



Course Programme

Medical Device Usability

Instructor: Dr Nick Bradley, BERGO UK	
Day 1: Wednesday 6 December 2023	
<i>Time zone: London (GMT)</i>	
09.00 – 09.15	<i>Objectives, Overview and Introductions</i>
09.15 – 12.15	1. Introduction to Usability Engineering <ul style="list-style-type: none">• What is Meant by Usability?• Legal Framework for Manufacturers• Overview of Usability Engineering Process in IEC 62366-1:2015 <i>Discussion: Experiences and Challenges</i>
12.15 – 13.15	<i>Lunch</i>
13.15 – 16.30	2. Usability Techniques <ul style="list-style-type: none">• Design Guidance in ANSI/AAMI HE75• User Research Techniques• User Interface Design Techniques <i>Workshop: Task Analysis</i>
Day 2: Thursday 7 December 2023	
<i>Time zone: London (GMT)</i>	
09.00 – 12.15	3. Managing the Risk of Use Error <ul style="list-style-type: none">• Why do Use Errors occur?• Case Studies Involving Use Error• Techniques to Manage Use Error <i>Exercise: Error Types; Workshop: Use Error Risk Analysis</i>
12.15 – 13.15	<i>Lunch</i>
13.15 – 15.15	4. Usability Evaluation <ul style="list-style-type: none">• Formative Evaluations• Summative Evaluations <i>Exercise: Cognitive Walkthrough</i>
15.15 – 16.20	5. Usability Documentation and Integration <ul style="list-style-type: none">• The Usability Engineering File• The HFE/UE Report for the FDA• Developing a Usability Engineering Process <i>Discussion: Next steps and challenges</i>
16.20 – 16.30	Course Summary and Conclusions