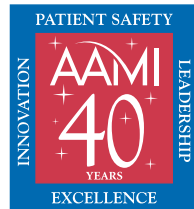




GMPs and Quality Systems: A New Role for AAMI



The mid-1990s brought a new revision of FDA's good manufacturing practice (GMP) requirements, and with it came a new role for AAMI. When FDA began revising the original 1978 regulations in the mid-1990s, the agency turned to AAMI for help. In a groundbreaking effort, AAMI and others created a process where FDA and industry learned together what meeting the new regulation would require. For AAMI, it established the organization as the leader in quality systems education for the medical device industry. AAMI's government education programs grew out of the effort and are now a mainstay of the association.

AAMI's educational programs present the state of the industry practice in implementing regulations and standards. AAMI's approach is unique in the industry: current regulations, up-to-date industry practices, diverse faculty backgrounds and perspectives.

Tammy M. Pelnik, The St. Vrain Group, Inc.,
AAMI course instructor



AAMI was one means by which FDA offered training on the new regulation and what meeting it required. FDA chose AAMI, working in partnership with others, to create a process where FDA and industry would learn together.

Kathy Warye, former AAMI vice president of
education and government programs

What are GMPs?

The good manufacturing practices (GMP) regulations outline a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

Interplay Between Standards, Regulation Gave AAMI Central Role

The worlds of medical device regulation and international trade had changed significantly since the first GMP regulation was published in 1978. The 1980s saw the coming together of the European Community, which emphasized voluntary standards as a form of regulation of medical devices. It became essential that regulators remove barriers to trade by harmonizing medical device regulatory requirements wherever possible, including in the area of GMPs—or quality systems as it was known internationally.

By the early 1990s, AAMI recognized the importance of international harmonization of standards and had taken a leadership role in many key international standards-writing efforts. This included TC 210, the International Organization for Standardization (ISO) committee that handles standardization of requirements and guidance in the field of quality management for medical devices. FDA was involved in these international committees and actively worked to harmonize the requirements of the new GMP regulation and international standards like ANSI/AAMI/ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*.

The current GMP regulation took effect on June 1, 1997.

Working through AAMI committees, leaders like industry's Ed Kimmelman [below left] and FDA's Kim Trautman [below right, pictured with Victor Dorman-Smith of Abbott Laboratories, Ireland] played major roles in the creation of international standards for quality systems for medical devices. Here, both are shown at a meeting of ISO/TC 210.



Global Harmonization Task Force (GHTF)

Representatives from the United States, the European Union, Canada, and Japan created this global consultative partnership in 1992 in order to harmonize medical device regulatory practices, including GMPs. This voluntary group includes representatives from national medical device regulatory authorities and the regulated industry. It aims to encourage convergence in regulatory practices by publishing and disseminating harmonized guidance documents on basic regulatory practice that can then be adopted or implemented by member national regulatory authorities.



As Secretariat of ISO/TC 210, AAMI established a Memorandum of Understanding with the GHTF. TC 210 has incorporated GHTF guidance into its standards and the two organizations have frequently held joint working group meetings aimed at harmonizing their documents related to quality systems.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1997

FDA Modernization Act signed into law; new quality systems regulation takes effect.

1997

AAMI launches Quality Systems course and exam, March 17–21.

1998

AAMI launches Design Control course.

Materials, Course Development Use Consensus Process

In May 1995, AAMI—with FDA's support—announced that it would launch an education program for GMP consultants, auditors, and corporate regulatory affairs professionals. The goal of the program was to establish a common body of knowledge of GMP requirements, bringing greater uniformity, consistency, and correctness to the interpretation and application of the medical device GMPs.

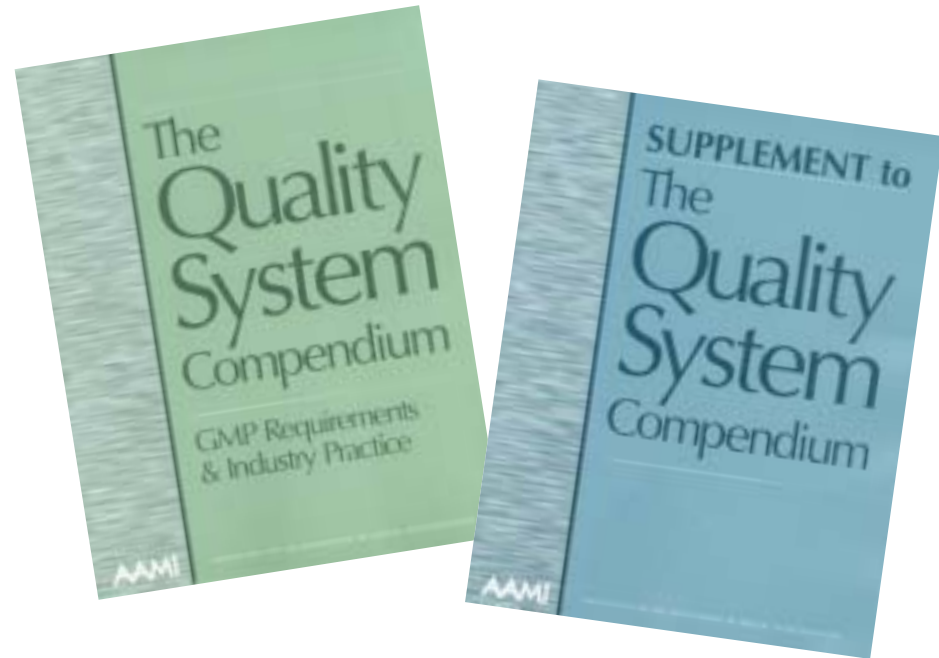
To help develop content for the courses, AAMI hired the consulting team of Ed McDonnell and Fred Hooten, both former FDA staffers. Following its standards model, AAMI formed a committee made up of representatives from industry, government, and private consulting that used a consensus process to interpret the emerging regulation. A two-year effort resulted in the course materials that would help both FDA and the industry understand and interpret the new GMP regulation.

In December 1996, their efforts resulted in the publication of *The Quality System Compendium*, the definitive desk reference on the new regulation. Each chapter includes a restatement of the relevant portion of the regulation, interpretations of the provision, and relevant industry practices.

In 2005, a supplement to the *Compendium* was published that included updated information about FDA's quality system regulation.

Content development was a considerable project given that FDA and industry participants were not just writing content but really working out interpretations of the regulation. In many ways, the content of the courses drove interpretation.

Kathy Warye



The advantage is that the materials we developed were not one person's opinion, but rather involved a collective effort that was constantly updated.

Vera Buffaloe

1999

AAMI invited by FDA to hold GMP/QS courses for European conformity assessment bodies.

1999

AAMI launches process validation course.

2000

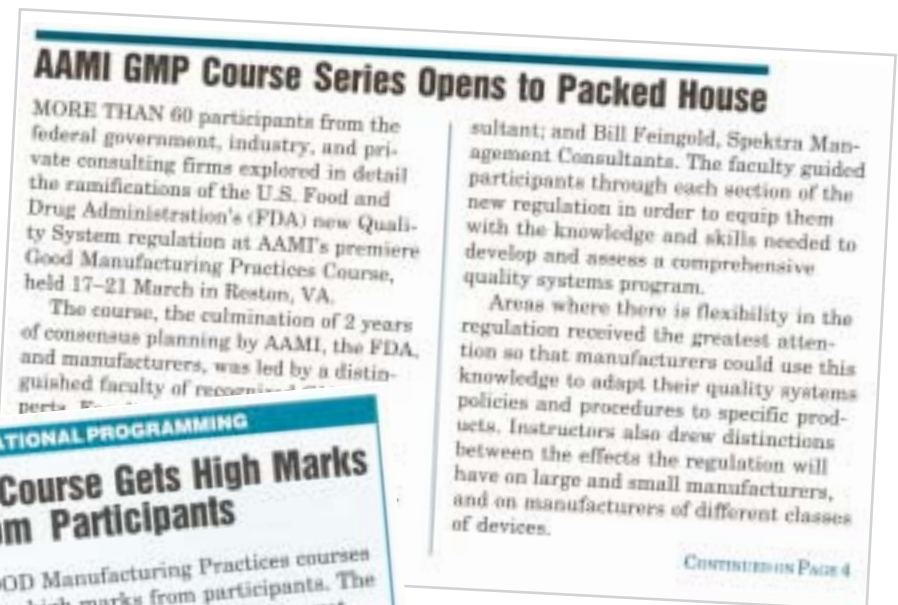
AAMI and FDA hold seminar on reuse of single-use devices.

Quality Systems Course Premieres in 1997 to Packed House, Sees Continued Growth

The first Quality Systems course premiered in January 1997 to a packed house. It offered four days of intensive, interactive instruction that stressed strategies participants could employ to implement the new requirements. A half-day examination followed the course, giving participants a chance to gauge their mastery of the materials presented. Faculty members were drawn from industry, consulting, and government. Attendees included both industry representatives and FDA professionals, all of whom needed to learn about the new regulation.

It received high marks from participants, who cited as valuable the shared FDA-industry learning experience, discussion of real-life situations, and the opportunity to hear firsthand about new interpretations and FDA expectations as the result of the new Quality Systems regulation.

AAMI's programs sell out on a regular basis. A core group of 24 industry representatives do the actual training for the courses. Perhaps most importantly, FDA also supplies a representative to attend each course. FDA involvement in the courses is an immense benefit to attendees and contributes to the popularity of the courses.



The support of FDA throughout the years has been invaluable to AAMI programs. The agency not only sends representatives to participate in courses, but also helps keep courses current.

Deborah Reuter,
AAMI Vice President of
Government Programs

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

2001
AAMI launches software validation course.

2002
AAMI receives funding from FDA to educate hospitals on the regulation for reprocessing SUDs, which results in AAMI's first live webinar.

2002
AAMI introduces courses on Industrial Sterilization and Risk Management.



AAMI course instructors John Sawyer [left], Vera Buffaloe, and Dan Weese at a 1999 course.

Vera Buffaloe

Vera Buffaloe is an author of AAMI's *The Quality System Compendium* and led the development of content for the Design Control and Process



Validation courses launched in 1998 and 1999, respectively. She has served as an instructor for AAMI's quality systems, design control, process validation, and CAPA courses since 1997. Currently president of Buffaloe Consulting, Inc., she has more than 25 years of experience as a regulatory and quality professional in the medical device industry.

Most companies want to understand what is required, and word has spread about the quality of these programs that set the standard for the industry.

Vera Buffaloe

Whatever Happened to GMP Certification?

AAMI originally envisioned the program to be a certification program, but the concept of certification was scuttled because of industry concerns over threshold requirements, retesting, and recertification. In a compromise, an exam is now offered upon completion of a course without formal certification attached to it. Ironically, today the course and the exam are so well thought of by both the industry and FDA that many consider passing the exam a requirement that carries almost the weight of a certification. In the end, the importance of the program was clear even without a certification requirement, through quality and impact on the community.



2003

AAMI launches Corrective and Preventive Action (CAPA) course.

2005

AAMI begins offering educational programming on the updated quality system standard, AAMI/ANSI/ISO 13485:2003.

2006

AAMI adds radiation sterilization course to educational offerings.

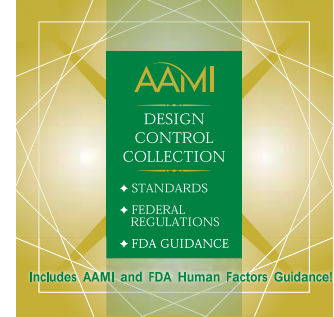
Courses, Materials Added In Response to Requests

Quality Systems course attendees consistently gave the course high ratings, but frequently requested more in-depth information on various subsystems of the regulation. In response to these requests, AAMI undertook new content development efforts and rolled out a series of short courses on specific topics starting in 1998. These short courses concentrated on specific sections of the GMP regulation:

- Design Control course, 1998, developed by Vera Buffaloe
- Process Validation course, 1999, developed by Vera Buffaloe
- Software Validation course, 2001, developed by Alan Kusinitz
- Corrective and Preventive Action (CAPA) course, 2003, developed by Vera Buffaloe and Ken Peterson
- Risk Management course, 2002, with 2005 revisions led by Tammy Pelnik, provide an in-depth examination of its role in the GMP regulation.

In addition, a new book, *Supplement to the Quality System Regulation*, was published in 2004 to keep manufacturers current on new strategies for compliance with the regulation and key areas that have experienced significant change in the years since the Compendium was first published. This project was led by Tammy Pelnik.

All of AAMI's courses and materials were developed with a consensus approach. Both industry representatives and FDA were involved in providing information and reviewing each course to make sure it included accurate interpretation of the regulation and reflected industry practice.



AAMI Launches New Process Validation Course, Developed Jointly with FDA

A NEW EDUCATIONAL TOOL designed to help manufacturers comply with the FDA's GMP/Quality System regulation and bring them up to date on the Global Harmonization Task Force's (GHTF) guidance on process validation was introduced by AAMI last month. "Process Validation Requirements and Industry Practice," a three-day course held in Washington, DC, is the latest addition to the growing family of quality systems-related products developed by AAMI over the past three years.

Like the first two courses, "Design Control Requirements and Industry Practice" and "GMP/Quality Systems Requirements and Industry Practice," this third course was developed with the shared-learning formula that continues to be well-received by both government and industry. Unique in the medical devices industry, this consensus approach is intended to promote in-

"This consensus approach promotes interaction and open dialogue."

teraction and open dialogue among regulatory affairs experts, quality systems professionals, manufacturing and process development engineers, and FDA staffers.

With 22 participants from industry and 12 from FDA's Center for Devices and Radiological Health participating in the course, this goal was met, according to Kathy Warye, AAMI's senior vice president, Education and Government Programs. "Process validation has been an

CONTINUED ON PAGE 2

After the initial courses, surveys indicated overwhelming requests for more courses. We added new topics in response to requests from participants.

Vera Buffaloe

AAMI-FDA Relationship Brings Agency Benefits

Starting in 2004, FDA has brought AAMI's Design Control, CAPA, and Process Validation courses in-house to train their Office of Compliance personnel. And, with FDA losing personnel due to retirements, the agency is having new staffers teach AAMI courses to gain exposure to industry.

AAMI and the Japanese Society of Medical Instrumentation (JSMI) have been collaborating for more than 30 years. At right, Masakazu Tsuzuki, MD [center], who first made contact with AAMI in 1974, is pictured with former AAMI Chair Stanton P. Nolan, MD [left] and Mike Miller.



Here, Harold Laufman is pictured with Masakazu Tsuzuki and other representatives from the JSMI during the 1982 AAMI Annual Conference.

Quality Systems Work Only One Aspect of Important Relationship with JSMI

When AAMI's quality systems course traveled to Japan, it was only one more example of an important collaboration between AAMI and the Japanese Society of Medical Instrumentation (JSMI) that began more than 30 years ago.



In 1974, Masakazu Tsuzuki, MD, who was chairman of the international liaison committee of JSMI (then known as MISJ) began corresponding with then-AAMI president Harold Laufman, MD, PhD.

He visited Laufman in America and then attended the 11th AAMI Annual Meeting in 1976 in Atlanta, GA. This was the first of 25 consecutive AAMI Annual Meetings that Tsuzuki would attend.

Over the years, JSMI has sponsored many educational programs at AAMI's Annual Conference. Since 1992, they have organized and supported joint JSMI-AAMI scientific sessions, and a special lunch for AAMI board members. They have invited many AAMI officers and staff to speak in Japan on many subjects. "We will continue to support this joint program, and we are also interested in expanding our international cooperation in the field of medical device regulations and R&D and also in the field of international telemedicine," says JSMI international committee chairperson Kenichi Matsumoto.

The following individuals deserve special recognition for their leadership in collaborative efforts between AAMI and JSMI:

- Masakazu Tsuzuki, MD. He is today an honorary member of JSMI, and is chairman of the board of directors of the International Medical Device Society of Japan
- Kenichi Matsumoto, chairman, International Liaison Committee, JSMI
- Masaki Takashina, MD, of the Surgical Center at Osaka University Hospital, Japan.
- Masako Kaufman, Liaison, JSMI

New Formats Broaden Course Accessibility, Tailor Content

Webinars

In response to demand, AAMI began bringing programs to its audience by holding webinars, or web-based seminars. These popular online sessions typically offer two-hour programs that focus on specific aspects of standards, regulation, procedures, or policies. Webinars allow thousands of people to participate. For example, almost 2,000 listeners tuned into AAMI's online seminar on the topic of the ISO 13485 standard, held in December 2003.

In-House Training

In-house training is another popular format increasingly being requested by program participants. Attendees impressed by the quality of AAMI's programs went back to their companies and encouraged management to bring AAMI training in-house. From four programs held in-house in 1999, the program has now grown to 26 programs held in-house in 2006.

European Notified Bodies

In 1999, the AAMI GMP/Quality Systems course and exam were selected by FDA as a component of the training curriculum for notified bodies and conformity assessment bodies (CABs).



A scene from AAMI's first webinar.



AAMI's quality systems courses have also made an international impact, with tailored programs being offered since 1997 in countries such as Germany, Japan, and Sweden. Here, a shot from a program held in Japan.

Each course incorporates hands-on exercises, so when participants return to their jobs, they are ready to use the tools and methods presented. As courses include both industry experts and FDA employees on the faculty, participants receive a breadth of perspectives.

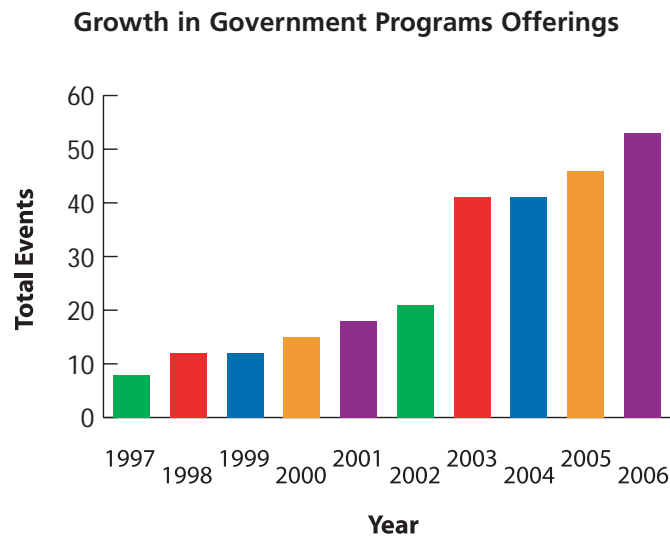
Tammy M. Pelnik, The St. Vrain Group, Inc.,
AAMI course instructor

Consensus, Training Success Opens New Opportunities for AAMI

Building on the success of the AAMI-FDA collaboration in the GMP arena, AAMI will be seeking new areas of collaboration with FDA, working with other interests, to achieve consensus on quality systems and other important areas of regulation. While AAMI has always served as an important neutral third party, its role as facilitator of consensus was heightened by the success of the GMP programs. AAMI has since played a leading role in questions like whether third party servicers would be regulated and resolving electromagnetic compatibility concerns. AAMI also had the opportunity to hold conferences and other consensus building activities in contentious areas such as the reuse of single-use devices.

In addition, the success of the standards-to-training-course format has resulted in the addition of new training courses based on AAMI standards documents. The last few years have seen the premier of three standards-based education programs:

- Building a Quality Management System in a Regulated Environment: a 13485 Workshop
- Industrial Sterilization for Medical Devices
- Radiation Sterilization for Medical Devices
- Risk Management for Medical Devices



Leah Lough

Leah Lough joined AAMI in 2001 as the senior vice president of education and government programs. During her tenure, the number of government programs and standards-related programs tripled. She is now AAMI's executive vice president for education and membership services.



Growth in Quality Systems and Standards-Related Program Attendance

