

Avéma

Pharma Solutions



Innovative products. Turn-key solutions.

Avéma Miami: R&D and Manufacturing of Solid Dose and Liquid products



Avéma Pharma Solutions

Eliminating lost time while transitioning from R&D to commercial launch

- Lessons Learned from our own CMO outsourcing -- we manage 30+ CMOs for PLD's Private Label market.
- Experience from on clients on-boarding Avéma as a CDMO for the development & production of liquid & solid oral dosage.
- We will share lessons learned and also use virtual tour to touch on some of your strategic challenges that you shared with us.



Agenda

- Welcome & Introductions
- Meeting objectives
 - Eliminate lost time between R&D and Commercial launch
 - Add the ability to better characterize the product prior to commercial production
- Discuss concerns raised by delegates
- Virtual tour of Avéma's R&D and Manufacturing facilities
- Q&A

Delegates' Strategic Challenges

- CMO, TT, Contract
- Approval, serialization, commercialization
- Process scale up for commercial, Managing global supply chain, Balancing resources and timeline
- Scale up, late phase, accelerated timeline
- **Vendors sticking to the deadlines, Preparing for pre-approval inspection, educating supply chain about services offered.**
- **Fast to clinic, fast to market, data integrity, documentation strategy with CMOs**
- Analytical Development , Product Characterization, Tech transfer
- Access to cutting edge technologies, Finding development partners, Finding partners that help us innovate for better cost
- **Transition to all-virtual environment, Evolving pipeline, Managing CDMOs through pandemic**
- **Commercial and clinical drug supplies, Scaling up Technical Operations, Lifecycle management**

Delegates' Strategic Challenges

- **Batch Size selection, PLCM, Component Procurement**
- **Finding a CDMO with right fit, Unreasonable terms and conditions in contract, Proper and agile quality management system**
- **Attracting resources in a competitive hiring market, Revamping overall strategy post-COVID, Automating operations**
- **Efficiency, biologics, internationalization**
- **CMO identification, Global logistic, Project timelines**
- **Novel technical implementation for commercialization, synergy between clinical and commercial operations, uncertainty of long term sustainability**

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Confidential

Avéma Miami

From product development to commercialization. We have the talent and tools necessary to assist you in taking your product to market



- 90,000 Sq. ft of cGMP manufacturing, QC, R&D site and offices to support:
 - Manufacturing Operations
 - R&D Laboratory
 - QC Laboratory
 - Engineering Services & EHS
 - Project Management
 - Production Planning & Logistics
 - Regulatory Compliance/QA
 - Validation/Technical Services
 - Human Resources
 - Information Technology
- **5.5-6.0 billion units annually** in solid oral dosage form manufacturing output

What to look for in a CDMO

- How we manage the initial RFQ
- Questions to ask
 - What investments have they made in new equipment?
 - How do they manage technology transfer from R&D/Pilot to Commercial manufacturing?
 - Do they have pilot manufacturing equipment
 - How do they manage communication throughout the development process?
 - Do they understand FDA requirements?

R&D and Small Scale Manufacturing

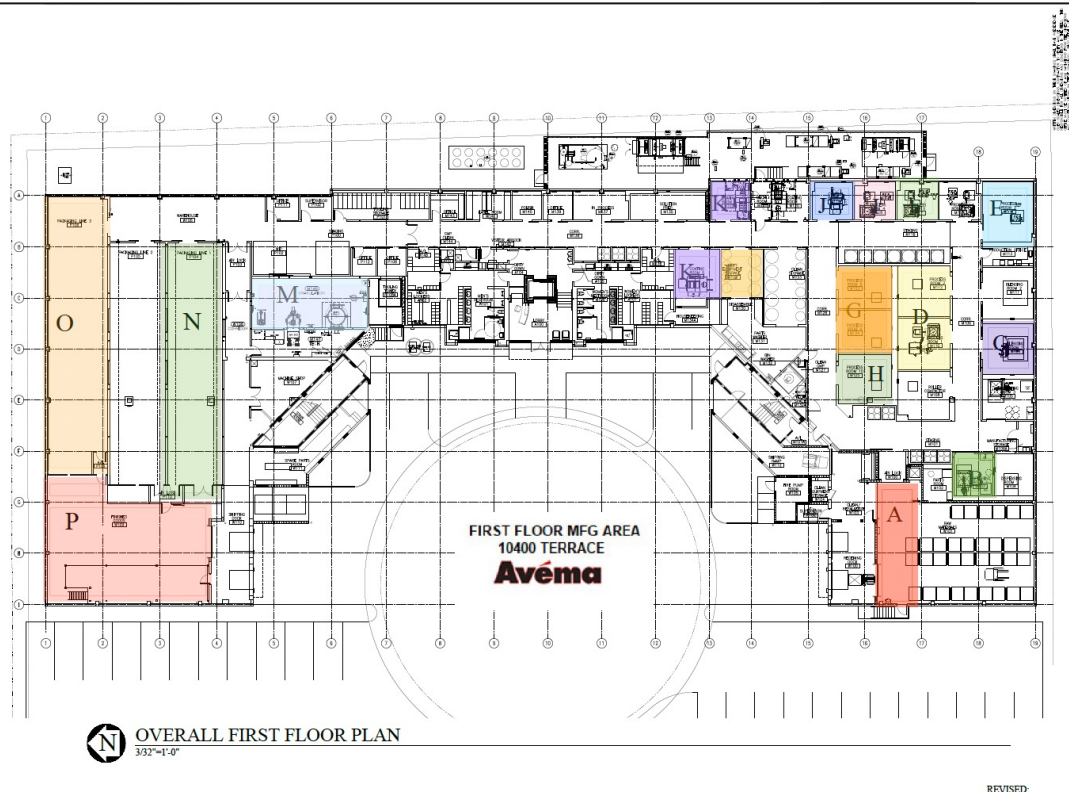
- Synergy with commercial scale up enhances speed to market
- The ability to develop product on small scale production equipment identical in specifications to the full size commercial .



“Small batches with short turn times around allow for more characterization of the process through design of experiments to support the FDA’s mandate on quality by design. Possibly leading to reductions in review time by the FDA and leading to fewer information requests or a faster approval cycle.”



Welcome to Avéma's R&D Facility



- Tour will take you through the areas we consider be unique
 - Synergy between R&D and Commercial production
 - Developing processes in miniature versions of equipment to enable seamless scale up
 - The challenges that can be overcome with this approach

R&D



What to look for in Manufacturing Capabilities

- Synergy with R&D and development
- The rationale for using Bin Blending
- Speed to Market with Scale Up

Commercial Manufacturing



What makes a good CDMO?

- CMO must be financially viable and poised for growth
- Must have new equipment and new capabilities
- The “right” size for your needs. Not so large that you are fighting for resources, not so small that resources are limited.

Why Avéma Contract Services?



- Experience managing CMOs
- Small scale/pilot production capabilities that mirror commercial equipment
- FDA approvals experience
- The right size for your needs.
- The right team – expertise + exceptional communications skills.

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