

Biocompatibility of Medical Devices – Two-Day Certification Course

September 18, 2023

8:00–8:30	Check-In	
8:30–8:45	Introduction to NAMSA's Certification Program	Céline Puleo
8:45–9:30	Historical Review of Biocompatibility:	Sylvie Framery
9:30–10:30	10993-1 : Evaluation and Testing Within a Risk Management Process	Sylvie Framery
10:30–10:45	Break	
10:45–11:45	ISO 10993-1 continued	Sylvie Framery
11:45–12:30	ISO 10993-12: Sample Preparation and Reference Materials	Alfred Dibao-Dina
12:30–13:30	Lunch	
13:30–15:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Alfred Dibao-Dina
15:00–15:15	Break	
15:15–16:00	ISO 10993-18: Chemical Characterization of Medical Device Materials	Alfred Dibao-Dina
16:00–17:00	ISO 10993-17 : Establishment of Allowable Limits for Leachable Substances	Alfred Dibao-Dina
17:00–18:30	Event Reception	

September 19, 2023

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