OFD BIO|PHARMA

PHARMACEUTICAL LYOPHILIZATION SERVICES

Creating solutions that improve lives through the science and craft of lyophilization.

EXPERIENCED PARTNERS

We have decades of experience collaborating with partners who challenged us to continuously raise the bar on our standards:

NASA

DEPARTMENT OF DEFENSE · UNITED STATES OF AMERICA

LARGE PHARMA

BIOTECH

LYOLOCK

LEARN.COLLABORATE.DEVELOP.COMMERCIALIZE.

THE OFD ADVANTAGE:

Project Management Through Our QBD Approach

LEARN

During our initial conversations with you, our team of experts will work to understand your goals.

COLLABORATE

We will work in partnership to target critical quality attributes and develop a customized design space for your project.

DEVELOP

At this stage, we refine the process and cycle until optimal yields are achieved and your exact specifications are met.

COMMERCIALIZE

Our unique manufacturing capabilities and broad spectrum of experience make commercialization a breeze.

OUR LYO-SERVICES COVER A RANGE OF CAPABILITIES

PRE-CLINICAL & PROCESS DEVELOPMENT	CLINICAL PHASES 1, 2 & 3	COMMERCIALIZATION
SERVICES		
+ Drug substance process transfer and/or development + Bulk, topical, oral, nasal or pulmonary requirements + Working backward from ideal product finished characteristics	+ Process scale-up to 1/10th or 110-120 liters bulk + Bulk small dosage formats	+ Engineering batches + Validation batches + Process flowcharting + Commercialization cGMP batches (1-1100 kg)
FORMULATION DEVELOPMENT	**ASSAY DEVELOPMENT & TRANSFER**	
+ Cryopreservative formulation development + Excipient evaluation + Thermal characterization analysis for pre- and post- lyo stability + Desired end phase – Crystalline or Amorphous	+ Assay qualification + Assay validation + QC testing	
DRUG PRODUCT PROCESS DEVELOPMENT	**REGULATORY SUPPORT**	
+ Analytical testing + Form design and delivery mode + Cleaning validation protocol	+ FDA submission assistance for new drug or device applications + Mock regulatory inspections + Pre-approval inspections + Annual approved product reviews + Routine GMP inspections	+ FDA submission assistance for new drug or device applications + Mock regulatory inspections + Pre-approval inspections + Annual approved product reviews + Routine GMP inspections + Post market surveillance
LYOPHILIZATION PROCESS	**FINAL PRODUCT FORMAT**	**FACILITIES**
+ Process parameter range effect analysis + Scale-up assistance or execution + Normal operating range and proven acceptable range + Bioavailability enhancement assessment + Milling, blending & granulating + Lyophilization process development + Collaboratively identifying variables that impact efficacy, solubility, bioavailability, and physical characterization	+ Bulk lyophilized powder for inhalation, pulmonary and topical scaffold inclusion + ODT – buccal, sublingual delivery vehicles + Inhalation lyophilized pellets for quick wetting / dry distribution + Bulk sheets for combination products or wound scaffolds + Small oral pads by variable depth	Medtech, Bulk API Class 100,000 ISO 5 / BSL 2

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OFD BIO|PHARMA

ABOUT OFD BIO|PHARMA

OFD Bio|Pharma, LLC has been providing biotechnology and pharmaceutical companies with custom lyophilization (freeze-drying) solutions for over 20 years. Whether your product is pre-clinical, in development, in a clinical phase, or commercially available, we have a tailored solution for you. Our services include Bulk API Lyophilization, Cycle Development and Testing.

To learn more, visit: **OFDBioPharma.com**