



**Workshop Title:** Regulatory Intelligence as a Strategic Imperative.

**Description:** This interactive workshop will examine the fundamentals of regulatory intelligence, including what it is and isn't, how it is conducted, the strategic value it brings to key partners and how it is an 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. The workshop will cover prescription drugs and biologics with a focus on the United States.

**Facilitators:**

Linda Bowen, Assistant Professor Temple University and Regulatory Intelligence consultant  
 Meredith Brown-Tuttle, Principal Consultant, Regulatorium  
 Matt Medlin, Manager, US Regulatory Affairs R&D Pipeline, Chiesi

**Tuesday 02 October 2018**

<b>7:00 am – 8:00 am</b>	<b>Registration and Continental Breakfast (<i>Ballroom D</i>)</b>
<b>8:00 am - 9:00 am</b>	Welcome & RI 101 – <i>Linda Bowen</i>
	Monitoring the regulatory landscape – <i>Meredith Brown-Tuttle</i>
	Locating and analyzing precedent – <i>Matt Medlin</i>
<b>9:00 am – 10:00 am</b>	Case studies in Regulatory Intelligence – <i>Linda, Matt, Meredith and workshop participants</i>
<b>10:00 am - 10:30 am</b>	<b>Refreshment Break (<i>Level 1 &amp; 2 Burrard Foyer</i>)</b>
<b>10:30 am - 12:00 pm</b>	Case studies in Regulatory Intelligence – <i>Linda, Matt, Meredith and workshop participants</i>
<b>12:00 pm – 1:00 pm</b>	<b>Lunch (<i>Ballroom D</i>)</b>
<b>1:00 pm – 1:30 pm</b>	Shaping the regulatory environment – <i>Linda Bowen</i>
<b>1:30 pm – 2:30 pm</b>	Hands on exercise in developing comments to draft documents - <i>Linda, Matt, Meredith and workshop participants</i>
<b>2:30 pm – 3:00 pm</b>	<b>Refreshment Break (<i>Level 1 &amp; 2 Burrard Foyer</i>)</b>
<b>3:00 pm – 4:00 pm</b>	Case Studies in Regulatory Intelligence - <i>Linda, Matt, Meredith and workshop participants</i>
<b>4:00 pm</b>	Adjournment