UPM

# Get To Market
# Get Ahead

## SOLID DOSE & SEMI-SOLIDS

- Tablets
- Capsules
- Creams
- Ointments

UPM Pharmaceutical's mission is to advance Client formulation development efforts to the fullest extent possible with the ultimate goal of commercialization, all while adhering to strict standards of quality, timeliness, scientific fundamentals, and affordability.


# UPM Pharmaceuticals (CDMO)

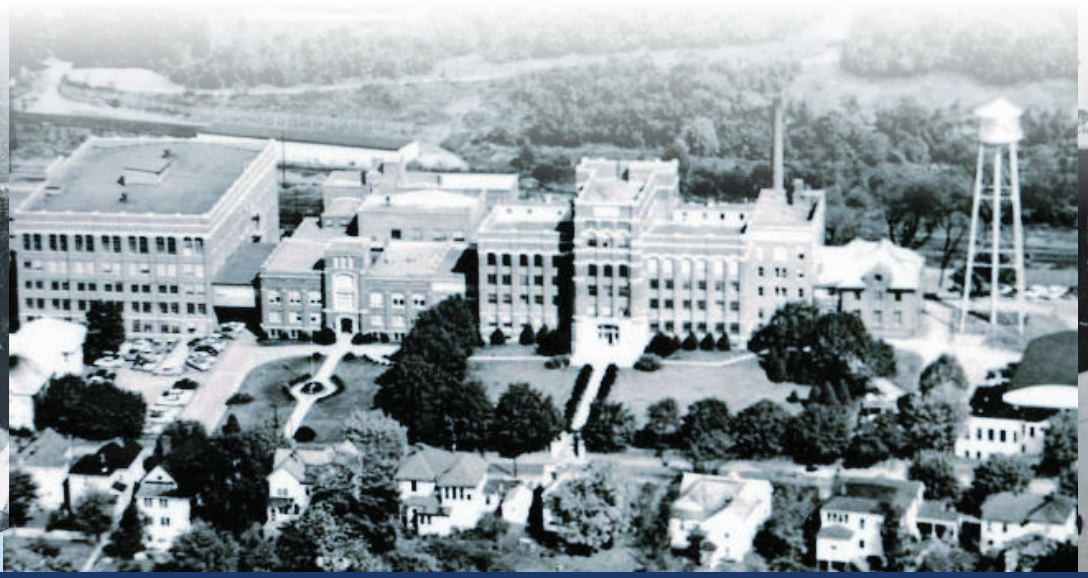
## LARGE & SMALL SCALE OPERATIONS WELCOME

**Supporting You At Every Stage.** As an experienced commercial partner, UPM has time-tested procedures in place to optimize production processes wherever you are in your journey. With this strong infrastructure, we can quickly devise the most efficient method to commercialize your product, quickly adjusting as necessary and making collaborative decisions that are truly in the best interest of your product and overall commercial strategy.


# Award Winning Site

## FDA APPROVED MANUFACTURING FACILITY

UPM Pharmaceuticals is an independent, highly experienced contract development and manufacturing organization (CDMO) located in Bristol, Tennessee. Characterized by its strict sense of quality, timeliness, sound scientific fundamentals, and affordability with which we complete our projects. Our history includes successful collaborative interaction with small virtual companies to multi-billion dollar organizations, providing them with customized product development services and well thought out scientific solutions.



# Local Heritage

## OVER A CENTURY OF MANUFACTURING HISTORY

The Bristol, TN facilities that UPM Pharmaceuticals currently occupies has over a century of continuous pharmaceutical operation. We continue this legacy of intellectual distinction and uncompromising performance with every new project. The talent and experience of our team, our dedication to science-based formulation design and our commitment to communication and timeliness have enabled us to offer the highest level of customized drug development services to our clients, from concept through commercialization.

**1899** — *King College*

**1917** — *S.E. Massengil Company*

**1971** — *Beecham Laboritories*

**1993** — *King Pharmaceuticals*

**2011** — *Pfizer Pharmaceuticals*

UPM

*UPM Pharmaceuticals, Inc*

**est. 2013**

# Financial & Organizational Overview

**BIG PHARMA SUPPLIER. AGILE CDMO PARTNER.**

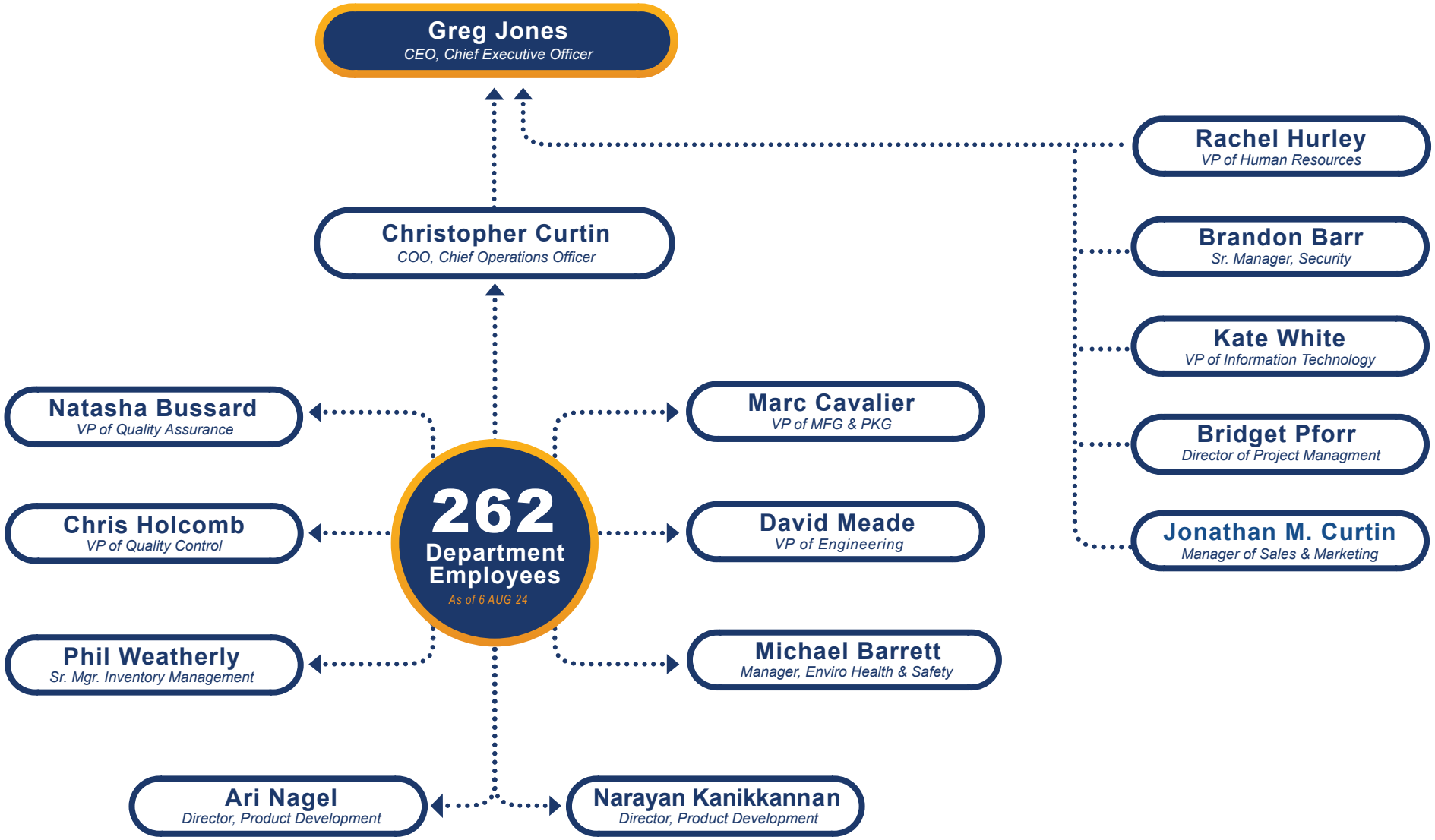
**As a privately owned company, UPM Pharmaceuticals is an independent, highly experienced contract development and manufacturing organization. Autonomously able to make investment and risk sharing decisions focused entirely on the best course of action for our relationship with clients and their projects success.**

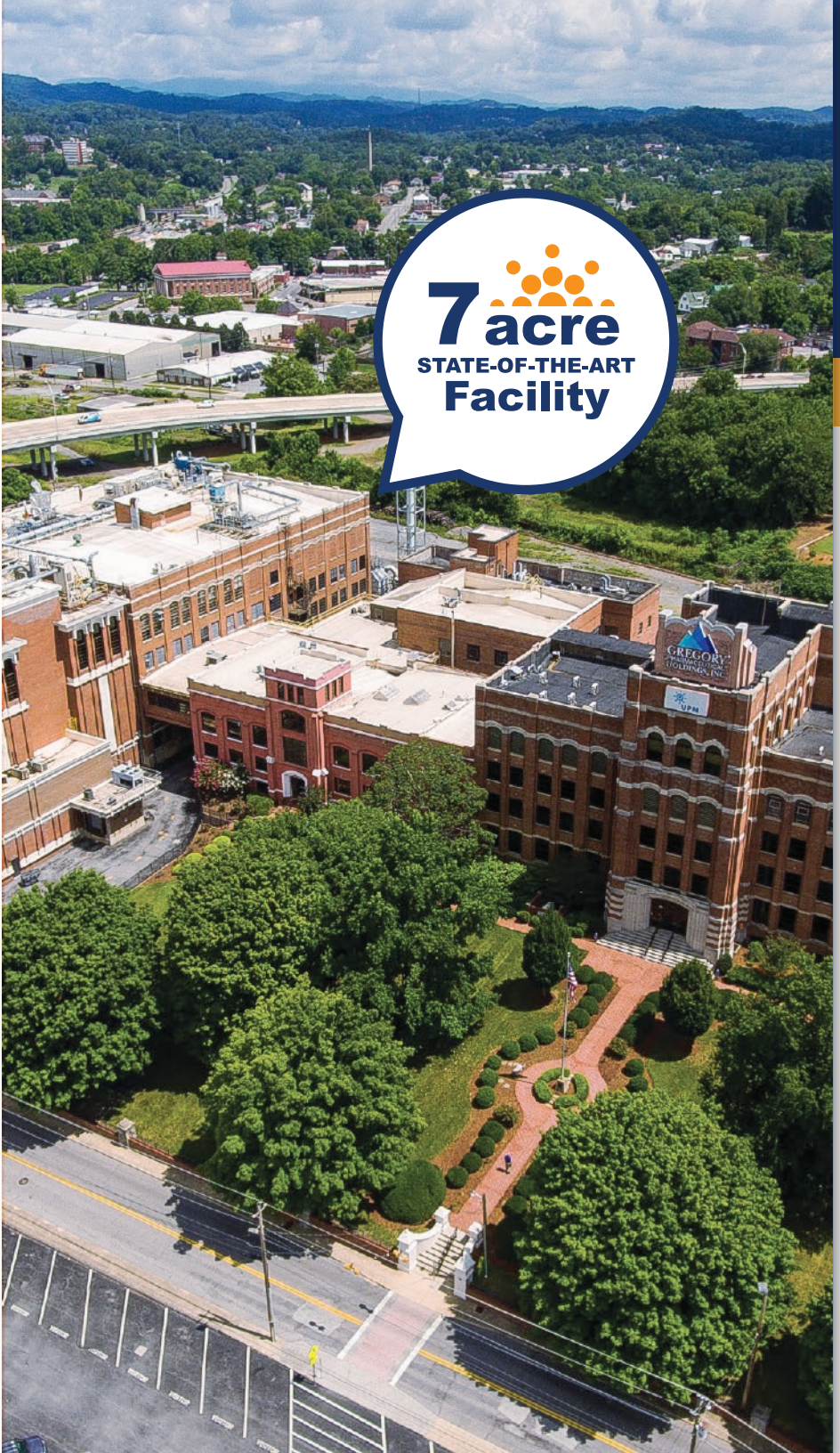
UPM has supported more than 80 projects from concept to market, but it's crossing the commercial finish line with our customers where we really excel—and where our greatest passion lies. Whether you're looking to formulate a complex compound or simply in need of a solid commercial manufacturing partner, UPM has the same unwavering objective: to get you to market.

## Competitive Landscape

- UPM does not own any proprietary technology
- Family owned and completely financially independent & stable
- Quicker decisions, better use of resources & timeline adherence
- We are Fee-For-Service, No Partnerships or conflicts with owned products.
- Capital Investment Opportunities: We are always open to discussions on equipment purchases & facility modifications if the project is substantial and both parties agree to investment.

# Corporate Flow Chart






# Manufacturing & Packaging Facility

## COMMERCIAL MANUFACTURING SITE

UPM conducts large-scale commercial manufacturing and packaging of semi-solid creams and ointments as well as oral solid dose drug product. Offering flexibility and designed to provide full tech transfer and scale-up support, the facility has an extensive track record of optimizing processes to achieve commercial success.

In addition to our production capacity, the site is also equipped to handle analytical, microbial and stability testing, with a full-service, analytical laboratory to support every facet through every phase of development.

## 475,000+ Sq ft Facility

- *240,000 Sq ft for Manufacturing*
- *160,000 Sq ft for Administrative Offices*
- *35,000 Sq ft for Raw Material and API*
- *3,200 Sq ft of DEA Approved Vault Space*
- *37,000 Sq ft for Packaging*
- *2,000 Sq ft for Label Storage*

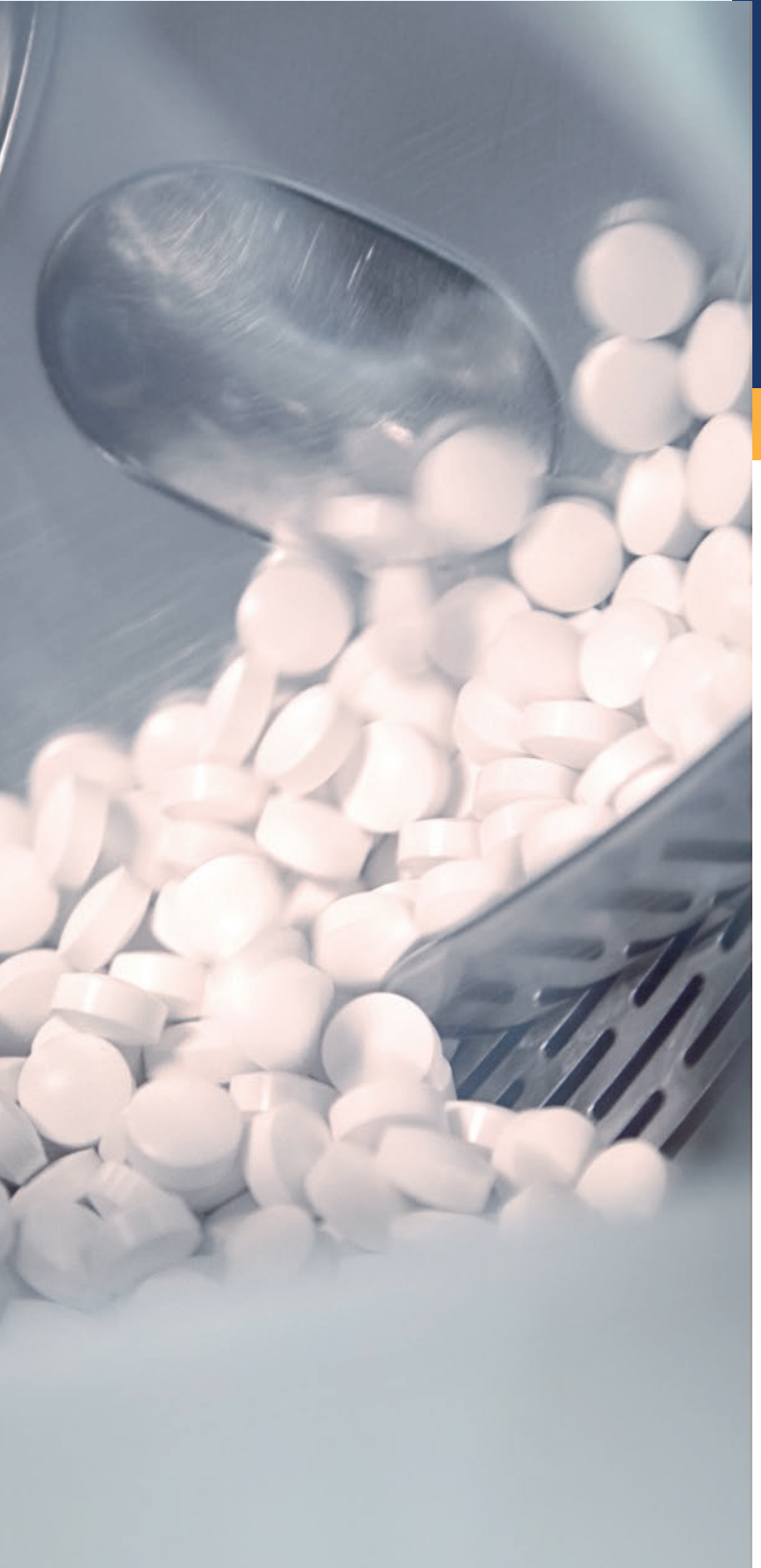

# Warehouse & DEA Approved Vault

## COMMERCIAL WAREHOUSE SITE

UPM also has 300,000 square feet of dedicated warehousing space. Our electronic inventory system is fully validated. All areas are temperature controlled, mapped, and are under constant surveillance by the automated electronic building system.

## 300,000 Sq ft Warehouse

- *250,000 Sq ft general warehouse*
- *Generators for critical systems*
- *20,100 Sq ft of office space*
- *8,300 Sq ft of Secured Storage Space*
- *8,600 Sq ft of Label Storage*
- *7 Loading Docks*



# Commercial Production Capabilities

## 1-SHIFT ANNUAL CAPACITIES

Producing over a billion doses annually of semi-solid creams and ointments, as well as, oral solid tablets and capsules. UPM serves as a Second-Source Supplier for several name brand, generic, nutraceutical and cosmetic products on the shelf and in the current market today.

### Creams/Ointments

- 1.3M Kg units *(annually)*

### Tablets

- 4.5B units *(annually)*

### Capsules

- 700M units *(annually)*

### Packaging Bottles

- 43M Bottles *(annually)*

### Packaging Tubes

- 2.5M Tubes *(annually)*

### Packaging Jars

- 4M Jars *(annually)*

# Pharmaceutical Technology

**WE CAN TAKE IT FROM HERE**

UPM has a strong legacy of successfully scaling up to commercialization, maintaining product quality and homogeneity from lab-scale to commercial quantities. We understand you are the greatest source of knowledge when it comes to your project's history as well as your long-term goals. Our multidisciplinary tech transfer team—comprising experts in R&D, manufacturing, engineering, quality and regulatory affairs—will work with you and your teams to understand your project from every aspect, with full transparency into all future activities and open access to all project stakeholders.

## Pharmaceutical Technology Mission

*Provide timely, integrated product development and manufacturing support leading to reliable & cost efficient, high quality commercial supply.*

# PharmTech Management

UPM's integrated PharmTech services insures that resources are closely involved and immediately available throughout the formulation, process development, and tech transfer processes. Whether for trouble-shooting, scale-up, or validation, this integration provides time and cost efficiency for you.

- **Formulation:** *Process Development for Tablets, Capsules, Semisolids & Ointments*
- **Manufacture of Clinical Supplies:** *Registration Batches for NDA's & ANDA's*
- **Technology Transfer:** *Scale-up to Commercial Scale Manufacturing*
- **Process Validation**
- **Trouble-Shooting, Investigations, Manufacturing & QA Support**
- **Technical Writing:** *Batch Records, Protocols & Reports*

# PharmTech Capabilities

UPM has a strong legacy of successfully scaling up to commercialization, maintaining product quality and homogeneity from lab-scale to commercial quantities. Scale-up and tech transfer in the pharmaceutical industry are intricate processes that require cross-functional collaboration and transparent communication to mitigate risks and avoid interruption to a project's progress. In a CDMO partnership, the expertise of the CDMO should mirror that of the client's organization to ensure a clear, mutual understanding of all development, manufacturing, quality and regulatory considerations.

- **Tech Transfer From Bench Scale To Pilot Scale To Commercial Scale Manufacturing**
- **Site Transfer Of Existing Development Or Commercial Products And Processes**
- **Development & Implementation of Analytical & Manufacturing Processes**
- **Process Development, For All Tablet And Capsule Unit Operations**
- **Project Management & Scale-Up Support & Risk Gap Analysis**

# Formulating Your Future

**ORAL-SOLID, SEMI-SOLID , POTENT & HORMONE PRODUCT**

## Development Scale Equipment

- **GEA PMA-1, SeJong SM-50L** High Shear Granulator
- **Mini-Glatt, Glatt GPCG-2** Fluid Bed Processor, **GPCG-30/60**
- **Alexanderwerk WP 120** Roller Compactor, **RFG 150** *Granulator*
- **Vector TFC-LAB** Micro Roller Compactor
- **Schaefer Lab-Cap** Encapsulator
- **Sty'l One** Multi-Layer Tablet Press
- **Korsch XL-100** Tablet Press
- **O-Hara** Pan Coater (15" to 30") & **Vector Freund LDCS** Pan Coater
- **V-Blenders,** 0.5-16 qt., 1-10 cu.ft.
- **Fitzmill & Comil** - Multiple Sizes
- **Ekato LM6, Ekato SRT-80** - Semisolid Processors

# Quality Control

## SUPPORTING YOU AT EVERY STAGE

Across all development stages, we approach every project with a commercial mindset. Analytical development is no exception. Working with you to gain a deep understanding of your project goals and challenges, we design detailed protocols for method development, validation and technology transfer based on your product profile and development phase.

### Quality Control Mission

*Provide a full range of analytical testing services for raw materials and drug products. Design detailed protocols for method development, validation and technology transfer based on the products phase in the drug development process.*

# QC Laboratory

UPM's Analytical Services Group has deep expertise in analytical method development and a complete understanding of all facets for the analytical testing of pharmaceutical drug products. UPM offers a full risk assessment report as required by ***ICH Q3D guidelines***. We usually complete the risk assessment report and then perform testing based on the client's decision.

## cGMP Labs

► **34,500 sq ft of cGMP Laboratory Space**

► **5 Subgroups**

- *Analytical Development*
- *Raw Materials*
- *Microbiology*
- *Drug Product*
- *QC Metrology*

## Focus

- Analytical Method Development
- Method Verifications & Validatons
- API & Excipient Release
- Full Micro Testing
- Drug Product Release

# Laboratory Capabilities

UPM'S LAB offers elemental impurity analysis services according to ***USP <232>/<233>*** and ***ICH Q3D*** which are ***Good Manufacturing Practice (GMP) compliant*** to support your elemental impurity risk assessment and GMP batch release testing. We have designed a calculated approach including options for semi-quantitative screening to support risk assessments, and fully-quantitative method development and validation along with routine analysis when appropriate.

## Analytical Methods

- Raw Materials & Excipients
- Drug Substances
- Drug Products
- Forced Degradation Including Photo Stability
- Full Stability Indicating

## Full Characterization & Identification

- Raw Materials & APIs
- Drug Substances
- Intermediates
- In-Process Lots
- Finished DP Stability
- Finished DP Release

## Dissolution Testing

*(Apparatus I, II & III)*

- Specialize in Immediate, Delayed & ER Testing
- Fully Compliant with ICH & USP Guidance
- Auto-Sampler Capability For Full Profile Studies
- In-Process & Release Testing

# Quality Control Overview

## STATE-OF-THE-ART INSTRUMENTATION

### CHROMATOGRAPHY

**EMPOWER 3 DATA ACQUISTION & INSTRUMENT CONTROL SOFTWARE**

- HPLC with Dual Wavelength & PDA Detectors (44)
- UPLC with Dual Wavelength & PDA Detectors (4)
- GC (4 Capable of Headspace Analysis) (5)

### DISSOLUTION BATHS (23)

- Appartatus I & II (21), Appartatus III (2)

### ICP MASS SPECTROMETRY

- Triple-Quadrupole, Universal Cell Inductively Coupled Plasma – Mass Spectrometry (ICP-MS) & Microwave Digestion Technologies

### UV SPECTROPHOTOMETERS (4)

### TOC ANALYZERS (3)

### PARTICLE SIZE ANALYZERS (3)

### FT-IR (2)

### RELIABLE, BRAND NAME EQUIPMENT IN HOUSE:

micromeritics Malvern Panalytical Agilent Waters DiSTEK SHIMADZU varian PerkinElmer

# Manufacturing

**BIG PHARMA SUPPLIER. AGILE CDMO PARTNER.**

Whether your product is oral-solid or semi-solid dose, establishing the appropriate analytical framework and formulation design is vital to ensuring optimal production at clinical and commercial scale. UPM's manufacturing experts have advanced several complex compounds from concept to commercialization, applying multidisciplinary expertise to develop the best processing conditions and formulation solutions for each unique product.

## Manufacturing Mission

*Proactively guide our commercial and clinical partners as their product(s) progress through its lifecycle by working together with forecasting, planning, preparing launch, launch & support of line extensions or new markets gained.*

# Manufacturing Processes

As an experienced commercial partner, UPM has time-tested procedures in place to optimize production processes wherever you are in your journey. With this strong infrastructure, we can quickly devise the most efficient method to commercialize your product, quickly adjusting as necessary and making collaborative decisions that are truly in the best interest of your product and overall commercial strategy.

## Mill/Sift

- Fitzmill (2)
- Trost Mill
- Stokes Mill (2)
- Quadro Comil (3)
- Sweco Sifter (2)

## Granulate

- High Shear Wet Granulator 10,120, 150 & 800L
- Littleford Day Mixer- 600L
- Glatt GPCG 30/60
- ACG FBE 300/500
- Fitzpatrick IR520 Dry Granulator, M5A Mill

## Dry

- Lydon Tray Dryer (5)
- ACG 350/500
- Cascade Tek TFO-3

## Blend

- Bin Blenders 128, 320, 800 & 2100L
- V-Blenders 0.5qt - 40 cubic ft
- Ribbon Blenders 120 &150kg

## Compression

- Fette Press (6) (4 single, 2 Dual)
- Stokes Press (3)
- Manesty Press (2)

## Coating

- O'Hara 15", 19", 24" & 30"
- Accela Cota Coater 48"(2)
- O'Hara Coater 60" (2)

## Encapsulate

- MG2/140
- MG Suprema (2)
- MG Planeta
- Capsule Polisher
- Weight Sorter

## Package

- Solid Dose Bottle Lines (3)
- Lakso 990 Slat Filler
- Bellatrix Vibratory

## SEMI-SOLID

## Mixers

- Ekato LM6 Mixer
- Ekato SRT-80 Mixer

## Mixing Tanks

- Portable Tank: 150 & 175 gal.
- Stationary Tank: 300, 500, 600, 2000 gal.

## Package

- Tubes Kalix Filler
- Jars Accuro Filler

# Packaging Line Equipment

**50-100 BOTTLES PER MIN ON AVERAGE**

## Solid Dosage Packaging Lines (3)

**Line 1 -** Lakso 990 Slat Filler Capable Of Packaging Solid Dose Capsules And Tablets, With Isolated Fill Room For Oxygen Sensitive Product And Nitrogen Flushing Abilities. Capable Of Serialized Aggregation.

**Line 2 -** Lakso 990 Slat Filler Capable Of Packaging Solid Dose Capsules And Tablets. Capable Of Serialized Aggregation.

**Line 3 -** Clinical Trial- Bellatrx Vibratory Filler Used For Packaging Small Scale Batches.

- **Print & Apply Labeler**
- **Banner Vision System**
- **UV Vision System**
- **Accraply Labeler**
- **Omega Desiccant Feeder**
- **MSG Outserter**
- **Omega Shrink Bundler**
- **Omega Unscrambler**
- **Lakso Slat Filler**
- **Kaps - All Capper**
- **Kaps - All Tightener**
- **Induction Sealer**
- **Cottoner**


# Quality Assurance

**EVERY RECORD, 24/7 DIGITAL ACCESS**

UPM's Quality Assurance team is dedicated to ensuring that only the highest quality products are manufactured. To accomplish this, quality assurance personnel are fully engaged in the process from start to finish.

## Quality Re-Assured

*QA personnel inspect and release raw materials, rooms and equipment prior to production as well as monitor the manufacturing process, perform in process inspections and review all documentation prior to completing material and batch dispositions.*

# Quality Assurance Services

The Quality Assurance team provides product support such as performing annual product reviews and post marketing surveillance. As part of becoming a UPM customer, UPM's document control group ensures that all documents related to your product are readily available 24 hours a day. Each customer is provided access to a customized internal website that houses all master and executed batch records, analytical data, stability reports, technical reports and so on.

## QA Compliance & Systems

- Documentum Administration
- SOP Control
- Data Archive
- BR Issuance
- E-Room Control
- Label Issuance
- Change Control
- Audits, Metrics, APR's
- Stability Chamber Control
- Trackwise Administration
- Complaints
- Vendor Qualifications
- QC Investigation Approvals

**29 Stability Chambers**

- 2,245 sq ft in Total
- 600 sq ft Controlled
- 1,645 sq ft Non-Con

## Manufacturing Support

- MQA Product Support
- Real-time Floor Presence
- Room Release
- Equipment Release
- In Process Inspections
- Acceptable Quality Level Inspections
- Raw Material Release / Sampling
- Component Release / Sampling
- Investigation Approvals
- Batch Record Approvals
- Protocol Review / Approval
- Product Development Support / Approval
- Serialization
- Aggregation
- Development
- Stability
- Raw Material
- Finished Product

## QA Technical Operations

- Site Investigations
- Compendial Review
- CAPA's

## Validations

- Equipment Validation
- Utilities Validation
- Cleaning Validation

# Certified Excellence

As your Partner in Quality & Compliance, the QA Department hosts 20+ Client Audits annually & performs internal audits in each of the six pharmaceutical systems.

## Drug Enforcement Agency

Cyclical Inspections: 2013-2024

- *No Notice Of Violations*
- *No Cause For Investigations*
- *Obtained Quota Routinely For Controlled Drug Substances*

## Food and Drug Administration

Cyclical Inspections: 2015,2016 & 2019

Last Inspection : April 2019

- *cGMP Inspection*
- *VAI Inspection Classification*

# FDA Quality Metrics Site Visit Program

The FDA Quality Metrics Site Visit Program was designed to provide FDA staff the opportunity to visit with drugmakers to “observe how quality metric data are gathered, collected and reported to management.”

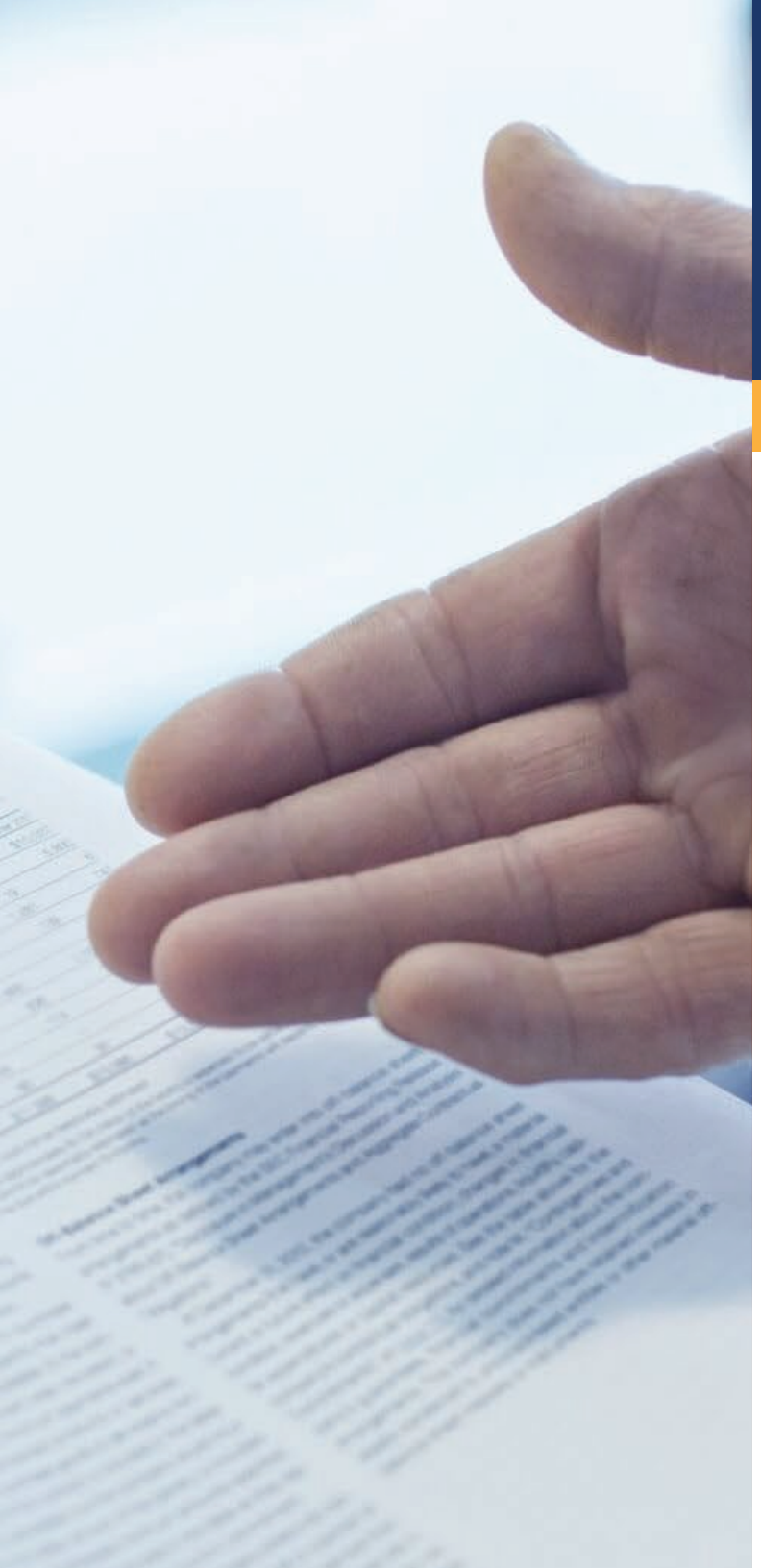
**UPM submitted a proposal to participate in the FDA Quality Metrics Site Visit Program for CDER & CBER. On May 17th, 2019, UPM was chosen to participate as a “CDMO Industry Representative,” for the purpose of hosting a six member FDA Panel to the UPM Pharmaceuticals Metrics Program.**

# FDA Quality Management Maturity Program

- UPM participated in the FDA Quality Management Maturity Program (QMM) in July 2021 along with 8 other companies.

- The FDA Quality Management Maturity Program is designed to gain insight from third-party assessments of a manufacturer's quality management system to inform future development of an FDA rating system to characterize quality management maturity.

- Rating system would allow a cross-sectional comparison of manufacturers and enable health systems, purchasers, etc. to differentiate drug manufacturers.



# Project Management Process

**EVERY PROJECT IS DIFFERENT, WE ARE FLEXIBLE.**

1. **Kick-off Meeting**
   - *Introductions, Meeting Frequency Established, eRoom Intro, Solubility Memo, Chemical Assessment*
   - *Project Overview By Client*
   - *Review Contract*
   - *Key Milestones*
   - *Project Plan*
2. **Order Materials**
3. **Align Activities**
   - *Analytical Development / Formulation / Process Development*
4. **Obtain Schedules**
5. **Meeting Agendas Issued** *Prior To Meeting w/ Team Members*
   - *Action Items, Current Status, Target Dates*
6. **Required Attendance For Team Leads**
   - *Pharm Tech, Mfg, Analytical Development, QC, QA*
7. **Meeting Notes Issued Post-Meeting**
   - *Completed Items, Decisions, Actions & Assignments*