

Validation Services Program (VSP)



Diversified Plastics, Inc. (DPI) adheres to a stringent quality management system that meets the requirements of ISO 9001:2015 and ISO 13485:2016 as well as FDA requirements. DPI's Validation Service Program (VSP) maintains quality validation standards across multiple industries. It provides the highest quality and fastest turnaround to support your development projects.

Key components of the VSP include:

- Validation standards/protocols across multiple industries.
 - Installation Qualification (IQ), Operational Qualification (OQ) Performance Qualification (PQ) – commonly used in the medical device and medical technology (medtech) industries
 - Production Part Approval Process (PPAP) – most frequently used in the automotive industry
 - Process Capability (Cpk) – used across a variety of industries
 - Process Failure Mode Effects Analysis (PFMEA)
- DPI's VSP employs specific tools and analyses, based on the validation requirements.
 - Measurement System Analysis Protocol (MSAP) – evaluation of the measurement system
 - Scientific Injection Molding (SIM) – systematic, analytical study of the molding process
 - First Article Inspection Report (FAIR) – dimensional evaluation
 - Design of Experiments (DOE) – understand relationship of process factors
 - Device History Record (DHR) – documentation of manufacturing and tracking



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- To perform efficient and effective validations, DPI utilizes a full suite of high-caliber equipment.
 - Zeiss DCC Eclipse 28X28 CMM with Touch Probe and Articulating Head
 - Numerex Coordinate Measuring Machine with Touch Probe, Model 1518-10BT
 - Vertex 210 Vision System
 - Surface Plates
 - Mark 2 HP Moisture Analyzer
 - Chatillon TCM201
 - Mecmesin Multi Test 5-i
 - Mitutoyo SJ-410 Profilometer
 - Thread Gauges, Radius Gauges, Torque Gauges, Force Gauges, Height Gauges and Fixtures

- The DPI team is here to support your validation needs.
 - Quality assurance (QA) team – nine-person QA team, combined experience of 146 years, led by a medical device veteran
 - Cross-functional project team – process engineer, tooling design and engineer, and project manager
 - Expertise in multiple high-tech industries – medical device, industrial, filtration, avionics, aerospace and automotive
 - In-house tooling, which can help shorten overall process
 - Vertically integrated with secondary operation validation



- DPI's VSP considers a variety of key factors when evaluating timing and price of a validation program.
 - Type of validation required
 - Critical dimensions – both quantity and process of measurement
 - Part size
 - Type of final report required
 - Destructive testing requirements (tensile testing)
 - Bio-burden testing
 - Weld-strength testing

DPI will provide a full quotation for each validation, specifying cost and timing. Using our VSP includes discounted pricing off standard rates for engineering and technical services.

Contact your DPI sales engineer to discuss your validation requirements and learn how our VSP can support your needs.

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