



FOCUS ON Customers and Patients

in full-service contract pharmaceutical development and manufacturing



A black and white photograph of a woman and a young boy running on a beach. The woman is on the left, wearing a light-colored jacket and jeans, and the boy is on the right, wearing a dark jacket and jeans. They are both smiling and running towards the camera. The background is a bright, sandy beach with some water visible in the distance.

NORWICH: Focusing on customers and patients

Norwich is a recognized leader in full service contract pharmaceutical development and manufacturing. As a single-source provider, Norwich offers customers solutions with the highest level of quality and reliability from product development to scale-up and commercial manufacturing through clinical services.



Operational Excellence

Over its 125-year history, Norwich has built a reputation for dependable product supply and established an unparalleled history of regulatory compliance. Using Lean Six Sigma principles, Norwich is continually improving operational systems and quality controls to create greater flexibility and responsiveness for each customer's product.

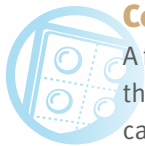
We find **ANSWERS** to customer challenges.
We **LISTEN**. We **FIND SOLUTIONS**.

FOR ALL STAGES OF THE PRODUCT LIFECYCLE ►



Product Development and Technical Services

Norwich offers comprehensive product development capabilities to provide customers with GMP and non-GMP pilot scale manufacturing for clinical trial materials and registration batches, analytical development, and testing services.



Commercial Manufacturing and Packaging

A full range of manufacturing and packaging capabilities that include potent, DEA-scheduled, tablet and capsule solid dosage forms.



Clinical Services

We combine comprehensive services and exceptional customer focus to offer a complete range of clinical services, including pharmacovigilance, bioanalytical services and clinical research programs.

ONGOING
PHARMACOVIGILANCE

BIOANALYTICAL
SERVICES

PRODUCT DEVELOPMENT
AND TECHNICAL SERVICES

CLINICAL
RESEARCH

PILOT SCALE
MANUFACTURING

COMMERCIAL
MANUFACTURING

PACKAGING AND
DISTRIBUTION

Product Development & Technical Services



Companies seeking product development and technical services can turn to Norwich for formulation, analytical method development and validation, process optimization and scalable manufacturing.

Product Development & Technical Services staff, equipment and facilities are dedicated to serve all of your small to mid-scale development and manufacturing needs.

Norwich development and pilot scale facilities are located within nearly 13,000 square feet of DEA approved, potent compound capable space that also contains two laboratories dedicated to support R&D and GMP development projects.

These facilities are strategically designed and equipped to provide solid dose manufacturing technologies in both GMP and non-GMP environments. The facilities, equipment and technology mirror Norwich commercial capabilities, allowing direct transfer from analytical to quality control, and enabling a fast track to trade production.

The Norwich team works with both immediate and modified release products, and has expertise in a number of unique dosage forms, including:

- ▶ Liquid filled hard gelatin capsules
- ▶ Extruded and spheronized beads
- ▶ Wurster coated beads and granules
- ▶ Tablet-in-tablet compression
- ▶ Mini-tablets filled into capsules
- ▶ Laser drilled tablets
- ▶ ODT tablets
- ▶ Solvent and aqueous processing

Commercial Manufacturing

Experienced Norwich staff employ cutting-edge technologies to satisfy a wide spectrum of project demands, including products that are challenging to manufacture. Our commercial production capabilities include:

- ▶ Potent compounds
- ▶ Wet and dry granulation
- ▶ Tableting, including bi-layer tabs
- ▶ Tablet coating and printing
- ▶ Fluid bed granulation and Wurster coating
- ▶ DEA schedule II-IV compounds
- ▶ Dry blending
- ▶ Encapsulation and capsule banding
- ▶ Solvent and aqueous coating
- ▶ Controlled and sustained release technologies

Norwich packaging suites are self-contained and include capabilities to finish solid dose formulations. Norwich packaging capabilities include:

- ▶ Solid dose
- ▶ Slat and slatless fillers
- ▶ Bottles and blisters





Clinical Services

Norwich Clinical Services is a global contract research organization

for the pharmaceutical and biotech industries. With a focus on improving outcomes for patients, Norwich partners with you to deliver visionary solutions with the highest level of quality and reliability.

- ▶ Comprehensive clinical services
- ▶ Targeted therapeutic experience
- ▶ Technology-driven capabilities
- ▶ Global research centers in North America, Asia and Europe

Dedicated Norwich program management will guide your research plan from the initial stages of development through study-end reconciliation with specific focus on budget efficiency and schedule adherence.

Norwich offers full-service clinical solutions:

- ▶ Phase I-III clinical trial recruitment and management
- ▶ Late phase services
- ▶ BA/BE studies
- ▶ Pharmacovigilance services
- ▶ Bioanalytical and laboratory services

We deliver what you ask for, when you ask for it.

A reputation for dependable product supply

Product delivery and quality assurance are business critical functions that Norwich performs utilizing Lean Six Sigma principles to ensure maximum operational efficiency. Norwich currently supplies product to customer markets in North America, Europe, Africa and Australia.

Norwich employs SAP as an operating platform to ensure that quality systems provide validation, change control, production support, documentation control and other cGMP services to both the plant and our customers.

Norwich's history of compliance means your patients can trust you

Norwich has a proven record of successfully meeting compliance requirements for regulatory agencies worldwide, including FDA, EMA and ANVISA.

Agency	Date	483's
FDA General GMP Inspections	December 2010	0
	April 2009	0
	July 2008	0
	June 2005	0
FDA PAI Inspections	July 2008	0
	May 2008	0
	June 2005	0
Agency	Date	Major Observations
EMA	June 2008	0
	May 2006	0
ANVISA	April 2009	0
RPDA (Germany)	February 2011	1
Korean FDA	May 2011	0



Focusing on customer care since 1887

SEE THE NORWICH ADVANTAGE AT www.norwichpharma.com

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