

January 23 – 24, 2017  
The Florida Hotel & Conference Center | Orlando, Florida

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**TE-17 | Tuesday, January 24 | 1:00 PM - 5:00 PM | One Day**

**Course Title: Temperature Monitoring and Traceability in the Cold Chain**

**Instructor:** Dr. Cesar “Jun” Bautista, Masy BioServices

**Track:** Thermodynamics

**Type:** Dimensional

**Technical Level:**

Beginner – course content is designed for students with no previous experience

Intermediate – students must possess as a basic understanding of course concepts

**Course Description:**

In this seminar, participants will learn effective temperature monitoring strategies for use in cold-chain transport and storage of temperature-sensitive products. NIST has collaborated extensively with the Centers for Disease Control to develop improved guidelines for temperature monitoring of vaccines at the provider-office level. As the range of temperature-sensitive products in our world continues to increase, so does the demand for accurate, traceable temperature monitoring solutions, coupled with cost-effective calibration methodologies. This one-day seminar is designed to address the needs of staff directly involved with the management, storage and transport of cold-chain products, as well as device manufacturers and calibration facilities endeavoring to meet the needs of this rapidly-expanding field. The seminar includes a lecture session followed by a hands-on learning experience.

**Lecture topics will include:**

- 1) Importance of continuous temperature monitoring in the cold chain
- 2) Discussion of digital thermometers suitable for monitoring vaccines and other pharmaceuticals, biologics, perishable foods, and other temperature-sensitive products, during both transport and storage
- 3) Selection of a digital thermometer to meet your application’s needs
- 4) Proper use of a digital thermometer, including handling, placement, data logging, interpretation of data, and maintaining data records
- 5) Traceability of temperature measurements
- 6) Thermometer calibration and verification methods
  - a. Overview of ISO/IEC 17025 and laboratory accreditation
  - b. Evaluating calibration reports and methods of outside calibration facilities
  - c. Determining thermometer calibration or verification requirements for your application
  - d. In-house testing using the ice melting point
  - e. Calibration by comparison to a reference thermometer
  - f. Measurement assurance programs and processes
  - g. Developing an uncertainty budget

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**Hands-on section:**

- 1) Digital thermometer use
- 2) Thermometer verification and calibration using an ice melting point
- 3) Control chart development and management
- 4) Practical methods for establishing and maintaining measurement traceability

**Instructor Biography**

Presenter: Dr. Cesar “Jun” Bautista has over 35 years of combined experience in metrology, 16 years of which are Biotech, Bio-Pharmaceutical, and Biomedical Device related. He has over 20 years of USAF PMEL experience, 6 years of combined experience as Sr. Director of Operations & Corporate Metrology, Regional Manager and Senior Vice-President of several third party calibration companies, one of which he co-founded. Jun, is currently the Sr. Director, of Laboratory Operations for Masy BioServices, one of the East Coast’s premier metrology services provider. Jun Bautista holds a B.S. Management Engineering, M.A. Public Administration, M.S. Systems Management, MBA from Harvard Business School and a Ph.D. in Biomedical Physics from the Massachusetts Institute of Technology. He also has A.A. degrees in Applied Electronics Engineering Technology and Post-Secondary Instructional Systems Development. He is affiliated with NCSL International, MSC, ASQ, and a member of the Panel of Experts for USP 41 and ASTM E 20, E60, and E56 committees. Dr. Bautista’s Post-doctoral research at MIT centers on the development of nano-metrology for use in the concepts and design engineering of smart plants and digital facilities for the manufacturing of bio-pharmaceutical products and biomedical devices, nano medicine, nano drug delivery systems advanced material products. He is one of the country’s leading pioneers in the use of the nano bubble procedure and the cellular level infusion of precious nano metal particles infused used for oncology applications and for the specific treatment of Glioblastoma Multiforme.