# Training and Education Opportunities for FDA and Industry Officials

**Moderator**
Nancy Singer, Compliance-Alliance, LLC

**Panelists**
Jane Kreis, Captain U.S. Public Health Service, FDA
Fatma Ail, P. FMA Consulting, LLC/DNV GL LA/ASQ MC
Daniela Drago, Ph.D. George Washington University

# Process

- Form groups of 4-5 people
- *Briefly* introduce yourself:
  - State your name, title, and number of years at your organization
- Identify the chairperson:
  - Person with the first letter of the last name closest to A
- From each slide describing a scenario, out of the four options listed, select the best option
- Reach *consensus* among the team members. If not, the chairperson chooses
- (Note: The slides with the answers will be posted after the session.)

# Expert Panel Members

- Jane Kreis, Captain U.S. Public Health Service, FDA.
- Fatma Ail, FMA Consulting, LLC.
- Daniela Drago, Ph.D. George Washington University.

# Question 1

Which statement is ***incorrect*** about the Commissioned Corps of the United States Public Health Service (USPHS)?

A. There are more than 6700 USPHS officers overseen by the Surgeon General.
B. USPHS has enlisted support staff.
C. USPHS are America's Health Responders.
D. PHS officers are eligible to retire and receive benefits after 20 years of service.

# Answer: **B**

Reference:

https://usphs.gov/

# Question 2

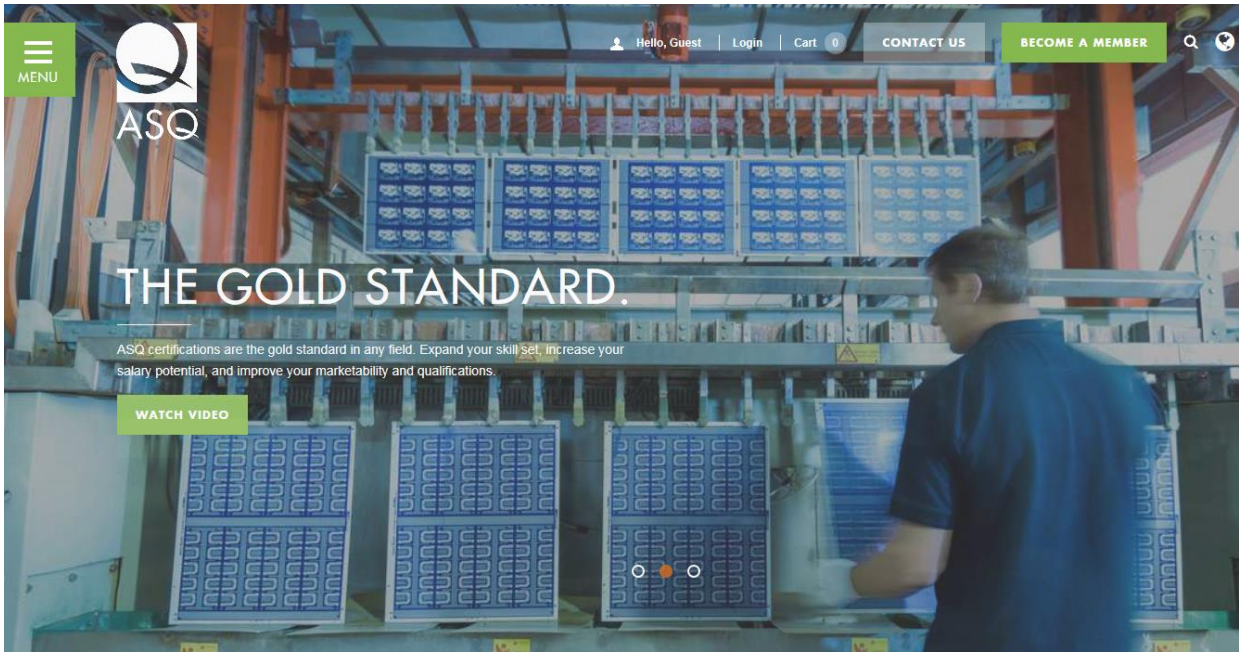
ASQ stands for

A. American Society for Quality Assurance
B. American Society for Quality
C. Association for Quality Assurance
D. Association of Scientist for Quality

# Answer: **B**

American Society for Quality

https://asq.org/



# Question 3

Some regulatory officials list RAC after their name. RAC stands for

A. Recognized Authority Credential
B. Regulatory Affairs Credential
C. Regulatory Affairs Certification
D. Regulatory Agency Citation

# Answer: **C**

Reference: http://www.raps.org/rac

- The RAC is a credential designed for regulatory professionals, with at least three to five years of regulatory experience.

- There are four different RAC exams:
  - The US, EU and Canada exams test regional regulations and involvement with regulatory bodies
  - The global exam focuses on international standards and guidelines
  - All four exams test for regulatory knowledge, critical thinking and analysis throughout the lifecycle of a product

# Question 4

Which statement is ***incorrect*** about the credentials/training given to FDA employees?

A. Basic criteria to be eligible for consideration as an FDA Consumer Safety Officer, a bachelor's or higher degree, including 30 semester hours in one or a combination of biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science.

B. Every employee needs to take a three week orientation course organized by Office of Training and Education (OTED) in Rockville, Maryland.

C. OTED offers inspectional training courses in which seasoned FDA professionals design, develop and teach the course in Rockville Maryland.

D. FDA has online courses which it allows state officials to take.

# Answer: **B**

Reference:

Consumer Safety Officer Positions at FDA

**https://www.fda.gov/AboutFDA/WorkingatFDA/default.htm**

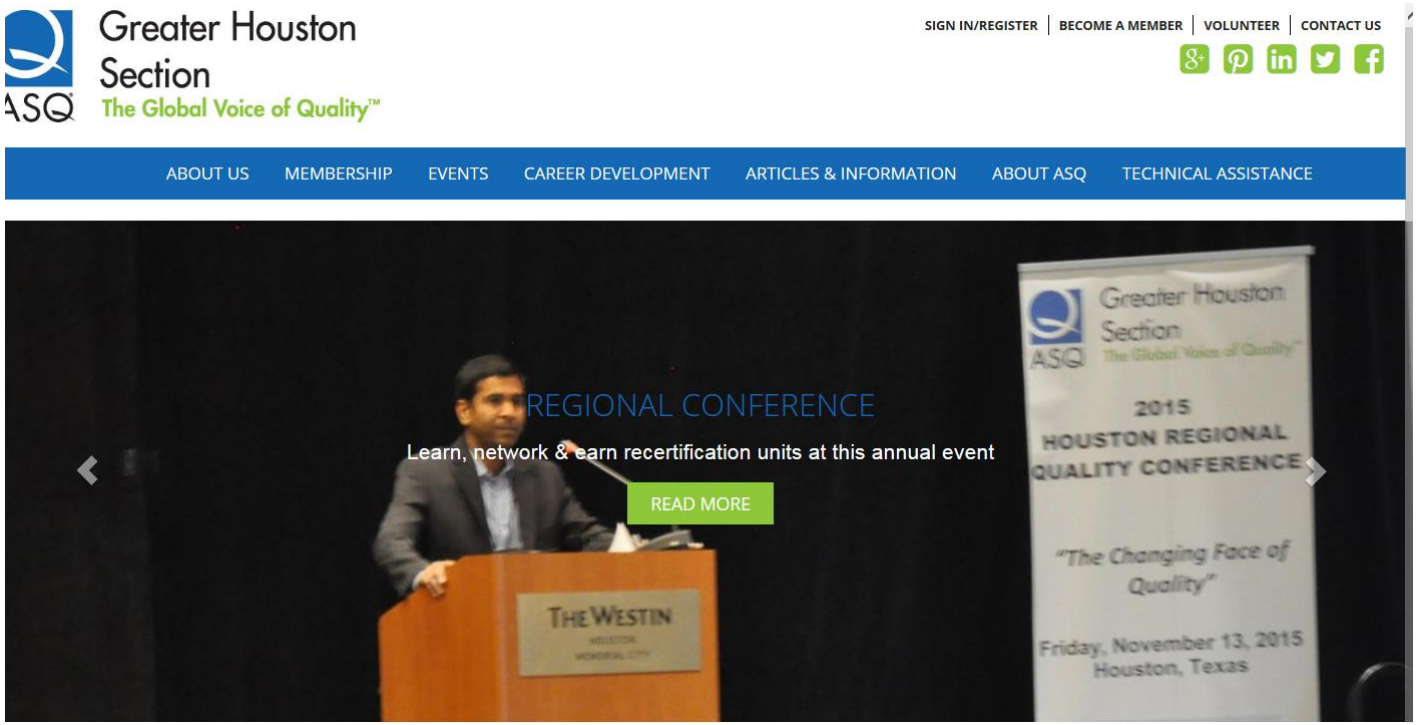
# Question 5

True for False

The American Society for Quality (ASQ) has a corporate office and there are local chapters (Sections).

# Answer: **True**

- You have to join the corporate to be eligible for the chapters.
- There is a Houston Section.



# ASQ Membership Dues

## INDIVIDUAL AND ORGANIZATIONAL MEMBERSHIP

Get professional development tools, networking opportunities with other people passionate about quality, and access to unlimited knowledge to guide you on the path to success. Make an impact on your career, your organization, and your everyday life with an ASQ membership.

Build and nurture your organization's culture of quality with the support of an ASQ Organizational Membership. The value it will bring your bottom-line is immeasurable.

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## ONE YEAR MEMBERSHIP

*Prices subject to change without notice

| Full | Associate | Student |
|---|---|---|
| $159 USD* | $99 USD* | $29 USD* |

# Why join ASQ

## Why Join ASQ? Let Us Tell You!

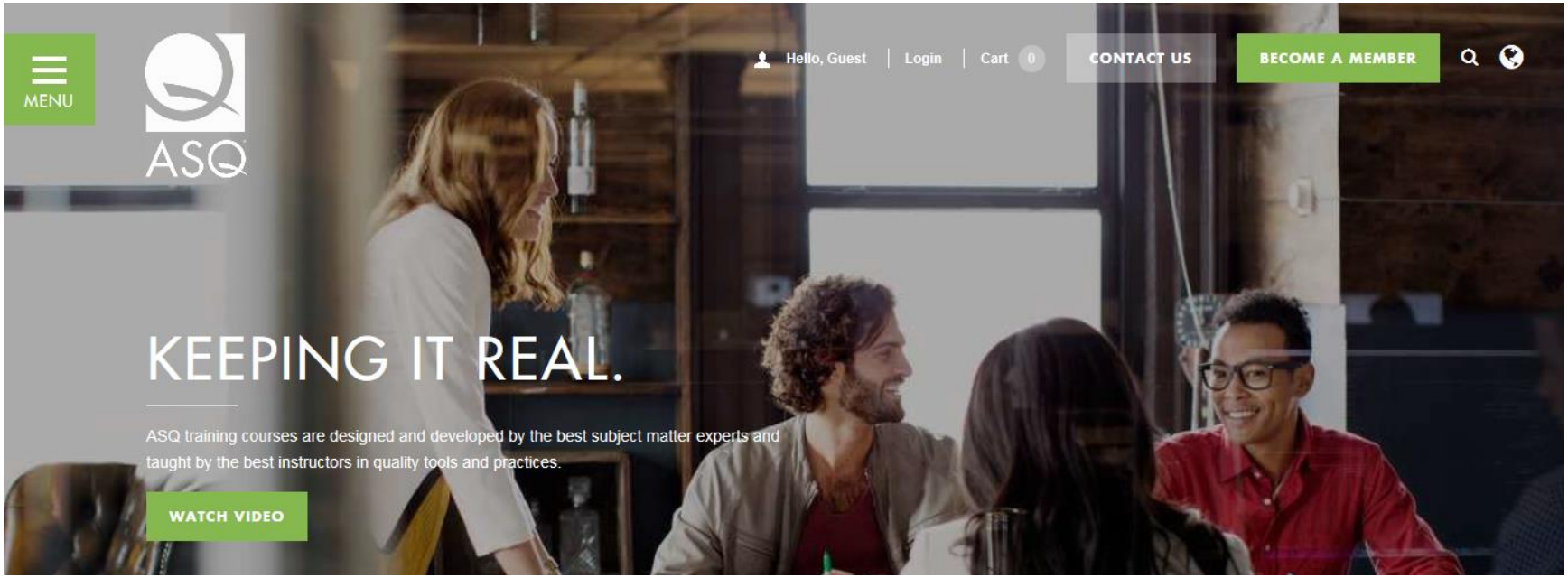
Whether you're looking to connect with other professionals, advance your knowledge and career, or grow your reputation as a thought leader, we've got the membership that's right for you.

ASQ offers the following memberships:

- Full membership
- Associate membership
- Student membership
- Senior membership
- Fellow membership (members only)
- Honorary membership
- Enterprise Quality Roundtable organizational membership
- Corporate organizational membership

# How to Join ASQ

Whey you go to https://asq.org/ you will see on the right side “become a member” click and follow instruction.



# Question 6

True or False

There are nine master's programs in regulatory affairs/science offered by US Universities.

# Answer: **False**

- There are more than 20 master programs in regulatory affairs/science offered by US Universities.

- Look for an accredited university program and ask questions:
  - What are the credentials of your faculty members?
  - Who is your typical student?
  - What is the rate and time to graduation?
  - What are the costs?
  - How many students are enrolled?
  - What is the program's format (online; on campus; blended)?
  - What do student do after they graduate?
  - What are some success stories about the program?

# Question 7

True or False

FDA requires that drug manufacturers provide annual training on good manufacturing practices/quality system regulations.

# Answer: **False**

Reference:

- 21 CFR 211.25

  Preamble: https://www.fda.gov/downloads/drugs/developmentapprovalprocess/manufacturing/ucm206779.pdf

# Sec. 211.25(a) Personnel qualifications.

Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. ***Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.***

# Comment 107 from the Preamble

Many comments questioned the frequency of the "continuing training" required in 211.25(a), asked for a definition of the word "continuing," and questioned who should receive what type of training. The requirement that training be on a continuing basis is intended to mean, for example, that a single training course at the time an employee is hired, with no subsequent training activities, is not sufficient. Subsequent training should be sufficiently frequent to assure that employees remain familiar with CGMP requirements. ***The Commissioner does not believe it would be prudent to specify time intervals for training in view of the broad nature of the drug industry and the wide range of employee functions covered by these regulations.*** The Commissioner believes this section is sufficiently clear in identifying "who should receive what training" in stating that each person engaged in the manufacture, processing, packing or holding of a drug product must have training in current good manufacturing practice that relates to that person's functions in the firm.

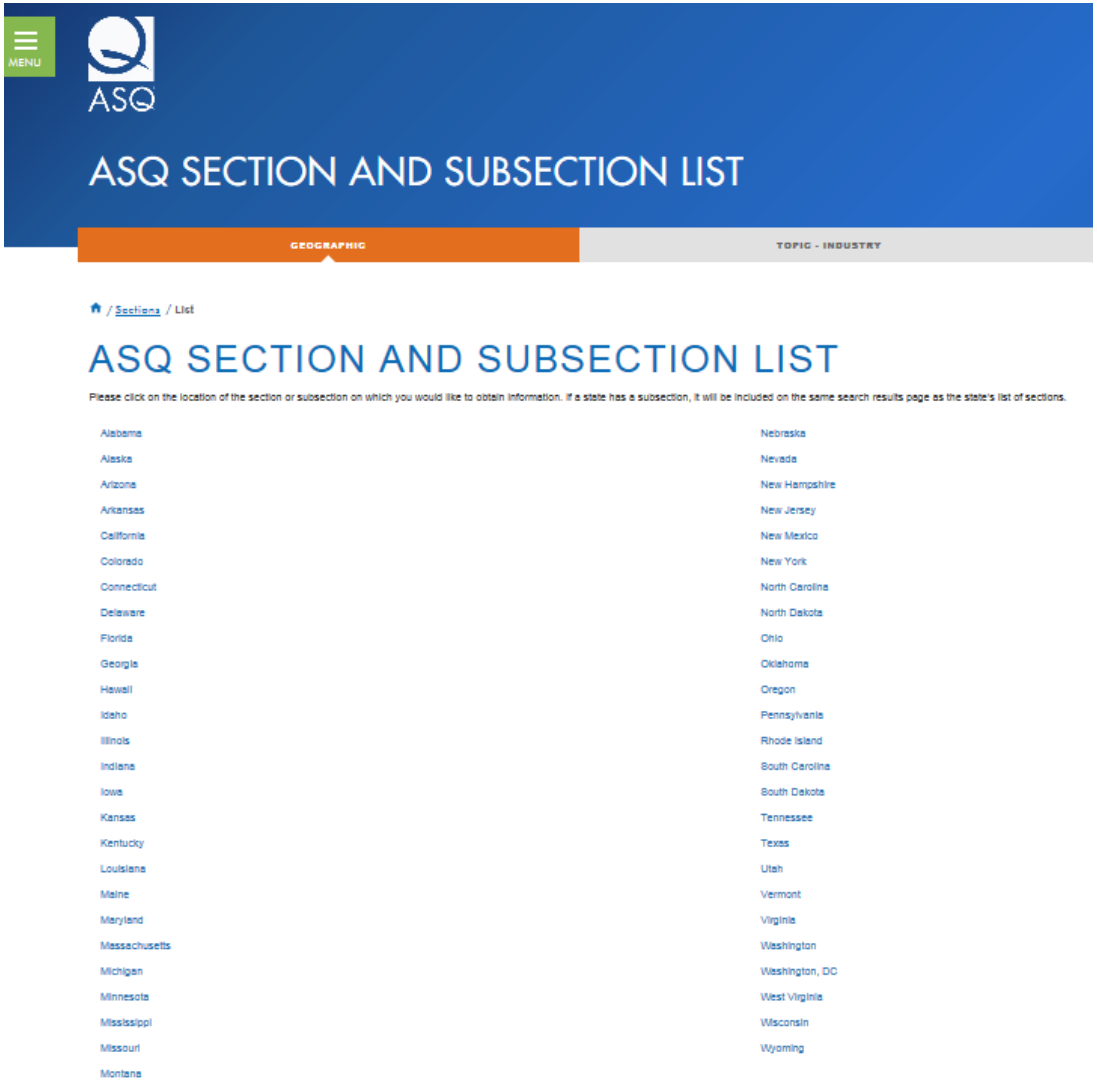
# Question 8

True or False.

There are nine local chapter in the US.

# Answer: **False**

There are more than 230 member-led local ASQ sections and subsections in North America.



# Local section benefits

Benefits for members may include:

- Regular Meetings
- Newsletters or other communication
- Professional development, such as courses, seminars, conferences, and certification exam preparation programs
- Leadership development through elected and appointed positions

# Examples of Activities at ASQ Houston Chapter

ASQ Greater Houston Section 1405 supports over 1,500 quality assurance professionals in the Houston area. Our members come from a wide variety of Houston industries. Our Section members supplement their member benefits in ASQ by getting involved in the local section. Some benefits of Section membership include:

- Networking opportunities
- Professional development dinner meetings
- Online professional development meetings
- Refresher courses
- Certification exams
- Recertification assistance
- Regional conference
- Other special events (e.g., plant tours, join meetings, holiday events, etc.)

# Question 9

When asked - “Why did you choose to pursue a master’s degree in regulatory affairs?” - applicants say:

A. It is a STEM degree that does not have a chemistry requirement.
B. It is an advanced degree that can be obtained in one year.
C. It is a degree that offers career flexibility.
D. They have a lot of extra free time and were looking for something fun to do with it.

# Answer: **C**

When asked - ”Why did you choose to pursue a master in regulatory affairs?” - respondents to a GW survey stated :

- **Reason #1: There is a Large Degree of Career Flexibility**
  - Wide range of potential employers (government agencies, industry, hospitals, universities, medical research firms, and private medical companies).

- **Reason #2: High Earning Potential**
  - According to the RAPS 2014 Scope of Practice & Compensation survey, "The regulatory profession continues to pay well, and salaries for regulatory professionals maintained a general upward trend.” Survey results showed that U.S. based regulatory professionals earned an average base compensation of $126,163. Average compensation ranged from $70,687 for associates to $227,357 for vice presidents.

- **Reason #3: Improve the Opportunity to Make a Difference**
  - Regulatory affairs professionals are integral in bringing essential health care products to patients, many of whom are suffering from life-threatening diseases

- **Reason #4: Collaboration with Other Professionals**
  - Professionals in regulatory affairs work in multi-functional teams. They are involved in the entire product life-cycle: from research and development, through clinical trials, to product launch and beyond.

- **Reason #5: An Intellectual Challenge**
  - Jobs in regulatory are increasingly complex. Regulatory professionals must demonstrate strong attention to detail, advanced problem-solving and communications skills, and the ability to think critically.

# Question 10

True or False

FDA is receptive to partnering with industry to provide training for FDA employees.

# Answer: **True**

Reference:

- GMP Tea
- Import Brokers Association
- To cross-pollinate the learning experiences of government and private sector by:
  - Establishing ongoing communication regarding GMP training in both government and private sector
  - International Collaboration

  https://www.fda.gov/internationalprograms/partnerships/default.htm

# Question 11

The American Society for Quality Assurance (ASQ) focuses on helping people:

A. In the US understand the requirements for product quality.
B. In North and South America understand the requirements for product quality.
C. In 150 countries understand the requirements for product quality.
D. In the US, Europe, and Japan understand the requirements for product quality.

# Answer: **C**

- ASQ champions people passionate about quality in more than 150 countries.

- ASQ operates Regional Centers in North Asia, South Asia, Latin America and the Middle East/Africa. ASQ's global offices provide local access to the quality community, career development, credentials, knowledge, and information services.

# Question 12

Most master programs in regulatory affairs:

A. Take 1 year and cost from $20,000 to $ 40,000.
B. Take 2 years and cost from $35,000 to $ 70,000 .
C. Take 2 years and cost from $25,000 to $ 60,000.
D. Take 3 years and cost from $60,000 to $ 90,000.

# Answer: **C**

- Most master programs take approximatively two years to complete.

- The total cost of tuition can vary widely *(from $25,000 to $ 60,000).*

# Question 13

True or False

FDA has an extensive array of online courses to train industry personnel about how FDA regulates medical devices.

# Answer: **True**

References:

https://www.fda.gov/training/default.htm

CDRH Learn

- Courses that are available

  http://www.fda.gov/training/cdrhlearn/default.htm

- Survey for other courses

  https://www.research.net/r/CDRHLearnSurvey

# Question 14

True or False

The American Society for Quality Assurance (ASQ) has eleven certifications for people in FDA regulated industries.

# Answer: **False**

- ASQ provides 19 different certification.

- One of them is Pharmaceutical GMP Professional CPGP

# Question 15

Students chose on-line programs over on-campus ones because:

A. They are less rigorous.
B. They provide flexibility and convenience.
C. Only few universities offer on-campus programs.
D. There is no interaction with fellow students and no need for participating in discussions.

# Answer: **B**

- One of the most attractive features of online programs is **flexibility and convenience**.
  - Busy professionals are flocking to online programs. Distance education speaks to professionals, who otherwise would not attend classes due to career and family obligations.

- Another major difference between traditional and online college programs is **feedback**.
  - Instructors for online courses seem to typically offer a higher level of feedback on assignments and papers.