

WHY ECVS

- A targeted professional company that provides its customers with personalized service with accountability.
- Issues that need immediate attention get resolved by experts on-site instead of by inexperienced junior personnel.
- Our Validation Specialists & Engineers have at least 15 years experience in your business, having held positions in the jobs where you need assistance.
- We have developed unique partnerships with several highly qualified Quality, Validation & Process Engineering companies, so we can provide our customers with a complete solution for their project if our resources lack the experience needed.
- If you succeed, we succeed. We enjoy what we do and we do it well because we've worked together as a team on important projects like yours.
- Integrity, Honesty, High Quality



CONTACT ECVS



Do you have questions or want a proposal?

Contact Us At:

ECVS, Inc.
9420 E. Golf Links, Suite #137
Tucson, Arizona 85730

Phone: (520) 647-3874

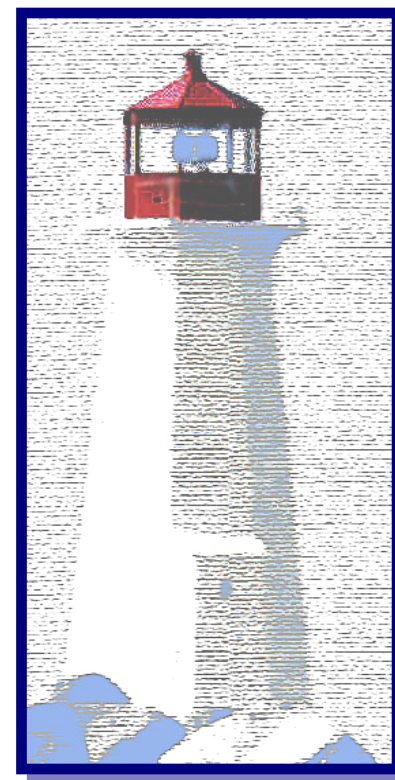
Or

(520) 820-1601

Email: info@ecvs-inc.com



ECVS INC.
ENGINEERING
CONSULTING &
VALIDATION SERVICES



Providing Light to Guide
Our Clients

ABOUT ECVS

ECVS was established in 1999 to provide its customers with a cost effective validation and engineering services solution. We are based in Tucson, AZ. and provide services to clients throughout North America, Europe, and SE Asia. Our clients include Pfizer, Bristol-Myers, Genentech, Sanofi-Aventis, Cardinal Health, Abraxis/Celgene, CBR, etc.

ASSOCIATES

Greg Lynch

Project Leader / Sr. Quality Engineer

Beth Lynch

Validation Engineer / Project Leader

Ray Beery

Sr. Validation Specialist

Leonard Sloan

Sr. Process Specialist

Robert Borghese

Sr. Quality and Compliance Specialist

John Dejovine

Sr. Project & Design Engineer
(Medical Device, Ophthalmic, Diagnostics)

Doug Smith

Sr. Validation Specialist

Michael Kaufer

Quality Assurance & Compliance Specialist

OUR SERVICES

*We use an integrated approach to your projects
— from small to large*

Engineering

- Design Review & Facility / Facility Master Plans
- Process Flow Diagrams & AutoCAD Drawings
- Project Management
- Start-up, Commissioning and FAT/SAT Support
- Process Optimization, DOE & Scale-up

Validation & Quality

- Planning: Validation Master Plans & Policy
- Protocol Generation & Execution (Facility, Utilities, BMS, Equipment, Process, Cleaning, Packaging, Computer/software) of Installation, Operation, and Performance Qualifications, and Process Validation
- Sterilization and Lyophilization Cycle Development, Optimization, and Validation
- Development of Standard Operating Procedures
- Quality Management System: CAPA, FMECA & HACCP, Gap Analysis & Audits to all standards such as FDA, EU, PIC/S, HSA, ISO13485
- cGMP & supplier or contract manufacturer audits



AREAS OF EXPERTISE

Pharm & BioTech

- ⇒ Aseptic Filling and Compounding
- ⇒ Fermentation & Purification Systems
- ⇒ Equipment Cleaning & Component Prep.
- ⇒ HVAC & Cleanrooms (Class M3.5/5.5/6.5)
- ⇒ BSL-2 & 3 Facility Design & Validation
- ⇒ Lyophilization & Drying
- ⇒ Utilities: WFI & Pure Steam & Gases
- ⇒ Cell Banks & Incubators
- ⇒ Isolators (Seed, BSL-2/3, and Sterile)
- ⇒ Sterilizers & Depyrogenation

API - OTC - Med. Devices

- ⇒ Compounding/Synthesis & Mixing
- ⇒ Filling and Packaging Systems
- ⇒ Chromatography / Lab Equipment
- ⇒ Process Capability & Quality Control
- ⇒ Spray-dryers & agglomeration systems
- ⇒ Control & Data Systems, GAMP
- ⇒ 21CFRs (111, 207, 210/211, 330, 600, 820) and international regulations
- ⇒ Quality Risk Management & Mitigation
- ⇒ Nutraceuticals (liquid & solid/powder)

AFFILIATED COMPANIES

- Water Dynamics Co.
- MKCS, Inc. (controls)
- The Compliance Team
- SeerPharma Pty Ltd. (IQA)