

Biocompatibility of Medical Devices – Two-Day Certification Course

October 20, 2020

8:30–8:45	Introduction to NAMSA's Certification Program	Sheri Krajewski-Bibins
8:45–9:30	Historical Review of Biocompatibility:	Don Pohl
9:30–10:30	10993-1 : Evaluation and Testing Within a Risk Management Process	Don Pohl
10:30–10:45	Break	
10:45–11:15	ISO 10993-1 continued	Don Pol
11:15–12:00	ISO 10993-12: Sample Preparation and Reference Materials	Phillip Smiraldo
12:00–1:30	Lunch	
1:30–3:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Phillip Smiraldo
3:00–3:15	Break	
3:15–5:00	ISO 10993-17 : Establishment of Allowable Limits for Leachable Substances	Phillip Smiraldo

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8:30–10:00	Biological Tests: What Manufacturers Should Know	Don Pohl
10:00–10:15	Break	
10:15–11:15	Biological Tests: What Manufacturers Should Know (cont.)	Don Pohl
11:15–12:15	Regulatory Agencies' Specific Approach to Biocompatibility	Don Pohl
12:15–1:45	Lunch	
1:45–2:30	Developing a Biological Safety Assessment	Phillip Smiraldo
2:30–5:00	Break and Final Exercises	