



STATEMENT OF GMP CREDENTIALS

September 9, 2015

Galbraith maintains a comprehensive Quality Assurance Program, supported by a full-time QA Manager and staff. The QA Department monitors all analyses to ensure that methods, practices, records and controls are in conformance with client designated regulatory requirements as well as Galbraith's own internal standards. All analytical work is supported by a system of controls, validations, inspections and audits.

Our Quality Assurance system is in compliance with the requirements for Good Laboratory Practices (GLP) and current Good Manufacturing Practices, as applied to analytical chemistry laboratories and as defined by the following regulations:

- 21 CFR 58 Good Laboratory Practice for Non-clinical Laboratory Studies
- 21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs
- 21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- 40 CFR 160 GLP Standards [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)]
- 40 CFR 792 GLP Standards [Toxic Substances Control Act (TSCA)]

At Galbraith, accuracy is everything and we go to great lengths to insure this in our deliverables:

- Electronic sample & data management system
- Customized quality control & summary reports for client projects
- Routine audits by clients as a support facility for FDA regulated studies
- Independent instrument calibration and certification
- Procedures maintained by statistical process control
- NIST-traceable standards

Galbraith is registered with the Food and Drug Administration as a drug establishment and our registration number is: **1000112629**.

Galbraith is accredited by A2LA as an ISO 17025 laboratory. See <http://galbraith.com/wp-content/uploads/2015/08/ISO-17025-Accreditation-Certificate-and-Scope.pdf> for a copy of our scope of accreditation.

Should you require additional information to evaluate Galbraith's potential to serve your needs, please contact me toll free at 877-449-8797, extension 1829.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lee Bates', is written over a white background.

Lee Bates
Senior Vice President