

**Event:** TAMPA 2011 CONFERENCE  
**Session:** Data Integrity: How to Verify, Validate, and Maintain  
**Session Leader:** Michael Osburn, Judy Samardelis, Lorrie Schuessler  
**Dates:** Monday and Tuesday 21-22 February 2011  
**Location:** Tampa, FL  
**Weblink:** <http://www.ispe.org/2011tampaconference/dataintegrity>



## Monday, 21 February

Start Time	End Time	Presentation Title	Speakers	Company	Total min.
7:00	8:00	Speaker / Leader Breakfast (invitational)			
7:30	9:00	Breakfast			60
9:00	9:15	<b>Welcome and Introductions</b>	Michael Osburn Judith Samardelis Loretta Vuolo-Schuessler	Eli Lilly QIAGEN GSK	15
9:15	10:00	<b>Regulatory Update: Regulatory focus on Data Integrity (EU and FDA)</b> <ul style="list-style-type: none"> <li>• Regulatory focus on data integrity (EU and FDA)</li> <li>• Regulatory considerations on specific topics: <ul style="list-style-type: none"> <li>o Migration</li> <li>o Service providers</li> <li>o Testing Tools</li> <li>o Infrastructure/Cloud issues</li> <li>o News on Part 11 and Annex 11</li> </ul> </li> </ul>	Sion Wyn	Conform IT	45
10:00	10:30	Networking Break			30
10:30	11:15	<b>Regulatory Update: Regulatory focus on Data Integrity (EU and FDA) - Continued</b> <ul style="list-style-type: none"> <li>• Regulatory focus on data integrity (EU and FDA)</li> <li>• Regulatory considerations on specific topics: <ul style="list-style-type: none"> <li>o Migration</li> <li>o Service providers</li> <li>o Testing Tools</li> <li>o Infrastructure/Cloud issues</li> <li>o News on Part 11 and Annex 11</li> </ul> </li> </ul>	Sion Wyn	Conform IT	45

11:15	12:00	<b>Information Lifecycle Management: Risks to Data Integrity</b> <ul style="list-style-type: none"> <li>• Introduction of information lifecycle management process, regulatory requirements and how it aligns to GAMP Records Management</li> <li>• Gain understanding of risk management principles that can be applied to information lifecycle management to assure regulatory compliance and satisfy business and legal requirements</li> </ul>	George Serafin	Deloitte	45
12:00	13:00	Lunch			60
13:00	14:00	<b>Part 11 EBR Implementation</b> This session will cover key aspects to a Part 11 EBR Implementation including: <ul style="list-style-type: none"> <li>• Overview of GAMP5 assessments</li> <li>• Overview of predicate rule requirements assessment</li> <li>• Overview of implementation of system security based on predicate rule requirements</li> <li>• Overview of Part 11 assessments including system and data</li> </ul>	Ivan Soto	Amgen	60
14:00	15:00	<b>Interactive Metrics Discussion: <i>What and How do we Measure?</i></b> This interactive session will use polling devices to identify key metrics and measurements. You will answer questions and rate scenarios, reviewing results in real time. Results will provide input for the GAMP Metric SIG to establish priorities.	Marc Monette	Allergan	60
15:00	15:30	Networking Break			30
15:30	16:15	<b>Record and Information Management</b> Business use, frequency, record classification and retention are all essential items necessary to develop a sound record retention program in support of your business needs. This presentation will lay the basic foundation in aid of developing a record and information management policy for your organization.	Judy Samardelis	Qiagen	45

16:15	17:00	<b>Data Integrity and the Human Animal</b> Talk will highlight the ways in which our own human foibles can sabotage the best-laid plans for integrity, and some common-sense strategies to mitigate them.	Mike Rutherford	Eli Lilly	45
17:00	17:00	<b>Seminar Adjourns, Reception</b>			0



## Tuesday, 22 February

Start Time	End Time	Presentation Title	Speaker		Total min.
7:30	9:00	Breakfast			90
9:00	9:05	Welcome Back and Outline for Day 2	Michael Osburn Judith Samardelis Loretta Vuolo-Schuessler	Eli Lilly QIAGEN GSK	5
9:05	10:00	<b>Software as a Service – Regulatory and Risk Concepts</b> Software as a Service (SAAS) model is an emerging technology based on cloud computing platforms where a vendor will provide a software platform for a customer to use in place of purchasing and implementing a local solution. FDA and validation concepts include the control of installation and the security of the data used in the application business workflows. A review of regulatory guidance and risk following GAMP will be presented in order to establish a common thinking with respect to meeting this emerging technology. Scope and challenges with respect to GxP and Non-GxP critical risks shall be discussed. Cloud computing concepts will also be reviewed.	Carl Dourambeis	STARLIMS	55
10:00	10:30	Networking Break			30

10:30	11:15	<p><b>Use of Automated Testing Tool to Support Computer Systems Validation</b></p> <p>This session will focus on the risk assessment methodology used to determine the level of risk associated with the use of test automation tools to support computerized systems validation in a regulated environment.</p> <ul style="list-style-type: none"> <li>• Test automation tools, although not directly involved in handling product or clinical data, play an important role in ensuring that critical GxP regulated systems are suitable from a patient safety, product quality and data integrity stand point and function as intended when deployed to support validation testing.</li> <li>• It is important to understand the context in which these tools are utilized in the validation of other regulated applications that may directly interact with product or clinical data.</li> </ul>	Jason Tepfenhardt	Genilogix	45
11:15	12:00	<p><b>Data Migration and Integrity</b></p> <p>The continuous cycle of change to business processes, the need for business process consolidation, as well as business mergers and acquisitions are just some of the reasons why the migration and consolidation of data may be required. Data migration activities are often perceived as disruptive and a threat to data availability. Many data migration projects do not meet timelines and generate cost overruns.</p> <p>This presentation provides guidance in hopes providing good practices that properly define customer expectations, minimize risk and provide for appropriate planning and data integrity. It will identify and address some of the most common misconceptions:</p> <ul style="list-style-type: none"> <li>• We can fix the data after we migrate it to the target system</li> <li>• We don't need a separate project for the data migration activities in this implementation</li> <li>• We need perfect data for the migration</li> <li>• We have no data quality problems in our legacy systems</li> <li>• We don't need a data migration methodology</li> </ul>	Winnie Cappucci	Bayer	45
12:00	13:00	Lunch			60

13:00	14:00	<p><b>Risk Considerations with Cloud Computing</b></p> <p>This session will cover key risk considerations for Cloud Computing, including:</p> <ul style="list-style-type: none"> <li>• Supplier considerations (how do we assess, reliance etc.)</li> <li>• Security (multiple-tenancy, controls of sensitive or business critical data etc.)</li> <li>• Validation (reliance on supplier, company responsibility or oversight, etc.).</li> <li>• Data integrity considerations</li> </ul>	Stephen Ferrell Jason Silva	QIAGEN Sidus Group	60
14:00	15:00	<p><b>Maintaining Data Integrity with a Managed Service</b></p> <p>A presentation with an interactive discussion on how to maintain data integrity with a Managed Service. This will include:</p> <ul style="list-style-type: none"> <li>• Quality expectations of external service providers</li> <li>• Clear Roles and Responsibilities that should be documented prior to engagement</li> <li>• The level of governance, monitoring and oversight that should be considered for sensitive or critical business data</li> <li>• Standards and Service Level considerations <ul style="list-style-type: none"> <li>o Availability and performance;</li> <li>o Change management</li> <li>o Quality of service;</li> <li>o Security;</li> <li>o Business continuity</li> </ul> </li> <li>• Inspection Readiness – how would your provider support you in an inspection?</li> </ul>	Anita Morrison	Eli Lilly	60
15:00	15:30	Networking Break			30
15:30	16:30	<p><b>Data Warehouse Integrity in Clinical</b></p> <p>Collection, translation, and storage of clinical data has become an ever increasingly difficult scenario within regulated R&amp;D environments. This session will focus on the challenges of implementing a data warehouse within a R&amp;D environment and how to properly ensure the integrity of data using a risk-based approach to validation. We will review and discuss some common lessons learned and how to translate those into a successful project. The presentation shall also provide commentary on the latest FDA guidance and how this may impact such situations</p>	Eric Staib	Covance	60

16:30	17:00	<b>Interactive Panel Q&amp;A</b> This will be a facilitated discussion that will allow attendees to ask GAMP Leaders and industry experts questions about current events, trends etc.. All speakers from the conference will participate.	Michael Osburn Lorrie Schuessler	GSK Eli Lilly	30
17:00	17:00	Seminar Adjourns			0