

CAPABILITY STATEMENT

Contact Information:
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Company Information:

GovMojo Inc. is a VA verified Service Disabled Veteran Owned Small Business (SDVOSB) and a Women Owned Small Business located in Massachusetts that provides pharmaceutical and biotechnology manufacturing support.

In the ever changing world of drug manufacturing it is critical that the quality of the products supplied or purchased must be an absolute. GovMojo's principle has over 25 years of worldwide validation and auditing experience within the pharmaceutical and biotechnology industries. We can provide you personnel, engineers and project managers to support validations and audits for small and large scale facility qualifications.

- Full Spectrum Validation Support (IQ / OQ / PQ / Process Validation)
- Project Management
- CAPA Investigations
- 483 Observation Remediation
- Consent Decree Remediation
- Internal and External Audits
- Equipment Specification Development
- Factory Acceptance Testing
- Training Programs for Staff

Differentiators:

Experienced:

- Small and large molecule formulation
- Sterile and non-sterile product presentations
- Tablet and capsule production
- Lyophilization
- Packaging
- Media Fills
- Shipping and Storage
- ETO Finished Product Processing
- Terminal Sterilization
- Facilities and Utilities

Recognized as a leading expert on autoclave usage and the instructor of the PDA's course on Technical Report No. 1 (2007) Revision, Validation of Moist Heat Sterilization Process: Cycle Design, Development, Qualification and Ongoing Control

DUNS: 081039415
CAGE Code: 81CB6
NAICS: 541614, 541330, 541611, 611430
WOSB, SDVOSB, LGBTBE



SERVICES

Equipment Specifications

Provide support to organization for the development of equipment specifications to meet cGMP requirements

Factory Acceptance Testing

Generate FAT documents and travel to vendor locations to execute testing

IQ / OQ / PQ Support

Full range of support to all types of manufacturing equipment

Significant Expertise in Autoclaves and Sterile Filling

Process Validation

Process validation support for all phases of manufacturing

Vendor Auditing

Perform audits of vendors to confirm they are in compliance with Quality Agreements and Regulatory requirements

In-house Training

Provide training on validation activities to help build internal resources

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Bringing Engineering and Humanity Together