NAMSA

Biocompatibility of Medical Devices – Two-Day Certification Course

8:00-8:15am	Introduction to NAMSA's Certification Program	Sheri Krajewski-Bibins
8:15-9:00am	Historical Review of Biocompatibility	Don Pohl
9:00-10:00am	10993-1: Evaluation and Testing Within a Risk Management Process	Don Pohl
10:00-10:15am	Break	
10:15-11:30am	ISO 10993-1 continued	Don Pohl
11:30am-12:30pm	ISO 10993-12: Sample Preparation and Reference Materials	Phillip Smiraldo
12:30-1:30pm	Lunch	
1:30-3:30pm	ISO 10993-18: Chemical Characterization of Medical Device Materials	Phillip Smiraldo
3:30-3:45pm	Break	
3:45-4:00pm	ISO 10993-18 wrap up	Philip Smiraldo
4:00-5:00pm	ISO 10993-17: Establishment of Allowable Limits for Leachable Substances	Phillip Smiraldo

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