## 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

VirginiaTech

Hyman, Phelps & McNamara PC

MEDMARC
Treated Fairly

**April 12 - 13, 2018**

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

## COURSE DESCRIPTION

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 risk
- 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

**Thursday, April 12, 2018**

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|---|---|
| 7:30 – 8:30 AM | **Registration and Breakfast** |
| 8:30 – 8:45 | **Introduction to Conference**<br>*George Flick* |
| 8:45 – 9:15 | **FDA's View of Compliance**<br>*Captain Joseph Salyer (FDA)* |
| 9:15 – 10:00 | **Non-Compliance – An Industry Perspective**<br>*Stan Mastrangelo* |
| 10:00 – 10:20 | **Break** |
| 10:20 – 11:00 | **Introduction to Products Liability – How It Affects Medtech Companies and the Relationship between Products Liability and FDA Regulatory Compliance**<br>*Sara Dyson, Courtney Young* |
| 11:15 – 11:45 | **Premarket FDA Regulatory Requirements**<br>*Jeff Shapiro* |
| 11:45 – 12:30 | **Emerging Challenges for Medtech Companies**<br>*Joseph Salyer, Jeff Shapiro* |
| 12:30 – 1:15 | **Lunch - East/West Falls Church Room** |
| 1:15 – 2:00 | **Quality System Regulation (QSR) - Where Do Companies Go Wrong?**<br>*Jeff Shapiro* |
| 2:00 – 2:45 | **Warnings, Labels, and IFUs and Products Liability**<br>*Brian Donato* |
| 2:45 – 3:00 | **Break** |
| 3:00 – 3:45 | **FDA Regulatory Requirements for Clinical Studies – Pitfalls to Watch Out For**<br>*Jeff Shapiro* |
| 3:45 – 4:15 | **FDA Reporting & Products Liability – Implications of Non-Compliance**<br>*Courtney Young* |
| 4:15– 5:00 | **Most Effective Risk Management Practices for Life Sciences Companies**<br>*Brian Donato ,Sara Dyson, Jeff Shapiro,* |
| 5:00 – 7:00 | **Reception - Falls Church Foyer** |

**Friday, April 13, 2018**

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|---|---|
| 7:30 – 8:30 AM | **Breakfast** |
| 8:30 – 9:15 | **How Design Characteristics and Process Validation Affect Products Liability**<br>*Alf Dolan* |
| 9:15 – 10:00 | **Regulatory Compliance & Products Liability from the "In-House Counsel" Perspective** |
| 10:00 – 10:45 | **The Failure-to-Warn Claim and How Your Sales Force, Advertising and Promotion Can Make It or Break It**<br>*Sara Dyson* |
| 10:45 – 11:00 | **Break** |
| 11:00 – 11:30 | **Products Liability – Managing Risk from Your Business Partners**<br>*Courtney Young* |
| 11:30 – 12:15 | **Conclusions: Advice for Life Sciences Companies in Road Ahead**<br>*Alf Dolan, Roger Thies, Sara Dyson* |
| 12:15 PM | **Adjourn** |