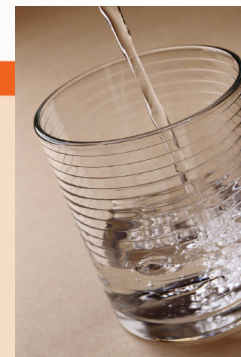




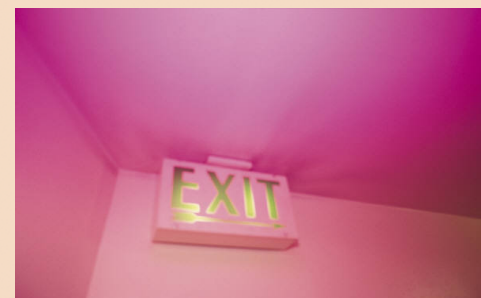
PhUSE Wayne, PA Single Day Event

Innovative System Validation

August 15, 2013



Housekeeping



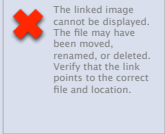


Agenda -Morning

Time	Title	Presenter
8.30 - 9.00	Welcome Refreshments Sponsored by Cytel	 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.
9.00 - 9.15	Welcome & Introduction	SDE Co-Leads, Ian Fleming & Karin LaPann
9.15 - 10.00	A Sponsor Perspective on Validating Regulated Systems: From Traditional Waterfall Approaches to Agile Continuous Improvement	Nathaniel Blevins, AstraZeneca
10.00 - 10.15	Morning Break Sponsored by Triangle Biostatistics	 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.
10.15 - 10.30	PhUSE	Frank Senk, PhUSE US Membership Director
10.30 - 11.30	Role of eClinical Systems in FDA Regulated Studies	Jonathan S. Helfgott, FDA
11.15- 12.00	Dedicated Q & A Session	Jonathan S. Helfgott
12.00 - 1.00	Lunch - Sponsored by Accenture	 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.

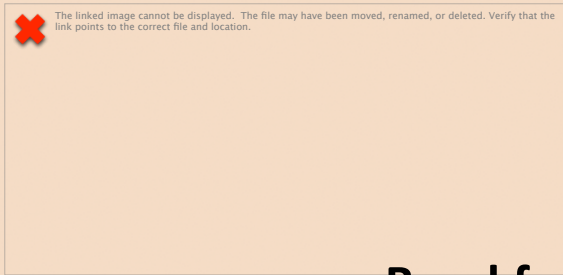


Agenda -Afternoon

Time	Title	Presenter
1.00 - 1.45	Use of Agile System Validation Methodologies for Rapid Product Enhancement	Terek Peterson & Giri Barasumarian, PRA International
1.45 - 2.30	Expediting the Validation Cycle with Virtual Machine Technology	John Leveille, d-Wise Technologies
2.30 - 2.45	<i>Afternoon Break Sponsored by PRA International</i>	 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.
2.45 - 3.30	Using Technology to Facilitate Validation and Auditing while Helping Sponsors Adjust to Novel Approaches	Rick Piazza, Medidata Solutions
3.30 - 4.15	Panel Discussions	SDE Co-Leads Ian Fleming & Karin LaPann
4.15 - 4.30	Closing Session	



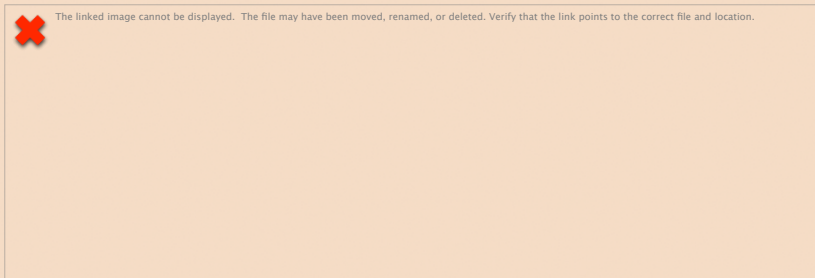
Break Contributors



Breakfast



Mid-Afternoon



Mid-Morning



General Contributors



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Venue Contributor

Shire Pharmaceuticals



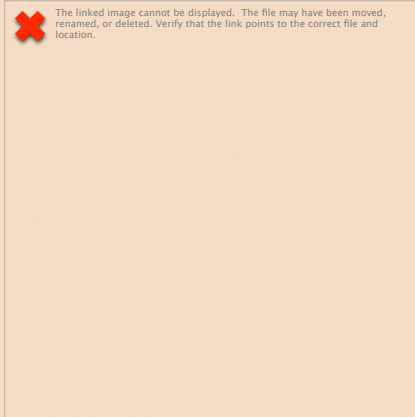
Lunch Contributor



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Give-away Contributor



Back packs



A Big Thank You...

- ☐ Speakers
- ☐ Shire Staff
- ☐ Phuse Committee
- ☐ Contributors
- ☐ Attendees

