

# NADERI ENGINEERING, INC.



BIO-PHARMACEUTICAL  
ENGINEERING & VALIDATION  
CAPABILITIES

*"Cost Effective Solutions Through Innovation"*

*1240 Powell Street, Suite 2-B  
Emeryville, CA 94608*

*Tel: (510) 547-4040  
Fax: (510) 547-4141  
Website: [naderiUSA.com](http://naderiUSA.com)*

## COMPANY IDENTIFICATION

NADERI ENGINEERING, INC. (NEI) is a multi-discipline Engineering, Documentation and Validation company. NEI provides cost-effective solutions to biotechnology and pharmaceutical industries. Our main office is located in Emeryville, California. Since its inception in early 1994, NEI has provided consulting services to companies throughout the United States, Canada and Europe. The company is forty (40) professionals strong.

Our focus is to provide a complete range of engineering, documentation and validation services for central plant, facilities, utilities and process and manufacturing. We achieve this by offering a professional team with experience in each respective area.

NEI offers the following services:

### ◆ VALIDATION SERVICES

- ◆ Master Plan Development
- ◆ IQ, OQ, PD/PQ Protocol Development and Execution
- ◆ Re-Qualification Projects
- ◆ Equipment, Software, 21CFR Part 11 Validation



### ◆ ENGINEERING CONSULTING SERVICES

**Facilities, Utilities, Instrumentation & Electrical, Automation and Process Engineering Support**

- ◆ Construction Punchlist/Support
- ◆ Engineering Checkout, Startup and Commissioning
- ◆ On-Site Staff Support

### ◆ DOCUMENTATION SERVICES

- ◆ Preventive Maintenance, Calibration and Operation SOPs
- ◆ BPRs and Sanitization SOPs

## **VALIDATION SERVICES**

NEI provides validation services in Equipment Validation, Laboratory Instrumentation, Software Validation and 21CFR Part 11 Evaluation and Remediation in accordance with cGMP requirements and ISPE Guidelines. We hire and maintain highly qualified individuals who have experience in developing and executing Installation Qualifications (IQ), Operational Qualifications (OQ), Performance Development (PD), Performance Qualifications (PQ) and Re-qualification (RQ) protocols. NEI provides validation services in the following areas:

### **UTILITIES / FACILITIES**

- ◆ Sterilizer IOQ and Load PD/PQ
- ◆ CIP and SIP IOQ, PD/PQ
- ◆ Room PQs
- ◆ Cold Room IQ, OQ, PD/PQ
- ◆ Compressed Gases IOQ, PQ
- ◆ Stills, WFI, Clean Steam IOQ, PQ
- ◆ HVAC IOQ, PQ, Cold Glycol System IQ and OQ

### **PROCESS EQUIPMENT**

- ◆ Media and Buffer Preparation, Holding Tanks IOQ
- ◆ Fermentation, Bioreactors, Small and Large, IOQ, System OQ
- ◆ Ultra-Filtration and Isolation IOQ
- ◆ Thermal Mapping, IOQ of Incubators, Freezers, Bio Safety and LAF Units, Thawers
- ◆ Chromatography Skids IOQ

### **FILL & FINISH**

- ◆ Freeze Dryer IOQ
- ◆ Glass Washer IOQ
- ◆ Filling, Stoppering and Capping Machines, Tray loader IOQ, PQ

### **SOFTWARE VALIDATION**

- ◆ 10CFR21 Part 11 Evaluation and Remediation
- ◆ Siemens Building Automation System (BAS) OQ and PQ
- ◆ DCS Protocol, IQ, OQ and PQ for Process Systems
- ◆ Instrumentation and Control I/O and J Panels IQ
- ◆ PLC- Driven Process Skids
- ◆ Process Controls Validation

## LABORATORY EQUIPMENT VALIDATION

- ◆ Lab Equipment Software Validation (Gas Chrom, HPLC, Densitometer, Scanner, Spectrometer, Threshold Workstation, FTIR Spectrophotometer, Microplate Reader, Capillary Electrophoresis, Nephelometer)
- ◆ 21CFR Part 11 Evaluation and Remediation

Our personnel have worked on validation projects for biotech companies such as **Bayer, Chiron, Abgenix, Genentech, Genentech-Espana, Vical and Biogen-IDEC Pharmaceuticals.**

## **ENGINEERING SUPPORT (Startup/Commissioning/Onsite Support)**

We offer individuals experienced in multi-discipline start-up, operations activities. We routinely perform start-up and commissioning of a variety of systems in accordance with the ISPE Guidelines for systems such as the HVAC, Cold Glycol, Instrument Air, Process Air, Hot Water, Chilled Water, Cooling Tower, Plant Steam, Purified Water, Caustic and Acid Dilution, Water for Injection (WFI), Clean Steam and Process systems such as Fermentation suite, purification suite, process tanks and fill lines.

NEI provides on-site staff support in engineering disciplines and validation to our clients' short term and long term needs. We provide highly qualified personnel with competitive rates.

We provide staff for engineering support work in instrumentation & controls, automation and process controls involving PLC, DCS and BMS.

We have qualified resources for biotech validation and documentation in areas of therapeutic and diagnostic manufacturing, facilities and utilities.

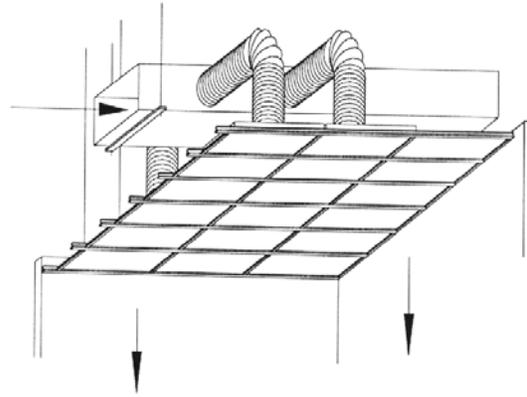
NEI supports numerous clients with their SOP Program in Preventive Maintenance (PM), Operating and Spare Parts Programs. At biotech companies, we specialize in preparing procedures for facilities, utilities, and process equipment.

Aside from working with the biotech companies, NEI has assisted numerous companies with their preventive maintenance and spare parts requirements for a wide range of equipment commonly used at industrial facilities and power generating stations.

## ENGINEERING SERVICES

### I. Mechanical

NEI provides mechanical engineering consulting and design services. Our experience involves biotechnology, industrial plants, commercial buildings and institutions. We have experience in HVAC and refrigeration system design and commissioning, cold glycol, chilled water, cooling tower, Water-For-Injection, Deionized Water, hot water, boilers, cold water, process piping, and laboratory facilities design.



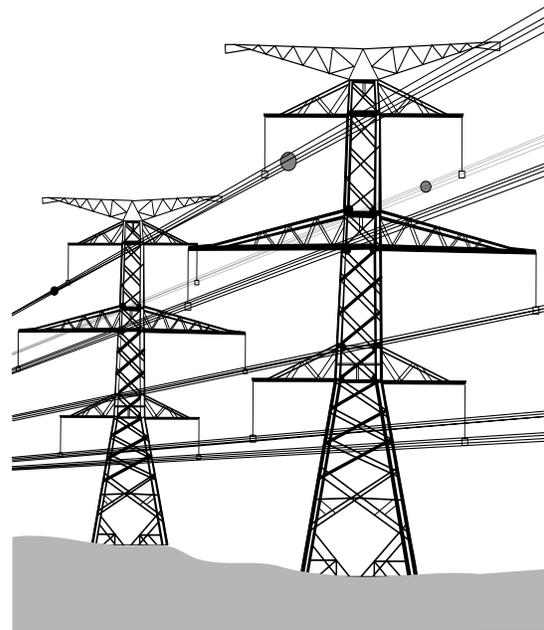
Our professionals have experience in design and validation of clean rooms, fume hoods, autoclaves, process tanks, and other laboratory support systems.

Some of our projects include designing ventilation systems for electronic fabrication shops and integrated waste management sites, HVAC design and equipment selection for computer rooms and P&ID development.

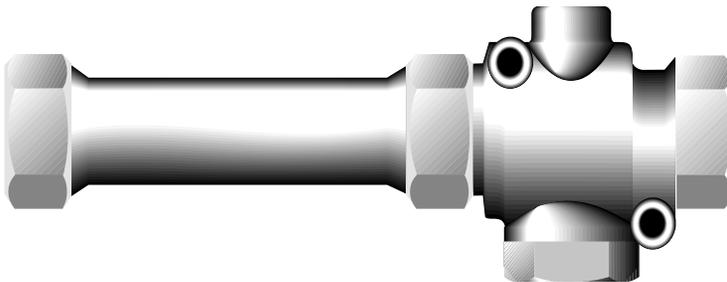
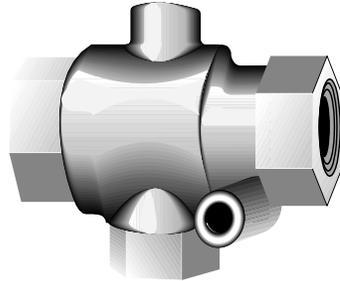
### II. ELECTRICAL

NEI offers the services of electrical engineers experienced in system design, procurement, system analysis, and construction support. Our services include, but are not limited to preparation of single lines, power, lighting and grounding plans, fire alarm and telephone system drawings.

We have completed electrical design modifications for production areas at biotech companies. NEI is strong in as-building electrical drawings for compliance and reconciliation purposes.



### III. PROCESS CONTROLS & INSTRUMENTATION

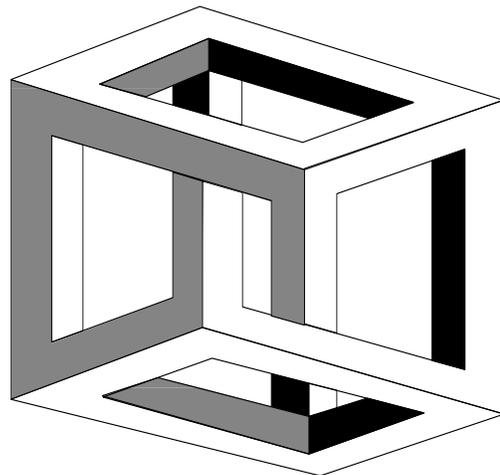


We offer support in PLC and DCS programming and validation. Our engineers have experience with the biotech projects as well as food industries. NEI provides full range of support for preparation of instrument data sheets, instrument calibration procedures, loop checks and design and selection of instrumentation and control systems.

### IV. ENGINEERING REVIEWS

NEI offers engineering reviews in the following capacities:

- ◆ **THIRD PARTY DESIGN REVIEWS**
- ◆ **FEASIBILITY STUDIES**
- ◆ **ENGINEERING SPECIFICATIONS**



Our technique in conducting on-site inspections and data collections will ensure that the reviews are performed accurately and cost effectively.

At biotech companies, we have provided plant inspections for Installation Qualification and as-building of drawings. NEI has been actively involved with forecasting long term energy requirements for central plant and cold glycol for a large pharmaceutical company.

We have conducted reviews of steam supply and condensate return systems corrosion for two institutions in the State of California. In another project, we reviewed the central plant heating and cooling capacities within an older eight story bank building for conversion to a modern office building.

## **DOCUMENTATION SERVICES**

NEI provides documentation services to our clients for compliance with the regulatory and industry requirements and standards. We have performed the following projects:

- ◆ Preventive Maintenance SOPs

NEI was responsible for developing SOPs for facility, utility and process systems at a 180 million dollar facility (130,000 sq ft) in Berkeley, CA. We developed over 100 SOPs for the project.

- ◆ Calibration, Operation and Sanitization SOPs

- ◆ Plant and Manufacturing Documentation

## **PRIOR WORK EXPERIENCE**

Naderi Engineering has completed a large number of projects at biotech companies. We have performed work for the following major clients:

- Genentech, South San Francisco and Vacaville and Porrino, Spain
- Bayer Healthcare, Berkeley, California and Clayton, North Carolina
- Abgenix, Fremont, California
- Alza, Mountain View, California
- Chiron, Emeryville, California
- IDEC Pharmaceuticals, Oceanside, California

A summary of the company work experience is as follows:

### **A. COMMISSIONING / STARTUP AND VALIDATION SERVICES**

- In January of 2004, Naderi Engineering was awarded the contract to commission and validate the 44,000 sqft Sterile Fill Facility at Bayer’s Campus in Berkeley, California. The scope includes the majority of the facilities, utilities, process and fill line equipment commissioning, IOQ and PQs.
- Naderi Engineering assisted IDEC’s NICO project with troubleshooting, commissioning and validation protocol execution of the following equipment:
  - ◆ Troubleshooting of plant steam supply.
  - ◆ Utility and Facility systems including compressed air, boilers, HVAC, air dryers and clean steam.
  - ◆ SIP and CIP troubleshooting of Buffer Prep Tanks, Product Pool Tanks, transfer lines and column packing tank. Start-up activities related to Ultrafiltration skid IQ, OQ and PQ completion.
  - ◆ Cycle development and PQ's of Glassware washers.
  - ◆ Cycle development and PQ's of COP washer.
  - ◆ Cycle development and PQ's of Chromatography Skids.
- Provided engineering checkout, construction coordination and validation of a manufacturing facility in Spain for Genentech. The systems include HVAC, utilities and process tanks.
- Naderi was responsible for commissioning and validation of HVAC, BMS, process tanks, and filling equipment such as Edwards Lyophilizer, filling and capping machines and vial washers for the new Abgenix manufacturing facility in Fremont.

Prior to this, we prepared around eighty (80) commissioning packages for all facility, utility and process equipment. The commissioning packages included the execution of Delta V DCS controls on all applicable equipment.

- Completed the commissioning and validation project for fill and finish and bulk pharmaceutical manufacturing buildings at Bayer. The tasks included facility qualifications and Room PQs, capping machine IOQ and PQ, sterilizer load PQ, CIP IOQ, Waterbath IOQ and Tank IOQs.
- Naderi Engineering, Inc. completed a major commissioning and validation project involving utilities, facilities and process equipment for clinical trials of a new drug at Bayer. The following equipment was part of the scope of work:
  - ◆ Clean Gases (O<sub>2</sub>, CO<sub>2</sub>, N<sub>2</sub>, Compressed Air)
  - ◆ Ambient WFI
  - ◆ 15L, 20L and 200L Fermenters
  - ◆ Integrity Testers, Filter housings
  - ◆ Various tanks from 35L to 6000L Media Tank, mixer motors
  - ◆ CIP System
  - ◆ Sterilizer IOQ and Dry Good Load PD/PQ
  - ◆ Freezers, Cold Room, Incubators, Blast Freezers, Thawer Unit
  - ◆ Laminar Flow Hoods
  - ◆ Fully automated UF Skid
  - ◆ Chrom Skids
- Naderi was the largest contractor to provide commissioning and validation services to qualify all process controls, BAS and DCS software validation for a Genentech in Vacaville, CA.

## **B. System Controls Automation, Software Engineering and Validation**

### **B.1 Building Automation System (BAS) / Siemens**

- For a Multi-Purpose Biotech Building (133,000 sqft, \$200 million project), Naderi Engineering participated in startup, testing, troubleshooting, system turnover and validation of the Landis and Staefa Building Automation System. The project duration was approximately one year and was completed in 1997.

We assisted the client with programming and validation of modifications to the system.

- For an existing manufacturing building, Naderi is involved with troubleshooting, test development and execution of IQs and OQs for the air handling units and the MBCs connected to the Landis and Staefa System. We have also reverse engineered the system to prepare as-built engineering drawings.

- At a new biotech facility, Naderi Engineering assisted the client with development of Factory and Site Acceptance Tests, Functional and Infrastructure Tests, Execution of the tests and Installation and Qualification Testing.

## B.2 DCS and Process Control Engineering

- Currently providing Project Management on a highly visible engineering and validation project with FDA deadlines for multiple legacy control systems. The project includes managing the budget, schedule, contractors, as well as interfacing with validation and QA organizations and reviewing deliverables for technical and quality aspects.
- At a biotech facility, Naderi Engineering performed startup / Testing, troubleshooting and validation of DCS (ABB Mod 300 System) and PLC driven vendor equipment and process controls for Purified Water, Purified Steam, Cold Glycol, hot and cold water, Instrument Air, Process Air, Cold Rooms, Chemical Dilution Systems, CIP, SIP, Thaw, Fermentation, Neutralization and Purification systems.
- Naderi Engineering provided the resources required for testing and validation of DCS at a biotech facility. The activities include the interface with the supplier of the system (Moore), Factory and Site Acceptance Tests and Functional Tests and execution of IQs, OQs, SIQs and HIQs.
- We prepared specifications for testing of the majority of the control systems associated with the utility and process systems at a facility.
- Assisted client’s QA building with all day-to-day design, modifications and engineering of instrumentation and control and electrical projects.
- Assisted a client with development, testing and implementation of software for Laboratory Information Management System and SDDs, HIQs and SIQs for various process control equipment.
- Assisted a client with hardware and software design, procurement and installation management of all laboratory computer systems.
- Assisted a client with modification of Allen Bradley PLC SLC500 for dead rungs and other functions associated with a sterilizer in QA Building.
- Assisted a client with design and fabrication of a control system for viral inactivation system and subsequent Engineering Checkout and validation of the system.
- Naderi assisted a client with Project Management of the Y2K on all Process Control Systems including DCS and Building Automation Systems in a major biotech manufacturing facility.

- We tested all QA, Process Sciences and R&D Laboratory Equipment for Y2K date code issues for the a major biotech client.

### B.3 QC Laboratory Software Validation

- Currently providing the project management and staff support of software validation associated with process controls and laboratory instrumentation in response to a Computer Compliance Requirement and 21CFR, Part 11 Compliance.

The QC Instruments includes Gas Chrom, HPLC, Densitometer, Scanner, Spectrometer, Threshold Workstation, FTIR Spectrophotometer, Microplate Reader, Capillary Electrophoresis, Nephelometer.

- Tested all QA, Process Sciences and R&D Laboratory Equipment for Y2K date code issues for the a major biotech client.
- Provide all activities associated with Laboratory Information Management System (LIMS) Validation during a two year contract.

### C. Facility Load Study for Utility Capacity Requirements

- Naderi Engineering was a major participant in a Study at a facility. This was a highly visible project which was steered by Corporate VP of Engineering from the corporate office. Naderi provided critical information regarding long term capacity needs at the Site for parameters such as cooling capacity (ammonia plant capacity), Purified Water (WFI) and electrical requirements. We also participated in preparing the report and made recommendations which were accepted by Corporate.

### D. Facility / Utility Design

- Naderi engineered, designed, entertained bids and selected contractor, project managed and performed startup and testing of 750 tons of additional cooling capacity for a biotech site. The project duration for this critical project from concept to operation took four months. Naderi was commended by the manager of engineering for expediting this project on a such short schedule.
- Modified the existing central compressed air system to increase capacity and remove operational problems and system troubles.
- Designed HVAC system for a number of utility buildings to eliminate existing problems and create manageable environment.
- Provided project management and engineering design for modifications to the central plant boiler house including demolition of a tall smoke stack and other structures.

- Provided designed modifications for an existing cooling tower filtering system and agitators of the chemical dilution systems.
- Provided designed and construction support for the expansion of the entry road at a facility. The project included preparation of all construction drawings associated with underground utilities and electrical, road construction, flat work, parking lot, guard house, security systems (cameras, card readers, turnstile and entry gate operators).

**E. Calibration, Operational and Maintenance SOPs**

- Naderi Engineering was the contractor to prepare over 125 SOPs for the new manufacturing facility. The scope included the entire SOPs associated with the mechanical, instrumentation and controls in areas of facilities, utilities and process.
- We have assisted the Maintenance department of a facility with preparation of SOPs for Sanitization of UF skids and Maintenance of central utilities.
- We assisted the Engineering Department of a biotech company with revision of the entire SOP documentation. This was a significant effort which spanned over all disciplines and included verification of equipment as-built configuration and reformatting of the SOPs into an automated data base which will not only ease the document retrieval but will also coordinate the performance of multi-discipline maintenance.
- Naderi is currently responsible for preparing all Operating SOPs associated with the facilities and utilities systems in a new facility in Fremont.