, which is based on ISO 9001:1994. ISO 13485:1996 contains requirements for medical device manufacturers in addition to the general quality system requirements found in ISO 9001:1994. ISO 9001:2000 has replaced ISO 9001:1994. Therefore ISO 13485:1996 must also be revised. FDA's Part 820 is not harmonized with ISO 9001:2000. FDA is working closely with the revisions to ISO 13485. We expect these revisions be complete by late 2002 or early 2003.

## **Why did FDA harmonize its quality system regulation with the ISO standards?**

- Many other countries rely on ISO standards in regulating medical devices. It is easier and less confusing for industry to develop a quality system if the quality system requirements of various countries are similar.
- FDA and device regulatory agencies from other countries can more readily rely on one another's inspections and exchange inspection reports if the quality system requirements are similar. This becomes important when countries negotiate agreements to exchange information with one another.

## **Why didn't FDA adopt ISO 9001 instead of developing its own regulation?**

FDA found that ISO 9001 did not totally serve its purposes. Also, ISO 9001 is revised periodically and might serve FDA's purposes even less well after future revisions. ISO 9001 is copyrighted and cannot be published as a Federal Regulation in the Federal Register.

## **Can't FDA just change Part 820 to harmonize it with the new ISO 9001:2000?**

FDA and medical device regulators from other countries see problems with enforcing some ISO 9001:2000 requirements relating to:

- Assuring customer satisfaction: This goes beyond the safety and efficacy of medical devices. Therefore, to a large extent the requirement to assure customer satisfaction outside the purview of medical device regulators.
- Engaging in continuous improvement (in regard to increasing efficiency): Improvement is within the medical device regulator's purview when it is done to correct violations. However, improvement for the sake of operating more efficiently is outside the purview of medical device regulatory agencies.
- Documentation: ISO 9001: 2000 requires less documentation. Auditors and investigator, whether they be from FDA or from some other organization,

need documentation to know what a company intends to do and what they actually did.

The committee revising ISO 13485 intends to address these issues in their revisions.

Also, ISO 9001:2000 is written using a process model approach instead of the twenty (20) element format used in ISO 9001:1987 and 1994. In a voluntary standards arena there is no requirement for a manufacturer to change the structure of its documentation to meet the format of the standard. In a regulatory environment, however, manufacturers often feel the need to align their documentation structure with that of the regulations.

FDA sees no safety or quality benefit in having the manufacturers completely change their documentation structure and systems to the process model. Manufacturers may choose whatever documentation structure and system works best for their organization and regulatory obligations. The reasons the authors of the new ISO 9001:2000 changed to a process model are not necessarily transferable to the medical device industry.

### **Why would device manufacturers want ISO 9001:2000 certification?**

- Many customers (hospitals, clinics, doctors, etc.) want their medical device suppliers to be ISO 9001 certified. Customers perceive some level of security in knowing they are buying from a manufacturer that has an ISO 9001 certified quality system.
- The European Union does not require device manufacturers to comply with ISO 9001 in order to obtain a CE mark. Manufacturers have several options including having their devices tested OR having a quality system. If they have a quality system they can design it to comply with the quality system standard of their choice. In theory, they could use FDA's Part 820. However, since many of their customers want them to have ISO 9001 certification, most medical device manufacturers choose to use ISO 13485 or EN 46001 to obtain a CE mark. These standards, which are currently being revised, reference the quality system requirements in ISO 9001:1994 and contain additional requirements for medical device manufacturers who are establishing or maintaining a quality system.