Developing a Robust Global GMP Regulatory Strategy for Live Biotherapeutic Product Manufacturing

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Siolta Therapeutics

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Your global CDMO for Microbiome Therapeutics

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Sponsor CMC Priorities for Defined LBPs: Product Development

Key development decision:
In-house product development or a blended approach w/ CDMO?

Initial PD activities and priorities:

- Initial product (strain) characterization
- Development (or transfer) of robust potency method
- Scaling API bench process (if needed)
- Equipment used for PD and supporting analytical representative of GMP
- Strategy for initial DP formulation and CCS
- Define target DS and DP specifications
- Feasibility batches / informal stability / storage condition
- Documentation of PD work (formal development report)

Sponsor CMC Priorities for Defined LBPs: Early Phase Clinical Supplies

Early clinical manufacturing decisions:

Fully in-house or outsourced manufacturing?

Additional GMP activities: Testing? Storage? Packaging?

Key CDMO capacities:

- Experienced personnel, adequately staffed and resourced
- Facility suitability, lead time, cold chain capabilities (if applicable)
- Tech transfer expertise (MF and QC)
- DS, DP, release testing, stability storage, warehousing, clinical packaging, shipping…
- cGMP quality systems appropriate for LBPs, including experienced Quality Unit
- CMC regulatory support
- Potential for long-term partnership

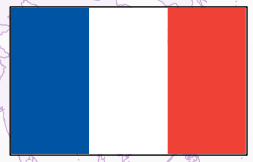
Since January 2017, we propose our expertise and services as a **CDMO**.

OUR ACTIVITY IS SPLIT IN 2 LOCATIONS

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ansm
Agence nationale de sécurité du médicament et des produits de santé

Main site – Center of Excellence



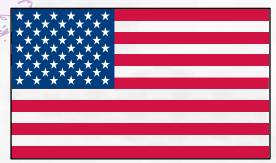
Aurillac Labs & Facility :

- Size: 45,000m²

FDA

KOREA MFDS

Tech transfer Lab up to 5L-scale bioreactors



Boston Lab :

- Size: ~250m2

R&D & INDUSTRIAL PLATFORMS

45,000m² dedicated to LBP manufacturing

Analytical R&D

LBP Drug Substance Manufacturing

DS1 : 20L – 300L – 3500L

DS4 : 2L – 150L

DS5 : 20L – 200L – 2000L

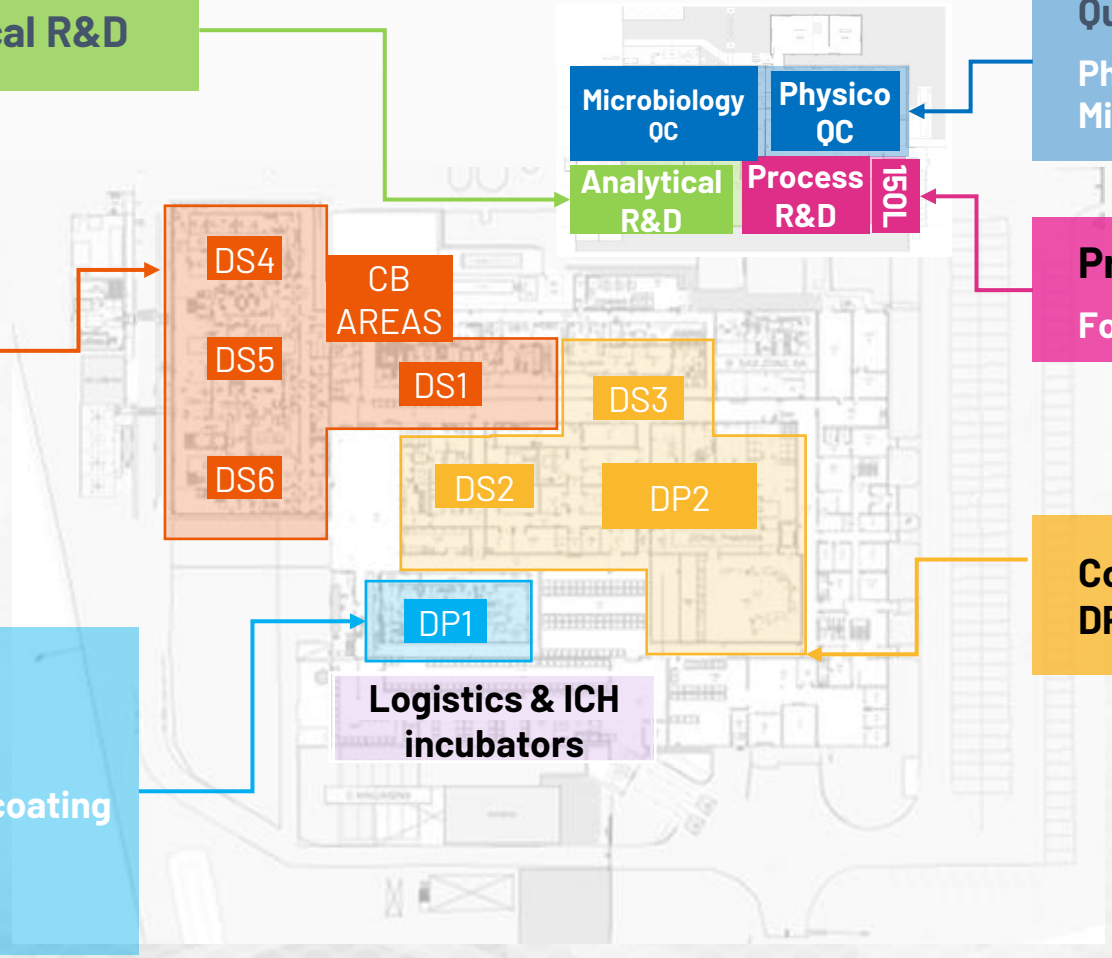
DS6 : 50L – 500L – 5000L

LBP Drug Product Manufacturing

2 Clinical lines

Encapsulation, tableting, bulk, Banding, coating

Topical options (Creams, Ointments & oil suspensions)



Quality Control

Physico Chemistry & Microbiology labs

Process R&D

For DS & DP

Commercial LBP DS & DP suites

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Anticipation the future

- New GMP suites designed for FDA inspection integrating needs for all clinical phases & commercial
- Integrated quality and process parameters (CQA & CPP) adapted to the project and the clinical step
- Long term partnership with our sponsors and our consultants
- Manage the subtle differences in recommendations vs obligations regarding the quality level

Steps to develop an International Regulatory strategy

- Build a strong experienced team
- Understand GMP readiness for GMP and PAI
- Invest in dedicated project compliance multi disciplinary team's member – Adapt well know GMP to LBP
- Constitute a Technical Transfer group to support project introduction

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Key Points to Avoid Pitfalls:

- Ensure to have “state of the art facility” & equipment to facilitate containment strategy
- Build a robust Contamination Control Strategy
- Integrate Biosafety and OGM evaluation in all Risk Assessment
- Implement good monitoring and practices to reduce cross-contamination

Point to Consider:

- Difficulty to implement GMP culture changes
- Develop an early strategy pathway to incorporate Compliance know-how from development to commercial

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