

<p>GLP authorities and multiple QAUs</p> <p>E.g. where developers are in one (or more places), business analysts somewhere else, project leader somewhere else again, and the testing team is distributed between different countries, to achieve round-the-clock testing, how to stay on top of reported problems, fixes, and re-testing, when you have several different sub-teams going on.</p>	<p>Advanced</p>
<p>Validation expectations beyond the GXPs (Sarbanes-Oxley/SOX, HIPPA, etc.)</p> <p>Also suggest looking at this the other direction – (what other things have come into scope for validation efforts – i.e. using PCI for security on records or using SAS70 for oversight of data centers. Expectations for CDISC standards)</p> <p>Does SAS70 really satisfy FDA expectations? Look at overlapping of the validation expectations for other areas.</p>	<p>Basic to Intermediate</p>
<p>Impact of the e-source guidance (and other upcoming regulatory guidance) on computer systems and auditing?</p> <p>EHR/EDC intersection – compliance in an “uncontrolled” environment, electronic source considerations, status of direct feeds from EHR to EDC, applying validation principles, etc. etc.</p> <p>Could be a joint topic/session with GCP.</p>	<p>Intermediate to Advanced</p>
<p>Consider putting together a panel discussion on Agile development and the validation expectations in its use?</p>	<p>Basic to Intermediate</p>
<p>Use of automated tools for software testing and their use in the regulated environment?</p> <p>How to and when to use? What are the expectations for validation and control?</p>	<p>Basic to Intermediate</p>
<p>Sunshine Act & Part -54 compliance</p> <p>Does using the same eRecords / Systems for both invoke validation? Or maybe the issue is convergence of different regulatory drivers to overlapping set of systems – what does Pharma Company do?</p> <p>Could be a joint topic/session with GCP</p>	<p>Basic to Intermediate</p>
<p>Considerations with use of mobile devices, new technologies in a regulated environment</p> <p>– What are the considerations for investigators reviewing ECGs or medical images on a smartphone; devices which are making diagnostic decisions, etc.</p>	<p>Basic to Intermediate</p>