VALIDATION CONSULTING

Equipment Qualification | Process Validation | Computer System Validation | Cleaning Validation | Analytical Method Validation

Equipment Qualifications

Manufacturing Equipment | Packaging Equipment | Laboratory Equipment

We provide documented evidence that a system or equipment has been installed and operate throughout anticipated operating range to conform to all user requirements, design & technical specifications, and regulatory requirements.

Process Validation

Manufacturing Process Validation Services involve a comprehensive and in depth exploration and evaluation of every aspect of the manufacturing environment, including but not limited to:

• Aseptic Processing Validation • Environmental Baselines • Liquids (sterile/non-sterile) • Ointments • Product Validation • Suspensions • Tablets

Computer System Validation and Data Integrity (DI)

We offer Computer System Validation for your Equipment Control System and other computerized systems such as Empower3, TrackWise, Track and Trace, Veeva Vault, LIMS, EtQ, Documentum, MODA, BMS etc. used in the GMP environment. Our Validation Engineers have many years' experience in validating vision systems, complex packaging systems, manufacturing systems including PLC/SCADA/DCS systems. We also offer validation support for Continuous Manufacturing Process. Systems and processes should be designed in a way that encourages compliance with principles of Data Integrity (DI)

Cleaning Validation

The prevention of cross contamination is an essential component of any GMP program and is necessary to ensure the safety of drugs, biologics and medical devices used in human or veterinary applications. We determine the cleaning processes for each piece of equipment.

Analytical Method Validation

Analytical Method Validation is defined as the process of providing (thorough Scientific Studies) that an Analytical Method is acceptable for its intended use. Analytical Methods Development and Validation play important roles in the discovery, development and manufacturing of pharmaceuticals. The official test methods that result from these processes are used by QC lab to ensure the identity, purity, potency and performance of drug products.

COMMISSIONING & QUALIFICATION

We can provide an efficient, effective documented program that follows and complies with global regulations and guidelines. Our engineering project life cycle experience ensures that commissioning and qualification issues impacting on the design phase of a project are fully considered and integrated at the start of a project. We provide consistent guidance for design, construction, and commissioning and qualification of manufacturing facilities.

We can perform C&Q for the following areas but not limited to:

- Facility and Utility
- Manufacturing Equipment with Control System
- Packaging Lines and Equipment with Computerized Systems

MMSTAN INC.

Reliable. Dependable. Sustainable.

Knowledgeable, Experienced Ex-FDA Drug Investigators and Industry Regulatory Experts partnering with unique solutions to achieve your goals in Pharmaceutical, Biopharmaceutical and Medical Device companies in US and International

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MMSTAN INC. is a premier, professional regulatory consultancy providing a full scope of regulatory services for Pharmaceutical, and Biopharmaceutical companies across the globe.

Our Ex-FDA Drug Investigators and Industry Experts provide sustainable compliance oriented solutions makes MMSTAN INC., a distinctive name in consultancy.

MMSTAN provides high quality, regulatory and compliance services by offering:

- Simple, cost effective, compliant and effective solutions to our clients to meet their goals with detailed support throughout the project life cycle
- US FDA Pre-Approval Mock Audits, M&A Due Diligence Audits and GxP Compliance Audits for GMP and Pre-Approval inspections of pharmaceutical and biological drug manufacturers
- Draft Warning Letter and FDA 483 observations' response letters to FDA, Remediate gaps as needed. Assist during Regulatory audits
- Provide recommendations for facility design, construction, or operation from a compliance perspective
- Assurance of independent, expert deliverables

Offering top quality, cost-effective Regulatory Consultancy Services, across the globe.

MMSTAN INC. offers GMP, validation and regulatory compliance solutions for companies seeking to obtain a competitive advantage and compliance to various areas of GMP. Our Pharmaceutical consulting team includes Ex FDA Drug Investigators and GMP consultants who have previously held leadership roles within the industry. Our Medical Device consultants have extensive knowledge of Medical Device regulatory requirements, including Medical Device classifications.

Our approach to current Good Manufacturing Practice (cGMP) is very concise and provides quality documents to your staff and then makes sure that it is followed and the results are documented.

Our Validation consulting services include C&Q for Facility Utility, Equipment, Packaging Lines, Cleaning Validation and Computer Systems Validation as well as Pharmaceutical and Medical Device Process Validation to PIC/S, ANVISA, EMEA, FDA, Health Canada and TGA regulations.

COMPLIANCE CONSULTING

Quality Systems I Regulatory Audits I GMP Trainings

Quality Systems

Manufacturers must establish and follow quality systems to ensure that their products consistently meet applicable requirements and specifications. Quality Risk Management is integral to an effective pharmaceutical quality system. It can provide a proactive approach to identifying, scientifically evaluating and controlling potential risks to quality. It facilitates continual improvement of process performance and product quality throughout the product lifecycle.

MMSTAN INC. offers the following services but not limited to:

• Site Master Validation Plans • Periodic Reviews • Change Control
• Procedures• Policies and Guidelines• CAPA •Calibration and PM Procedures • GAP Analysis / Risk Assessments • GMP Training • GAP Analysis and Remediation

Regulatory Audits

MMSTAN INC. designs audit and corrective action plans to accommodate our client's needs, including MHRA, EMEA, and FDA regulations.

We offer the following services but not limited to:

Pre-Approval FDA Mock-Audits, Preparing SMEs with Mentoring and Coaching for anticipated Regulatory Audits • API, OSD, Sterile and Bio-Pharmaceutical Manufacturer Audits

• Internal Audits • DI Audits and Remediation Contract Manufacturing GMP Audits • Vendor Audit
• Create Responses for Regulatory Audit Observations

GMP Training

MMSTAN INC. provides cGMP training programs to fit for client needs from cGMP orientation new hires through annual cGMP Training on various cGMP Modules. Our new hire cGMP orientation is an overview of basic GMP concepts and emphasizes, to new employees, the importance of understanding and following governing regulations. This will give them a good background to promote regulatory compliance when they receive On-the-Job Training (OJT).

- Harmonized compliance efforts across diverse business software systems, for globally dispersed facilities and complex regulatory requirements

- Our results oriented, client-tailored approach has successfully assisted numerous multinational companies to be in compliance with both domestic and international regulatory bodies

- Providing Interim Control for Consent Decree activities in major US Pharmaceutical Companies

- Multidisciplinary team of consultants to perform system implementations under the FDA Consent Decree environment
- Project Management functions (Initiation, planning, execution, control, etc.) to assure certification for manufacturing sites

- Tireless and dedicated consultants assigned to your project and help to deliver sustainable results

Impeccable regulatory consulting services for total client satisfaction.

Current Good Manufacturing Practice (cGMP) regulations require all manufacturing processes are clearly defined and controlled. Any changes that have an impact on the quality of the drug are evaluated and validated as necessary. All critical processes are validated to ensure consistency and compliance with specifications. Pharmaceutical companies are keenly aware that they must ensure ongoing compliance with the regulations and be in a state of "inspection-ready" in the event of an inspection from a regulatory body.