

Biocompatibility of Medical Devices – Two-Day Certification Course

September 8, 2025

8:00–8:30	Check-In and Breakfast Buffet	
8:30–8:45	Introduction to NAMSA’s Certification Program	Sheri Krajewski
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, A further discussion	Philip Smiraldo
5:00–6:30	Event Reception	

September 9, 2025

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	