



Nelson Labs[®]

A Sotera Health company

Biocompatibility Testing for Medical Devices Training & Workshop

Location: Philadelphia PA

Wednesday, October 26, 2022

8:00 am	Registration Begins
8:30 am	Introduction to Nelson Labs – Mike Pizzi
8:35 am	Introduction to Biocompatibility and to Risk Assessment
9:00 am	Device Categorization – Why Device Descriptions Are Critical
10:00 am	Morning Break
10:15 am	How to Meet the Physical/Chemical Information Requirement for Every Device
10:45 am	What is Extractables & Leachables Test and How to Use the Data
11:30 am	Sample preparation – Details That Manufacturers Should Know
12:15 pm	Lunch Break
1:15 pm	Biocompatibility Testing Review and Discussion (Including Failures)
2:45 pm	Formulating Risk Assessments (Including BEPs, Gaps, and BERs)
3:15 pm	Afternoon Break
3:30 pm	Maintain Regulatory Relationships During a Submission – Tips to Have Successful Conversations When Disagreements Arise
4:30 pm	End Workshop Day 1

*Times and topics subject to change



Biocompatibility Testing for Medical Devices Training & Workshop

Location: Philadelphia PA

Thursday, October 27, 2022

8:00 am	Hands on Workshop Begins
	Samples Distributed for the Projects – Explanation of Intended Use
8:10 am	Teams will be given real life examples of medical device and understand their intended use and risk
8:45 am	Formulate Your Biological Evaluation Plan (BEP)
	Using your team, formulate a BEP for your subject device
10:00 am	Morning Break
10:15 am	Sample Preparation Considerations
12:00 pm	Lunch Break
1:00 pm	Test Result Determination and Failure Investigation
2:00 pm	Formulate your Biological Evaluation Report (BER)
3:00 pm	Afternoon Break
3:15 pm	Receive Regulatory Feedback
3:45 pm	Assessing Device and/or Standard Changes
4:30 pm	End of Workshop Day 2

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