NORWICH

ONE Comprehensive Solution

in full-service contract pharmaceutical development and manufacturing

THE Norwich Advantage

Norwich is a recognized leader in full service contract pharmaceutical development and manufacturing. As a single-source provider, Norwich offers customers greater flexibility, resources and speed that result in a streamlined progression from product development to scale-up and commercial manufacturing through clinical services.

Operational Excellence

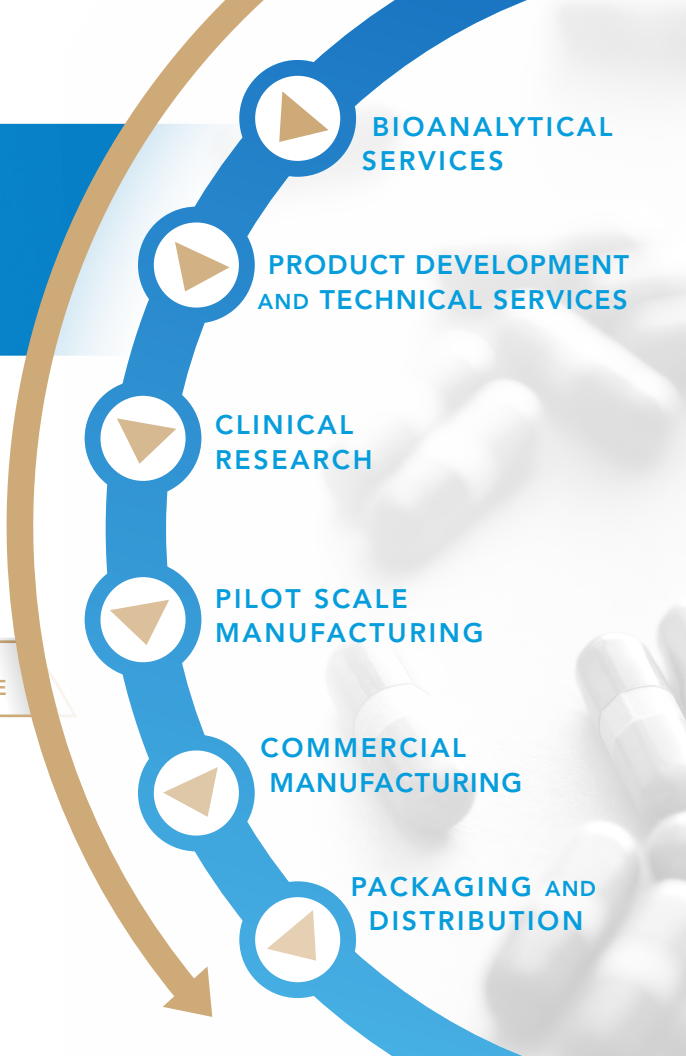
Over its history, Norwich has built a reputation for dependable product supply and established an unparalleled history of regulatory compliance. Using Lean Six Sigma principles, Norwich is constantly improving operational systems and quality controls to create greater flexibility and responsiveness for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

ONE COMPREHENSIVE SOLUTION
FOR ALL STAGES OF THE PRODUCT LIFECYCLE

Product Development and Technical Services
Norwich offers comprehensive product development capabilities to provide customers with R&D, GMP pilot scale manufacturing, analytical development and validation, and testing services.

Commercial Manufacturing and Packaging
A full range of manufacturing and packaging capabilities and resources includes non-potent and potent, tablet and capsule, and solid dose 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.



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 8,000 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 R&D and 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
- Mini-tablets filled into capsules
- Laser drilled tablets
- ODT tablets

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 commerical production capabilities include:

- Potent compounds
- Wet and dry granulation
- Tabletting, 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 contract research organization that combines clinical expertise, therapeutic experience, equipment and processes to manage and overcome challenges with specific focus on cost efficiency and schedule adherence. Norwich Clinical Services offers its customers:

- Pharmacovigilance services supported by a 24x7 call center and Oracle AERS software
- Bioanalytical services utilizing API 4000 LC/MS systems with UPLC
- Medical writing
- Biostatistics
- 72-bed, clinical trial facility with the expertise to conduct pharmacokinetics studies,including bio-availability and bio-equivalence studies, drug metabolism studies, dose proportionality studies and multiple dose studies

Operational Excellence

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 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.

AN UNPARALLELED HISTORY OF COMPLIANCE

Norwich has a proven record of successfully meeting compliance requirements for regulatory agencies worldwide, including FDA, EMA and ANVISA. In fact, FDA has never issued a warning letter to the Norwich facility.

AGENCY	DATE	483s
FDA General GMP Inspections	December 2010	0
	April 2009	0
	July 2008	0
	June 2005	0
FDA PAI Inspections	July 2008	0
	May 2006	0
	June 2005	0

AGENCY	DATE	MAJOR OBSERVATIONS
EMA	June 2008	0
	May 2006	0
ANVISA	April 2009	0

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