

Biocompatibility of Medical Devices – Two-Day Certification Course

4 October 2021

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:	Dr. Sylvie Framery
9:30–10:30	10993-1 : Evaluation and Testing Within a Risk Management Process	Dr. Sylvie Framery
10:30–10:45	Break	
10:45–11:15	ISO 10993-1 continued	Dr. Sylvie Framery
11:15–12:00	ISO 10993-12: Sample Preparation and Reference Materials	Dr. Nicolas Martin
12:00–1:30	Lunch	
1:30–3:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Dr. Nicolas Martin
3:00–3:15	Break	
3:15–5:00	ISO 10993-17 : Establishment of Allowable Limits for Leachable Substances	Dr. Nicolas Martin
5:00–6:30	Event Reception	

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8:30–10:00	Biological Tests: What Manufacturers Should Know	Dr. Sylvie Framery
10:00–10:15	Break	
10:15–11:15	Biological Tests: What Manufacturers Should Know (cont.)	Dr. Sylvie Framery
11:15–12:15	Regulatory Agencies' Specific Approach to Biocompatibility	Dr. Sylvie Framery
12:15–1:45	Lunch	
1:45–2:30	Developing a Biological Safety Assessment	Dr. Nicolas Martin
2:30–5:00	Break and Final Exercises	