



VALIDATION

Expert Guidance Outcomes

For Operations Staff:

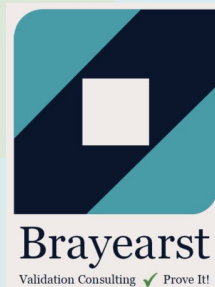
Our validation services enhance process efficiency and reliability, making your daily operations smoother and more productive, ultimately leading to improved results.

For Quality Staff:

Deliver higher quality products, meet customer expectations, and reduce defects. Our validated processes elevate quality assurance, ensuring satisfaction and brand integrity.

For Project / Engineering Staff:

Gain a valuable reference point with our baseline validation data. It assists in technical issue investigations, aiding your team in resolving challenges swiftly and effectively.



For Regulatory Staff:

We provide comprehensive validation documentation, easing audits and demonstrating compliance. With our support, you'll confidently present proof of acceptable performance to auditors.



(443) 248-0530



www.brayearst.com



contact@brayearst.com

Achieve FDA Compliance and Operational Excellence

Experience uninterrupted manufacturing and revenue generation, safeguarding your business's future.



Common Problems

- * FDA-regulated manufacturers struggle to keep up with compliance requirements, leading to potential risks.
- * Producers grapple with product quality issues, which can damage their reputation and market standing.
- * Companies lack the in-house expertise or resources required for comprehensive process understanding.
- * Management worries about not having robust validation documentation that can withstand scrutiny during audits.
- * Projects may encounter scheduling delays in market entry, resulting in lost revenue opportunities.

Brayearst Validation Consulting's Solution

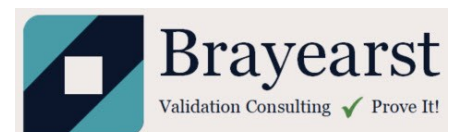
Brayearst specializes in applying Six Sigma methodology to process validation in FDA-regulated industries. This unique expertise allows you to optimize manufacturing processes for profitable outcomes, ensuring efficiency and compliance simultaneously.

We offer a broad range of validation services, ensuring that clients have a one-stop solution for all their process validation needs.

Installation Qualification (IQ), Operation and Performance Qualification (OQ/PQ), Process Performance Qualification (PPQ), Cleaning Validation, Test Method Validation, and Software Validation

Merits

- * Industry Longevity: Over 30 years of professional experience in chemical and medical device manufacturing industries
- * Educational Background: A bachelor's degree in chemical engineering from Carnegie Mellon University
- * Regulatory Expertise: chemical industry compliance activities for EPA which evolved with medical devices for FDA
- * Six Sigma Black Belt Certification: a statistical background enhanced by following a rigorous methodology
- * Leadership and Team Management: led a team of validation engineers during projects with a variety of requirements
- * Technical Training Delivery: taught and facilitated training sessions



(443) 248-0530



www.brayearst.com



contact@brayearst.com