



## The CECON Consulting Group

### Science and Engineering Consultants

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## Pharmaceutical Consulting

Have a tough pharmaceutical problem? CECON's pharmaceutical consultants can provide the solution. Our pharmaceutical consultants have decades of experience in drug discovery and development, documentation, regulatory matters, manufacturing, analysis and management.

### Drug discovery and development moving slowly?

*Accelerate with our experts in these areas:*

- Quality Assurance/Quality Control
- Product: Preformulation, Dissolution and Stability
- Drug Delivery: Dosage Forms, Formulation
- Controlled Release
- Package Development
- Regulatory Affairs for FDA Registration and Compliance
- Pharmaceutical Analysis
- Drug Metabolism and Pharmacokinetics
- Safety Assessment and Toxicology
- Clinical Trials, Protocol Design and Management
- Diagnostics
- Clinical Statistician
- Medicinal Chemistry
- Patent Preparation and Litigation

### Documentation, review and writing bogging you down?

*Cecon has experts with hands-on experience:*

- Prepare and Review of CMC Section of IND, NDA and ANDA
- Establish USP Liaison and Compendial Method Development
- Assist in the Medical Devices, 510(k) Registration
- Documentation System Development

### Manufacturing problems or inefficiencies?

*CECON's problem solvers have manufacturing experience in:*

- Scale-up in Bulk Chemicals and Dosage Forms
- Process Engineering
- Troubleshooting Production Processes

### Regulatory matter expertise needed?

*CECON can provide on-site expert support in:*

- OA/QC Systems Development and Management
- Validation in Manufacturing Process, Cleaning, Software
- Analytical Laboratory Certification
- cGMP, GLP and GCP Compliance
- Pre-approval Inspection Preparation
- Qualification of Facilities and Equipment in IQ / OQ / PQ
- Training per cGMP

### Tough analytical problems?

*We have testing and test equipment experts:*

- Methods Development and Validation
- LIMS and Laboratory Automation
- USP Methods and Testing
- Specialized Techniques in Analysis
- Laboratory Planning and Design

### Business opportunities being missed?

*We have managerial experts in:*

- Pharmaceutical Licensing
- FDA Liaison
- Outsourcing, Third Party Manufacturing and Contract Laboratories
- Marketing Strategy and Survey
- R & D Planning
- Project Planning and Management
- Economics and Cost Studies
- Acquisitions, Joint Ventures

### None of the above, but still have technology needs?

*Consider these areas and go to [www.cecon.com](http://www.cecon.com)*

- Chemistry (Biochemistry, Inorganic, Organic)
- Chemical Engineering
- Bioengineering
- Chemical and Biochemical Separations
- Analytical Chemistry
- Materials Science (Metals, Alloys, Ceramics, Composites and Inorganic Materials)