



ENDOTOXIN TESTING – PRINCIPALS, BEST PRACTICE AND LIVE APPLICATION TESTING USING THE SIEVERS ECLIPSE

WHEN

March 21 2022,
08:30 – 15:30

WHERE

Kfar Maccabiah Events and Convention Center, Peretz Bernstein Street, Ramat Gan

AGENDA

08:30	Morning Reception
09:00 – 10:30	<p>Understanding Bacterial Endotoxin testing:</p> <p>Reaction basics (LAL clotting reaction; Endotoxin structure; Glucan interference)</p> <p>Methods of detection</p> <p>Data integrity and calculation</p>
10:30 – 10:45	Coffee break
10:45 – 11:30	<p>Endotoxin limits:</p> <p>Setting endotoxin limit for a product</p> <p>MVD and MVC</p>
11:30 – 12:15	<p>Interfering factors</p> <p>Principals and practical approaches</p>
12:15 – 12:30	Coffee break
12:30 – 13:15	Eclipse live presentation
13:15 – 14:00	Lunch
14:00 – 15:30	<p>Hands on application laboratory – bring your samples!</p> <p>Examples and discussion of products with difficult matrix</p> <p>We will give a chance to test live 1-2 products you'll bring from your laboratory</p>

RSVP ON: WWW.LUMITRON.CO.IL

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TOTAL ORGANIC CARBON – NEW REGULATIONS, CLEANING VALIDATION AND PHARMA 4.0 GUIDELINES FOR LAB & ONLINE TOC TESTING

WHEN

March 22 2022,
08:30 – 15:30

WHERE

Kfar Maccabiah Events and Convention Center, Peretz Bernstein
Street, Ramat Gan

AGENDA

08:30	Morning Reception
09:00 – 10:30	<p>New Regulations explained:</p> <p>USP <643> changes and solutions</p> <p>Data Integrity Regulatory requirements and User expectations</p>
10:30 – 10:45	Coffee break
10:45 – 11:45	Lean lab integration of data Integrity for TOC and Conductivity
11:45 – 12:00	Coffee break
12:00 – 13:15	<p>Online TOC and Conductivity Measurements:</p> <p>Getting ready for Pharma 4.0 with Sievers M500</p>
13:15 – 14:00	Lunch
14:00 – 14:45	Quantitative methods verification VS Pharmacopeia requirements
14:45 – 15:30	<p>Cleaning Validation method compliance</p> <p>Quantitative methods for CV as per ICHQ2R1</p> <p>Interactive session for experts and newcomers</p>

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