



# 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.



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# 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



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