CONFERENCE SPEAKERS

Alfred Dolan

President

Health Care Technology Consultants

Brian J. Donato, Esq.

Senior Counsel

Hyman, Phelps & McNamara PC.

Sara E. Dyson, Esq.

Assistant Vice President of Risk Management Medmarc Insurance Group

George J. Flick, Jr.

Distinguished Professor

Virginia Polytechnic Institute and State University

Stan Mastrangelo

Retired

Abbott Laboratories

Captain Joseph Salyer

Director Regulatory Operations | CDRH U.S. Food & Drug Administration

Jeffrey K. Shapiro, Esq.

Director

Hyman, Phelps & McNamara PC.

Roger C. Thies, Esq.

Senior Counsel

Hyman, Phelps & McNamara PC.

Courtney Stevens Young, Esq.

Senior Attorney | Risk Management Medmarc Insurance Group



GENERAL INFORMATION

Seminar Registration

The course registration fee is \$1650. Medmarc insureds and clients of Hyman, Phelps & McNamara are entitled to a discounted registration fee of \$1300.

To register for the seminar, please go to: http://bit.ly/VT100185

Attendance for this conference is limited to the first 50 registrants in order to provide maximum opportunity for networking and access to the nationally and internationally recognized instructors.

For General Questions, please contact: 703-652-1362 or riskmanagement@medmarc.com.

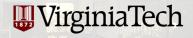
Refunds and Cancellations

Request for refunds will be honored when received fourteen calendar days prior to the program. However, another person may be substituted at any time for this program. A \$250.00 administrative fee will be deducted for cancellations. In the unlikely event this program is cancelled or postponed due to insufficient enrollments or unforeseen circumstances, we will fully refund registration fees but cannot be held responsible for any other expenses, including cancellation or change charges assessed by airlines, hotels travel agencies, or other organizations.



PRODUCTS LIABILITY & REGULATORY COMPLIANCE

EFFECTIVE PRACTICES FOR AVOIDING LITIGATION
AND ENSURING SAFE MEDICAL DEVICES







April 12 - 13, 2018

Virginia Tech Executive Briefing Center 900 N. Glebe Road, Arlington, Virginia



Medical devices are regulated heavily by FDA-both before and after they are marketed. Manufacturers are also required to meet international standards. Failure to meet the challenges presented by these requirements exposes a company to a higher risk of products liability.

This conference will enhance your ability to meet these regulatory challenges and mitigate products liability risk.

Education Highlights:

- Reporting requirements and how they affect products liability
- How to reduce products liability risk with sales force, advertising, and promotion compliance techniques
- Key FDA regulatory requirements that must be followed and their relationship to products liability
- Products liability from industry and in-house counsel perspectives
- How your business partners can increase your products liability risk
- How products liability results from the failure to implement international product design standards
- How improper recalls can create products liability

Who Should Attend:

- In-house counsel
- QA/RA professionals
- Risk managers
- Project managers involved in design and development

AGENDA Room Location - Ballston Room

Jeff Shapiro

Thursday, April 12, 2018

7:30 – 8:30 AM	Registration and Breakfast	3:45 – 4:15	FDA Reporting & Products Liability – Implications of Non-Compliance
8:30 – 8:45	Introduction to Conference		Courtney Young
	George Flick		
8:45 – 9:15	FDA's View of Compliance	4:15-5:00	Most Effective Risk Management Practices for Life Sciences Companies
8.43 – 9.13	Captain Joseph Salyer (FDA)		Brian Donato ,Sara Dyson, Jeff Shapiro,
	Josephani Sesseri Garyer (1214)		
9:15 – 10:00	Non-Compliance – An Industry	5:00 – 7:00	Reception - Falls Church Foyer
	Perspective Stan Mastrangolo		
	Stan Mastrangelo	Friday, April 13, 20	018
10:00 - 10:20	Break	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
10:20 – 11:00	Introduction to Products Liability – How It Affects Medtech Companies and the	7:30 – 8:30 AM	Breakfast
	Relationship between Products Liability	8:30 – 9:15	How Design Characteristics and Process
	and FDA Regulatory Compliance		Validation Affect Products Liability
	Sara Dyson, Courtney Young		Alf Dolan
11:15 – 11:45	Premarket FDA Regulatory	9:15 – 10:00	Regulatory Compliance & Products
718	Requirements		Liability from the "In-House Counsel"
	Jeff Shapiro		Perspective
11:45 – 12:30	Emerging Challenges for Medtech	10:00 – 10:45	The Failure-to-Warn Claim and How
11.45 – 12.50	Companies	10.00 10.45	Your Sales Force, Advertising and
	Joseph Salyer, Jeff Shapiro		Promotion Can Make It or Break It
			Sara Dyson
12:30 – 1:15	Lunch - East/West Falls Church Room	10:45 – 11:00	Break
1:15 – 2:00	Quality System Regulation (QSR) -	10.43 – 11.00	Diedk
	Where Do Companies Go Wrong?	11:00 - 11:30	Products Liability – Managing Risk from
	Jeff Shapiro		Your Business Partners
2:00 – 2:45	Warnings, Labels, and IFUs and		Courtney Young
	Products Liability	11:30 – 12:15	Conclusions: Advice for Life Sciences
	Brian Donato		Companies in Road Ahead
2:45 – 3:00	Break		Alf Dolan, Roger Thies, Sara Dyson
		12:15 PM	Adjourn
3:00 – 3:45	FDA Regulatory Requirements for Clinical Studies – Pitfalls to Watch		
	Out For		