eci

PHARMACEUTICALS

ECI Pharmaceuticals...Proven Results!

ECI

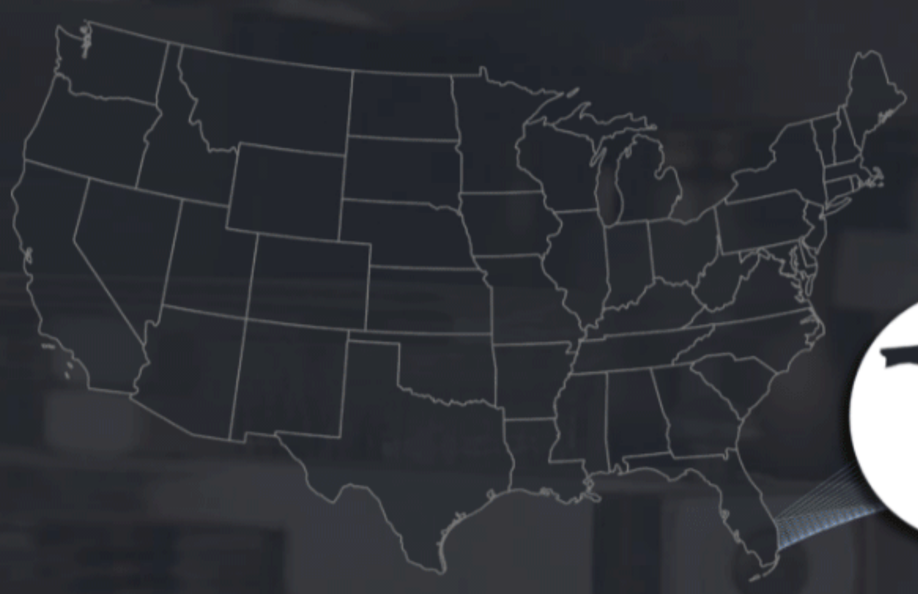
Pharmaceuticals

Established in 2010, ECI is a pharmaceutical company that focuses on developing and marketing products that are manufactured at its cGMP facility located in Fort Lauderdale, Florida. Over the years, ECI has been a trusted name in pharmaceutical manufacturing providing affordable generic medication to consumers through its vast distribution channels. Our customer base includes all major Wholesalers, Retailers, Group Purchasing Organizations, Long Term Care, and Hospitals.

MISSION

Quality Statement

ECI Pharmaceuticals is committed to patient safety and drug efficacy of our products through compliance to regulatory requirements and Quality Management System standards.



PROVEN

Results

ECI seeks out opportunities where there may be shortages or where improvements can be made on existing products. We are currently filing several NDAs and ANDAs with the Food and Drug Administration utilizing the 505(b)(2) pathway.

COMPANY

Overview

ECI Pharmaceuticals, LLC is a privately-held U.S. manufacturer of generic prescription pharmaceuticals. ECI performs pharmaceutical research and development, as well as, it markets/distributes a broad range of generic prescription products in many therapeutic categories and dosage forms.

Throughout the United States, ECI's label is recognized by:

- Retail Pharmacy Chains
- Mail Order Pharmacies
- Pharmacy Benefit Managers
- Managed Care Facilities
- Group Purchasing Org.
- Wholesalers
- Distributors
- Hospitals

Products are marketed in a variety of dosage forms including:

- Tablets
- Capsules
- Creams
- Lotions
- Liquids
- Powders

ECI has Abbreviated New Drug Applications (ANDA's) approved by the Food and Drug Administration (FDA) and has several products in its pipeline that include ANDA's and NDA's.

Executive Management Team

> The quality of our organization is reflected in the standards and attention to detail we set for ourselves. It's our responsibility.

John H. Copanos
CEO and Founder
Mr. Copanos, third generation pharmaceutical manufacturer, began his career in Baltimore, Maryland, working at Enzytek, Ltd., an API manufacturer of Beta-lactam antibiotics. He then joined Consolidated Pharmaceuticals Inc., eventually ascending to Director of Sales and Marketing. In 2000, Mr. Copanos founded Kirk Pharmaceuticals, Inc., an OTC solid and liquid-dose manufacturing firm. In 2004 Mr. Copanos founded his second company, Andapharm LLC, a solid-dose specialty manufacturer focusing on controlled substances and HRT products. In 2006, the two companies – with combined annual sales of approximately $18 million – were sold to a publicly traded company.

Bob Franks
General Manager
Bob's career spans more than 30 years serving in various roles in the pharmaceutical industry. His background as an executive leader includes an extensive track record of inspiring and developing strong management teams. Bob has demonstrated the ability to leverage the combination of general management, corporate strategy, and software implementation to turnaround and grow businesses. He began his career at Johnson & Johnson in accounting where he was responsible for financial reporting, budgeting, internal auditing plant controller, and new ERP systems for multiple J&J companies. He then moved on to Pfizer to implement a new worldwide clinical studies software application. Over the last 20 years, Bob worked with one of the leading ERP software providers implementing projects for more than 35 generic pharmaceutical companies. Bob attended Rutgers University where he earned a M.B.A in Finance/Accounting and a B.A. in Economics.

Dusty Snoeberg
Acting GMP / Quality Advisor
Dusty has more than 24 years of combined FDA and Industry experience regarding interpretation and implementation of FDA regulatory requirements. Her focus has been specifically the implementation of quality systems (CGMP's) as it pertains to 21 CFR 210, 211. She holds a Bachelor's Degree in General Science and has completed master level courses in Pharmaceutical Manufacturing at the University of Cincinnati Pharmacy College.

Andrew Berk
Senior Director | Business Development and Strategy
Andrew is third generation in the Generic Pharmaceutical Industry, both his Father and Grandfather were involved in the Development, Manufacturing, and Sales of some of the very first Generic Pharmaceuticals in the United States. Prior to joining ECI, Andrew was with SST Corp., a 75 year old API Company, where he led In/Out licensing for both API and Finished Dosage. Before joining SST, Andrew was with Ascend Labs from 2004-2014, where he served as Vice President of Business Development, overseeing all aspects of Ascend's licensing and development portfolio. During his tenure at Ascend the company grew from a zero base of sales to over $100 million dollars, earning the distinction of becoming an IMS ranked "top 10 fastest growing Generic Pharmaceutical company" before Ascend was acquired by Alkem Labs.
Andrew received a Bachelor of Science degree from Syracuse University.

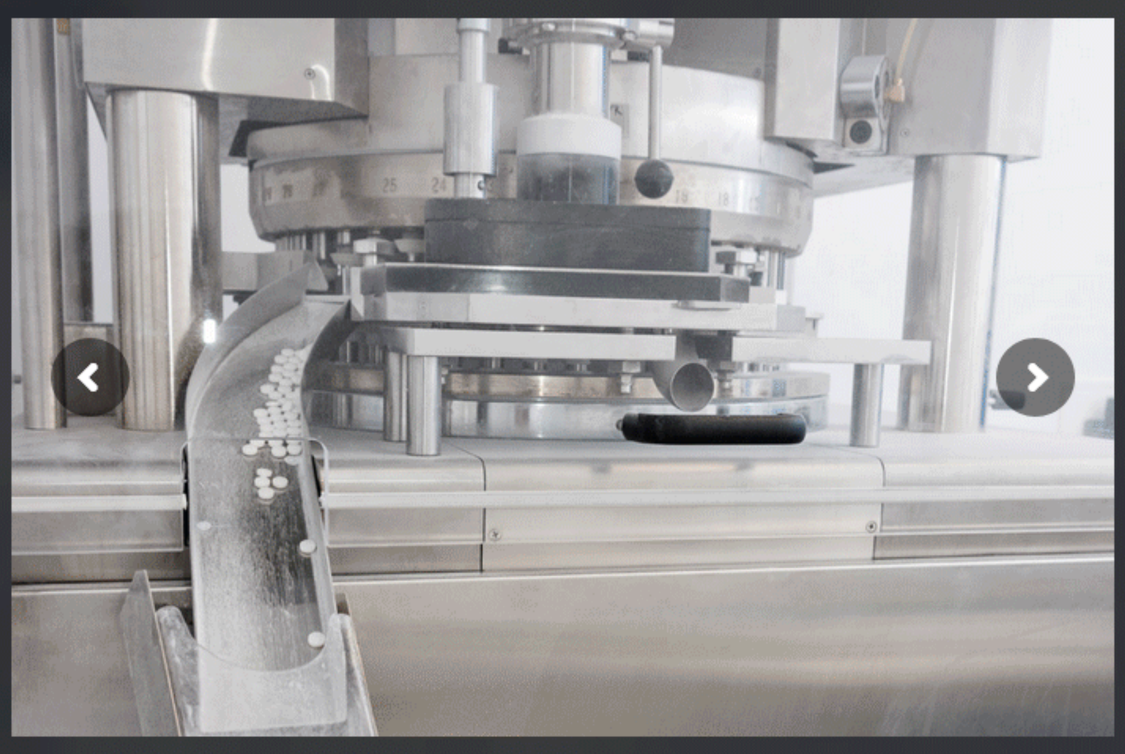
Shane Snoeberger
Acting Vp of Compliance
Shane is a USMC Veteran with over 16 years of experience in complying with the 21 CFR parts 211, 820, and 1300 regarding manufacturing Pharmaceuticals and Medical Devices. He has a Master's in Business and is a Certified Quality Engineer (CQE). Shane is also a Florida Certified Designated Representative (CDR). His career has encompassed both the Quality/Regulatory and Operations/Production sides of the Pharmaceutical business.

MANUFACTURING Facility

ECI's manufacturing facility includes controlled areas for hormonal, high-potency/microdose and ODT products.

State-of-the-Art cGMP Manufacturing Facility:

- 65,000+ sq. ft. facility
- Site is FDA, DEA, and DOH/DBPRS compliant
- Manufacturing, QC lab, R&D manufacturing, R&D analytical testing, clinical packaging, warehouse
- Licenses (includes Schedules I-V)
  - FDA registration (twice inspected and approved)
  - DEA licenses (Manufacturing, Import, Export & Wholesale)
  - State licenses (Manufacturing and Wholesale)



Capabilities

ECI Pharmaceuticals offers a broad range of U.S.-based manufacturing capabilities that allow for the processing of a variety of solid and liquid oral dosage forms.

- Tablets, capsules, powders, and oral solutions requiring degrees of high-shear granulation, fluid-bed processing, bi-layers, and film coating.
- Immediate release, extended release, hormone containment, cytotoxic containment, and ODT technology products.

PRODUCT Development

- Focus on systematic development of value-generating products within our 505(b)(2) and Generics development portfolio.
- Efforts targeted at continued expansion into complex dosage forms, multiple therapeutic classes, high barrier-to-entry, and difficult-to-formulate products.
- NDA's and ANDA's for products that range in various dosage forms including tablets, capsules, oral solutions, suspensions, powders, creams, and ointments.

ANALYTICAL Development

- Full release and stability test methods for new materials and products
- Method validation and qualification as required by cGMPs
- Method transfers, as required
- Laboratory investigations as required by CAPAs, RCAs and cGMPs
- Detailed testing for improved accuracy and reduced costs

CONTACT

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Send Us a Message

ECI is an industry leader and committed to the highest standards. We want to hear from you – contact us using the attached form or e-mail us at customerservice@ecipharma.com.

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