

COMMISSIONING

SERVICES GUIDE

Start-up, Verification & GMP Compliance

DME Alliance has over a decade of experience providing exclusive services to the regulated life sciences industry. We implement a science and risk-based approach to the verification of process systems & utilities in line with ASTM E2500 standards. DME is heavily staffed with Subject-Matter Experts in GMP equipment, clean utilities, process technology and automation – enabling us to handle the most challenging of regulated process systems. Our commissioning and validation engineers have hands-on experience with the verification of GMP facilities for manufacturing vaccines, therapeutic proteins, monoclonal antibodies, parenteral products, solid dosage & bulk pharmaceutical APIs.

DME Alliance’s commissioning & validation capabilities, in combination with our process engineering, risk evaluation, equipment design and management capabilities, enable value-added turnkey project implementation. The DME Alliance project delivery strategy combines strong project management, web-based cost controls, consistent client communication and a qualified technical team for a proven formula that reduces the total installed-cost of regulated facilities.



SUMMARY OF SERVICES

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|------------------------------------|-------------------------------|--------------------------------------|
| ◆ Process Systems Verification | ◆ Project Planning & Delivery | ◆ Validation Master Plan |
| ◆ Commissioning of Utility Systems | ◆ Risk Assessment | ◆ Impact Assessment |
| ◆ GMP Equipment Troubleshooting | ◆ Gap Analysis | ◆ IQ / OQ / PQ |
| ◆ Protocol Development & Execution | ◆ Contamination Control | ◆ Cleaning & Thermal Validation |
| ◆ Supplier Audits | ◆ Enhanced Design Review | ◆ Cycle Development |
| ◆ Vendor Surveillance | ◆ Subject-Matter Experts | ◆ Automation Verification |
| ◆ Source Inspection | ◆ PHA analysis: HAZOP / FMEA | ◆ Standard Operating Procedures |
| ◆ Equipment Startup | ◆ Design Qualification | ◆ Quality Standards & Specifications |
| ◆ FAT / SAT | ◆ GAMP Compliance | ◆ ASTM E2500 Implementation |

TEL 610.366.1744 www.dmealliance.com ...where process science meets engineering excellence. SM

VERIFICATION & COMPLIANCE SERVICES
ENGINEERED FOR SUCCESS