



# Course Programme

## Medical Device Usability

<b>Instructor:</b> Dr Nick Bradley, BERGO UK	
<b>Day 1: Tuesday 17 June 2025</b>	
<i>Time zone: London (BST)</i>	
09.00 – 09.15	<i>Objectives, Overview and Introductions</i>
09.15 – 12.15	<b>1. Introduction to Usability Engineering</b> <ul style="list-style-type: none"><li>• What is Meant by Usability?</li><li>• Legal Framework for Manufacturers</li><li>• Overview of Usability Engineering Process in IEC 62366-1:2015 +AMD1:2020</li></ul> <i>Discussion: Experiences and Challenges</i>
12.15 – 13.15	<i>Lunch</i>
13.15 – 16.30	<b>2. Usability Techniques</b> <ul style="list-style-type: none"><li>• Design Guidance in ANSI/AAMI HE75:2009/(R)2018</li><li>• User Research Techniques</li><li>• User Interface Design Techniques</li></ul> <i>Workshop: Task Analysis</i>
<b>Day 2: Wednesday 18 June 2025</b>	
<i>Time zone: London (BST)</i>	
09.00 – 12.15	<b>3. Managing the Risk of Use Error</b> <ul style="list-style-type: none"><li>• Why do Use Errors occur?</li><li>• Case Studies Involving Use Error</li><li>• Techniques to Manage Use Error</li></ul> <i>Exercise: Error Types; Workshop: Use-Related Risk Analysis (URRA)</i>
12.15 – 13.15	<i>Lunch</i>
13.15 – 15.15	<b>4. Usability Evaluation</b> <ul style="list-style-type: none"><li>• Formative Evaluations</li><li>• Summative Evaluations</li></ul> <i>Exercise: Cognitive Walkthrough</i>
15.15 – 16.20	<b>5. Usability Documentation and Integration</b> <ul style="list-style-type: none"><li>• The Usability Engineering File</li><li>• The HFE/UE Report for the FDA</li><li>• Developing a Usability Engineering Process</li></ul> <i>Discussion: Next steps and challenges</i>
16.20 – 16.30	<b>Course Summary and Conclusions</b>