**Joint EU Medical Devices Industry position on modification of ISO 13485**

International standards should not contain regional or national regulatory requirements. Therefore ISO 13485 should not be modified to contain regulatory requirements such as Post Market Surveillance.
A standard cannot be a duplication of regulatory requirements but is a document that provides for voluntary demonstration of conformity to certain elements of such regulatory requirements. In addition ISO 13485, which is an adaptation of the international ISO 9001 quality management system standard for medical devices, cannot incorporate requirements beyond quality management system elements. Such incorporation would bring it out of sync with the generic quality management system standard.
It has been brought to our attention that ISO TC 210, the ISO technical Committee that developed ISO 13485, is seeking perspectives on whether a revision of this standard would be needed and, if yes, what should be the content of such revision.
It is our understanding that:

1) The scope and intention of ISO 13485 are to outline the requirements for a Quality Management System for the design and manufacture of medical devices and its content and structure are based on the generic standard ISO 9001.
2) During 2008-2009 ISO/TC 210 examined the possibility of a review of ISO 13485 to align with ISO 9001:2008 and concluded that the revision was at this point not needed. A technical report was deemed appropriate to point out the nuances between the two standards.
3) The last revision of ISO 13485 is dated from 2003 while the last revision of ISO 9001 is dated from 2008; this version being presently in the very preliminary stages of next revision.
4) The role of standards in a regulatory framework is clearly outlined in GHTF document SG1 N44.

When ISO 13485 is due to come up for revision, EMIG would support maintaining consistency between ISO 9001 and ISO 13485 for relevant requirements.

However, the European Medical Devices Industry strongly believe that ISO 13485 shall continue to be seen as an International Quality Management System Standard that can be used by any manufacturer of Medical Devices on a voluntary basis to frame its internal Quality Management System. The use of the standard ISO 13485 will provide presumption of conformity with the Quality Management System requirements for medical devices. Conformity to other regulatory requirements can and should not be included in an international Quality Management System standard.