



Pharmaceuticals (GMP) and Manufacturing Plants

CONSULTING AND RESOURCES

We offer consulting services in regulatory areas for commissioning (start up), qualification and validation. We follow the good manufacturing practices (cGMP) to assure compliance with industry standards enforced by FDA, MHRA, EMEA and others. We have experience working with facilities that manufacture solids (tablets and capsules), creams, ointments, liquids, aerosols and parenteral products (injectables). Knowledgeable in equipment and systems for manufacturing, packaging, utilities, facilities, laboratories and automated computer systems for manufacturing and utilities. We are experienced in performing studies and qualifications for Cold Chain processes and their related equipment and software.

We have intellectual capital to support all areas of manufacturing, packaging, laboratory and utilities for pharmaceutical medical devices and biotechnology processes. We can provide support for all your scientific resource needs for your daily operations (short and long term projects).

TRAINING

We offer training in areas related to good manufacturing practices (cGMP), good documentation practices, basic qualification and validation principles, qualifications of purified water systems used for medical products, qualifications of HVAC systems and Clean Rooms. We can also provide you with tailor made trainings according to your special requirements. We are certified by the Puerto Rico College of Engineers and Surveyors to offer continuing education. In addition, we are a certified technical training provider for CANIFARMA (National Association of Pharmaceutical Chemists and Biologists of Mexico, AC)

METROLOGY

Our Metrology Department offers installation, calibration, maintenance and repair of process and laboratory instruments. Below are some of the variables of the instruments that we service:

INSTRUMENTS CALIBRATION CAPABILITIES			
Pressure	Air / Mass Flow	Voltage	Volume
Vacuum	Weight	Current	pH
Diff Pressure	Force	Resistance	Conductivity
Temperature	Dimension	Speed	Resistivity
Relative Humidity	Gas	Light	ORP
Dew Point	Time	Sound	Chlorine
Level	Mass	Viscosity	Turbidity

- WE OFFER:**
- Installation, calibration, sales and rental of temperature and Relative Humidity Chart Recorders and data loggers.
 - Calibration, repairs and maintenance of equipment and monitoring instruments used in cold rooms, warehouses and incubators.
 - Thermal distribution studies in cold rooms, warehouses and incubators. We have in stock over 100 data loggers to measure temperature and relative humidity.

RENTAL, CALIBRATION AND REPAIR OF EQUIPMENT

We offer rental, calibration and repair of thermal validation equipment:

VALIDATION THERMAL EQUIPMENT	
Ellab Temp/RH Loggers	Temp Transmitters/RH
Ellab Temp/RH (ETO) Loggers	Pressure Transmitters
LogTag Temp/RH Loggers	Kaye Validation Equipment

Temperature Range (-196 to 1370°C).

All our rental instruments have been calibrated using NIST Traceable Standards. Validation of Ellab and Kaye systems are frequently updated. Copy of validation report is provided with rental service.



All our services are performed using International ISO9001 and ISO17025 Quality guidelines. Feel free to contact at contactus@provensmart.com or 787.807.7877 us to discuss your needs and/or application.