DPT & Confab

Discover the Difference℠

DPT®

Confab®

A DPT COMPANY

Who we are

- DPT and Confab are Contract Development and Manufacturing Organizations (CDMO)
- We provide comprehensive pharmaceutical development and manufacturing services
- We specialize in:
  - Semi-solids (Sterile & Non-sterile)
  - Liquids (Sterile & Non-sterile)
  - Solid dose
- We have operations in the USA and Canada.

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Our History

1938 Founded as Texas Pharmacal Company

1966 Acquired by Warner-Lambert

1979 Acquired by Alcon

- Contract manufacturing begins at San Antonio site
- Alcon changes the name to **D**ermatological **P**roducts of **T**exas

1990 Acquired by DFB Pharmaceuticals

2001 Lakewood, NJ site acquired from West Pharmaceutical Services

2006 New, state-of-the-art 40,000 ft^2 Center of Excellence for Research & Development opens

2008 $50+ million facility expansion and enhancement plan begins

2010 DPT launches expanded sterile development and manufacturing capabilities

2012 Acquired by Renaissance Acquisition Holdings

2013 DPT/Confab alignment

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Customers

- Emerging companies with diverse funding & business models
- Global pharma
- Specialty pharma
- Consumer healthcare
- Animal health
- Biotechnology

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Combined Dosage Form Capabilities

Capabilities	DPT San Antonio	DPT Lakewood	Confab Montreal
Development Services	✓	✓	✓
Sterile Manufacturing Services			
Injectables		✓	
Ophthalmics		✓	
Nasal Sprays		✓	
Ointments		✓	
Non-Sterile Manufacturing Services			
Aerosol foams & Sprays	✓		
Rectal/Vaginal applications	✓		
Extrusions	✓		
Tablets			✓
Capsules			✓
Suppositories			✓
Creams	✓		✓
Emulsions	✓		✓
Gels	✓		✓
Lotions	✓		✓
Ointments	✓		✓
Solutions	✓		✓
Suspensions	✓		✓

Advantages

- Broader range of services
- Complimentary manufacturing capabilities
- Expertise in product development, tech transfer & scale up
- Ability to manufacture a wide range of products across multiple dosage forms
- World-wide distribution

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Operations

DPT & Confab operate four locations in the US and Canada

San Antonio, TX

Lakewood, NJ

San Antonio, TX

Montreal, QC

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San Antonio, TX
Research & Development

- End to end pharmaceutical development services
- The expertise of over 50 world-class scientists
- Coordinated activities with engineers and technicians throughout DPT
- 40,000 ft^2 of lab space

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Development Expertise

Formulations	Route of Administration
Aerosols	Nasal
Creams	Ophthalmic
Emulsions	Oral
Extrusions	Parenteral
Gels	Pulmonary
Lotions	Topical
Ointments	Injectable
Solutions	Rectal
Suspensions	Vaginal

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Development Services

- Small molecules, proteins & peptides
- Large molecule
- Pre-formulation & Formulation
- Analytical development and validation
- Process development and validation
- Stability studies: ICH and custom
- Clinical trial material manufacturing
- Testing services for nasal products
- Regulatory submission support
- In vitro release testing (IVRT)
- QbD Services
  - Formulation
  - Process Development
  - Scale-up

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Packaging Services

- Identification & sourcing services
- Specification development
- Dose volume evaluation
- Drug/package compatibility
- Container/closure compatibility
- Commercial scale fill and finish assessment
- Equipment sourcing, design, engineering, qualification and validation

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San Antonio, TX
Semi-solids & Liquids Manufacturing

- Manufacturing solutions for semi-solid & liquid dosage forms
- Clinical & Commercial scale
- ≈ 650 employees
- On-site QC and Micro labs
- 450,000 ft^2 of infrastructure

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cGMP Compounding Capabilities

- Pilot, clinical, and commercial scale
- Batching flexibility from 0.3 kg - 25,000 kg
- Controlled substances Schedule II – V
- XP rated compounding suites
- Lighting options for light-sensitive materials
- Advanced air filtration and handling
- Nitrogen/inert gas blanketing
- Direct to line packaging

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Filling & Finishing Capabilities

- Advanced barrier systems
- Airless pumps
- Aluminum canisters
- Applicators
- Bottles
- Jars
- Laminate tubes
- Metal tubes
- Metered dose pumps
- Large format syringe

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Quality and Regulatory History

Our commitment to quality – ensuring your products meet the highest quality standards

- Over 42* audits completed in 2013
- Weekly audits by:
  - FDA, DEA, & EMA
  - EHS inspections
  - Customers

*Semi-solids & Liquids facility, San Antonio, TX.

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Lakewood, NJ
Sterile & Specialty Product Manufacturing

- Aseptic manufacturing solutions for sterile dosage forms
- ≈ 250 employees
- On-site QC and Micro Labs
- 180,000 ft^2 of infrastructure

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Lakewood, NJ
Sterile & Specialty

- 180,000+ ft^2 of manufacturing, laboratory, and support infrastructure
- 5 Grade A aseptic filling suites
  - SVP MAC
  - Ophthalmic solution
  - Multi-Dose nasal
  - Ointment / Gel
  - Ointment suite
- 4 Grade C filling suites
- 7 classified processing and support suites including XP rated compounding suite
- DEA, Class I-V

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Filling Capabilities

- Micro-dose Vials
- Multi-dose pumps
- Tubes
- Ophthalmic Solutions
- Otic Solutions
- Vials (MAC)

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Laboratory Services

Micro – Analytical – Biotech

- Environmental Monitoring for Classified areas
- Sterility testing using an isolator system
- In-house microbial identification
- Media prep lab with autoclave
- In-house test method validation
- Microbial limit testing (MLT)
- Antimicrobial effectiveness testing (AET)
- Biotech Assays

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SVP Capabilities

- 5,000 ft^2 of newly constructed manufacturing area
  - Consists of Grade D, C & B classified zone
- Modular construction – very flexible and cleanable
- Designed with future expansion in mind

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IMA Washer and Depyrogenation Tunnel

- Vial washer & depyrogenation tunnel in Grade D zone

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IMA Filler

- Grade B- In room
- Grade A- Inside filler enclosure
  (RABS)

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Quality and Regulatory History

Our commitment to quality – ensuring your products meet the highest quality standards

- Over 21* audits completed in 2013
- Weekly audits by:
  - FDA, DEA, & EMA
  - EHS inspections
  - Customers

*Sterile & Specialty Products facility, Lakewood, NJ

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Confab

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Montreal

- 140,000 square feet facility
- 400 highly trained and experienced employees
- 36 manufacturing suites
- 18 packaging suites
- Narcotic license (vault level 10)

Product Categories

- OTC
- Drug identification products
- NDA
- ANDA
- Nutraceuticals
- Veterinary products

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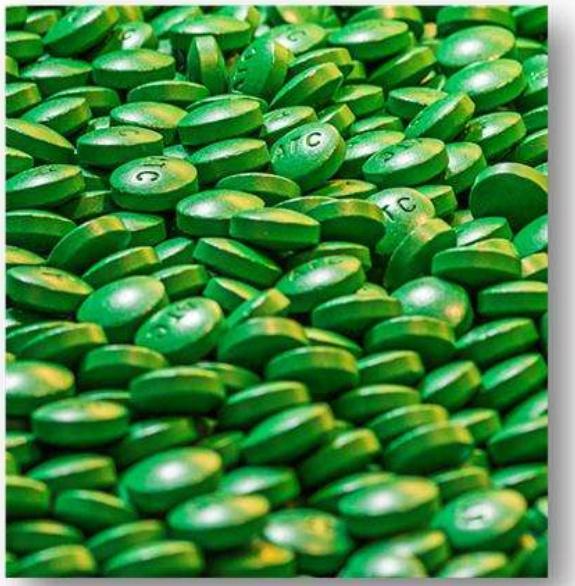
Solid Dose Manufacturing & Packaging

- Powder Mixing
- Standard Granulation
- High Shear Granulation
- Powder Compaction
- Tableting – (regular, double core, double layer)
- Tablet Coating
- Encapsulation –(capsule-into-capsule)
- Tablet Printing
- Blistering



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Liquid Manufacturing & Packaging

- Solutions
- Suspensions
- Pastes
- Creams
- Ointments
- Gels
- Lotions
- Suppositories –aluminum & plastic shell
- Plastic unit-dose
- Metal & plastic tube filling
- Jars
- Bottles

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Development Services

- Formulation
- Re-engineering of manufacturing & packaging
- Technical transfers- manufacturing & packaging

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Compliance

- Health Canada
- FDA
- EMA

Mutual Recognition Agreement - between Canada & 17 countries in Europe. No need for inspection. No need for product retesting

Contact Us

www.dptlabs.com

1-866-225-5378

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