ComplianceOnline
The Largest GRC Advisory Network

ComplianceOnline In-person Seminar

Clear as MUD: Obtaining & Marketing your 510(K) with Today's FDA

January 27, 2012, Salt Lake City, Utah

Location:

Hilton Salt Lake City Center
255 South West Temple
Salt Lake City, Utah 84101
Phone: (801) 238-4830

Speaker:

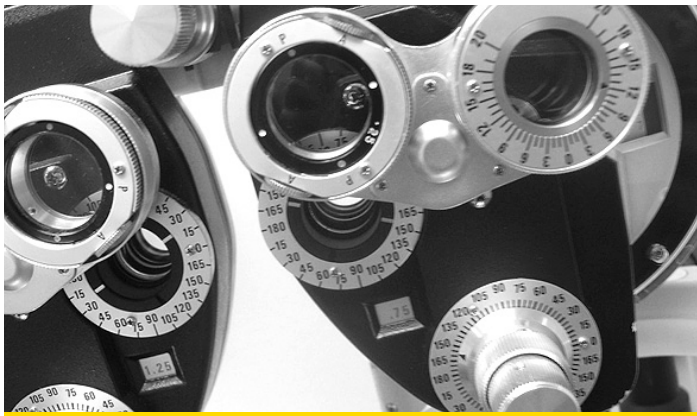
Mark DuVal
President, DuVal & Associates

Mark DuVal, J.D., is President of DuVal & Associates, P.A., a law firm dedicated to counseling companies in the medical device, pharmaceutical, biotech, food, and nutritional supplement industries. His practice includes providing strategic regulatory advice, developing compliance programs, designing and implementing sophisticated marketing programs, counseling on reimbursement matters, conducting sales training and interfacing extensively on behalf of companies with the FDA with relation to product approvals and clearances, clinical trial negotiations, approvals, policy arguments, appeals, etc.

Speaker:

Mark Gardner
Associate Attorney, DuVal & Associates

Mark Gardner, M.B.A., J.D., is an Associate Attorney at DuVal & Associates, P.A., a law firm dedicated to counseling companies in the medical device, pharmaceutical, biotech, food, and nutritional supplement industries. His practice focuses on compliance (federal and state anti-fraud and abuse laws, anti-kickback analysis, HIPAA & HITECH, and development of training and compliance programs) and promotion (appropriate and lawful off-label dissemination procedures, sales contracts, labeling and advertising review, continuing medical education programs (CME), product launch campaigns, pre-approval communications programs, direct-to-consumer (DTC) advertising, and domestic and international web strategy).



Knowing how to get your application through FDA quickly can save millions of dollars in unnecessary investment burn. Mr. DuVal, a national authority on the 510(k) program regularly negotiates with FDA, the 510(k) issues for his clients.

Mr. DuVal will teach you the tips and tricks of the trade that he has learned in the trenches with FDA. Both attorneys also participate in the national dialogue on the proposed changes to the 510(k) program. Mr. Gardner will focus on pre-clearance/pre-approval communication, as well as the promotional issues companies face once they are on the market.

What Past Attendees Say:

"I found the training very helpful. Personal experience in communicating with FDA and details like "bring your own projector" were much appreciated."

- RA Manager, Terumo Medical

"The seminar was very interesting and informative."

- RA Specialist, B. Braun Medical, Inc.

"Speakers were very good and knowledgeable. examples were good and we could relate to them."

- RA Manager, Terumo Medical

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Learning Objectives:

- How to obtain a 510(k) in today's environment at FDA? How to position your 510(k) submission?
- How to fashion the intended use statement and argue the technological characteristics are the same and do not raise "new types" of questions of safety and effectiveness?
- What to do when things do not go right? How to answer Additional Information (AI) letters ? When and how to push back meetings with FDA ?
- Whom to include and how to prepare the appellate process at CDRH, what avenues to pursue and when?
- When you get your 510(k), how to market a product with a general intended use statement when your product can be used in many specific indications/patient populations?
- What communication and dissemination strategies you should adopt? What to do when FDA disagrees with your promotional positioning?

AGENDA

Areas Covered

- An update on what is happening politically with FDA and Congress on the 510(k) program.
  - Update on the activities of FDA's internal working groups
  - The Institute of Medicine's report on the 510(k) program and the advocacy of AdvaMed , MMDA, LifeScience Alley and the Minnesota Medical Device Alliance.
- A brief review of the statute, regulations and guidance documents that are the underpinnings of the 510(k) program; along with insights on the direction CDRH is headed today with the 510(k) program;
- An examination of common mistakes seen in drafting and prosecuting 510(k)s through the regulatory process and how to make the best submission possible the first time through, including:
  - Understanding that today's 510(k) is no longer a cut and paste boilerplate document, it is an advocacy document from submission to clearance that requires strategic and tactical implementation;
  - Choosing the right predicate, the use of multiple predicates, split predicates and when to argue "technological precedent;"
  - Understanding the intricacies behind "substantial equivalence" including the "same intended use" statement—when it is modified by the submission content and how new and multiple uses come into play;
  - Examining the criterion of "same technological characteristics" and how to position it with CDRH;
  - A review of what belongs in a submission and what doesn't;
  - An honest look at when data, especially clinical data, will be needed; when to meet with FDA and thoughts on filing IDEs;
  - A discussion of when a de novo becomes an attractive option and how to go about it; and
  - A primer on your relationship with the reviewer, Branch Chief and Division Director.

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- What to do when things don't go right
  - Answering Additional Information (AI) letters
  - The use of outside experts
  - When and how to push back
  - Meeting with FDA and who to take and how to prepare
  - The appellate process at CDRH,
  - What avenues to pursue and when, including the use of the Office of the Ombudsman.
- When you get your 510(k) what do you do with it?-marketing your 510(k) including:
  - Beginning with the end in mind-providing marketing, clinical and reimbursement input before a 510(k) is submitted to explore
    - What claims will make the product differentiable in the marketplace vs.
    - The constraints found in the labeling of your chosen predicates vs.
    - The level of substantiation required vs.
    - The impact on reimbursement coding, coverage and payment;
  - A deep dive on your labeling-
    - What is on- or off-label
    - A review of CDRH's General vs. Specific Use Guidance document and the position of today's CDRH;
  - What can you do to promote your general intended use and how to deal with specific indications
    - The three "buckets" of promotion, communication and dissemination;
  - A primer on communication strategies in
    - Press releases, websites
    - Notices of Availability (NOAs)
    - Providing grants for CME and physician-initiated trials
    - Market research, speaker's bureaus, social media and the like
  - What to do when FDA disagrees with your promotional positioning-including a brief update on enforcement

Who will benefit:

- CEOs
- VPs, Directors and Heads of: Quality Assurance, Compliance, Validation & Regulatory Affairs
- Regulatory affairs
- Attorneys
- Quality Assurance
- Risk Managers
- Risk Management team members
- Quality Engineering
- Market Research
- Clinical
- MDR Reporters
- Production
- Engineering & R&D
- Professionals involved with premarket notification to the FDA
- R&D personnel involved in approving the design of medical devices
- Sales personnel involved in approving the marketing of medical devices

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Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1- 650-620-3937.
- Call +1 - 650-620-3937 or Fax your PO: 650-963-2556.
- Mail your check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

Terms & Conditions

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Cancellations and Substitutions

Written cancellations received at least 15 calendar days prior to the start date of the event will receive a refund - less a $150 administration fee. No cancellations will be accepted - nor refunds issued - within 15 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future ComplianceOnline event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that ComplianceOnline cancels the event, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Registration Form

☑ **YES!**

I want to attend ***Clear as Mud: Obtaining & Marketing your 510(K) with Today's FDA*** on

☐ Friday, January 27, 2012, 9 AM to 5 PM, Salt Lake City, Utah

I understand the fee per attendee includes the workshop, all course materials, breakfast and lunch

From Dec 21 to Dec 31	**$479**
From **Jan 01 to Jan 15**	$499
From **Jan 16** onwards	$599

Register for 4 and the 5th person goes FREE !!!

Attendee 1 : Name ..... Title ..... Email .....
Attendee 2 : Name ..... Title ..... Email .....
Attendee 3 : Name ..... Title ..... Email .....
Attendee 4 : Name ..... Title ..... Email .....
Attendee 5 : Name ..... Title ..... Email .....

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(Signature required on credit card and bill-me orders.)

Print name .....
☐ Bill me/my company $ .....
Purchase order # .....
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556

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