

# Toxicological Risk Assessment for Medical Devices: Impact of ISO 10993-17:2023

## Day 1: Toxicological Risk Assessment (TRA)

08.30 – 09.00	<b>Registration and breakfast</b>
09.00 – 09.10	<b>Welcome by Medicoindustrien</b>
09.10 – 10.10	<b>TRA as per ISO 10993-1: Biological Safety Assessment</b> <ul style="list-style-type: none"><li>- Strategy as per ISO 10993-1</li><li>- Chemical characterization as per ISO 10993-18: when a TRA is needed</li></ul>
10.10 – 10.30	<b>Coffee break</b>
10.30 – 11.30	<b>E&amp;L studies</b> <ul style="list-style-type: none"><li>- Study design</li><li>- Data generated as input for TRA</li></ul>
11.30 – 12.00	<b>Cases – How to design and actual data generated during a study for implantable device</b>
12.00 – 13.00	<b>Lunch</b>
13.00 – 14.00	<b>TRA: Paradigm and Process</b> <ul style="list-style-type: none"><li>- Hazard Identification</li><li>- Dose-response evaluation</li><li>- Exposure Assessment</li><li>- Risk Characterization</li></ul>
14.00 – 14.30	<b>Workshop on how to find relevant toxicological data</b>
14.30 – 14.50	<b>Coffee break</b>
14.50 – 15.45	<b>When there is no data</b> <ul style="list-style-type: none"><li>- Grouping</li><li>- Read across</li><li>- In silico</li></ul>
15.50 – 16.00	<b>Wrap up and conclusions</b>

## Day 2: Focus on the new TRA terms/parts in ISO 10993-17:2023

08.30 – 09.00	<b>Breakfast</b>
09.00 – 10.10	<b>What is new in ISO 10993-17</b> <ul style="list-style-type: none"><li>- New clauses</li><li>- New flowcharts</li><li>- POD</li><li>- UF</li><li>- TSL</li><li>- EEDmax, etc.</li></ul>
10.10 – 10.30	<b>Coffee break</b>
10.30 – 11.30	<b>Total quantity (TQ)</b> <ul style="list-style-type: none"><li>- How to calculate it</li><li>- How to use it</li></ul>
11.30 – 12.00	<b>Cases – TRA for implantable devices</b>
12.00 – 13.00	<b>Lunch</b>
13.00 – 14.00	<b>MOS</b> <ul style="list-style-type: none"><li>- Definition</li><li>- How to assess it</li><li>- Use of terms such as EEDmax</li></ul>
14.00 – 14.30	<b>Workshop on TSL (toxicological screening limit)</b>
14.30 – 14.50	<b>Coffee break</b>
14.50 – 15.45	<b>Hand-on experience on new concepts</b> <ul style="list-style-type: none"><li>- How does a new TRA look like</li></ul>
15.45 – 16.00	<b>Wrap up and conclusions</b>