Agenda

Day 1

9:15 a.m. – 9:45 a.m. Welcome and Overview: The Social Media and Pharma — Key Challenges for Industry

Social media is constantly changing. What worked last year isn't working today, regulators are planning new guidance and new platforms are emerging as old ones mature and change. To set the tone for the workshop, conference Chairman Dale Cooke, consultant to dozens of life sciences companies, will give us tales from the trenches of social media marketing and an outlook for what the industry can expect in the next month, year and decade from the FDA and major social media platforms.

Dale Cooke, President, Philly Cooke Consulting

9:45 a.m. – 12:00 p.m. Working with Patient Communities

Online patient communities have a lot to offer drug and devicemakers. Modern day treatments are discussed in these forums months (and even years) before they're even submitted for approval. In these forums, key opinion leaders can boost awareness of a drug — or kill a company's reputation. There's a right way and a wrong way to interact in these forums, and this panel will explain to participants what to say (and not to say) to make the right impression on these critical consumers.

Brian Lowe, CEO, Inspire
Ben Heywood, President, Patients Like Me (Invited)
Eric Peacock, Cofounder, My Health Teams (Invited)

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:00 p.m. Recruiting for Clinical Trials via Social Media

The first place people go to find out about their illnesses is online, where they quickly seek out the latest information about the drugs and devices that can help them. That makes social media a perfect place to find study subjects who may want to know more about a new trial. But working in social media poses its challenges, too. How do you recruit without offending? What's the best way to conduct follow up? How do you connect patients with investigators without angering physicians? Jonathan Commons has been working in pharma for 12 years, and currently manages digital recruitment strategies for

Quintiles, the world's largest CRO. He'll explain their best practices for online recruitment of study subjects.

Jonathan Commons, Vice President of Health Engagement & Communications, Quintiles

2:00 p.m. – 3:00 p.m. Ten Social Pitfalls to Avoid

Marianne Slivcova has been advising pharma companies about compliance with FDA and international regulators for more than 18 years. In this session, she will explain, with illustrations from industry, some of the risks to be considered operating in the social media world. Whether you're already up and running, or still testing the waters, the pitfalls Marianne will share are topics every life sciences marketer should have on their radar.

Marianne Slivcova, Senior Corporate Counsel, Bristol Myers Squibb

3:00 p.m. – 3:15 p.m. Break

3:15 p.m. – 4:15 p.m. Getting to Yes — The Path to Satisfying Both ROI and FDA

Sean Nicholson has helped dozens of drug and device companies go from frightened neophytes to social media rock stars, and he knows that the first step is often the hardest. What are the questions to ask, what are the right metrics to track and how do you define social media success? These are all questions that brands ask themselves before they launch onto a new platform. His simple and direct approach to assessing the risks and rewards of jumping into a new platform has taken the pain and uncertainty out of the process for dozens of companies and it can for you, too, when you follow his simple rules.

Sean Nicholson, Director, Social Media Strategy, Intouch Solutions

4:15 p.m. – 5:30 p.m. Become a Facebook and Twitter Superstar

Most companies only know the barest minimum of what Facebook and Twitter can do. Each platform has hacks and variables that only the savviest social networkers know. Shewn Gee is among them. Shewn will help you take your social media operation to the next level by looking at the best way to operate on Facebook and Twitter.

Shwen Gee, Associate Director, Global Digital Customer Engagement, Biogen (Invited)

5:30 p.m. – 6:30 p.m. Wrap-up and Reception

Day 1

8:30 a.m. – 9:00 a.m. Coffee and Breakfast

9:00 a.m. – 10:00 a.m. FDA's Current Thinking on Social Media

The FDA has published four guidances to help industry master social media marketing, with more on the way, and the agency is already plunging in with enforcement. Surely, more is on the way. Find out what the agency plans for the future in this presentation.

10:00 a.m. – 10:45 a.m. The Challenge to Industry to Embrace Social Media

The time for pharma and device companies to fully engage in social media is now. Peter Pitts, FDA's former associate commissioner for external relations, makes the case that the agency and the industry both need to make putting life sciences companies into social media a priority. It's where the patients are. It's where the data is going to be found that will revolutionize the way the industry thinks about its customers and it simply is too important a communications tool for life sciences companies not to be there. In his outspoken and thought-provoking style, Peter will kick off the debate with a call to action and a reasoned argument for social media.

Peter Pitts, President, Center for Medicine in the Public Interest

10:45 a.m. – 11:00 a.m. Break

11:00 a.m. – 12:00 p.m. Correcting Misinformation: Should You Do It and How

A user of your product posts some incorrect information about it online. What do you do? Correct it? Ignore it? Your policy can, and probably should, vary depending upon where the information is posted because the obligations vary by venue. What if it's posted to your Facebook page? A patient's page? An online forum? Direct tweeted? Bradley Merrill Thompson, leader of the mHealth Regulatory Coalition, will walk you through the questions to ask and the guidance from FDA that will allow you to set policy that is responsible and compliant.

Bradley Merrill Thompson, Member, Epstein, Becker & Green

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:00 p.m. Adverse Event Reporting and Social Media

When it comes to social media, adverse events reporting is one of the most challenging regulatory requirements to translate from real life to a virtual world. What is an online adverse event report? What steps must a company take to address it, and when must it be reported to the FDA?> Recent guidance tried to help clarify these questions for drug and devicemakers, but the reality is still murky. Anne Maher will walk users through the FDA requirements, plus illustrate her presentation with some interesting real-world examples of adverse events that don't neatly fit into the FDA's scenarios, and how to deal with them.

Anne V. Maher Kleinfield, Partner, Kaplan & Becker

2:00 p.m. – 3:00 p.m. Off-Label Promotion – Social Media Pitfalls

A poster on your company's Facebook page suggests a medication is good for an off-label use, or asks if the company recommends using a product for an off-label use. What is a company's responsibility in these situations and how can it respond to these situations and stay in compliance with the FDA? Does the answer vary by venue? Company supported website vs. independent forum vs. open social media platform? What are the best policies and practices to have in place so that when this happens – and it will – your employees know the right way to respond so they don't break the law, but don't unnecessarily limit your ability to make the most of legitimate off-label product discussions.

Alan Minsk, Partner, Arnall Golden Gregory

3:00 p.m. – 3:15 p.m. Break

3:15 p.m. – 4:30 p.m. Panel — Industry Attitudes and Barriers to Adoption of Social Media

To cap off this two-day event, Peter Pitts will invite four industry leaders in social media to drop the gloves and share what they really believe the future is for social media and drug and devicemakers. This lively roundtable will feature assessments of the compliance challenges that companies face, which are the real barriers to adoption and what these opinion leaders are watching and waiting for to signal that social media is as important as any other communications tool open to drug and device companies.

Peter Pitts, President, Center for Medicine in the Public Interest, Moderator

4:30 p.m. Adjourn Workshop