EUROPE AND REVISION TO ISO 13485

ISO 13485-2003 is a worldwide accepted standard and has proven both its usefulness for regulatory purposes as well as its applicability in the industrial environment. In addition it is widely comparable with the legal requirements for quality systems in other GHTF member's legislation, which is an important aspect for European exporters. We would not see any great difficulty in taking over the currently proposed changes from ISO 9001 to ISO 13485 (after critical review) but we do not see any need to do this now or in the near future.

On another aspect, the proposal at the last GHTF steering committee meeting, to add basic elements of risk management out of ISO 14971 into ISO 13485 would be a major change in ISO 13485. This should be avoided since it would open the possibility of bypassing the requirements of ISO 14971 and lead to difficulties in regard to the question of what kind of risk management is sufficient to be in conformance with both ISO 13485 (as well as the European Medical Device Directives).