

**Event:** TAMPA 2011 CONFERENCE  
**Session:** Inspection Readiness Workshop: From Site Preparation to Successful Execution (E04)  
**Session Leader:** Janet Bowen, Kimberly Snyder, Phil Russ, Rebecca Waterbury  
**Dates:** 21-22 February 2011  
**Location:** Tampa, FL



**\*\*Please note this class is highly interactive. Course materials include interactive discussions, worksheets, skits, role playing, practice interviews, etc. Please bring your computer and clear your schedule so that you can actively participate.**

## Monday, 21 February

Start Time	End Time	Presentation Title	Speaker	Company	Total min.
7:30	9:00	Breakfast for Attendees			
9:00	9:15	<b>Welcome &amp; Introductions</b> (group activity)	Waterbury	Abbott Vascular	15
9:15	10:00	<b>Understanding The Focus of an Inspection</b> -Submission Documents, -Regulatory Requirements, -Jurisdiction, -Response Documents -New FDA Guidance Documents	Rebecca Waterbury Janet Bowen	Abbott Vascular Commissioning Agents	45
10:00	10:30	Networking Break			
10:30	11:15	<b>Inspection Support Requirements</b> -Managerial & Executive Support, -Site Tours, Technical Demonstrations -CMO (perhaps 3-4) -Complex supply chain	Janet Bowen  Phil Russ	Commissioning Agents Innovative Consultants GXP	45
11:15	12:00	<b>Inspection Logistics, Essential Elements for Inspection Preparation &amp; Execution</b> -The nuts and bolts of Inspection logistics including subject matter expert preparation, inspection roles, audit etiquette and industry best practices.	Rebecca Waterbury All	Abbott Vascular	45
12:00	13:00	Lunch			
13:00	14:45	<b>Quality System Gap Assessments for Inspection Preparation</b> -Learn how to evaluate your site's existing Quality System as part of inspection preparation. This tool can also be used for continuous improvement and CAPA activities. (group activity)	Phil Russ  Rebecca Waterbury	Innovative Consultants GXP Abbott Vascular	105
14:45	15:15	Networking Break			
15:15	16:00	<b>Special Considerations for Laboratories</b> -Methods Validation, -Laboratory Equipment, -Chemical Storage & Control, etc.	Kimberly Snyder	Proteus Biomedical, Inc	45
16:00	16:45	<b>Creating a Tour Flowmap</b> -Learn a systematic way to prepare all areas of your site for a potential tour during an inspection. This class activity evaluates tour route layout as well as area process-flow. (group activity)	Rebecca Waterbury	Abbott Vascular	45
16:45	17:00	<b>Daily Recap</b> -Topical Recap -Open Q&A	All		15
17:00		Seminar Adjourns, Reception for all attendees in Exhibit Hall	N/A	N/A	0

## Tuesday, 22 February

Start Time	End Time	Presentation Title	Speaker		Total min.
7:30	9:00	Breakfast			
9:00	9:30	<b>Considerations for Facility, Processes and Equipment</b> -Facility preparations -Scheduling tours during specific operations -Calibration procedures and reports -Equipment Qualification and organization of packages, -Engineering/Maintenance Programs	Janet Bowen	Commissioning Agents	30
9:30	10:00	<b>Special Considerations for Computer Systems</b> -Part 11 Compliance -FDA Guidance Documents -Delineating a "Quality" or "Compliant" Computer System -Accessibility to a computer system during an inspection	Kimberly Snyder	Proteus Biomedical, Inc	30
10:00	10:30	Networking Break			
10:30	12:00	<b>Preparing Employees for an Inspection (Part I)</b> -Operator and Supervisor Training, -Basic Interview Skills (group activity)	Rebecca Waterbury	Abbott Vascular	90
12:00	13:00	Lunch			
13:00	13:15	<b>Mock Inspection 1</b> (group activity) Participate in a "mock FDA inspection" in the comfort of a classroom. Practice your interview skills in a safe environment before going into the real inspection.	All		15
13:15	14:30	<b>Preparing Employees for an Inspection (Part II)</b> -Subject Matter Expert Training, -Advanced Interview Skills	All		75
14:30	15:00	Networking Break			
15:00	16:00	<b>Preparing Employee for an Inspection, Cont.</b>	All		60
16:00	16:15	<b>Mock Inspection 2</b> (group activity) Participate in a "mock FDA inspection" in the comfort of a classroom. Practice your interview skills in a safe environment before going into the real inspection.			15
16:15	17:00	<b>Daily Recap</b> -Topical Recap -Open Q&A -Roundtable Discussion (time permitting)	All		45
17:00		Seminar Adjourns			0