Advancing Topical Formulations Into GMP Manufacturing

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Overview

- Brief Introduction
- Testing & API Characteristics
- Formulation
- Microbiology
- Extraneous Preparation
- Safety
- Process Scale-Up
  - Container Closure Selection
- Summary
About Us

- Client-Centric Project Approach
- 17 Years of Service
- Privately Held & Fee for Service Focused
- 190 Employees & Growing
- 68,000 sq. ft. Facility
- 18,000 sq. ft. Dedicated to HP/C
- Diverse Mix of Clients
- Experience with Complex Formulations

Preclinical Development
- Animal Efficacy Formulations
- Tox Formulations
- Preformulation Testing
- Compound Characterization & Selection

Formulation Development
- Formulation Screening & Prototype Development
- First-in Man / Fit for Purpose formulations
- Solutions for Poorly Soluble Compounds & Controlled Release

cGMP Manufacturing
- CTM Mfging
- Scale Up
- Clinical Packaging & Labeling
- Distribution
- Tech Transfer

Analytical Services
- Prototype Stability
- API & Drug Product Method Development
- Product Release
- ICH Stability Testing
- CTM Storage

Focused on Rapid, Cost-Effective Solutions
cGMP Manufacturing Services

- CTM Manufacturing/Packaging/Labeling
- FIM → Commercial
- CTM Storage & Fulfillment
- Highly-Potent/Cytotoxic Compounds
- Tech Transfer
- Engineering Batch
- Product Specifications
- Protocols & Batch Records
- CoAs

From Proof of Concept to GMP

- Processing & Scale-Up
- Safety
- Extraneous Preparation
- Microbiology
- Formulation
- Testing & API
Analytical Testing & API

- Safety Classification (On-boarding)
- Stability Indicating Method
- Cleaning Method
- Polymorph
- Representative API

From Proof of Concept to GMP

- Testing & API
- Formulation
- Microbiology
- Extraneous Preparation
- Safety
- Process Scale-Up
Formulation

- Stock Formulation
  - Data-Driven?
- Preservative (Assay)
- Stability Indicating Method
- Common Excipients & Sourcing
- Placebo Matching
- Patient preference (gel, cream ....)

From Proof of Concept to GMP

- Process Scale-Up
- Safety
- Extraneous Preparation
- Microbiology
- Formulation
- Testing & API
Microbiology

- Indication and Clean Room Classification
- AET and MET Testing
- Specific Assay for Preservative

From Proof of Concept to GMP

- Microbiology
- Extraneous Preparation
- Safety
- Process Scale-Up
- Testing & API
**Extraneous Preparation**

**Compound Pharmacy**
- Quick to Clinic
- Lower Cost
- Support with In-Use Stability
- Sourcing of Materials
- Align with Pharmacy Capability and Equipment

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**From Proof of Concept to GMP**

- Process Scale-Up
- Safety
- Extraneous Preparation
- Microbiology
- Formulation
- Testing & API
Safety

- Expertise for Handling HP/C
  Match OEL with Facility Design & Engineering Controls

- OEL (µg/m³)
  - Employee Safety

- Match ADE to Cleaning Limits

- ADE (µg/day)
  - Patient Safety

*Once in solution avoid skin contact

From Proof of Concept to GMP

- Process Scale-Up
- Safety
- Extraneous Preparation
- Microbiology
- Formulation
- Testing & API
Process Scale-Up

- Mixing Vessels Based on Viscosity and Formulation Type
- Solvent Evaporation (Concentration and Release Results)
- Order of Addition
- pH (Time and Adjustment Strategy)

Dispense Technology

- Accuracy
- Single vs. Multi-Use Dosing
- Interface with delivery technology
Container Closure

- May Not Be Elegant for Phase 1
- Single Use vs. Multi-Use
- Sourcing
  - Supplier Qualification and GMP Status
  - Time
- Compatibility and Stability

Summary

- Select Data-Driven Formulation
- Robust Analytics
- Align with CMO to Match Corporate Goals
- CMC Leadership

*What works for one API may not work for another*
THANK YOU

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