

# CVO-CyberConseil 2010 Training Agenda

## LIFE SCIENCES INDUSTRY

			JAN.	FEB.	MARCH	APRIL	MAY	JUNE	JULY	AUG.	SEPT.	OCT.	NOV.	DEC.	page
<b>VALIDATION / QUALIFICATION</b>															
<b>A10</b>	Manufacturing Computerized System and Equipment Validation	3 days		<b>2-4</b>											8
<b>A11</b>	Information System Validation	3 days								<b>15-17</b>					10
<b>QUALITY / REGULATIONS</b>															
<b>B10</b>	ICH Q10: Pragmatic Implementation	2 days			<b>14-15</b>										13
<b>B27</b>	Electronic Records and Computerized Systems Management, there is a consensus!	2 days		<b>1-2</b>											14
<b>B28</b>	Medical Device Regulation: US FDA, European MDD and CE Marking	2 days				<b>5-6</b>									15
<b>RISK MANAGEMENT</b>															
<b>B29</b>	Risk Management applied to Medical Devices (ISO 14971:2007)	2 days			<b>12-13</b>										17
<b>B30</b>	Risk Management in Health Industry (ICH Q9)	2 days				<b>3-4</b>									18
<b>C13</b>	OOS/CAPA – control your Out Of Specifications and optimize your corrective actions	2 days										<b>2-3</b>			19
<b>AUDITS / INSPECTIONS</b>															
<b>B103</b>	Internal quality audit – The tool for improvement and regulatory compliance (ISO 19011)	2 days								<b>7-8</b>					21
<b>B104</b>	Internal quality audit and supplier audit	2 days					<b>21-22</b>								22
<b>B8</b>	FDA: missions, regulations, getting ready to pass an inspection	2 days			<b>19-20</b>										24
<b>ENGINEERING / PROJECTS</b>															
<b>A17</b>	DR/DQ: Design Review / Design Qualification	2 days											<b>8-9</b>		27
<b>B34</b>	GAMP 5: Pragmatic Use for Regulatory Compliance	2 days								<b>20-21</b>					28
<b>D22</b>	Utilities: key points for URS and validation	2 days									<b>11-12</b>				29