UI Pharmaceuticals

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2020-2021 Overview
UI Pharmaceuticals
Then and Now

- Founded in 1974 at the University of Iowa
- Largest FDA approved University associated CDMO in US
- Manufacture an average of 100 product batches a year for 80-100 clients
- SafeBridge categories 1-3 and DEA Schedule I-V capable
- Inspected by PAI, FDA, EMA (non-sterile)
- Currently support projects spanning preclinical to commercial stages
Why Choose UI Pharmaceuticals?

Unrivaled customer service and value

Technical people talk to technical people

Speed and Flexibility

Ability to assist in all phases of Biotech and Pharmaceutical development from ‘IND Tox to Exit’, Phase 1 trials to commercial supply
UI Pharmaceuticals Capabilities

→ **Formulation Development**
  • Expertise ranges from fit-for-purpose to robust commercial manufacturing
  • Small molecule, peptide, and protein formulation and lyophilization cycle development support

→ **Sterile Manufacturing**
  • Batch sizes range from 0.3 to 200 L
  • Vial sizes range from 2 mL to 100 mL

→ **Non-Sterile Manufacturing**
  • Projects include powder in a bottle, tableting, encapsulation, oral solution, and transdermal patches

→ **Analytical Laboratory**
  • In-process, finished product, and stability testing capabilities
  • Methods development for API and finished product
UI Pharmaceuticals Is a Full-Service Provider

*Overview of Client Utilization Based on 2019 Revenue

- Sterile: 53%
- Analytical Services: 26%
- Non-Sterile: 19%
- Formulation: 3%
Typical Product Timeline

→ An average project takes 18-20 weeks from quote to released material
From Intake to Quote – How We Get There

➔ UI Pharmaceuticals intake questionnaire
➔ Assigned to Project Specialist
➔ Client Documents
  • RFP, Project Outline, General Requirements
  • Grant Outline
  • Safety information about product (SafeBridge, Tox Report, OEL)
  • Material Spec Forms
➔ Desired Services and Timeline
  • Formulation, manufacture, release testing, on-going testing/stability
Sterile Manufacturing

- Product mix: ~50% small molecules, ~50% biologicals

- Current facility supports development through commercial
  - Two vial filling liquid lines
  - One vial filling and Lyophilization line
  - Batch sizes range from 0.3 to 40 L
  - Maximum 40 L bulk volume or 4,000 vials

- Dedicated/disposable product contact parts
  - No cleaning validation needed

- Peristaltic pump feed lines
  - Typically line loss ~ 100 mL

- Expansion facility coming on line Q2 2021
  - Two fully automated, ISO 5, integrated isolator lines
  - Maximum batch volume of 200 L
  - Lyophilization capacity of 4,000 - 20,000 vials

- Vial sizes range from 2 mL to 100 mL
Non-Sterile Manufacturing

- Eight Non-Sterile Manufacturing Suites
  - High Potency Suite (Safe Bridge 3 and Schedule I-V)
  - Coating Suites
- Batch Sizes
  - Solids – Up To 100 Kg
  - Semi Solids/ Gels – Up To 100 Kg
  - Liquids – Up To-800 L
- Project capabilities support development to commercial projects
  - Stainless Steel Mixing Vessels and V-Blenders
  - Capsules (Over-Encapsulations, API Direct Fills, Blends)
  - Powder In Bottle Fills
  - Liquid, Gel, and Capsule Fillers
  - Tablet Presses and Coaters
  - Fluid Beds
  - Wet Granulation and Milling
  - Kitting (Assembling, Labeling and Organizing)
Analytical Laboratories

→ Our focus is on quality and compliance while remaining flexible and creative
  • Aid in study design
  • Method development and validation

→ Experienced in ICH guidelines for assay and related substance methods

→ API and finished dosage form

→ Routine in-process, finished product and stability testing to support CMC

→ Ability to run robust stability programs to support CMC
  • Storage conditions: -80°C, -20°C, 5°C, 25°C/60% RH, 30°C/65% RH, 40°C/75% RH

→ Validated SLIM Data Management System has ability to perform statistical analysis and shelf-life prediction
Recent formulation development projects:
- Sustained release matrix tablet products
- Immediate release capsules
- Sterile injectable products
- Dermatological formulations

Excipient Compatibility Studies

Solid State Characterization of API

DP characterization (stress testing, solubility, stability)

Lyophilization Cycle Development and scale up

Early-stage support through access to faculty research in the UI College of Pharmacy (Nanoparticles, 3D printing, diagnostics)
Thank you for reaching out to us!

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