



**ASQ**

AMERICAN SOCIETY  
FOR QUALITY™

Food, Drug, and

**FDC**

Cosmetic Division

**An Overview  
of the  
American Society for Quality's  
Food, Drug and Cosmetic Division**

*presented by*

*Ed Arling, Amgen, Inc.*

*Region 13*

*FDC Division Regional Councilor*



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# How It All Started

- In 1960, the Food and Allied Industries Division formed.
- In 1974, this division merged with the Drug and Cosmetic Technical Committee to create what is now the Food, Drug and Cosmetic Division.

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# FDC Vision & Mission

## ***Our Vision***

Resources for quality systems and leadership development in FDC-regulated industries.

## ***Our Mission***

To achieve increased customer satisfaction and continuous improvement by identifying, communicating, and promoting knowledge and the use of management concepts, technologies, and regulations as they relate to quality principles in all functional areas of the food, drug, and cosmetic industries.

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# Who makes up Our Membership?

- Quality professionals
- Regulatory affairs and compliance professionals
- Scientists
- Engineers and manufacturing professionals
- Auditors and consultants

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# What Our Membership Looks Like

- Representation
  - 61 Countries
  - 50 States including Washington, DC, Puerto Rico and the U.S. Virgin Islands
- Total membership
  - 5522
- Member types
  - Majority are Regular and Senior
  - 35 Fellows among our ranks
- Roles & Responsibilities
  - More than 50% hold management responsibility
  - Most hold at least one ASQ Certification and belong to 2.5 divisions





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# ASQ Region Map



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# What is the FDC Division?

- Professional Development
- Conferences/ Workshops/ Seminars
- Certification
- Publications/ Newsletters/ Website

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# Professional Development

- Focus your professional development resources through industry-specific
  - Conferences
  - Workshops
  - Seminars
  - Webinars
  - Certifications
  - Publications



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# FDC Conferences

- West Coast
  - Ofelia Barretto
- East Coast
  - Tony Carfangno
- Midwest
  - June Morita
- Southeast
  - Mike Ferrante

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# Past Conference Presentations

- “Packaging and Labelling-Regulatory Compliance and Expectations” by Steven McNett, Vice President Quality Control, Anderson Packaging Company
- “Legal Issues – Before, During and After Inspections” by Frederick Branding, R. Ph., J.D., Partner – Reed, Smith Law Firm
- “FDA Drug Inspection Update: International Inspection Program/Amendments to cGMP Regulations” by Sue Bruederle, Investigator, FDA Chicago District, Hinsdale Resident Post





# Past Workshops

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- "GMP Series: Quality and Productivity in a GMP Microbiology Lab - Survival in a "More with Less" Environment"
- "Manufacturing and Quality Control of Standard Microbial Cultures for Use in Food, Drug and Cosmetic Industries"



# ASQ Certifications

- Mark of excellence
- Demonstrates that the certified individual has the knowledge to assure quality of products and services
- An investment in your career and in the future of your employer.
- “ASQ believes the integrity of the exams is a key factor in why companies rely on them as a foundation for training and assessing their quality staff.”

J.W. Moran and P. C. La Londe,  
Quality Progress, **33**, 4, (2000).

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# ASQ Certifications and the FDC Division



- The FDC Division has been instrumental in its efforts to establish new certifications
  - HACCP Auditor - CHA
  - Certified Pharmaceutical GMP Compliance Professional - CPgmpCP



# CHA Certification

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- Originally began as the CQA-HACCP.
  - The Hazard Analysis and Critical Control Point was an add-on to the Certified Quality Auditor certification
- HACCP has evolved over the years. As a result, the ASQ Certified HACCP Auditor exam has also evolved.
- The Body of Knowledge has been updated to include the principles of management systems auditing and the analytical tools of quality assurance.



# Certified Pharmaceutical GMP Compliance Professional



- Body of Knowledge Drafted
- Next Steps
  - ✓ Certification Board approved CPgmpCP at 2008 WCQI meeting in Houston
  - Survey
  - Economics
  - Exam Questions

# Recent Publications

- *The Certified HACCP Auditor Handbook* was developed by the FDC Division to assist the certification candidate in preparing for the CHA examination.
- *Pharmaceutical Certification Book – Coming Soon!*
- Past Articles in *Control* (Division Newsletter)
  - *“U.S. Food Safety: Home-Grown Problems Abound”*
  - *“The Philosophy of Quality: At the Intersection of Service and Supervision”*
  - *“The FDA Takes Action Against Unapproved Drugs”*
  - *“Food Safety in a Global Marketplace”*
  - *“Childhood Lead Exposure”*
  - *“Cosmetic Good Manufacturing Practice Guidelines”*

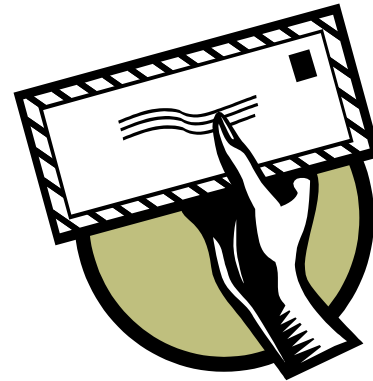


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# Industry Information

- Gain valuable information, via newsletters delivered to your mailbox or desktop.
- Visit web site for links to industry resources



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# FDC Division Web Contents

[www.asq.org/fdc](http://www.asq.org/fdc)

- Division and Committee Contact Information
- Conference and Workshop Information
- Newsletters
- Discussion Boards
- Career Services

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# Networking

- Expand your network of quality professionals in your field.



- Includes professionals from the food, pharmaceuticals, cosmetics, and related products industries.



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Thank you for your time!

May I answer any  
questions?