Program Outlines

1. Information Services

(1) Providing information on the website (http://www.jaame.or.jp/) (from 1997)
(2) Providing information by JAAME SEARCH (on Internet) (from 1997)
- Medical Devices Approval Information
- Information for Pharmaceutical Affairs Law and Notification from the Ministry of Health, Labour and Welfare
- Medical Devices Recall Information, etc.

(3) JAAME Communications (by fax and e-mail) (from 1997)
(4) Publications
- Video: Medical Devices and Pharmaceutical Affairs Law, etc.

2. Regulatory Affairs

(1) Regulatory Seminars (from 1989)
Seminars are conducted to explain the essence of and suggest points to be remembered relating to the filing of medical device applications for approval and license pursuant to the Pharmaceutical Affairs Law, attached data and notices.

(2) Seminars for Technical Directors of Medical Device Repair Services (from 1995)
Pursuant to Enforcement Regulation 188 of the Pharmaceutical Affairs Law, basic and specialized seminars registered by the Minister of Health, Labour and Welfare are conducted relating to the qualifications of technical directors of medical device repair services.

(3) Seminars for Managers of Medical Device Distribution and Rentals (from 1996)
Pursuant to Enforcement Regulation 162 or 175.1 of the Pharmaceutical Affairs Law, seminars registered by the Minister for Health, Labour and Welfare are conducted relating to the qualifications of the medical device distribution and rental managers.

(4) Seminars for Technical Directors of Medical Device Manufacturers (from 1996)
Pursuant to Enforcement Regulation 91.3 of the Pharmaceutical Affairs Law, seminars registered by the Minister for Health, Labour and Welfare are conducted relating to the qualifications of the technical directors of medical device manufacturers.

(5) Seminars for Marketing Superviser-generals (from 2013)
Pursuant to Enforcement Regulation 85.3 of the Pharmaceutical Affairs Law, seminars registered by the Minister for Health, Labour and Welfare are conducted relating to the qualifications of the marketing superviser-generals of medical device authorization holders.

(6) Medical Device QMS Introductory Course (from 1997)
A beginner’s course on the QMS system is offered.

(7) Continuous Education and Learning (from 1997)

Following seminars are conducted.

a Business Environment Surrounding Medical Devices

b Trends and Future of Regulations for Medical Device in US and EU

3. Medical Affairs

(1) Basic Seminars on Safety of Medical Devices (Seminars on ME Technology) (from 1986)

Co-sponsored by the Japan Society for Medical Electronics and Biological Engineering, sessions relating to biomedical engineering are provided, focusing on the safety of medical equipment/systems.

(2) Seminars for Medical Gas Maintenance and Control Technicians (from 1989)

Seminars are conducted for technicians in charge at health care facilities in order to enhance the effectiveness of the notices from the Ministry of Health and Welfare relating to the maintenance and control of medical gas supply systems.

(3) Seminars and Examinations for Certified Hemodialysis Technicians (from 1989)

Commissioned by the joint technical committee for hemodialysis therapy (joined by five organizations: Japanese Society of Nephrology, Japanese Urological Association, Japanese Society for Artificial Organs, The Japan Society for Transplantation, Japanese Society for Dialysis Therapy) , seminars are conducted that will qualify candidates to take an examination to become certified dialysis technicians and the examinations are administered.

(4) Seminars and Examinations for Certified Respiratory Therapists (from 1996)

Commissioned by the joint committee of the three scientific societies (Japanese Association for Thoracic Surgery, The Japanese Respiratory Society and Japan Society of Anesthesiology) for certification of respiratory therapists, seminars are conducted which will qualify candidates to take an examination to become certified respiratory therapists and the examinations are administered.

(5) Seminars on Home Mechanical Ventilation (from 1999)

Seminars are conducted for medical staff using home use medical devices in order to disseminate safe and effective operation of home mechanical ventilation devices.

4. International Cooperation

Support of International Communication(from 1985)

Considering the international developments in deregulation and harmonization of standards, interactions with overseas relevant organizations are actively pursued through participation and exchange of opinions in global medical device conferences, etc.

5. National Examination Programs

National Examinations of Clinical Engineering Technologists（from 1988）

Based on the provisions in Article 17 of the Law for Clinical Engineering Technologists, JAAME was appointed in 1988 by the Ministry of Health, Labour and Welfare as the designated testing agency and executes a program relating to the administration of the national examination of clinical engineering technologists.

6. Certification Programs

Certification Service Under Pharmaceutical Affairs Law (PAL) (from2005)

Based upon the provisions of Article 23, Paragraph 2, of PAL, JAAME offers a certification service as a registered certification body for designated controlled medical devices, etc. (controlled medical devices or in vitro diagnostic drugs designated by the Minister of the Ministry of Health, Labour and Welfare, after the relevant standards are established by the Minister.)

7. Medical Device Strategy Institute（MDSI）

Think tank investigating and researching mid to long term business opportunities surrounding the medical device industry, operating as a medical device strategic research center.

Activities

(1) Issue Research Papers
- project type
- proposal type

(2) Strategy Meetings
(3) Entry supports to medical device business for new businesses
(4) Study sessions for Asian health care strategies
(5) Contract researches, etc.