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Example of Validation Master Plan, Validation Protocols & Validation Completion:

The Engineered Systems Group (ESG) has extensive experience in implementing FDA validation in Industrial gases plants since its inception in 1998. The ESG has been involved in well over 30 validation projects. The capabilities of the ESG extend beyond validation into cGMP compliance with ESG engineers having accredited cGMP training.

AMCS has invested considerable resources in building a cGMP knowledge base and experience in order to reduce the cost of cGMP compliance to its customers. The ESG has been retained by a major Industrial Gases Manufacturer in the U.S to lead the design and implementation of their corporate validation/ cGMP compliance activity. The scope of the work encompass a large number of medical gases facilities, including Bulk/merchant air separation, CO2, Cylinder filling, and Hospital systems

AMCS is a member of the CGA Medical Gases committee, and participates in its related task forces, as well as ISPE, ASQ (FD&C),IVT, PDA. As a company, our commitment is to stay abreast of regulatory developments impacting the industrial gases community.

Project:

Prospective turnkey validation of existing 1150 ton / day (pipeline connected) bulk medical gas manufacturing process / facility that had been seized by the FDA.

Activities:

Development and creation of a Validation Master Plan in a manner that provided integration with corporate policies and systems, addressed areas requiring mitigation in the CGMP risk assessment control plan, and provided integration to the validation strategies.

Validation Time Line:

Key to the successful execution was the creation of a validation time-line that demonstrated client's commitment to FDA.

Validation Protocols & Methodologies:

The development and creation of validation protocols for process and control systems that were appropriately compliant to the requirements and guidance of the FDA (21 CFR 11, 210, 211 Electronic Record-keeping & Signatures, Process Validations), design of evaluation and test methodologies to demonstrate the system's ability to meet criteria for success, on-site execution of the protocols (24-7 as needed), and completion of permanent documentation for compliance files.

FDA Inspection Report:

Due to the nature of the facilities posture with FDA, AMCS also provided support through the

subsequent FDA inspection which would determine the ability of the client to return to production. *All activities required planning and integration with the client's Corporate and local offices and employees in order to successfully meet schedules. Facility was successfully re-inspected by the FDA and allowed to go back into production by FDA.*