The Right Fit for a Successful Finish

CAPABILITIES OVERVIEW

TEDOR PHARMA

6 FEBRUARY 2020

PRESENTED TO

THE RIGHT SIZE CDMO

Company Overview

- Founded in 2001
- Headquartered in Cumberland RI
- 40,000+ sq. ft. cGMP facility
- FDA Registered and Inspected
- DEA Licensed – Schedules CII through CV

THE RIGHT SIZE CDMO

Experienced Leadership Team

Doug Drysdale

President & CEO

- 28 years of healthcare experience
- Former Chairman & CEO at Pernix Therapeutics
- Founding CEO of Alvogen, Inc.
- Former Head of M&A at Actavis

Terry Novak

Chief Operating Officer

- 30+ years of pharma industry experience
- Former COO at Pernix Therapeutics
- Former President of CDMOs -Norwich, Patheon & DSM

Steve Tannenbaum

Chief Financial Officer

- 30+ years of pharma industry experience
- Former CFO at Copley Pharmaceuticals & Precision Dermatology

Mike Maciocio

Vice President, Operations

- 25+ years pharma industry experience
- Extensive GMP, clinical development, and supply chain experience
- Former R&D and Manufacturing leader with Pfizer and Hoechst Celanese

Dave Vario

Vice President, Quality & Regulatory

- 25+ years pharma industry experience
- Extensive GMP, quality systems, and regulatory experience
- Former QA leader with Immunogen and Bristol-Myers Squibb

Raghav Gupta

Senior Director, Formulation Development

- 21 years of pharma industry experience
- Former Head of R&D/AR&D at Cipla (Invagen)
- Extensive experience in solid dose development & scale-up

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Customer-focused Experience

We work with TEDOR because they're not so big that we get lost in the shuffle, yet they have the breadth of services and expertise we require.

– Mid-size Pharma Client

- 18 years of successful experience in:
  - Formulation development
  - Analytical method development
  - PI-III CTM manufacturing and scale-up
  - Immediate, modified and extended release oral solid dose products
- Proven project and account management systems to ensure efficient completion of every project and security of supply
- Focused on high standards of quality, compliance and customer service to ensure project success

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Proven Results for Our Customers

- 17 FDA product approvals
  - *6 product launches in a single year*
- PAI approval – January 2019
- Successful regulatory inspections
  - *FDA (January 2019 – PAI & General)*
  - *DEA (November 2019)*
- *5 successful customer audits in 2019*

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Core Competencies

- Formulation development
- Dry blends
- Wet granulation
- Pellet-based formulations
- Controlled substances
- Immediate, modified & extended release formulations
- Analytical method development & validation
- Complete stability offerings
- eCTD regulatory filing

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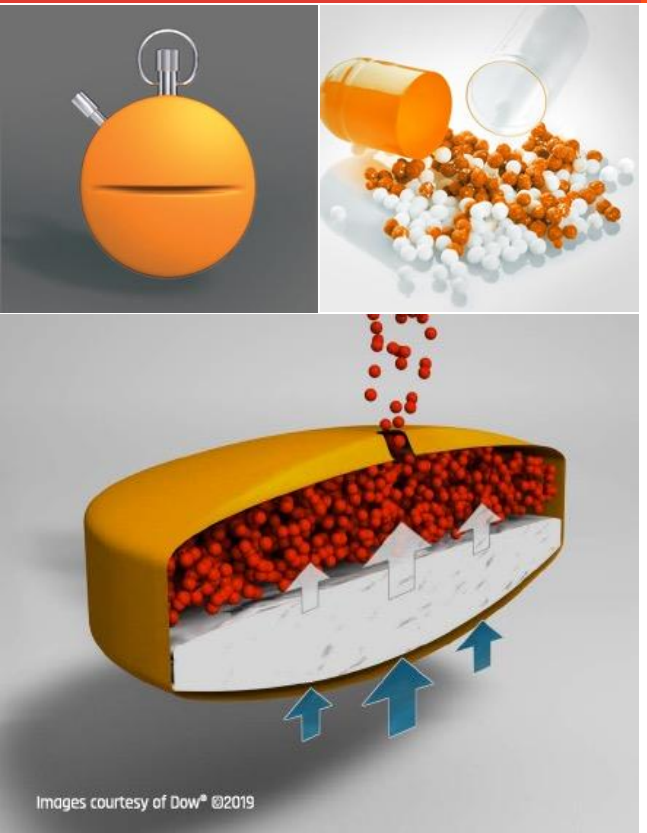
Specialized Experience



- Extensive DEA-scheduled products CII-CV
- Formulation development with poorly soluble or highly variable APIs
- Ensuring content uniformity of multi-API products
- Pelletized products
  - High drug loading
  - Sustained and/or delayed release coatings
  - Controlled substances
  - Pellets in a capsule or pellets compressed into a tablet
- Abuse deterrent products using polyoxide excipients
- Life cycle management IP
  - FLEXITAB™ breakable extended release technology

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Life Cycle Management IP

Flexible and precise dosing from a single extended release tablet

FLEXITAB™
Extended Release Technology

- An innovative and commercially validated technology
- Provides products with extended release tablets that can be taken intact or broken without a loss in performance
- Increases the quality of life for patients while ensuring dosage compliance.
- Opportunity to extend product life cycle through 505(b)(2) regulatory pathway

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FLEXITAB™ Unique Features

Employing patented novel, cost-effective technology to generate easily breakable, controlled release tablets

- Breakable controlled release tablets
  - Maintain their drug release profile when broken
  - Will not dose dump when exposed to alcohol, even after prolonged exposure
- Employs simple and proven proprietary ingredients
- Patents granted in US, Canada, UK, Spain & Germany through 2036
  - Pending in France, Spain & Italy
- Commercially validated in the US, Canada and Europe
- 3 products approved ands marketed in 25 countries
- Manufactured with conventional equipment

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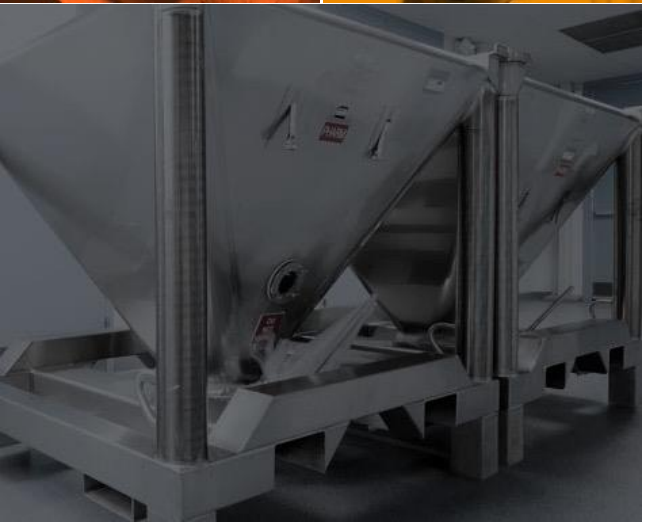
14 Production-ready CGMP Suites



- Dedicated Suite for Fluid Bed Coating, Drying, & Granulation
- Four (4) Dedicated Solid-Dose Blending Suites
- Nine (9) Modular Suites provide Flexibility, Setup, Clean-up and Transition (rapid turnaround)
- Two (2) Hopper Rooms with Gravity Fed Connection to Compression or Encapsulation Machines
- Vacuum Tray Drying Oven Room with Granulation Capacity (220 kg)
- Ability to Process Solvent and Aqueous Based Granulations
- Aqueous coating using 48” Acela Coater

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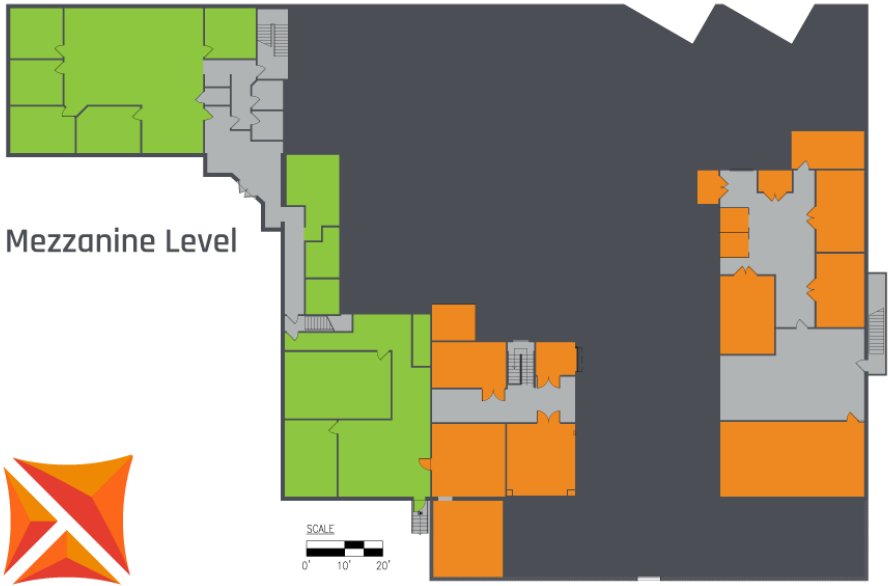
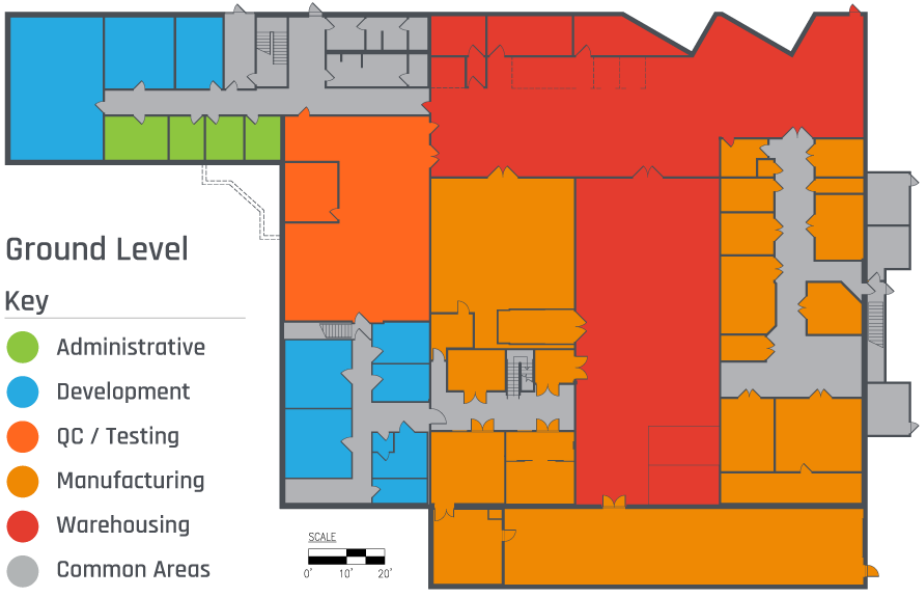
Site Footprint





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Annual Tablet & Capsule Capacity

Tableting/Compression Capacity*

JCMCO	130 million
Hercules	240 million
Libra	290 million
Gemini	1.8 billion
Total Capacity	**2.5 billion**

Encapsulation Capacity*

GKF 330	60 million
GKF 400	80 million
GKF 2500	400 million
Macular	80 million
Total Capacity	**620 million**

At TEDOR, we have the capacity to handle any project from early-stage clinical trials through scale up and into final commercialization

– Doug Drysdale, President & CEO

* Based on running two 8-hour shifts per day

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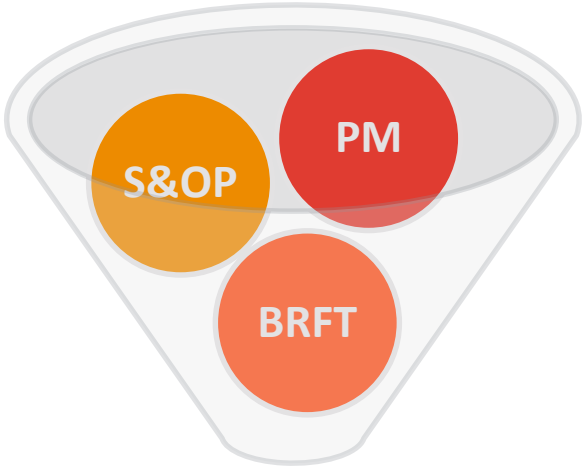
Milestone-Based Project & Account Management

Project Management

- *Assessment*
- *Planning*
- *Execution*
- *Launch*

Account Management



On-Time Delivery

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Why TEDOR is the Right Fit For You

- History of successfully executing oral solid dose development, clinical trial and commercial products
- Track record of FDA approvals & solving complex formulation and development challenges
- Patented technology for Life Cycle Management
- High standards of quality, compliance and customer service to ensure security of supply

Small enough to care.
Experienced enough to deliver.

TEDOR THE RIGHT SIZE CDMO

THE RIGHT SIZE CDMO

Contact Information

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Case Studies

SOLVING ORAL SOLID DOSE CHALLENGES

CASE STUDY

Solving A Difficult Tablet Formulation That Combined Multiple APIs

THE CHALLENGE

Develop a tablet formulation that combines three separate APIs with wide differences in strength, one of which has sticky properties.

THE SOLUTION

- Daily hands-on communication with the client
- Experiments to determine:
  - *Correct level of excipients needed*
  - *Excipients whose particle size married well to APIs*
- A multi-step staged geometric mixing of APIs and excipients
- Sticky API was wet granulated, dried, and milled.

THE OUTCOME

The manufacturing process TEDOR developed consistently produced uniform results. The product was approved and commercialized, and is currently in production at TEDOR.

CASE STUDY

Devising An Extended Release Dosage Form Using A Ribbon Blender

THE CHALLENGE

Carry out the tech transfer of an extended release product from a Big Pharma client, which required a bioequivalence study. The product failed the bioequivalence study when initially manufactured with a ribbon blender.

THE SOLUTION

- Inspection of every manufacturing step to eliminate potential causes.
- The amount of isopropyl alcohol (IPA) in the formula needed to be reduced for ribbon blending
- Avoided change in formula thus avoiding fed Bio-study and prevented delay in FDA approval

THE OUTCOME

After reformulation, the product successfully passed the bioequivalence study and was approved by the FDA.

It will be commercialized in the first quarter of 2019.

CASE STUDY

Successful Encapsulation Involving A Combination Of Three APIs

THE CHALLENGE

Develop a Schedule 3 controlled substance using three APIs with wide differences in strength. One API was in short supply at the vendor.

THE SOLUTION

- TEDOR facilities are fully equipped for Schedule 3 controlled substances
- Careful management of excipient selection, amount, grade, and mixing
- Experiments helped determine ideal screen size for APIs
- A multi-step geometric mixing process
- An additional API supplier was qualified and its batches validated

THE OUTCOME

TEDOR was successful in producing a consistently uniform product. The product was approved and commercialized in 2014. TEDOR has scaled up production from 110,000 to 900,000 capsules.

CASE STUDY

Successfully Formulating A Poorly Soluble And Highly Variable API

THE CHALLENGE

Formulate a highly complicated tablet product with a poorly soluble API that has highly variable bioavailability. An initial formulation with a matching dissolution profile, failed its pilot biostudy.

THE SOLUTION

- Initially attempted to find suitable dissolution medium.
- The product is pH-dependent water soluble, limiting media sources available
- Used the physical behavior of the formulation to our advantage
- Reformulation utilized a lubricant-based wet granulation method
- Used to slow down the tablet's disintegration time
- Matched the DT/physical behavior and achieve compliance of dissolution to USP

THE OUTCOME

Reformulation was successful in slowing down the initial burst of the tablet and its disintegration time. The product passed its second biostudy and six months stability test. The product will be filed by our customer in the first quarter of 2019.