



Regulatory Managers Bootcamp
Sunday, 10 September 2017

**All attendees need to bring a fully charged laptop to the workshop. Limited power is available.*

8:00 am	Registration and Continental Breakfast
8:00 am	<p>Networking—Learn About the Background and Experience of the Participants</p> <ul style="list-style-type: none"> • Introduce yourself and meet your colleagues • Expand your personal and professional network <p>Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic</p>
8:20 am	<p>Hidden Challenges of Working in a Regulatory Environment—If Only I Knew Then What I Know Now</p> <ul style="list-style-type: none"> • Listen to the experiences of senior regulatory professionals • Get advice about the essential skills you need to succeed <p>Susan Alpert, MD, PhD, FRAPS, principal, SFA Consulting LLC John Tomczak, director of quality, Bard Electronic Systems–Dymax Facility Robert Yocher, MS, RAC, CQA, FRAPS, senior vice president regulatory and quality, HeartWare Inc (retired) and member, RAPS Affiliate Board Rainer Voelksen, FRAPS, vice president regulatory and quality affairs, Occlutech</p>
9:00 am	<p>Making Your Manager Listen: What to Say and How to Say it</p> <ul style="list-style-type: none"> • Learn techniques to help you influence your manager • Practice the techniques and receive feedback <p>Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance-Alliance</p>
10:00 am	Refreshment Break
10:30 am	<p>Writing Under Pressure</p> <ul style="list-style-type: none"> • Identify tools that enable you to answer your reader’s questions • Apply the tools to write clear and concise documents quickly <p>Daniela Drago, PhD, RAC, director regulatory affairs, The George Washington University</p>
12:00 pm	Lunch
1:00 pm	<p>Who is Out to Get You—Understanding the Threats From Inside and Outside Your Organization</p> <ul style="list-style-type: none"> • Understand who can be held liable under the law

	<ul style="list-style-type: none"> • Learn how to avoid being misinterpreted • Identify the information to include and exclude when writing emails <p>Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance-Alliance</p>
2:30 pm	Refreshment Break
3:00 pm	<p>Handling Difficult Situations in the Workplace</p> <ul style="list-style-type: none"> • Work with your colleagues to analyze challenging situations in the workplace • Compare your answers with industry leaders <p>Don Boyer, RAC, FRAPS, president, BOYER@RegulatorySolns Todd Chermak, RPh, PhD, divisional vice president innovation and development, established pharmaceuticals, Abbott Virginia Perry, RAC, FRAPS, founder and partner, Perry-D’Amico and Associates Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic</p>
4:00 pm	Adjourn