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**Presentation Title**: ISO-9000 as an Alternative to FDA Regulation for Medical Device Servicers and Remarketers

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**Abstract:** In December 1997, the Food and Drug Administration (FDA) announced its intention of regulating the service, refurbishing, and remarketing of medical equipment. Since then, numerous meetings and discussions were held with the participation of manufacturers, healthcare organizations, servicers, remarketers, and professional organizations. Based on this feedback, the FDA drafted a "guidance document" that is scheduled to be published by the end of 2001. This document will require the adoption of "voluntary standards," including the disclosure of certain information and a registry to record complaints.

Although often referred to as the "remarketer regulation," the guidance is very wide in scope. It covers all those who service equipment that they do not own and those who sell or donate any equipment, even if no service was performed. In other words, this regulation will cover all manufacturers, independent service organizations (ISOs), share services, and numerous in-house clinical engineering departments that perform inspection, repairs, and preventive maintenance. In addition, it also includes all the companies that buy and sell used equipment and the healthcare and non-profit organizations that sell or donate excess or obsolete inventory. The total number of organizations covered is estimated to be around 20 to 35 thousands.

Instead of waiting for all the parties involved to develop a new set of standards after the FDA publishes the guidance document, the ISO-9000 quality standard should be considered as an alternative. First, this is a well-established, worldwide-recognized standard. Second, this is the same standard to which almost all major manufacturers comply, so it will be difficult for them to reject this proposal. Third and most importantly, the ISO-9000 registration offers independence and flexibility that no other alternative can claim. There are numerous registrars and consultants who are totally independent of the various interested parties, yet they all have a vested interest for the candidate organization to succeed in the initial registration and retain its status. Finally, the FDA has already harmonized its Quality System (QS) regulation with ISO-9000, and even JCAHO has decided to integrate ISO-9000 into its own standards for healthcare organizations; so the likelihood of its acceptance is high.

To visualize how ISO-9000 can be used to the advantage of servicers and remarketers, a detailed comparison will be made to the QS regulation and the new FDA guidance document. Furthermore, the total cost for implementing ISO-9000 (i.e., training, consulting, and registration) will be calculated and discussed, as well as ways to obtain financial assistance.

The potential penalties of not implementing the "voluntary standards" are quite severe for everyone. The first injury or death of a public figure or relative of a powerful politician linked to a poorly serviced or refurbished medical device could force the FDA to apply all the applicable portions of the QS regulation. Many manufacturers and FDA "hardliners" are itching for such an opportunity, now that they have managed to force the reprocessors of devices labeled for single use, including the hospitals, to register with the FDA and comply with the QS regulation.

**Biography:** Binseng Wang earned his doctor of science (Sc.D.) degree from the Massachusetts Institute of Technology (MIT). He has been certified as a clinical engineer (CCE) by the International Certification Commission on Clinical Engineering and Biomedical Technology (ICC), and as a Quality Management System (QMS) Provisional Auditor by the Registrar Accreditation Board (RAB). He worked over 20 years in Brazil, first at the State University of Campinas, where he was a faculty member and the founder and first director of its Center for Biomedical Engineering, later designated a *collaborating center* of the World Health Organization (WHO). Later, he served as Special Advisor on Equipment to the Secretary of Health of Sao Paulo State, Brazil, where he established a comprehensive policy for technology planning, management, and service. He was a visiting scientist at the National Institutes of Health (NIH), Bethesda, MD, where he developed a method for integrating MRI and PET images of the brain with three-dimensional data obtained from electromagnetic recordings and stimulation. In 1992, he joined MEDIQ/PRN Life Support Services, the largest medical equipment rental company in the US. Currently he holds the position of National Quality Director. He has worked in several Latin American and Caribbean countries as a consultant to PAHO/WHO, World Bank, and Inter-American Development Bank. He has also provided consultation services to manufacturers on design, manufacturing, standards/regulatory compliance, and export opportunities. He is a well-known author and speaker in the fields of healthcare technology management, servicing, and regulation.

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