

## Biocompatibility of Medical Devices – Two-Day Certification Course

### September 16, 2024

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| 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          | Céline Furne                           |
| 10:30–10:45 | Break  |  |
| 10:45–11:45 | ISO 10993-1 : Evaluation and Testing Within a Risk Management Process (cont.)” | Céline Furne                           |
| 11:45–12:30 | ISO 10993-12: Sample Preparation and Reference Materials                       | Alfred Dibao-Dina<br>Valériane Levelut |
| 12:30–13:30 | Lunch  |  |
| 13:30–15:00 | ISO 10993-18: Chemical Characterization of Medical Device Materials            | Alfred Dibao-Dina<br>Valériane Levelut |
| 15:00–15:15 | Break  |  |
| 15:15–16:00 | ISO 10993-18: Chemical Characterization of Medical Device Materials (cont.)    | Alfred Dibao-Dina<br>Valériane Levelut |
| 16:00–17:00 | ISO 10993-17, Toxicological Risk Assessment Basics                             | Alfred Dibao-Dina<br>Valériane Levelut |
| 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<br>Valériane Levelut |
| 8:30–10:00  | Biological Tests: What Manufacturers Should Know           | Céline Furne                           |
| 10:00–10:15 | Break  |  |
| 10:15–11:30 | Biological Tests: What Manufacturers Should Know (cont.)   | Céline Furne                           |
| 11:30–12:30 | Regulatory Agencies’ Specific Approach to Biocompatibility | Céline Furne                           |
| 12:30–13:30 | Lunch  |  |
| 13:30–14:30 | Developing a Biological Safety Assessment                  | Alfred Dibao-Dina<br>Valériane Levelut |
| 14:30–15:00 | Open Questions   | Alfred Dibao-Dina<br>Valériane Levelut |
| 15:00–17:00 | Break and Final Exercises                                  |  |