# Selecting a Laboratory for Pharmaceutical Stability Testing

**By Katherine Robertson, Business Technical Manager, Impact Analytical**

## Introduction

Because stability testing must be performed to the standards of the FDA and other government agencies, the protocols are rigorous, the procedures are highly regulated and both staff and equipment are quite expensive. As a result, fewer pharmaceutical companies and contract research organizations (CROs) have integrated stability testing capabilities and more are turning to comprehensive analytical laboratories such as Impact Analytical for this and other testing services.

Stability testing can be performed as part of a larger Extractables/Leachables program, or as quality testing of a drug product and drug substance to determine shelf life. While many laboratories can offer selective services, the best arrangement for many CROs, pharmaceutical and medical device companies is to partner with a laboratory to provide stability testing services on an ongoing basis. Over time, our personnel become familiar with your staff, products and procedures and can provide you a seamless and cost-effective resource.

When selecting a laboratory for pharmaceutical stability testing, look for a partner with significant experience evaluating many different material types, with a complete range of testing environments, and the most advanced analytical equipment.

### The Testing Process

The purpose of stability testing is to determine the overall stability of a drug substance or analyte. Method development may be required to characterize possible degradation products and determine conditions for the stability testing. These conditions should include the effects of temperature, humidity or other means of stress upon the pharmaceutical product. The final method used to analyze the test material and degradants should be a validated method, establishing such parameters as linearity, limits of detection and quantitation, robustness, accuracy/recovery and precision. With advanced equipment and techniques such as gas or liquid chromatography and mass spectrometry, researchers can characterize the API, impurity, or other analyte with an extraordinary degree of accuracy. Any observed alteration in an analyte may be an indication of degradation.

The stability testing is performed under a protocol agreed to by the testing lab and the sponsor, and that also meets federal guidelines. Accelerated degradation testing that follows established guidelines may also be used; this involves stressing the pharmaceutical product by means of higher temperature and humidity. Analysis of the drug substance or analyte is performed at regular intervals according to the protocol, and at the conclusion of the study, a final report is prepared and submitted it to the sponsor.

**About the Author**

Katherine Robertson, Business Technical Manager, Impact Analytical Specializing in infrared spectroscopy and nuclear magnetic resonance (NMR) spectroscopy. She is responsible for the day-to-day operations of the core laboratories of Impact Analytical including molecular characterization, separation science, and thermal analysis.

A veteran analytical chemist with more than 20 years of experience, she has significant experience as a study director and principal investigator of GLP and cGMP analytical projects. Prior to joining Impact Analytical, she was a research chemist at Michigan Molecular Institute and a laboratory specialist at Virginia Polytechnic Institute and State University. She earned her Bachelor of Science degree in biology from the Virginia Polytechnic Institute and State University.

**About Impact Analytical**

Impact Analytical is a contract analytical testing laboratory providing pharmaceutical testing for regulatory and drug development needs. Utilizing a new state-of-the-art 17,000 sq. ft. analytical testing facility, Impact Analytical provides release testing, R&D support, method development and validation, extractable/leachable studies, stability studies, actives quantitation and raw material testing. Impact Analytical is ISO 9001:2008 certified, DEA licensed, FDA registered, cGMP and GLP compliant.

### What to Look For in a Lab

For all intents and purposes, these are the procedures that are followed in virtually every stability testing laboratory in the country. To be an effective stability testing partner, however, a lab must be held to a higher standard.

### Start With the Scientists

Look for a laboratory with a staff with a high proportion of master's and doctoral degrees in fields specifically related to chemistry and pharmaceuticals. For consistent, high-quality results, seek scientists and technicians trained and experienced in the specific procedures required by your testing needs.

### Certified compliance

To be of any real value, a stability testing laboratory must be compliant with cGMP and GLP standards and operate in accordance with guidelines established by the FDA and the I nternational Conference on Harmonisation. Verify current certification by CLIA or other regulatory bodies.

### Formalized Quality Assurance

To satisfy government protocols, data collection must be documented and verified. A laboratory that provides a rigorous quality assurance program to audit both research and reports will give peace of mind to sponsors and regulators alike.

### Cutting-edge Technology

Look for a laboratory that keeps facilities and equipment up to date, including the latest technology in mass spectrometry, molecular characterization, gas and liquid chromatography, and inorganic spectroscopy.

### Secure and Regulated Storage

For longer-term studies, the laboratory will need secure storage facilities that can maintain environmental conditions without interruption over the course of several years, including deep freeze and variable temperature and humidity stability chambers. These systems should be monitored continuously with backup contingencies.

### Beyond Stability Testing

An effective laboratory partner will also be able to provide for laboratory needs that go beyond just stability testing and may include material characterization, methods development and release testing, in addition to regulatory consulting. Impact Analytical, for example, maintains facilities and equipment for a full range of analytical testing, including elemental analysis, gas separation, liquid separation, molecular characterization and thermal/mechanical properties.

### Exceptional Communications

For the best outsourced relationship, seek a laboratory that excels at communication and customer service and actively encourages a partnered relationship. Look for an atmosphere that encourages a team approach between the company and the laboratory. In addition to these qualities, Impact Analytical also has in place a Project Coordinator, whose role is to facilitate information and customer service.

### An Integrated Capability

Equally important or perhaps more importantly, using a specialized analytical testing laboratory brings focused expertise, innovative solutions and new techniques to the table. Additionally, a singular focus often means you've attracted the best experts in a variety of scientific disciplines. Ultimately, the focused analytical capability of an analytical laboratory means better science. And, in the end, better science means better products.