# A2LA Accreditation Case Study

DDL

Testing Experts. Service Specialists.

American Association for Laboratory Accreditation

# DLL, Incorporated

Case Study

## *packaging, materials, and medical device testing body*

When a medical device, drug delivery system, or packaged healthcare product reaches a clinician, patient, or end user, there is an expectation that it will perform as intended and remain safe, sterile, and effective throughout its lifecycle. That confidence depends not only on the product itself, but also on the packaging, materials, components, and distribution conditions that protect it from manufacturing through final use.

For medical device and pharmaceutical manufacturers, packaging is a critical part of product performance and regulatory compliance. It must protect sterile barriers, withstand transportation and handling, support shelf-life claims, and help ensure that products arrive in a condition suitable for clinical or consumer use.

That is where DDL, Inc. plays a key role.

DDL, Inc. is an independent, third-party testing laboratory that supports medical device, pharmaceutical, biotech, and combination-product companies with testing services used to validate packaging systems, evaluate materials and components, and support product development, regulatory submissions, and commercialization.

DDL is especially known for packaging validation and distribution simulation services, including accelerated and real-time aging, package integrity testing, seal strength and sterile barrier evaluations, and related testing used to demonstrate that products can withstand the conditions they may encounter in storage and distribution. The business also provides specialized capabilities in materials and product testing, including mechanical testing, inspection technologies, small-bore connector testing, and industrial CT scanning for complex components and assemblies.

Because DDL's customers operate in highly regulated healthcare markets, they rely on testing partners that understand quality systems, documentation expectations, and recognized industry standards. DDL supports these needs as an ISO/IEC 17025 accredited laboratory through A2LA, providing objective, technically sound testing data that customers can use to support audits, design verification, regulatory filings, supplier qualification, and ongoing product quality requirements.

## A Robust Quality Management System

DDL first became accredited in 2015 and currently operates several ISO/IEC 17025 test laboratories across the US, as well as an FDA registered laboratory. All their locations operate under the same quality management system (QMS), ensuring tests are conducted accurately and consistently across each location. Maintaining their accreditation and operating under one QMS allows their customers to consolidate testing to reduce vendor risk and streamline regulatory submission packages.

***"ISO/IEC 17025 provides a great foundation for a very robust QMS," said Suzette Glennon, Quality Assurance Manager, DDL."It has made our QMS strong, and a strong QMS means more business, especially with high-risk customer such as pharmaceuticals."***

DDL's internationally recognized ISO/IEC 17025 accreditation gives their customers confidence that the quality of their test results are reliable and accurate, while also saving them time during the onboarding process.

"One big benefit is that we have less customer audits because of our accreditation,"adds Suzette. "Because we're accredited, our customers can forgo auditing us, and it makes it easier for our customers to onboard us into their list of approved vendors and suppliers."

With the support of A2LA, DDL has expanded their scope of accreditation over the years to include their growing service offerings. By adding services to their scope of accreditation, DDL can better meet the needs of customers who are looking to conduct many different accredited tests with one service provider. A2LA has also supported DDL with attentive customer care from staff and assessors, and by identifying areas for improvement and ensuring they properly meet requirements, even in complex scenarios.

"A traditional proficiency testing program isn't very straightforward for us because of the nature of our testing," said Jean Tuomala, Senior Compliance Specialist.

***"In lieu of a traditional proficiency testing program, A2LA's requirements allow us to conduct proficiency testing via inter-laboratory and interlaboratory comparisons."***

DDL is proud to list their accreditation symbol on their website, in onboarding documentation, and other marketing materials. It also serves as evidence of the organization's commitment to providing their customers with the most reliable test results, so that they may make critical decisions regarding the safety of their products. Their customers can feel confident when submitting regulatory filing knowing their results are dependable and accurate.

***Suzette said, "I would recommend accreditation to anyone that is interested in growing their business."***

## Why A2LA?

A2LA is among the largest accreditation bodies in the world, and the only independent, 501(c)3, non-profit, internationally recognized accreditation body in the United States that offers a full range of comprehensive conformity assessment accreditation services.

The A2LA Mechanical field of testing relates to tests, measurements, and evaluation of physical properties of materials, components, and assemblies across a wide variety of industries and products. Learn more about A2LA's Mechanical Testing Accreditation Program at A2LA.org/accreditation/mechanical-testing.

Ready to begin your accreditation journey? Take the first step toward improving the quality of your test results and request an estimate today. Visit A2LA.org/estimate-request.