

Biocompatibility of Medical Devices – Two-Day Certification Course

5:00-5:15am	Introduction to NAMSA's Certification Program	Sheri Krajewski-Bibins
5:15-6:00am	Historical Review of Biocompatibility	Don Pohl
6:15-7:00am	10993-1: Evaluation and Testing Within a Risk Management Process	Don Pohl
7:00-7:15am	Break	
7:15-8:30am	ISO 10993-1 continued	Don Pohl
8:30-9:30am	ISO 10993-12: Sample Preparation and Reference Materials	Phillip Smiraldo
9:30-10:30am	Lunch	
10:30am-12:30pm	ISO 10993-18: Chemical Characterization of Medical Device Materials	Phillip Smiraldo
12:30-12:45pm	Break	
12:45-1:00pm	ISO 10993-18 wrap up	Phillip Smiraldo
1:00-2:00pm	ISO 10993-17: Establishment of Allowable Limits for Leachable Substances	Phillip Smiraldo

5:00-7:00am	Biological Tests: What Manufacturers Should Know	Don Pohl
7:00-7:15am	Break	
7:15-8:15am	Biological Tests: What Manufacturers Should Know (cont.)	Don Pohl
8:15-9:15am	Regulatory Agencies' Specific Approach to Biocompatibility	Don Pohl
9:15-10:15am	Lunch	
10:15-11:30am	Developing a Biological Safety Assessment	Phillip Smiraldo
11:30am-2:00pm	Break and Final Exercises	