The role of a trusted PLGA partner in Advancing Resorbable Polymers for Controlled Drug Release

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CRS 2025 ANNUAL MEETING & EXPOSITION
PHILADELPHIA, PA
JULY 13-18, 2025

NEXT-GENERATION DELIVERY INNOVATIONS

Outline

1. Drug delivery and Long-Acting Injectables
2. ICH Q10: Lifecycle of Pharmaceutical product development
3. PLGA: A Tunable and Multifaceted Material
4. ICH Q8: Quality-by-Design for LAIs
5. Manufacturing LAIs and Critical Process Parameters
6. The role of a Trusted Partner
7. Corbion Biomaterials

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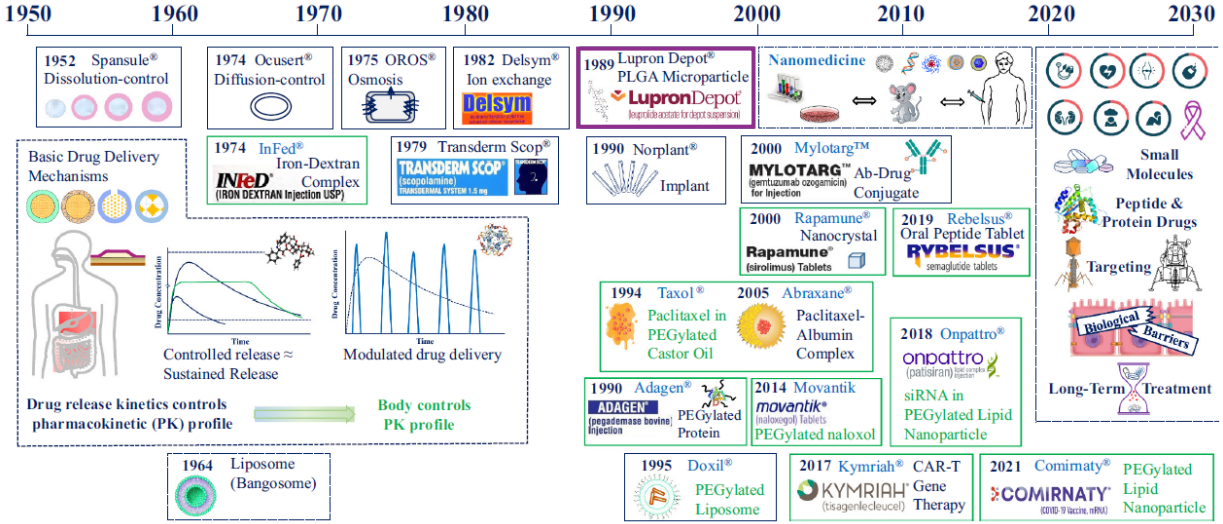
Evolution of drug delivery systems



Evolution of drug delivery systems: From 1950 to 2020 and beyond; Kinam Park and al., Journal of Controlled Release, (2022)

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Long-acting Injectables using PLGA formulations

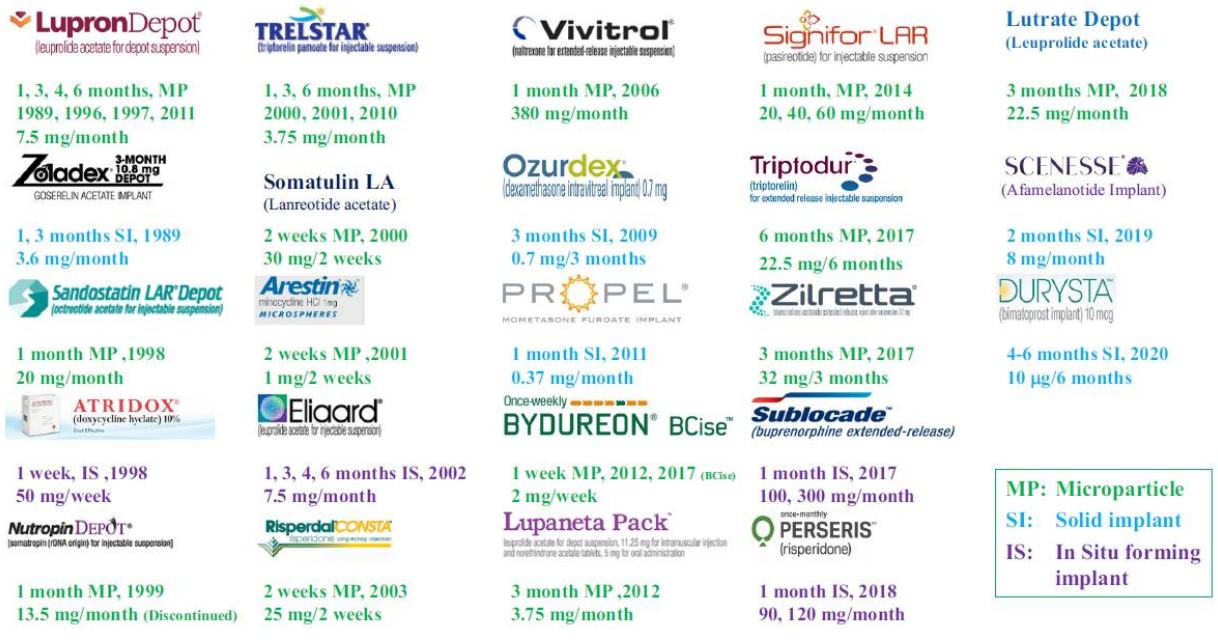

Fig. 2. Injectable long-acting PLGA formulations approved by the U.S. FDA. All products are based on microparticle, in situ forming implant, and solid implant formulations.

April 2023: **Uzedy, TEVA**
1, 3 month IS
125mg and 250mg

Evolution of drug delivery systems: From 1950 to 2020 and beyond; Kinam Park and al., Journal of Controlled Release, (2022)

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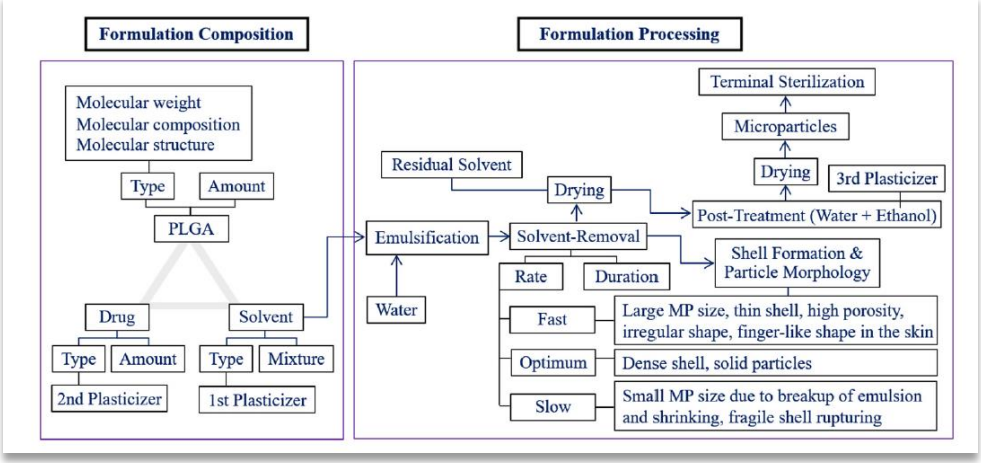
Pharmaceutical development: Lifecycle Stage Goals (ICH Q10)

Overcoming challenges during development process and trial-and-error risks

Lifecycle Stage Goals (ICH Q10)

Development → Technology transfer → Commercial Manufacturing → Product discontinuation



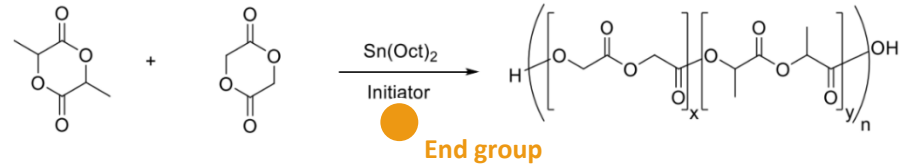
K. Park. J Control. Release 382 (2025) 113758

Corbion PURASORB®

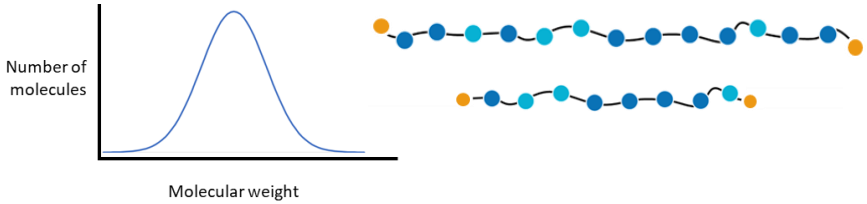
- Polymer Knowledge
- Quality & Consistency
- Trusted Supply Chains
- Value of Strategic Partnerships

What is poly(lactide-co-glycolide) PLG/PLGA?

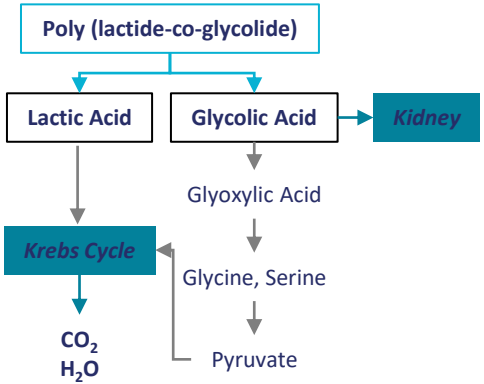
- *Polymer is a substance composed of macromolecules* (IUPAC)
- *PLGAs are copolymers: A polymer derived from more than one species of monomer.*



Poly(lactide-co-glycolide)



PLGA, **PLG**, poly(lactic-co-glycolic) acid or poly(lactide-co-glycolide)



Hollinger & Battistone (1986), Clin Orthop & Rel Res; No. 207: 290
Bostman (1991), JBJS-A; 73A: 148

PLGA is valued for its biocompatibility, biodegradability, and regulatory acceptance

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PLGA tunable and multifaceted material

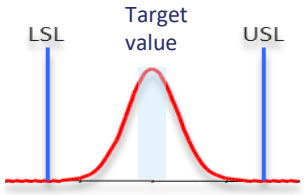
PLGA is not 'one-size-fits-all': Its polymer nature requires deep understanding for successful drug design

Common Misconceptions about PLG/PLGA

✖ Myth: PLGA is hydrophobic and dissolves in all organic solvents
✓ Fact: Solubility varies

✖ Myth: Only molecular weight matters
✓ Fact: Other factors like molecular composition and structure are crucial

⚠ No universal PLGA standard
⚠ PLGA-based polymer choice will affect drug performance
⚠ The natural variability in polymer production should be considered when formulating new products
⚠ Each formulation should study polymer specifications



Batch number
Lot-to-lot variation

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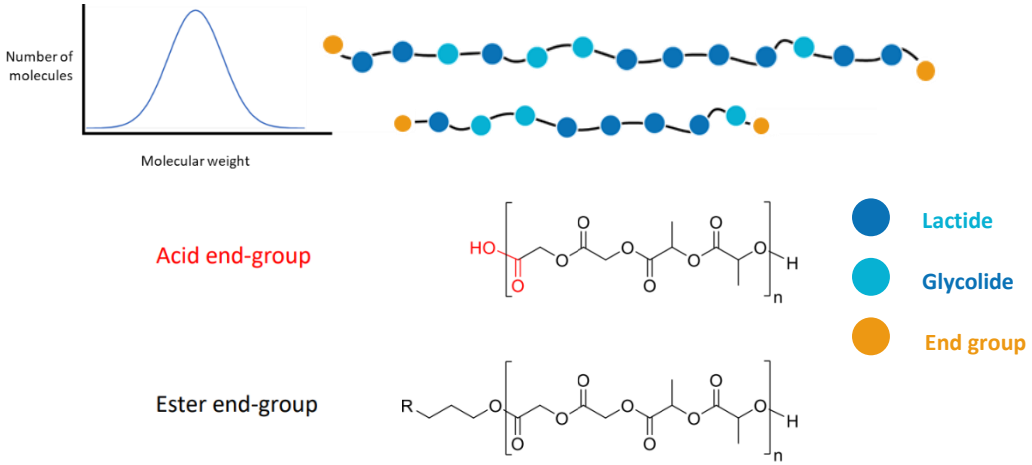
Critical Success Factors in PLGA-Based Development

PLGA Characterization: Essential for regulatory and performance predictability

- Molecular weight
- Molecular composition mol ratio (L:G): 50:50 or 75:25
- End group type
- Molecular structure: Linear, branched
- Microstructure (monomer sequence length)



Customization enables tunable drug release to tackle solubility and hydrophobicity challenges

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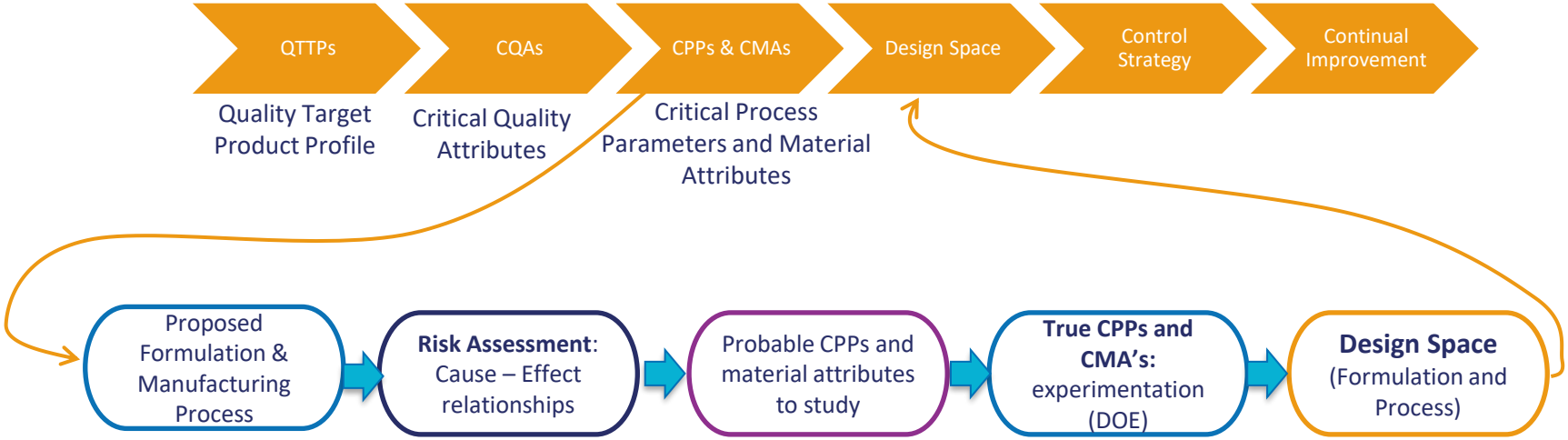
Quality by Design (QbD) adopts a structured, science-based methodology

ICH Q8 Elements of Pharmaceutical development



Corbion support the validation of the partner design space, by providing PLGAs that accounts for the typical variability in polymer manufacturing.

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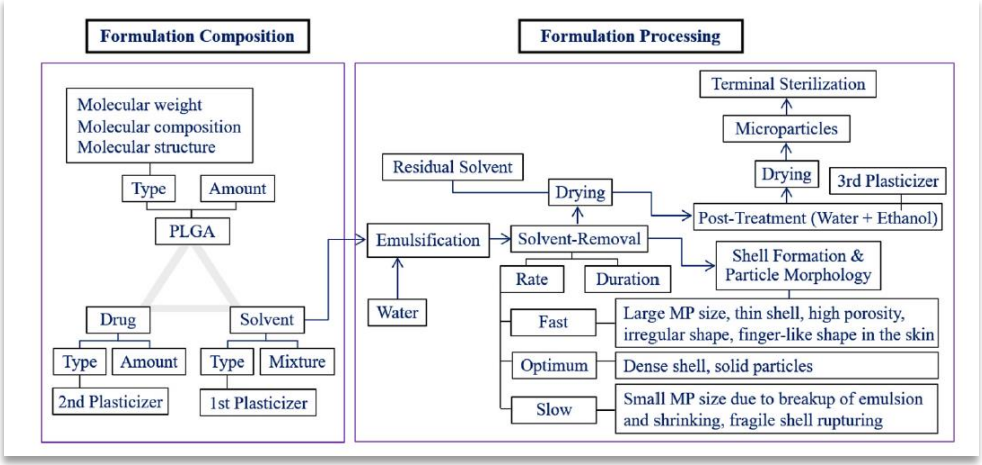
Trusted PLGA Supplier = Success Factor

Empowering smarter control through deep understanding of CPPs, CMAs, and Design Space

ICH Q10 Development → Technology transfer → Commercial Manufacturing

Ensure **commercial robustness** by establishing production readiness, maintaining regulatory compliance, and delivering consistent, high-quality products.



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PLGA:

- Material Supply: Consistency, compliance
- Technical Support: Expertise for formulation, scale-up
- Innovation Enablement: Access to custom PLGAs, novel processing insights
- Regulatory Readiness: Documentation and data packages

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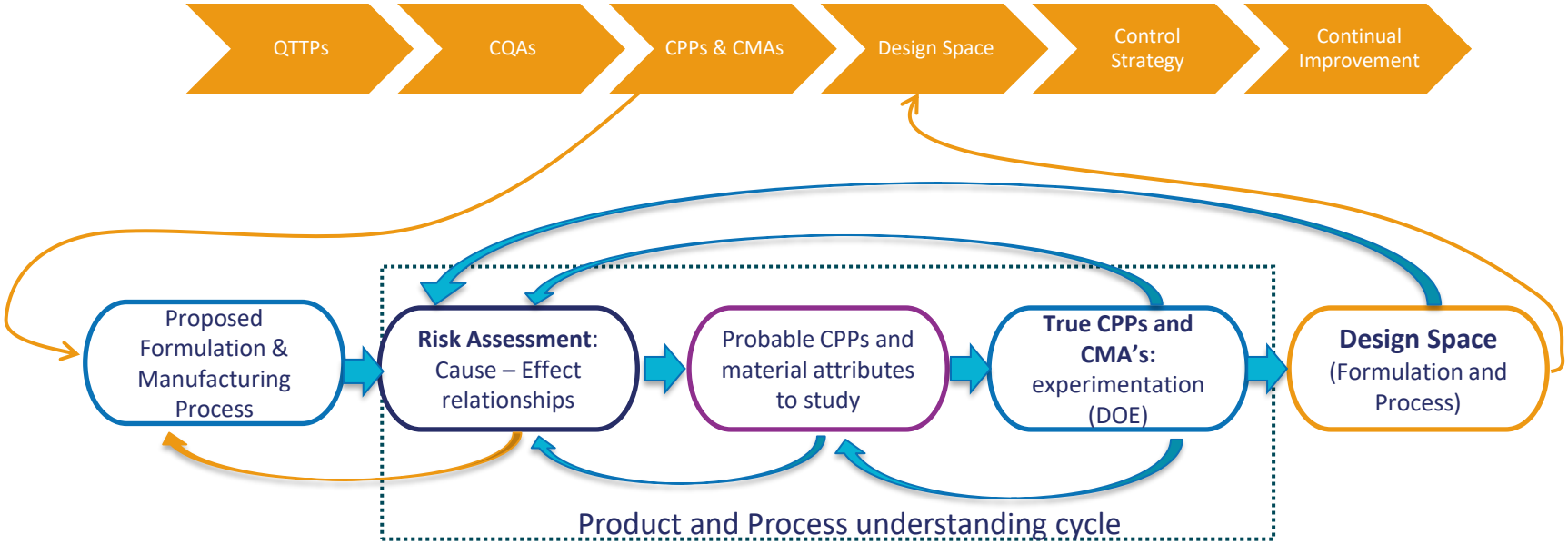
Quality by Design (QbD) adopts a structured, science-based methodology

Product and Process understanding cycle



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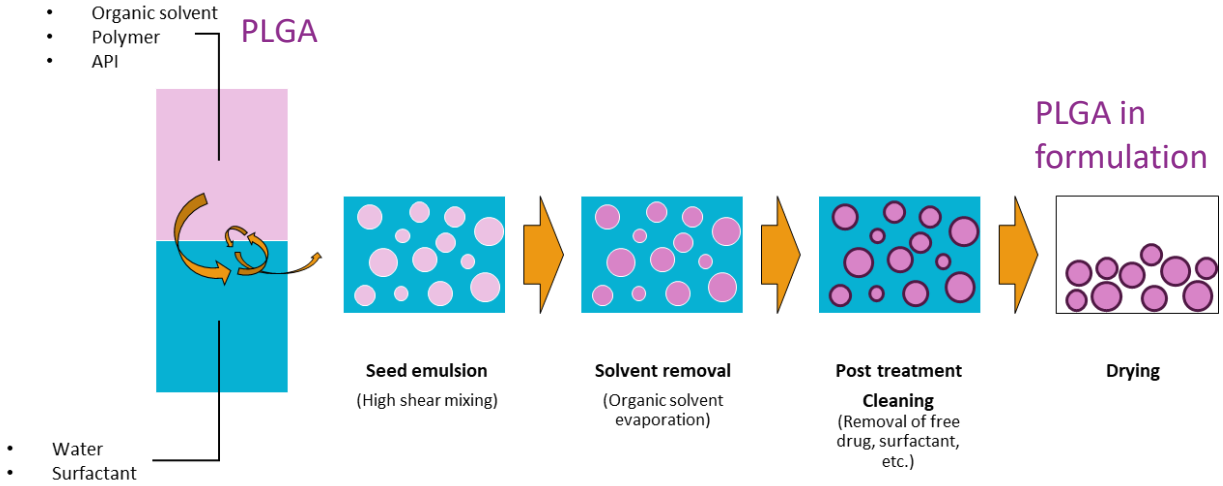
Critical Success Factors in PLGA-Based Development LAIs

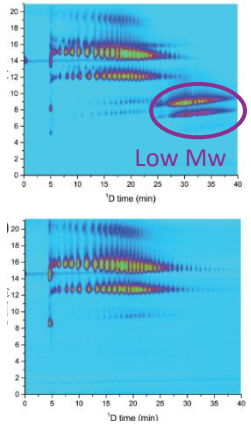
PLG properties may change significantly after processing



PLGA Characterization: Essential for regulatory and performance predictability

Hyphenated techniques

To study polymer



[1]D: SEC
[2]D: RPLC (Reversed Phase Liquid Chromatography)

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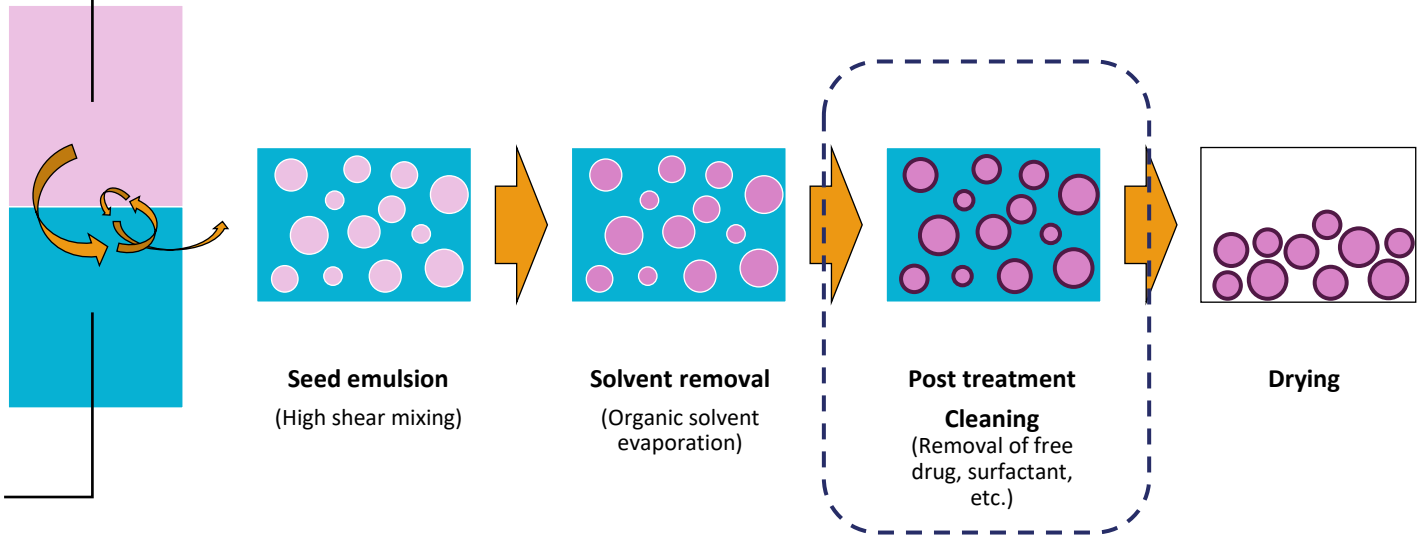
Critical Success Factors in PLGA-Based Development LAIs

Factors like processing steps and interactions with other ingredients can alter the behavior in the final product

- Organic solvent
- Polymer
- API



- Water
- Surfactant

The Impact of post-processing temperature on PLGA microparticle properties
Andrew Otte and al., Pharmaceutical Research, (2023)

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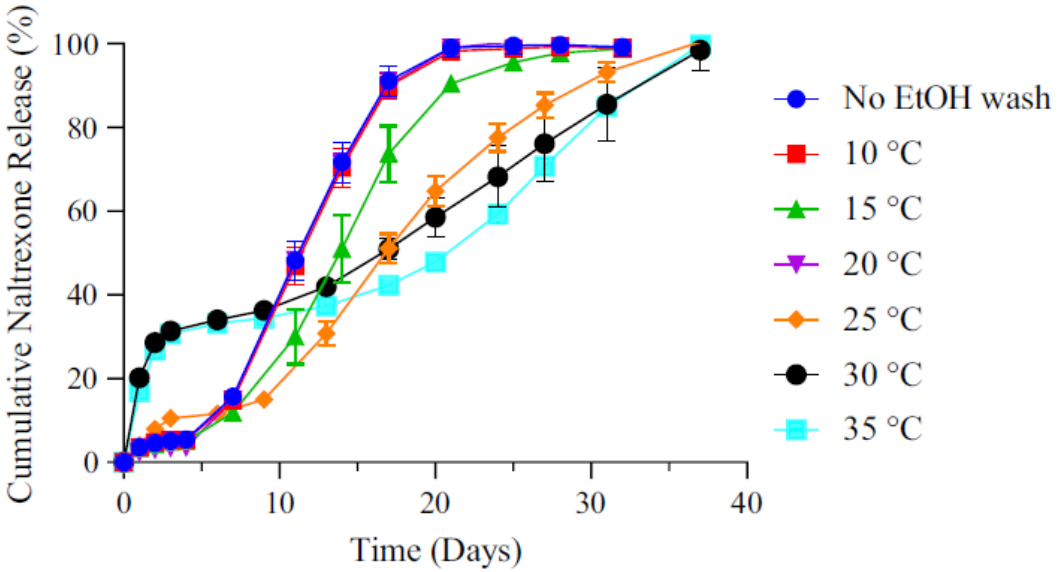
Critical Success Factors in PLGA-Based Development LAIs

Ethanol wash and temperature effect on drug release

Vivitrol®
(naltrexone for extended-release injectable suspension)

1 month MP, 2006
380 mg/month

API: Naltrexone
Treatment of addiction
(alcohol and opioid)



The Impact of post-processing temperature on PLGA microparticle properties
Andrew Otte and al., Pharmaceutical Research, (2023)
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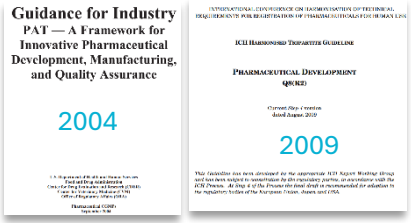
Critical Enablers to establish the Design Space

⚠ Traditional: empirical, PhD-style experimentation→ The one-factor-at-a-time method

⚠ Issues with scaling assumptions and material variability

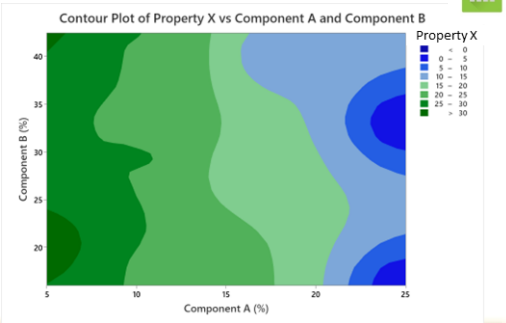
Establishing the Design Space

- Defines safe and effective operating ranges
- Supports regulatory submissions, tech transfer, optimizations
- Visual tool for process robustness



Design of Experiments (DOE)

Minitab® jmp



PAT tools:

- **Process Analyzers:** NIR, Raman, PSD, UV, TOC…
- **Multivariate (MVDA)** tools for design, data acquisition and analysis
- **Process control** tools
- **Process Modelling**

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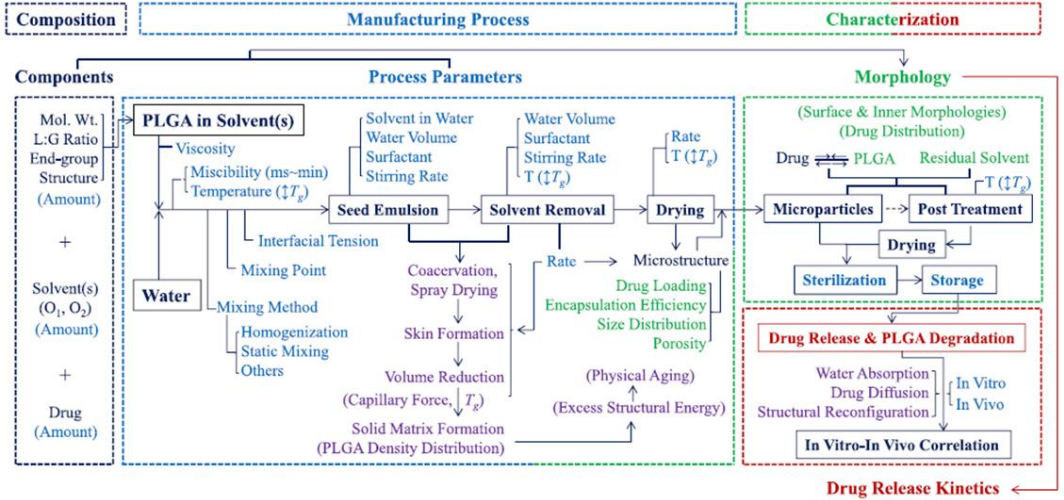
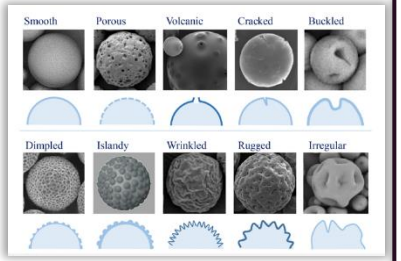
Critical Enablers Factors in PLGA-Based Development LAIs

Multivariate Data Analysis (MVDA) Integrate complex data sets: initial conditions, process parameters and quality data





Quality data
Microparticles
Thickness
PSD
Appearance
Encapsulation
Release profile (time)
…

Initial conditions
Solvent amount
Solvent ratio
Drug amount
Drug Lot/supplier
Solvent lot
PLGA Mw
…

Parameters in time
Temperature
Concentration
Pressure
Flow
RPM
Level
…

Formulation composition, manufacturing process, and characterization of poly(lactide-co-glycolide) microparticles;
Kinam Park, Yan Wang and al., Journal of Controlled Release, (2021)

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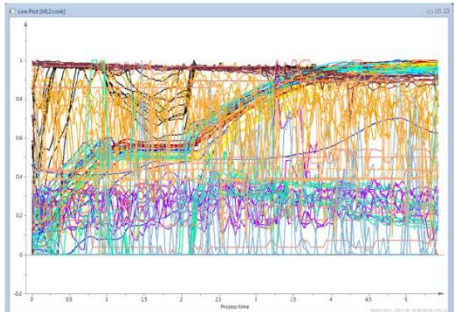
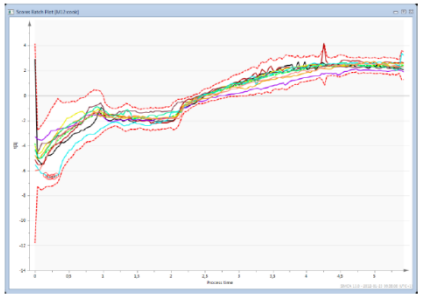
Critical Enablers based on ICH Q8 and Q10

From univariate to multivariate data analysis to understand the full picture and make better products!

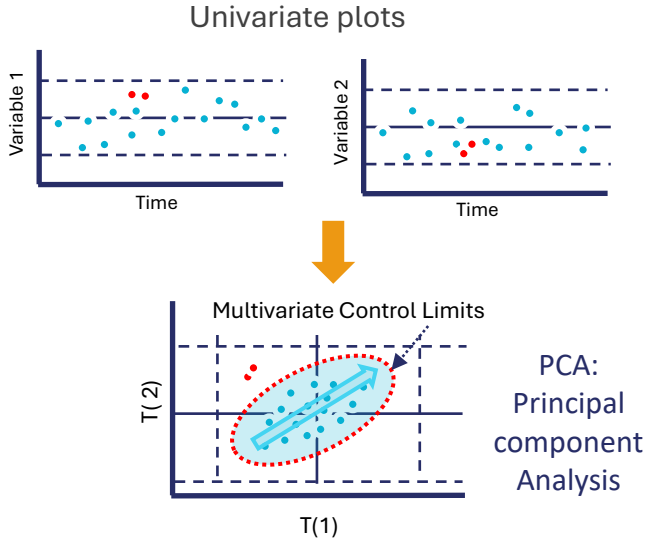


Raw data from 20 batches for which 12 variables have been measured during process evolution

MVDA



Same data (20 batches -12 variables) after SIMCA



PCA: Principal component Analysis

SIMCA®

SARTORIUS

NCSS Statistical Software

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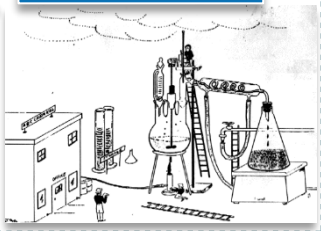
At Corbion, we partner with you on every step of the journey

From development and scaling to successful commercialization

Development → Technology transfer → **Scalability** → Commercial Manufacturing → Product discontinuation



Ensure **commercial robustness** by establishing production readiness, maintaining regulatory compliance, and delivering consistent, high-quality products.

Lab Work

- Proof of feasibility
- Small scale studies
- Product samples
- Knowledge generation

Process Conceptualization

A. Ready to use process technologies
B. Custom process design and optimization

Technology Demonstration

- Confirmation of process concept (piloting)
- Data for scale-up
- Product sample generation

Technology Transfer

A. Existing asset
B. New asset

Process Validation

Demonstration of product capabilities of the process

Ensuring scalability and performance consistency

E.H.Stitt Chem. Eng. J. 2002, 47-60

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Key Takeaways

1. **PLGA-based LAIs** are at the forefront of improving therapeutic outcomes and patient compliance
2. **PLGA is versatile but complex:** success needs a strong understanding of its behavior.
3. **Key factors** include proper material characterization and control of processing steps.
4. **Quality by Design (QbD)** helps reduce risks and meet regulatory goals.
5. **Multivariate Data Analysis** supports process control and outcome prediction.
6. **A reliable PLGA supplier like Corbion** enables smarter development and faster success.
7. **Corbion is your partner** through development, scale-up, and commercialization.

Introduction to Corbion Biomaterials

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NEXT-GENERATION DELIVERY INNOVATIONS

Global biobased ingredient provider with unique technology platform

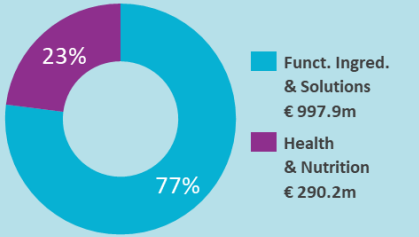
€1.3bn
net sales

€175m
Adjusted EBITDA

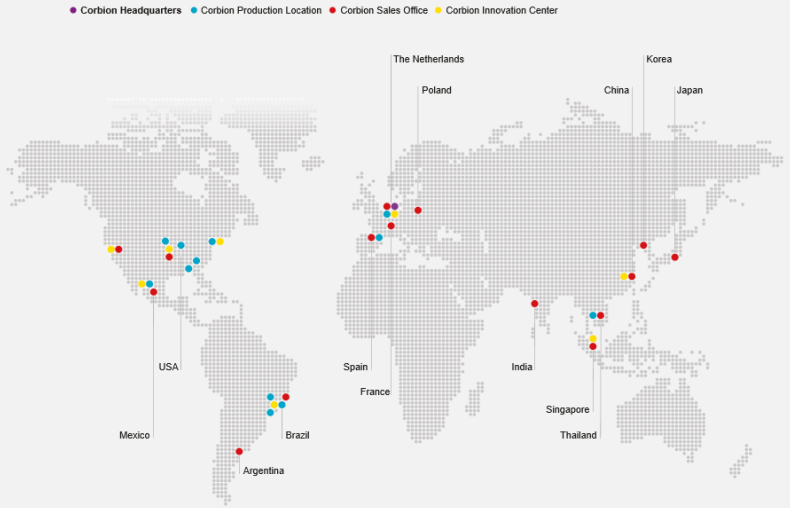
2,399
Employees

Key figures (2024)

NET SALES



NET SALES PER REGION



- Largest producer of lactic acid with global footprint
- Leading market positions in sustainable food solutions
- Unique technology platform: fermentation
- 14 manufacturing facilities, 8 innovation centers, and sales offices across the world

Corbion Biomaterials is the supplier of choice of resorbable materials in the medical and pharmaceutical industry.

We enable our partners to create patient-friendly solutions that improve lives and well-being, while preserving an affordable healthcare system.

For all.

Preserve what matters

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NEXT-GENERATION DELIVERY INNOVATIONS

PURASORB® used in medical applications for more than 45 years

Corbion

Biodegradable Orthopedic Implants

Drug Delivery Solutions

Cardiovascular Stents

Bio-stimulatory Dermal fillers

Regenerative medicine

Resorbable polymers with a long track record and excellent *in vivo* **biocompatibility and biological safety**

Versatile portfolio and properties with applications in many biomedical areas

Corbion Biomaterials locations

The Netherlands – Gorinchem

- Historical site
- R&D Laboratory
- Pilot Plant Facility
- Dedicated cGMP manufacturing facility

United States - Tucker

- Dedicated cGMP manufacturing facility
- Large volumes capabilities

PURASORB® Bioresorbable polymers for advanced medical solutions

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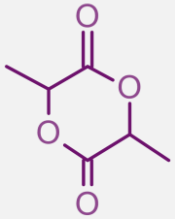
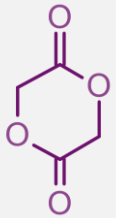
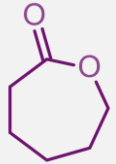
Building blocs



Lactide



Glycolide



ε-Caprolactone

Polyethylene glycol

PURASORB® Bioresorbable polymers for advanced medical solutions

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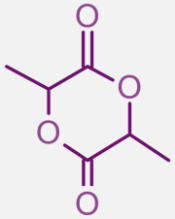
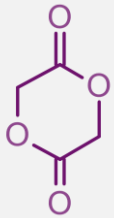
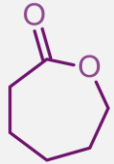
Building blocs



Lactide



Glycolide



ε-Caprolactone

Polyethylene glycol

PATTERN
- Homo-polymers
- Co-polymer

LENGTH
- IV 0.1 to 6.0dl/g

ARCHITECTURE
- Di- / Tri- blocks
- Linear or branched

PURASORB® Bioresorbable polymers for advanced medical solutions

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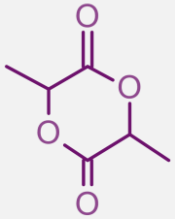
Building blocs



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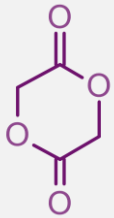
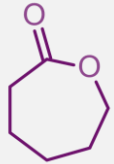


Glycolide



ε-Caprolactone

Polyethylene glycol

Tunable material properties:

Strength | Flexibility | Degradation | Viscosity | Water absorption | Adhesion | Temperature gelation | Self-assembly properties

PURASORB® Bioresorbable polymers for advanced medical solutions

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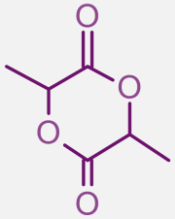
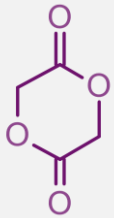
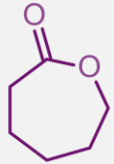
Building blocs



Lactide



Glycolide



ε-Caprolactone

Polyethylene glycol

Microparticles | **In Situ Depot** | **Implants**

PURASORB® portfolio

- Pharma grade, GMP material
- Excellent biocompatibility and safety profile; building blocks used in approved medical applications
- Tunable degradation
- Well-referenced polymers
- Constant quality and reproducibility
- Dual manufacturing
- DMF available

PURASORB® Getting the name right

Corbion

G: Identifies the second monomer for co-polymers

50: Gives the ratio (mol %) of the first monomer
(if the product is a co-polymer.)
In this example: 50 mol % DL-lactide.

"P" : Polymer

PURASORB® P DL G 50 02 A

A: Identifies the end-group chemistry of a polymer:
- "A": Acid.
- No "A": ester-capped.

DL: Identifies the monomer the polymer consists of:
- DL for DL-lactide,
- G for glycolide and,
- C for ε-caprolactone.

02: Gives the midpoint of the inherent viscosity (IV).
In this example it is 0.2 dl / g.

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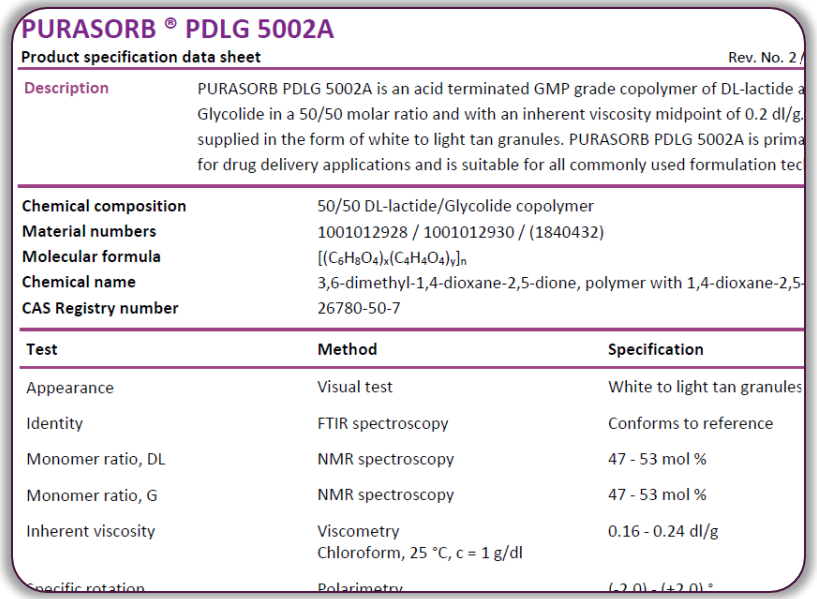
PURASORB® R&D

An integrated approach to help you identify your Critical Material Attributes

PURASORB® R&D to support you in CMAs identification.

- Our **GMP PURASORB®** polymers are provided with a **CofA**.
- However, regulatory agencies may ask for justification of polymer specifications and their range, e.g.: IV
- We will provide you with the right Purasorb® R&D samples to justify specification limits, e.g.:
  - → IV of 0.16 and 0.24 d/g in example



PURASORB ® PDLG 5002A

Product specification data sheet Rev. No. 2 /

Description	PURASORB PDLG 5002A is an acid terminated GMP grade copolymer of DL-lactide a Glycolide in a 50/50 molar ratio and with an inherent viscosity midpoint of 0.2 dl/g. supplied in the form of white to light tan granules. PURASORB PDLG 5002A is prima for drug delivery applications and is suitable for all commonly used formulation tec
Chemical composition	50/50 DL-lactide/Glycolide copolymer
Material numbers	1001012928 / 1001012930 / (1840432)
Molecular formula	$[(C_6H_8O_4)_x(C_4H_4O_4)_y]_n$
Chemical name	3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with 1,4-dioxane-2,5-
CAS Registry number	26780-50-7

Test	Method	Specification
Appearance	Visual test	White to light tan granules
Identity	FTIR spectroscopy	Conforms to reference
Monomer ratio, DL	NMR spectroscopy	47 - 53 mol %
Monomer ratio, G	NMR spectroscopy	47 - 53 mol %
Inherent viscosity	Viscometry Chloroform, 25 °C, c = 1 g/dl	0.16 - 0.24 dl/g
Specific rotation	Polarimetry	(-2.0) - (+2.0) °

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Complex chemical structures

Various chemistries including
- L-, D-, (D,L)-Lactide
- Glycolide
- Caprolactone
- PEGs
- And others

Various architectures
- Linear
- Branched
- Homo- and Co-polymers

Various Specifications
- Large range of IV
- Extra Pure version

Large formulations and processing opportunities

- Micelles | Liposomes | Microparticles
- Thermo-gelling polymers
- Reticulated implants | Nanoparticles
- Advanced thermo- or mechanical properties

A systematic approach to development of new polymers

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Target Product Profile discussion

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R-batch	D-batch	E-batch	GMP	Commercial
• Laboratory	• Pilot	• Production	• Production	• Production

Partner

Proof-of-concept	Proof-of-Development	Pre-clinical studies	Clinical (1, 2 & 3) phases	Registration and commercialization
• Benchtop	• In vitro work	• In vivo work	• Human studies	• Marketed

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