



# 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

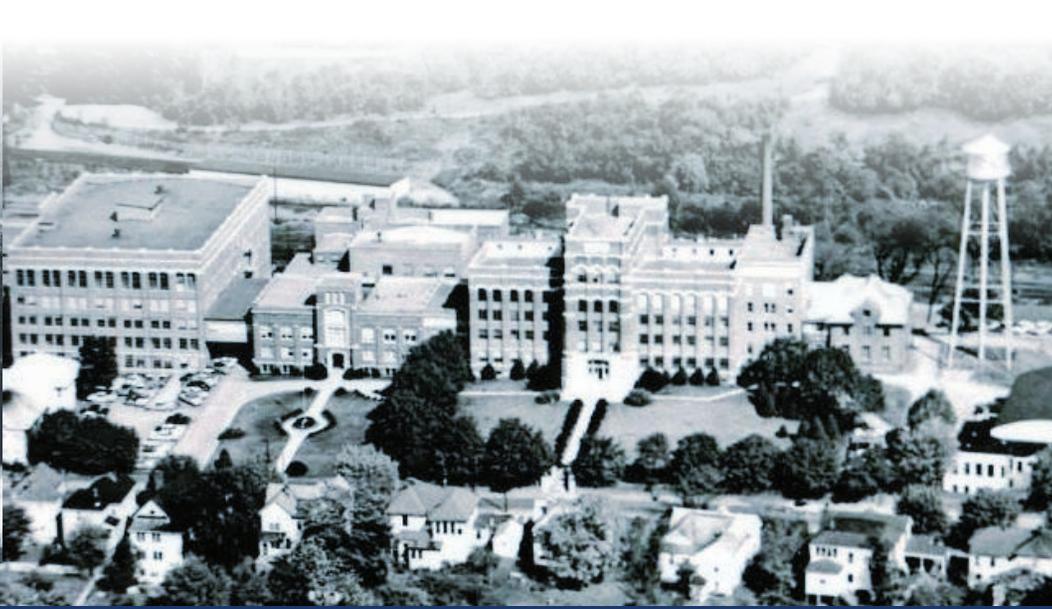
**Supporting You At Every Stage.** As an experienced commercial partner, UPM has time-tested procedures in place to optimize production processes wherever you are in your journey. With this strong infrastructure, we can quickly devise the most efficient method to commercialize your product, quickly adjusting 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.





# 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.**

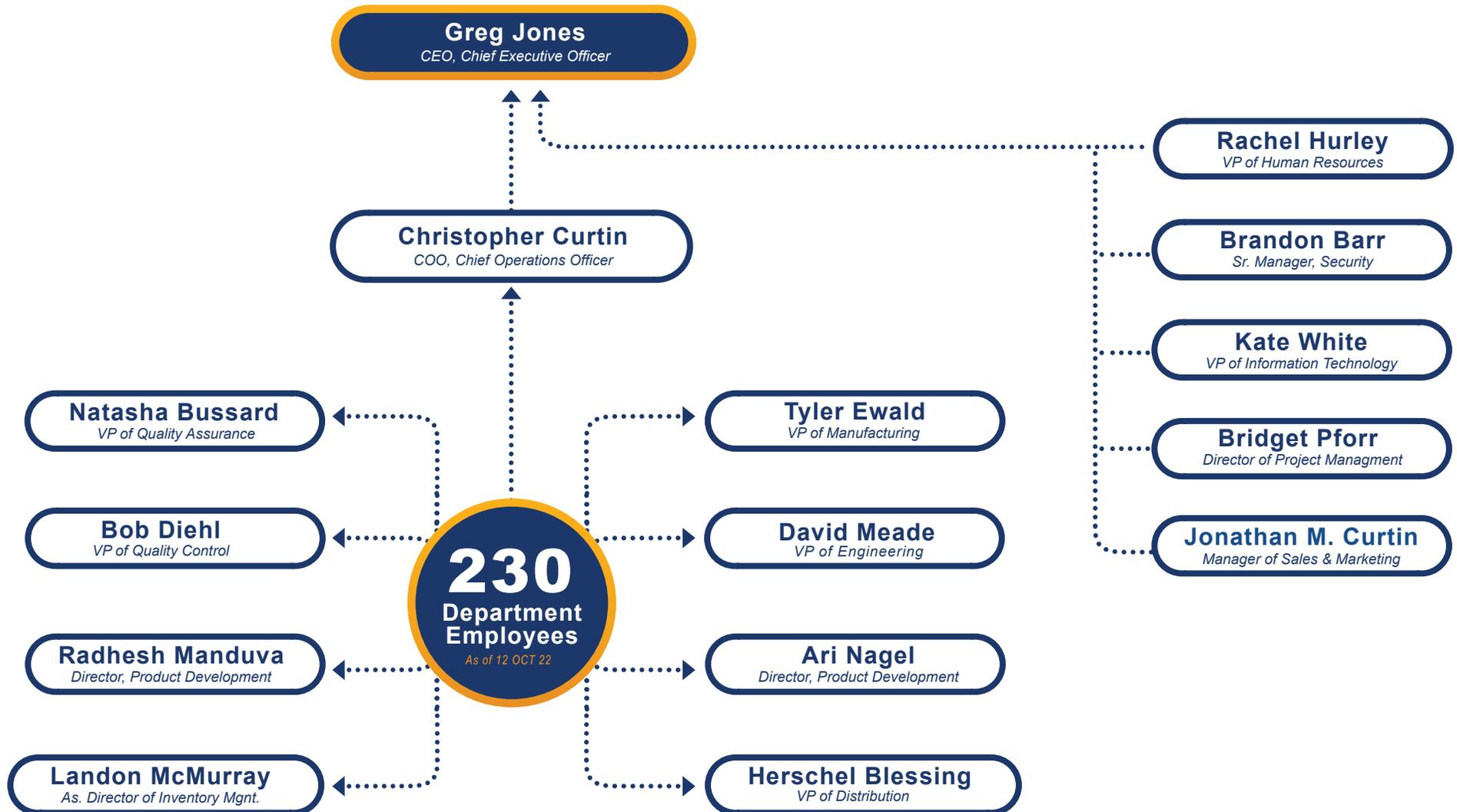
UPM has supported more than 80 projects from concept to market, but it's crossing the commercial finish line with our customers where we really excel—and where our greatest passion lies. Whether you're looking to formulate a complex compound or simply in need of a solid commercial manufacturing partner,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

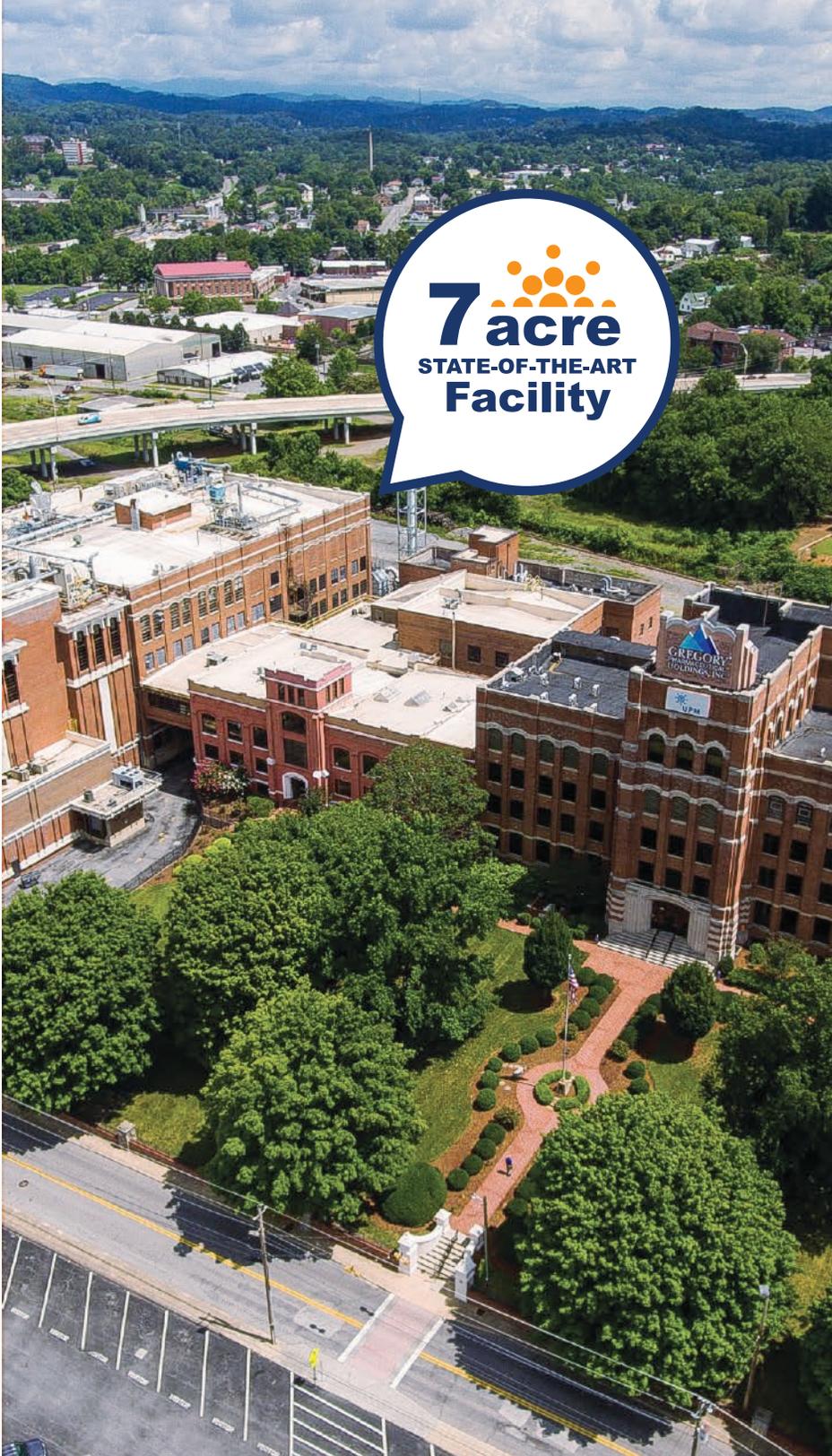
## **Competitive Landscape**

- 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*
- *4,200 Sq ft of cold room storage*
- *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 & Cleaning 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**
- **Vector TFC-LAB Micro Roller Compactor**
- **ACG-AFT-LAB Encapsulation & 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 Project Management

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 risk assessment and the client's decision.

## cGMP Labs

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

▶ **5 Subgroups**

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

## Experience

- Experienced Chemists & Biologists (39)
- 10+ Yrs Experience (25)
- Graduate Degrees (7)
- Some Up To 30 Yrs Experience in Analytical Development.

## Focus

- Analytical Method Development
- Method Verifications & Validations
- API & Excipient Release
- Full Micro Testing
- Drug Product Release
- Systems Integrity

# Laboratory Services

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*
- *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 ACQUISITION & 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:**

Waters • Agilent • Distek • Shimadzu • Malvern  
Varian • Perkin Elmer • Micromeretrics



# 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 Sifter
- Sweco Sifter (2)

## Granulate

- High Shear Granulator
  - 10L, 120L, 150L, 800L
- Littleford-Day Mixer
- Roller Compactor
- Glatt GPCG 30/60
- ACG 350/500 Combo

## Dry

- Lydon Tray Dryer (5)
- ACG 350/500 Combo

## Blend

- Bin Blender (2)
  - 128L, 320L, 800L, 2100L Bins
- V-Blenders (7)
  - 1, 3, 5, 10, 20, 40 Cubic Foot

## Compression

- Fette Press (6)
  - (4 single, 1 Dual)
- Stokes Press (3)
- Manesty Press (3)

## Coating

- OHara 15", 19", 24" & 30" Lab Coat
- 48" Coating Pan

## Encapsulate

- Solid Fill
  - MG2/140
  - MG Suprema (2)
  - MG Planeta

## Package

- Solid Dose Bottle Lines (3)
- Semi-Solid Tube Line
- Semi-Solid Jar Line



# Packaging Line Equipment

50-100 BOTTLES PER MIN ON AVERAGE

## Solid Dose 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.

**Line 3** - Clinical Trial - Bellatrix vibratory filler used for packaging small scale batches.

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



# Label House

## OFF-LINE SERIALIZATION

### **KRAUS FK Codingline (1)**

- *Equipped with LAETUS hardware & software to pre-print cartons*

### **LAETUS Model MV-220S (2)**

- *Capable of printing both kinds of labels on one machine for Case & Bottle Labels offline*
- *Each label/carton produced will contain a serialized 2D barcode with human readable text beside it, describing the makeup of the barcode*
- ***GTIN** (Global Trade Identification Number), the **Serial Number**, the **Lot Number** and the **Expiration Date** accurately printed offline.*



# 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

- *Change Control*
- *Audits, Metrics, APR's*
- *Documentum Administration*
- *QC Investigation Approvals*
- *Trackwise Administration*
- *Stability Chamber Control*
- *BR Issuance*
- *E-Room Control*
- *SOP Control*
- *Data Archive*
- *Label Issuance*
- *Serialization*
- *Product Development Approval*

## Manufacturing Support

- *MQA Product Support*
- *Real-time Floor Presence*
- *Raw Material Release*
- *BR Approval*
- *Investigations*
- *Protocol*
- *Product Development Support*
- *In Process Inspections*
- *AQL's*
- *Component Inspections*
- *Raw Material Sampling*
- *Room Release*
- *Equipment Release*

## Data Reviews

- *Raw Materials Release*
- *Analytical Development*
- *Stability*

## Stability

- **29 Stability Chambers**
- *2,245 sq ft in Total*
- *600 sq ft Controlled*
- *1,645 sq ft Non-Con*

## Validations

- *Equipment*
- *Utilities*
- *Cleaning*

## 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: 2013-2021



- *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*



## UPM Metrics Program

UPM established a metrics program in the beginning of 2016, where UPM Metrics are reported monthly to Management as well as Quarterly meetings are held with Sr. Management / Management Team.

- **Batch Record Documentation Errors**
- **Product Complaints**
- **Deviations & Investigations (QA & QC)**
- **CAPAs**
- **QC Documentation & Analyst Errors**
- **Stability Testing**
- **Cleaning & Room Release Inspections**
- **APRs**
- **Change Controls**
- **Internal Audits**

## **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 submitted a proposal to participate in another FDA Pilot program called FDA Quality Management Maturity Program (QMM) and was chosen along with 8 other companies. (Program in progress)
- 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*