NAMSA

Biocompatibility of Medical Devices – Two-Day Certification Course

September 16, 2024

8:00–8:30	Check-In	
8:30–8:45	Introduction to NAMSA's Certification Program	Céline Puleo
8:45–9:15	Historical Review of Biocompatibility	Sylvie Framery
9:15–10:30	ISO 10993-1 : Evaluation and Testing Within a Risk Management Process	Sylvie Framery
10:30–10:45	Break	
10:45–11:45	ISO 10993-1 : Evaluation and Testing Within a Risk Management Process (cont.)"	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 (cont.)	Alfred Dibao-Dina
16:00–17:00	ISO 10993-17, Toxicological Risk Assessment Basics	Alfred Dibao-Dina
17:00–19:30	Event Reception	

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8:00–8:30	ISO 10993-17, Toxicological Risk Assessment Basics (cont.)	Alfred Dibao-Dina
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
14:30–15:00	Open Questions	Alfred Dibao-Dina
15:00–17:00	Break and Final Exercises	