

# Validering af IT-systemer

## Program

**Mandag 6. februar 2023**

09.00 – 09.10	<b>Login</b>
09.10 – 09.15	<b>Velkommen, introduktion og præsentation af materiale</b>
09.15 – 09.30	<b>Validation of IT-systems</b> <ul style="list-style-type: none"> <li>• GAMP®</li> </ul>
09.30 – 09.50	<b>Workshop 1 (Fælles)</b> <ul style="list-style-type: none"> <li>• Categorize software and Hardware.</li> </ul>
09.50 – 10.00	<b>Pause</b>
10.00 – 10.50	<b>Annex 11 and 21 CFR Part 11</b> <b>Key Term</b> <b>Data Integrity</b>
10.50 – 11.00	<b>Pause</b>
11.00 – 11.30	<b>Risk assessment</b>
11.30 - 12.30	<b>Workshop 2 (Break out room)</b> <ul style="list-style-type: none"> <li>• Risk Assessment</li> </ul>
12.30 – 13.30	<b>Frokost / Lunch</b>
13.30 – 13.50	<b>Workshop 2 (Break out room)</b> <ul style="list-style-type: none"> <li>• Risk Assessment</li> </ul>
13.30 – 13.40	<b>Supplier Assessment</b>
13.40 – 13.50	<b>Validation Master Plan</b>
13.50 – 14.00	<b>Pause</b>
14.00 – 14.20	<b>Specifications</b>
14.20 – 15.00	<b>Workshop 3 (Break out room)</b> <ul style="list-style-type: none"> <li>• User Requirements Specification</li> </ul>

**Tirsdag 7. februar 2023**

09.00 – 09.10	<b>Login og spørgsmål fra i går</b>
<b>09.10 – 09.20</b>	<b>Configuration and design Development, and Review of software</b>
09.20 – 09.50	<b>Workshop 4</b> <ul style="list-style-type: none"><li>• Controls</li></ul>
09.50 – 10.00	<b>Pause</b>
10.00 – 10.10	<b>Udførelse af validering</b> <ul style="list-style-type: none"><li>• Test</li><li>• Reporting</li></ul>
10.10 – 10.50	<b>Workshop 5 (Break out room)</b> <ul style="list-style-type: none"><li>• Test script</li></ul>
10.50 – 11.00	<b>Pause</b>
11.00 – 11.15	<b>Workshop 5 (Break out room)</b> <ul style="list-style-type: none"><li>• Test script</li></ul>
11.15 – 11.30	<b>Handover</b> <ul style="list-style-type: none"><li>• Service Level Agreement</li></ul> <b>Validated state</b> <ul style="list-style-type: none"><li>• Maintenance</li><li>• Incidents and changes</li></ul>
11.30 – 12.00	<b>Workshop 6</b> <ul style="list-style-type: none"><li>• Maintenance</li></ul>
12.00 – 13.00	<b>Frokost / Lunch</b>
13.00 – 13.50	<b>Decommissioning of IT systems</b>
13.50 - 14.00	<b>Pause</b>
14.00 – 14.30	<b>Cloud solutions</b>
14.30 – 15.00	Afslutning og evaluering