

# MARSQA MONITOR

**MARSQA  
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## Dr. Frances Kelsey, Thalidomide, and Future Directions

The recent death of Dr. Frances Kelsey, in August 2015 at the age of 101, has prompted the scientific community to remember her incredible contributions to society. In particular, Dr. Kelsey was well recognized for her efforts and stubborn refusal to approve thalidomide, a sedative that was widely available in 46 countries prescribed for morning sickness during pregnancy. Despite drug company pressure, Dr. Kelsey repeatedly concluded that the drug applications lacked in reliable data [about the safe use of the drug]. The drug was never marketed in the U.S. however, was occasionally used off-label in the United States. “Researchers in Germany and Australia linked thalidomide to clusters of rare, severe birth defects—hands and feet projecting directly from the shoulders and hips—involved thousands of babies ([FDA, 2013](#)).”

Dr. Kelsey’s efforts to ensure scientifically reliable evidence and safety of the drug and the “impact of the near disaster” ([FDA, 2013](#)) led the way for the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act. This amendment required FDA approval before submitting a marketing application as well as requirement of the company to prove safety as well as effectiveness of the intended treatment ([FDA, 2009](#)).



Frances Kelsey works with her major professor, E. M. K. Geiling, in the Department of Pharmacology at the University of Chicago, around the late 1930s.

Photo above from [FDA, 2013](#).



Thalidomide belongs to a class of drugs known as immunomodulators.

In 1998, the FDA approved the drug's use in the treatment/prevention of Erythema Nodosum Leprosum (ENL) also known as Hansen's Disease. The drug works by reducing inflammation, redness, and has also been

Well controlled studies of thalidomide would have prevented the necessity for this prosthetic apparatuses ([Time, 2013](#)) worn by an individual afflicted by teratogenic effects of thalidomide

found to reduce the formation of blood vessels that feed tumors.

In 2006 the U.S. FDA “granted accelerated approval for thalidomide i.e. THALOMID® for the treatment of multiple myeloma patients ([National Cancer Institute, 2013](#)).” The FDA oversees a mandatory Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) program that provides education to patients, prescribers and pharmacies regarding thalidomide’s safety to prevent fetal exposure during pregnancy ([National Cancer Institute, 2013](#)).

Additional Article Sources: [FDA](#), [WebMD](#), [Wikipedia](#); <https://embryo.asu.edu/>

## 25 June 2015 MARSQA Meeting Recap

MARSQA hosted a successful membership meeting this past June in Lahaska, PA. Mike Hourigan dazzled members with his dynamic and interactive keynote address and Deborah Parker presented a detailed drive through the road of biologics. Read on for more information and some fun pictures!

### Keynote: Navigating through Waters without Getting Wet

Presented by Mike Hourigan

MARSQA's keynote speaker, Mike Hourigan, presented a dynamic, informational, and fun presentation focused on how to lead an organization during a time of change. His presentation discussed reasons behind change, helping others work through change, praise, communication, stages of change, and acknowledging your support network.



Mike stressed the importance of communication in a “3-D Process: Discussed, Dissected, and Digested.” Through the four stages of change (denial, resistance, exploration, and acceptance/commitment, change can be a little bit less ‘scary’ and ‘overwhelming’ in a work environment for management and employees.

### Biologics Super Highway - An Auditor's On-Ramp

Presented by Deborah Parker, B.A , Compliance Specialist, GQRC-ANA Bristol-Myers Squibb

During the June membership meeting, Deborah Parker from Bristol-Myers Squibb gave an entertaining, and informative, talk entitled, “The Biologics Super Highway – An Auditor’s On Ramp”. The theme of the talk was delightfully engaging, highlighting how biologics (cars) and small molecules (trucks), and the technologies used in their analysis, are coming together in the laboratory.

Deborah gave an overview of the science behind an ELISA (Enzyme-Linked ImmunoSorbent Assay), and briefly compared acceptance criteria for small and large molecule assays. She then spoke about the similarities and differences between Bioequivalence (BE) studies for small molecules and Biocomparability (Biocomp) studies for large molecules related to clinical design.

Lastly, she held a discussion of Biosimilars which are large molecules similar but not identical to originator compounds, and emphasized how much testing must be done to truly demonstrate that a new large molecule is equal in principle to the approved drug.



## 25 June 2015 MARSQA Meeting Recap



MARSQA Disclaimer:  
Please note, during membership meetings,  
photography during the meeting may  
occur. If you do not wish you photograph  
to be included in upcoming MARSQA  
newsletters, please e-mail  
[newsletter@marsqa.org](mailto:newsletter@marsqa.org)



## FDA connects through social media: Pinterest



### 21 Pinterest Topic Boards

- Heart Health
- Women's Health
- FDA en Espanol
- Tobacco Education & Prevention
- Animal Health
- Safe Sharps Disposal
- Patient Lifts
- Nutrition Facts Label
- FDA Infographics
- Drug Topics
- National Women's Health Week
- Drug Information Videos
- From Our Perspective
- Back to School
- Diabetes
- Have a Happy and Safe Halloween
- Minority Health
- Recipe for Food Safety
- November 4 Caregivers
- National Women & Girls HIV/AIDS Awareness Day
- One Week for Better Health

## FDA Pinterest Pins

### Drug Topics

### Drug Topics

Access to important drug information. Center for Drug Evaluation and Research <http://www.fda.gov/Drugs>

U. S. Food and Drug A...

86 Pins

714 Followers

Unfollow board

**Warning about low blood sugar treatment** Use may cause serious lung condition in infants, newborns

Pinned from fda.gov

**New option to treat adults with schizophrenia** Drug also helps with treatment of depression

Pinned from fda.gov

**New treatment for certain non-small cell lung cancer** inhibitor helps block growth, spread of tumors

Pinned from fda.gov

**NSAIDs can raise chance of heart attack, stroke** Drug warning label to be revised

Pinned from fda.gov

**Learn all the essential components** Register now for this free event!

Pinned from fda.gov

**First-Time Generic Drug Approvals** for June 2015

Pinned from fda.gov

**Cough-and-cold products with codeine** being evaluated Use may cause breathing problems in children and teens

Pinned from fda.gov

**New treatment for most common cause of cystic fibrosis** Progressive lung disease affects 30,000 in U.S.

Pinned from fda.gov

**ADHD patch can cause permanent loss of skin color** Warning to be added to labeling

Pinned from fda.gov

**GDUFA Hiring Event - Registration** now open for outside candidates See ODER-wide positions, submit resume!

Pinned from fda.gov

**New Risk Evaluation and Mitigation Strategies website** Provides centralized, user-friendly source for approved REMS

Pinned from fda.gov

**Antiplatelet drug prevents formation of blood clots** Targets patients with coronary artery disease

Pinned from fda.gov

**Drug approved to treat rare lung disease** Women of childbearing age most often affected

Pinned from fda.gov

**New treatment options for irritable bowel syndrome** Disorder affects 28 million Americans

Pinned from fda.gov

**Infographic: su colesterol** Cómo funcionan las estatinas

Pinned from fda.gov

**FDA Small Business Regulatory Education for Industry (REdI) Conference** "Focus on CGMPs and FDA Inspections" Summer 2015 July 15-16, 2015

Pinned from fda.gov

Pinterest is a visual bookmarking tool that helps you discover and save creative ideas like home improvement, crafts, recipes, and now the FDA! Think of Pinterest as a virtual bulletin board to pin ideas/information. Go to [pinterest.com](http://pinterest.com) and create an account to start 'pinning.'

## FDA—Keeping Pace: FDA Draft Guidance for Industry: Social Media Outlets and Drug/Device Promotion

The Internet and various social media platforms have increasingly enabled drug and device manufacturers to be more actively engaged with consumers and healthcare professionals as a means to disseminate product information. The June 2014 FDA Draft Guidance regarding Social Media describes FDA’s current views regarding how manufacturers, packers, and distributors of prescription human/animal drugs and medical devices should present benefit/risk information in a social media platform. In particular social media platforms with character space limitations, such as microblog messaging (e.g., messages on Twitter or “tweets,” which are limited to 140 character spaces per tweet) and online paid search (e.g., “sponsored links” on search engines such as Google and Yahoo).

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for regulating the manufacture, sale, and distribution of drugs and medical devices in the United States. This authority includes oversight of the labeling of drugs and medical devices (21 U.S.C. 53 352(a)) and the advertising of prescription drugs and restricted medical devices...promotional labeling for drugs and devices and advertisements for prescription drugs and restricted devices \**misbrand the product* if they make representations about the use of a product without disclosing certain information about the product’s risk.

### The following basic parameters are expected for social media content:

- Inclusion of the Benefit and Risk information within the advertising and promotional labeling
- Should be accurate, not misleading, and reveal material facts
- Information is to be kept within the same character-space-limited area, otherwise the social media platform is not adequate for public communication
- Risk information should minimally include the most serious risks associated with the product
- Hyperlinks to product information should be considered an essential element of the social media piece

\*21 U.S. Code § 352 - Misbranded drugs and devices, and 21 U.S. Code § 333—Penalties

Source: FDA, 2014; <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf>



### *INSTANT CURE!*

Promotional material that pre-date FDA regulations on advertising were not sufficiently informative and often touted unevaluated medicinal products and claims.

## MARSQA Member Spotlight: Jigna Patel

### Where do you work and what is your specialty?

I work at Merial, A Sanofi Company, as a GLP/GCP QA professional. Merial is Sanofi's animal health division. My Specialty is auditing studies for FDA, EPA and EU regulatory compliance.

### What was your pathway to the regulatory world?

My hands-on experience of working in R&D analytical GMP/GLP environment paved my path into the regulatory world. I have been in Pharma R&D industry since 2002. I was working in R&D analytical lab for 10+ years before I made the switch to regulatory world in 2013. I have been working in a GCP/GLP QA group for 2 years now, since then, it has been a very exciting learning experience.



Jigna Patel

### What is your favorite movie and why?

My Favorite movie is Schindler's List by Steven Spielberg. I like this movie as Schindler does everything in his power to help those people in need, "return to their families as men, not murderers." My favorite line from this movie is "whoever saves one life saves the world entire". It is my favorite movie, as plot of this movie is similar to the legacy, I want to leave behind.

### What is the legacy that you would like to leave behind?

The legacy I want to leave behind is helping people in need; by changing their thoughts and outlook towards life rather than giving them the feeling of helplessness or dependency. Knowing the legacy I want to leave behind helps me stay focused on what I am doing in the present so that my goals are in line with that legacy. It offers a concrete sense of purpose in choosing what I am giving my energy to.

We make a living by what we get but we make a life by what we give- Winston Churchill.

## MARSQA Computer Validation Committee Update

The MARSQA Computer Validation Committee is happy to be able to provide several computer validation trainings to the MARSQA membership this year.

In May, Basic Computer System Validation took place at the C\*ck 'n' Bull Restaurant in Lahaska. Over 30 people attended the training, which included an overview of the system life cycle phases, focusing on selected concepts of computer validation activities in accordance with each phase. Everyone enjoyed the delicious lunch served each day, lots of networking, and games with prizes awarded. It was informative and fun for both the presenters and those attending the training.

On **September 30**, the CVC will be hosting Computer Validation Training - Special Topics of Interest, Updates on Recent Regulatory Guidance. This is a brand new one day class that will offer an overview and discussion of recent guidance documents from the FDA and other regulatory agencies that have been recently published.

The training will be held at Peddler's Village in Lahaska, PA. **Registration is now open on the MARSQA website. Don't miss this new exciting class!** The meeting will precede the MARSQA member meeting on **October 1, 2015**.

On **November 18 and 19**, the CVC will be hosting our Advanced CV class in Lahaska, PA. This course will build on the basic computer validation concepts. The Advanced Training course has been held in the past, but will be completely updated for this year's training. So stay tuned for the agenda! But mark your calendar, you don't want to miss this!

If you have any questions or are interested in joining the CVC, please contact Chris Wubbolt at [chris.wubbolt@gacvconsulting.com](mailto:chris.wubbolt@gacvconsulting.com) or Denise Botto at [denise.botto@inventivhealth.com](mailto:denise.botto@inventivhealth.com).

## Become a MARSQA Sponsor!

Is your company interested in becoming a MARSQA sponsor? To become a sponsor you can host a MARSQA meeting, provide catering, or support to MARSQA.

*Benefits include:* Advertise in the MARSQA newsletter, acknowledgement on the MARSQA website and member meetings, free job postings, and free registrations for MARSQA member meetings or training events. Sponsorship Levels include: Platinum, Gold, Silver, Bronze, and In Kind

For more information, contact a MARSQA Board Member or review the Sponsorship Policy on the MARSQA website (<http://marsqa.org/>).



**Advertising Space Available...**

For more information on placing your advertisement in the MARSQA newsletter contact a MARSQA Board Member on the MARSQA website

<http://marsqa.org/>



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Email: [contact@qacvconsulting.com](mailto:contact@qacvconsulting.com)*

Upcoming Events

MARSQA  
Fall Membership  
Q32015 Meeting

1 October 2015

11:00am-3:30pm

C\*ck and Bull Restaurant  
Peddler's Village, Lahaska, PA

4Q2015 MARSQA Meeting:  
scheduled for 8 Dec 2015

- Computer System Validation Quarterly Meeting
- GLP Discussion Group
- Digital Signature Use in Regulated Environment Highway, Presented by: *Santosh Tharkude, Sr. Compliance Auditor, Bristol-Myers Squibb*
- Regulatory Compliance and Quality Governance Challenges of Cloud Service Providers, Presented by: *Dave Evans, Managing Director, Accenture*

See [www.marsqa.org](http://www.marsqa.org) for meeting details and registration information

MARSQA Computer  
Validation Training:

30 September 2015

8:30 am - 4:30 pm

C\*ck and Bull Restaurant  
Peddler's Village, Lahaska, PA

This training will provide an overview and discussion of guidance documents from the FDA and other regulatory agencies which have recently been published.

Registration Fees:  
\$125 for Members and \$150 for Nonmembers

See [www.marsqa.org](http://www.marsqa.org) for meeting details and registration information

To contact the entire  
MARSQA board please e-mail:

[board@marsqa.org](mailto:board@marsqa.org)

For individual Board Member  
e-mail addresses, please see:

<http://www.marsqa.org/board.shtml>

Bright Idea Corner

Submit topics for presentations, volunteer to present on your area of expertise or suggest ideas for the next newsletter.

Contact us at: [newsletter@marsqa.org](mailto:newsletter@marsqa.org)