

Biocompatibility of Medical Devices – Two-Day Certification Course

January 16, 2023

8:00–8:30	Check-In and Breakfast Buffet	
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	
10:45–11:45	ISO 10993-1 continued	Don Pohl
11:45–12:30	ISO 10993-12: Sample Preparation and Reference Materials	Don Pohl
12:30–1:30	Lunch	
1:30–3:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Philip Smiraldo
3:00–3:15	Break	
3:15–4:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Philip Smiraldo
4:00–5:00	ISO 10993-17 : Establishment of Allowable Limits for Leachable Substances	Philip Smiraldo
5:00–6:30	Event Reception	

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7:30–8:30	Breakfast Buffet	
8:30–10:00	Biological Tests: What Manufacturers Should Know	Don Pohl
10:00–10:15	Break	
10:15–11:30	Biological Tests: What Manufacturers Should Know (cont.)	Don Pohl
11:30–12:30	Regulatory Agencies’ Specific Approach to Biocompatibility	Don Pohl
12:30–1:30	Lunch	
1:30–2:30	Developing a Biological Safety Assessment	Philip Smiraldo
2:30–5:00	Break and Final Exercises	