



**Master Class in Regulatory Intelligence: RI as a Strategic Imperative
Sunday, 10 September 2017**

****All attendees need to bring their laptop to the workshop***

This interactive workshop will examine the fundamentals of global regulatory intelligence (RI), including what it is and isn't, how it is conducted, the strategic value it brings to key partners and how it is imperative to regulatory decision making throughout a development program and lifecycle management of a therapeutic product. Discussion and hands-on exercises will provide insights on the collection, analysis, communication, and management of regulatory intelligence, with an emphasis on translating RI into a competitive advantage. The workshop will cover prescription drugs, biologics and medical devices with a focus on the US, EU and Canada.

Facilitators:

Kimberly Belsky, senior director regulatory intelligence, Mallinckrodt Pharmaceuticals

Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi

João Duarte, associate director, Europe regulatory policy and intelligence, Takeda

Robert Kester, associate director, global regulatory affairs and chief of staff Oncology & IVD group, Merck & Co Inc.

Matt Medlin, manager US regulatory affairs R&D Pipeline, Chiesi

James Monroe, clinical regulatory specialist, Siemens Laboratory Diagnostics

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| 7:00 am | Registration and Continental Breakfast |
| 8:00 am | Introduction—Linda Bowen, MS, RAC, FRAPS Case Study Kick-Off—Kimberly Belsky RI Basics 101—João Duarte |
| 9:00 am | Monitoring the Regulatory Landscape—Matt Medlin and James Monroe |
| 10:00 am | Refreshment Break |
| 10:30 am | Locating and Analyzing Precedent—Kimberly Belsky, Robert Kester and James Monroe |
| 11:30 am | Due Diligence—Linda Bowen, MS, RAC, FRAPS and Robert Kester |
| 12:00 pm | Lunch |

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| 1:00 pm | The Consultation/Commenting Process—João Duarte |
| 1:30 pm | Partnering With Groups Outside of Regulatory—Kimberly Belsky and Matt Medlin |
| 1:45 pm | Case Studies in Regulatory Intelligence—All Facilitators |
| 2:30 pm | Refreshment Break |
| 3:00 pm | Case Studies: Breakout Groups and Presentations—All Facilitators |
| 3:45 pm | RI: A Look to the Future—Linda Bowen, MS, RAC |
| 4:00 pm | Adjourn |