



Michiharu (Mic) Miyahara

President & CEO of EMERGO Japan

Michiharu Miyahara is the President and CEO of Emergo Japan K.K. in Tokyo and oversees all operations in the country. Mr. Miyahara has more than 20 years of experience with quality assurance and regulatory issues facing medical device manufacturers selling in Japan. Mr. Miyahara was the Director of the Regulatory Affairs and Quality Assurance Advisory Service Group consulting division of KPMG in Tokyo, a division he started within KPMG in 1995 and became the leading consulting firm in Japan. On October 1, 2008, this KPMG division merged with Emergo Japan which Mr. Miyahara now spearheads.

EXPERIENCE:

President & CEO, EMERGO Japan – 2008 - Present

Responsible for the development of Emergo Japan KK business objectives in the areas of Japanese PAL registrations, audits, STED's, marketing and sales of Emergo Group worldwide services. Manages and directs Emergo Japan KK Designated Marketing Authorization Holder services and activities. Manages and directs staff on a day to day basis to ensure superior customer relations, effective work practices. Development of relationships with notified bodies in Japan, and other potential sources for lead generation activity. Growth of sales in Japan and worldwide areas that Emergo Group services
Responsible for profitability of Emergo Japan KK

Director, RA and QA Advisory Service Group KPMG MMC K.K. (Tokyo, Japan) – 1995 to 2008

Established KPMG MMC as KPMG Japan's ISO consulting business in 1995 and developed QS-9000 business, healthcare industry service group, accredited ISO9000 lead auditor training course and RAQA practice. Director in charge of the RAQA advisory group of KPMG MMC K.K. which is a member firm of KPMG Japan. Provided implementation consulting services for over 100 clients in Japan in the areas of ISO9001:2000 and ISO13485:2003. Implemented procedures to support the manufacturing of Medical Device and IVD samples. Responsible for the management of the Quality Management System and RAQA advisory service group. Significant contribution to the establishment of KPMG Registrar K.K. as one of world-wide projects of KPMG

Supervising Senior, Tax Department, KPMG (Los Angeles, CA) – 1992 to 1995

Provided tax compliance service for Japanese companies in the US especially for the entertainment industry and financial industry. Managed outbound business from Japan for small and medium companies.

Supervising Senior, Tax Department, KPMG (Tokyo, Japan) – 1988 to 1992

Provided tax compliance and accounting service for Japanese companies. Involved in the development of International Business Service project for outbound business from Japan to foreign countries.



Michiharu (Mic) Miyahara, continued...

AREA OF EXPERTISE:

- Experienced in short-term and implantable catheters for intravenous and cardiac uses
- Experienced in respiratory products
- Experienced in dental and orthodontic products
- Experienced in artificial joints and related products
- Knowledgeable of electronically operated medical devices
- Experienced in regulatory aspects of medical devices with software applications
- Published two ISO9001 related books and ISO13485 interpretation text.
- Instructor experience for ISO9001 seminars especially for healthcare industry, accounting firms, construction industry, and also ISO13485 interpretation seminars and ISO14971 seminars.
- Instructor experience for PAL reform act, new PAL regulation
- Compiled Pre-market Approval/Certification applications for various types of devices
- Compiled license applications for MAH, manufacturers, repairers and distributors for various medical device & IVD companies
- Compiled Technical Files for CE Marking approval for various types of devices
- Provided ISO 9001:2000 implementation consulting for various industries, especially for accounting firms, construction industry, healthcare industry including hospital and QS-9000 related companies
- Provided ISO 13485:2003 implementation consulting for major IVD and medical device companies
- Provided CMDCAS implementation consulting for dental product manufacturers
- Knowledgeable in sterilization validation and environmental compliance activities
- Familiar with clinical research applications including regulatory file creation, IRB approvals, site monitoring, and clinical data analysis
- Expert knowledge of risk management systems to conduct risk analysis activities for devices

TRAINING and CERTIFICATIONS:

- Certified Quality Auditor – IRCA
- Pass USCPA for Accounting 1 & 2 and Business Law

EDUCATION:

- Graduated Hosei University, Bachelor of Business Administration, Tokyo, Japan
- Took extension class for accounting & taxation for entertainment industry at UCLA, Los Angeles, CA