



**Our goal is to provide world class support services that keep your projects on time, within budget, and compliant to all regulatory authorities.**



## Cold Chain Management

### PARTNERSHIP FOR SUCCESS

At BMA, we strive to develop a true partnership with our clients. We have found this collaborative approach to be most beneficial, providing excellent results for both the study team and project. Our staff will provide the highest quality support, while allowing your internal resources to focus on other critical functions.

### CUSTOMER RELATIONSHIPS

Customer relationships are critical. BMA recognizes that your success requires accurate, timely, and precise communication. We provide highly professional customer service to you, your study staff and clinical customers.

### PENNSYLVANIA

1540 McDaniel Drive  
West Chester, PA 19380  
Tel. 610-430-1847  
Fax 610-430-1970  
Info@bmclaughlin.com  
www.BMAEast.com

### ARIZONA

16515 South 40th Street  
Suite 125  
Phoenix, AZ 85048  
Tel. 480-659-9120  
Fax 480-659-9193  
Info@bmclaughlin.com  
www.BMAWest.com



**B. McLAUGHLIN**  
ASSOCIATES, INC.

A Helping Hand in Clinical Research<sup>SM</sup>

[www.coldchain.bmawest.com](http://www.coldchain.bmawest.com)

How can we help you?

B. McLaughlin Associates, Inc (BMA) has over 15 years of experience as a woman-owned CRO providing targeted, cost effective clinical research support. We have extensive experience across many therapeutic areas with a strong focus in Oncology and Biologics. Our customizable team has partnered with leading companies to successfully complete projects on time and with the highest level of compliance. At BMA, we have the capabilities and knowledge to tailor our services based upon your needs. Allow us to help you achieve your goals.

**SUPPORT  
SOLUTIONS  
THAT WORK  
FOR YOU**

## Flexible Solutions for Your Business Needs

### YOUR NEEDS, OUR SOLUTION

Your first choice for quality, cost-effective Drug & Biologics Temperature Monitoring. Drugs and Biologics can require continuous temperature monitoring from manufacture to subject administration in order to document safety and efficacy. BMA will manage continuous temperature monitoring to ensure that the cold chain is adequately maintained.

### PROJECT COLD CHAIN DEVELOPMENT

#### Proactive Planning

- Development of study-level procedures
- Creation of temperature monitoring documentation
- Delivery of customized training to sponsor team and monitoring staff
- Selection of temperature monitoring equipment based on sponsor provided specifications

### COLD CHAIN CAPACITY

#### Mitigating Risk

- Assessment of site cold chain storage capability
- Identification of resolutions to impediments in appropriate transport and storage of temperature sensitive drugs and biologics
- Evaluation of existing site temperature monitoring systems to ensure compliance with sponsor specifications
- Provide training to site staff on cold chain practices

### CONTINUOUS COLD CHAIN MONITORING

#### Quality Management

- Ongoing site monitoring for cold chain compliance
- Dissemination of study specific temperature monitoring devices
- Facilitate transport and storage deviation reporting
- Identify and enable fulfillment of corrective action plans

### CUSTOMIZABLE SERVICES

#### Tailored Partnership

- Audit-ready documentation prepared and maintained
- Employ the use of sponsor and distributor's randomization and distribution systems
- Certified field monitors to conduct initiation, interim & closeout visits
- Negotiation of site specific cold chain budgets
- Maintenance of sponsor systems & databases