



# VALIDATION SERVICE PROGRAM (VSP)

Aprios adheres to a stringent quality management system that meets the requirements of ISO 9001:2015, ISO 13485:2016, and FDA requirements. Our 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 VSP



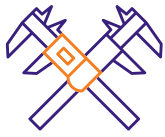
### VALIDATION STANDARDS/ PROTOCOLS

- **Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)** – Commonly used in the medical device and medtech industries.
- **Production Part Approval Process (PPAP)** – Most frequently used in the automotive industry.
- **Process Capability (Cpk)** – Used across various industries.
- **Process Failure Mode Effects Analysis (PFMEA)** – Evaluates potential process failures.



### TOOLS AND ANALYSES

- **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)** – Understanding the relationship of process factors.
- **Device History Record (DHR)** – Documentation of manufacturing and tracking.



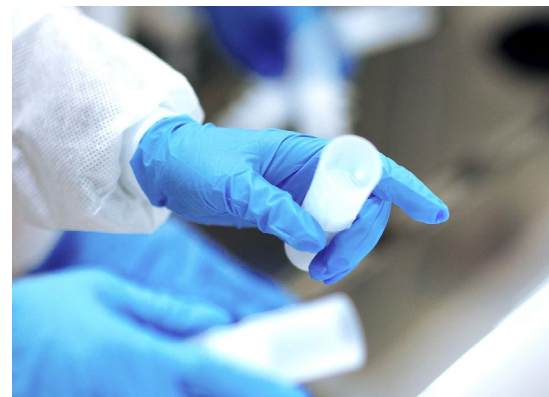
# VALIDATION SERVICE PROGRAM (VSP)

## VSP Equipment and Support



### HIGH CALIBER EQUIPMENTS

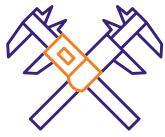
- Zeiss DCC Eclipse 28X28 CMM with Touch Probe and Articulating Head.
- Numerex Coordinate Measuring Machine with Touch Probe, Model 1518-10BT.
- Vertex 210 Vision System.
- Surface Plates.
- Mark 2 HP Moisture Analyzer.
- Chatillon TCM201.
- Mecmesin Multi Test 5-i.
- Mitutoyo SJ-410 Profilometer.
- Thread Gauges, Radius Gauges, Torque Gauges, Force Gauges, Height Gauges and Fixtures.



### TEAM SUPPORT

- **Quality Assurance (QA) Team** – A nine-person team with 146 years of combined experience, led by a medical device veteran.
- **Cross-Functional Project Team** – Includes process engineer, tooling design engineer, and project manager.
- **Expertise Across Industries** – Medical device, industrial, filtration, avionics, aerospace, and automotive.
- **In-House Tooling** – Shortens overall process time.
- **Vertically Integrated** – Includes secondary operation validation.





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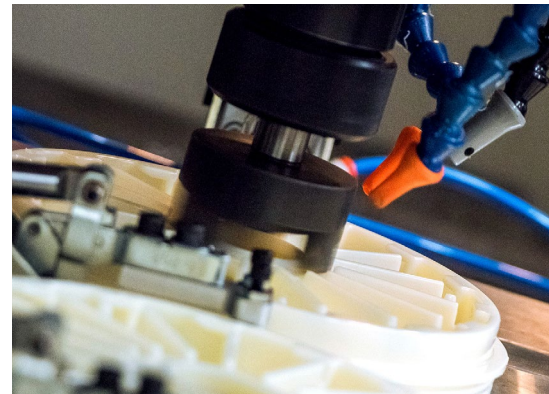
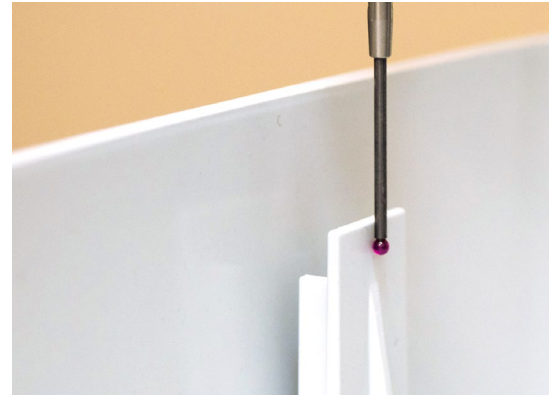


### VALIDATION PROGRAM CONSIDERATIONS



- Type of Validation Required.
- Critical Dimensions - Quantity and measurement process.
- Part Size.
- Final Report Type.
- Destructive Testing Requirements - Includes tensile testing.
- Bio-burden Testing.
- Weld-Strength Testing.

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



### CONTACT US

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For more information, please scan the QR code below.

