

Biocompatibility of Medical Devices - Two Day Certification Course

8:00–8:30	Check-In	
8:30–8:45	Introduction to NAMSA's Certification Program	Celine Puleo
8:45–9:30	Historical Review of Biocompatibility:	Sylvie Framery, Ph.D
9:30–10:30	10993-1 : Evaluation and Testing Within a Risk Management Process	Sylvie Framery, Ph.D
10:30–10:45	<i>Break</i>	
10:45–11:15	ISO 10993-1 continued	Sylvie Framery, Ph.D
11:15–12:00	ISO 10993-12: Sample Preparation and Reference Materials	Alfred Dibao-Dina, Ph.D
12:00–13:30	<i>Lunch</i>	
13:30–15:00	ISO 10993-18: Chemical Characterization of Materials	Alfred Dibao-Dina, Ph.D
15:00–15:15	<i>Break</i>	
15:15–17:00	ISO 10993-17 : Establishment of Allowable Limits for Leachable Substances	Alfred Dibao-Dina, Ph.D
17:00–18:30	Event Reception	

8:30–10:00	Biological Tests: What Manufacturers Should Know	Sylvie Framery, Ph.D
10:00–10:15	<i>Break</i>	
10:15–11:15	Biological Tests: What Manufacturers Should Know (cont.)	Sylvie Framery, Ph.D
11:15–12:15	Regulatory Agencies' Specific Approach to Biocompatibility	Sylvie Framery, Ph.D
12:15–13:45	<i>Lunch</i>	
13:45–14:30	Developing a Biological Safety Assessment	Alfred Dibao-Dina, Ph.D
14:30–17:00	<i>Break and Final Exercises</i>	