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# QbD-Driven Approach to Early-Stage Drug Delivery Innovation with the Hydralese® Polymer Platform

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PODD



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# Thank you for joining us and welcome

1. Hydralese® Introduction
2. Process Overview
3. Model API Release & Degradation
4. Capability & Resource Demonstration

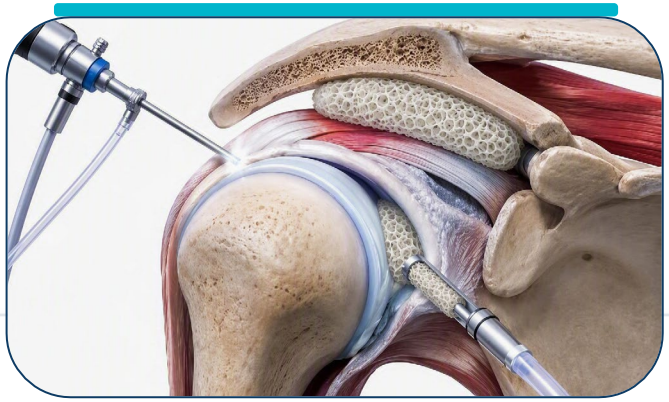
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# One material science base, **three paths to market**

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## Hydralese®MT

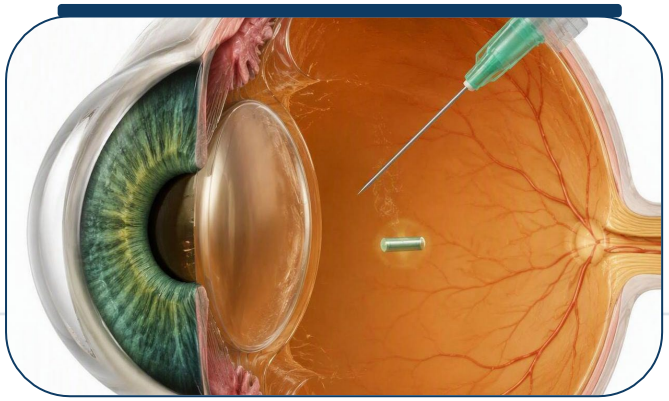


One polymer platform, various implantable device form factors.

**Shoulder Spacer / Patch** Subacromial insert for cuff tears
Stage = EFS Clinical
**Surgical Heart Valve** Durable replacement for diseased valves
Stage = Feasibility
**LAA Closure Clip** Epicardial closure to cut stroke risk
Stage = Feasibility

**ORTHOPEDICS · VASCULAR**

## Hydralese®Rx



One material, many long-acting therapeutic delivery routes.

**Ophthalmic implants** Sustained release replaces monthly injections ; Stage = Feasibility
**Women's health** Discreet multi-month intravaginal delivery
Stage = Feasibility
**Metabolic disease** Fewer injections via long-acting depot
Stage = Concept

**OCULAR · WOMEN'S HEALTH · METABOLIC**

## Hydralese®Tx



PGE+ polymer engines for non-viral payload delivery.

**iPSC reprogramming kit** Pre-complexed PGE-mRNA; Stage = Pre-Launch
**Mucoadhesive delivery** Cationic charge grips moist mucosa for local release; Stage = Feasibility
**Non-viral transfection** DNA, mRNA & other nucleic acid payloads at high efficiency; Stage = Feasibility

**DNA · mRNA · NUCLEIC ACIDS**

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# Hydralese®Rx

Expansion of custom drug delivery product development utilizing the Hydralese® library of polymers

A tunable material system, **not a fixed polymer grade.**

## Tunable Chemistry

Patented Hydralese® chemistry affords multiple chemical modifiers

- Monomer selection
- Molecular weight
- Hydrophobicity
- Crosslinker



## Form Factors

Versatile form factors for multiple routes of administration, manufacturable at ambient conditions

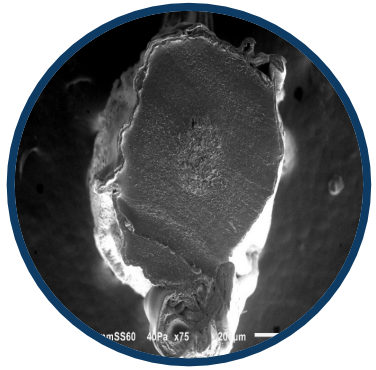
- Monolithic implants
- Core/sheath implants
- Coatings
- Closed geometry implants



## Drug Delivery

Hydralese® polymers can be used to deliver small molecule APIs, biologics, and in multipurpose technologies

- Release mechanism – combination of drug diffusion and polymer erosion



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# **Phase 0** Product Development Process

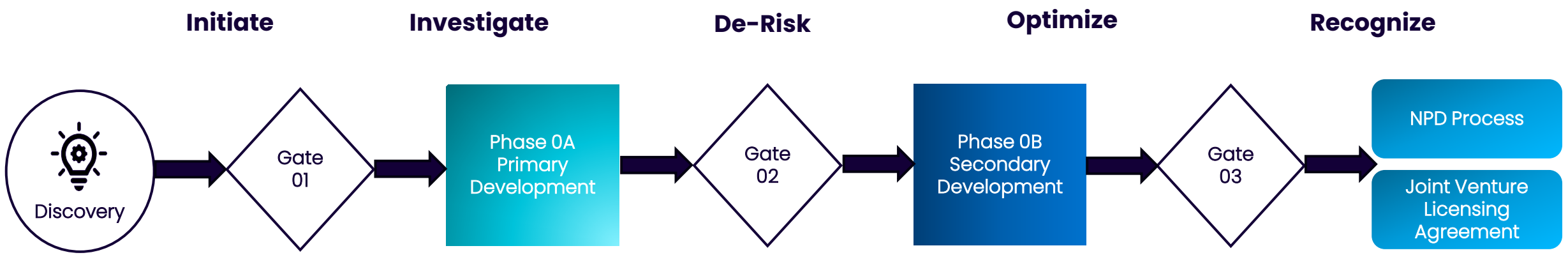
*Technology Readiness Level*

**TRL 1** – Basic Principles Observed

**TRL 2** – Technology Concept Formulated

**TRL 3** – Experimental Proof of Concept

**TRL 4** – Technology Validated in lab




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# Process Overview

Ensuring quality and reproducibility in each step of custom formulation development

## Formulation







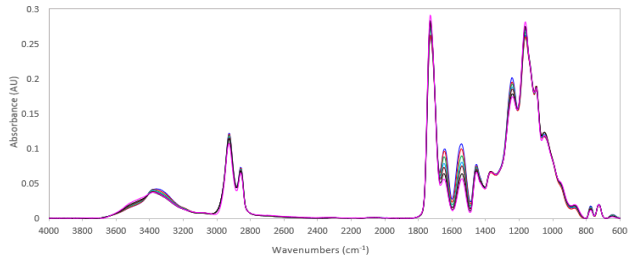


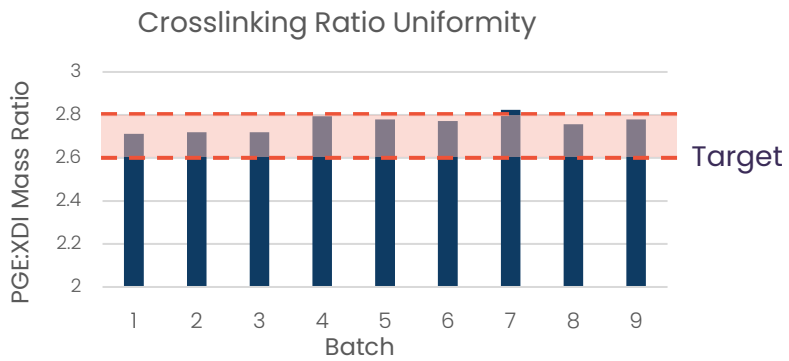
- ✓ Formulation component **viscosity matching** by rheometry
- ✓ **Formulation component density** measurement for accurate dispensing

## Form Factor Molding





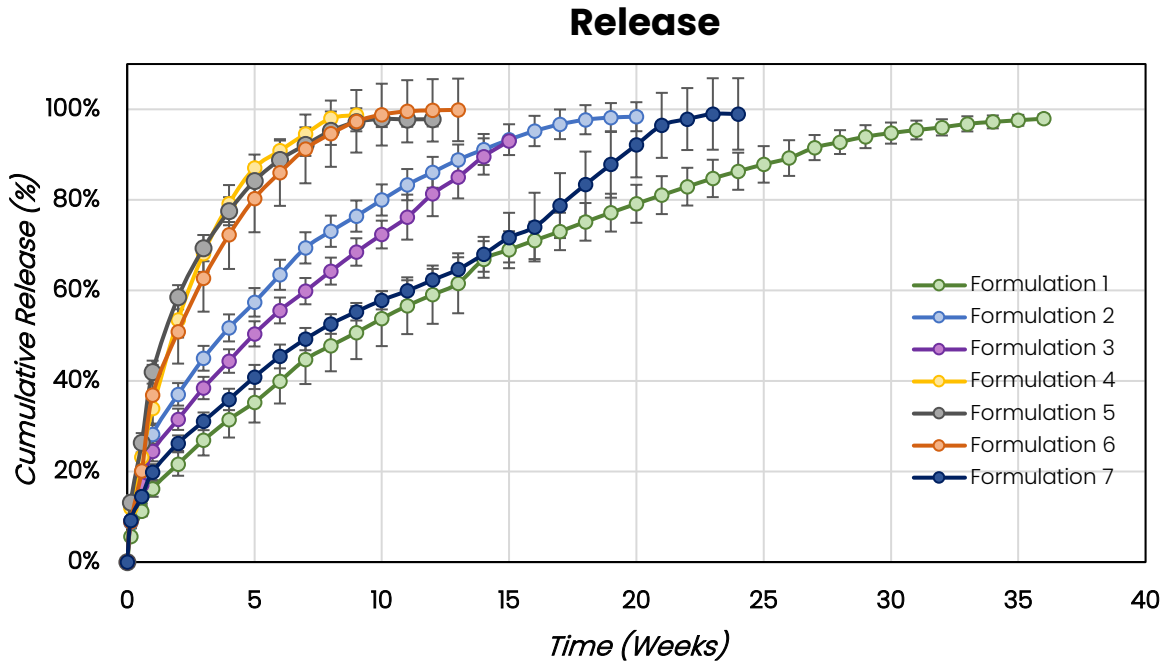



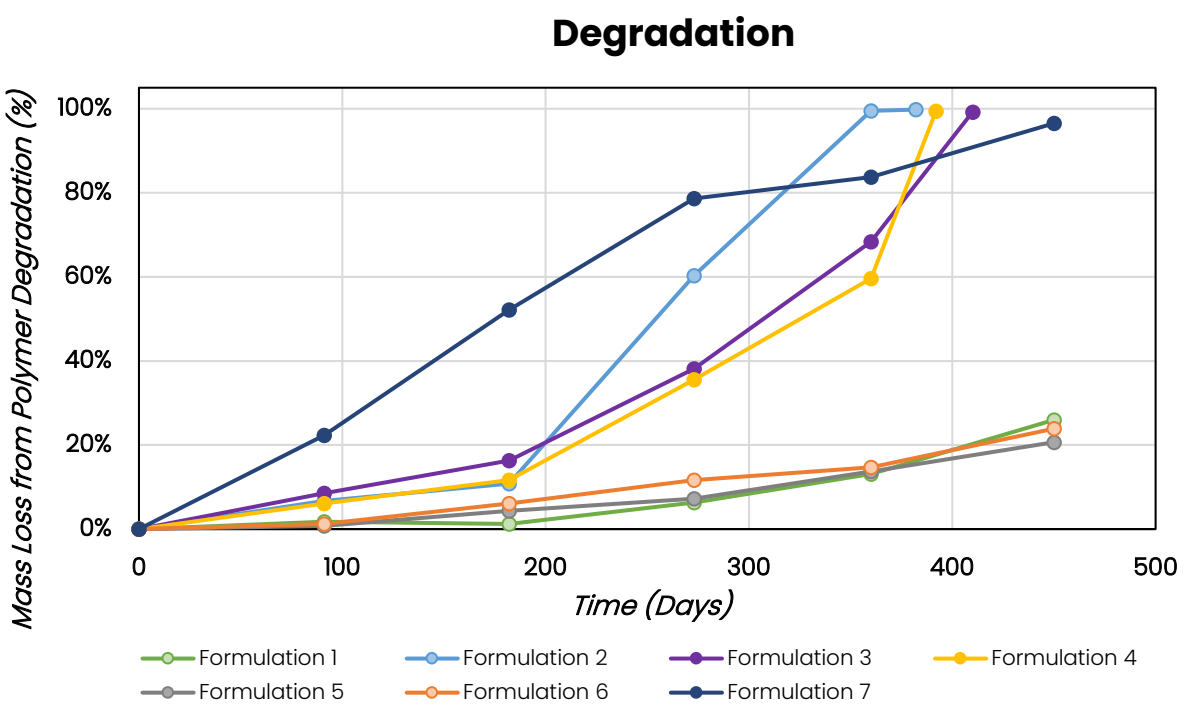

- ✓ API content assay to ensure **target loading consistency**
- ✓ Extraction of API, spectroscopic analysis of **PGEU crosslinking density for uniformity**

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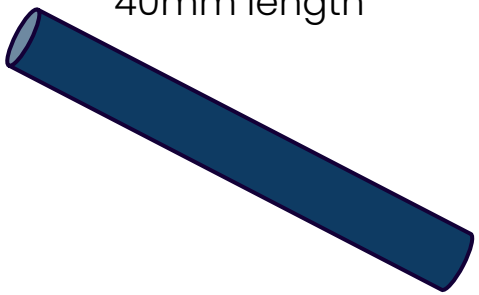
# Tunable release and degradation profiles of **Hydralese®Rx**

- Hydrophilic model API
- 25mg/mL API solubility in $H_2O$
- High loading (40-60% API w/w)
- Chemistry enables preservation of release kinetics while **significantly accelerating degradation**




3mm diameter x
40mm length



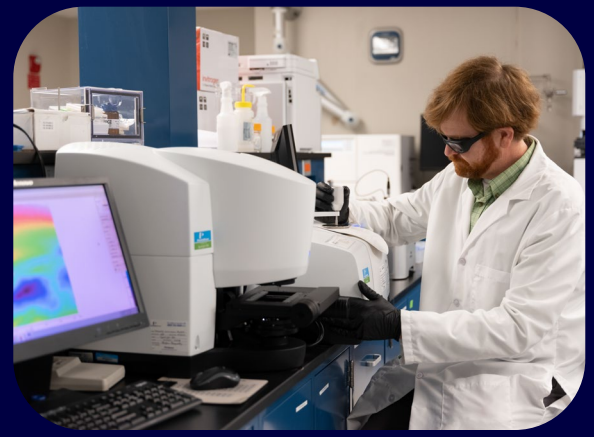
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# Analytical Testing & Method Development

On-site analytical testing and test method development supports the development of custom drug release technologies.

- HPLC
- LC-MS
- GPC
- GC
- Thermal analysis
- Rheology
- UV-Vis
- FTIR
- Raman
- NMR







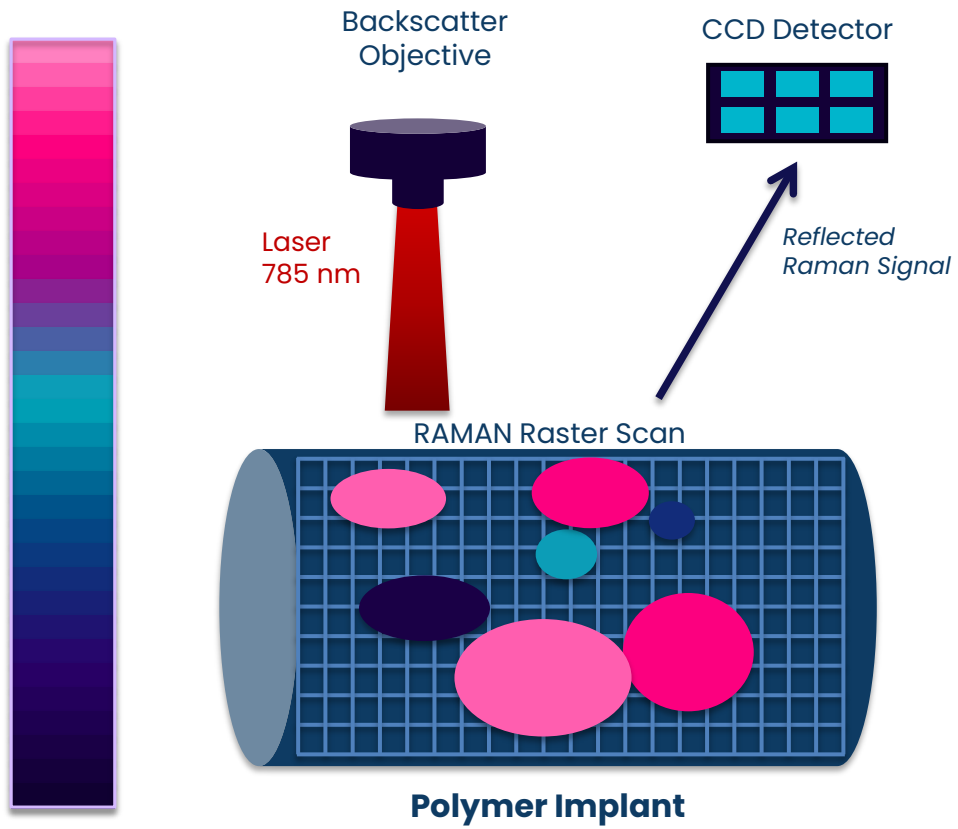

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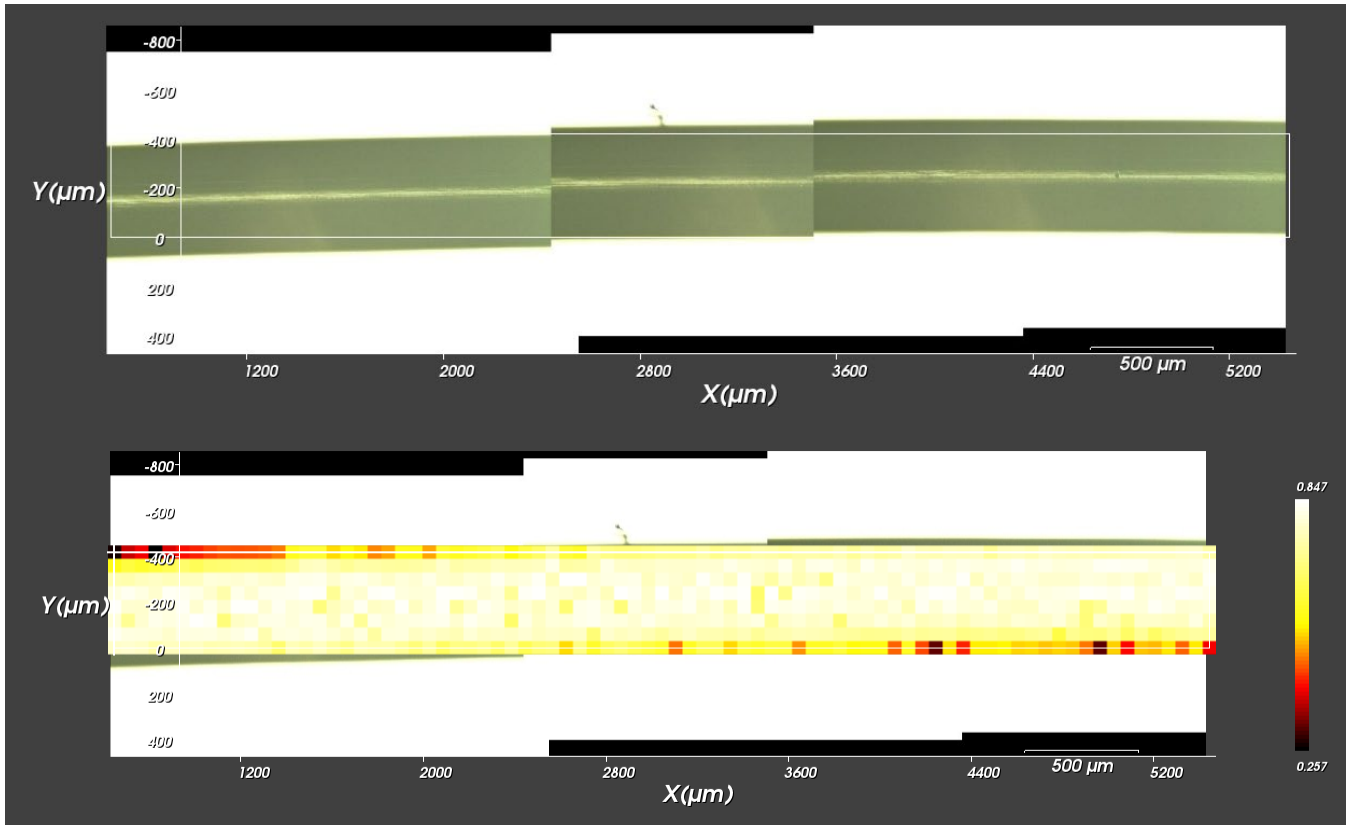
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# Capability Demonstration

## Spectroscopic Analysis of API-Loaded Implants




*Principal Component Analysis:*

Neat API

Neat Polymer

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MICHELIN

# Digital Twin Platform for **Accelerated Development**

We are partnering with Michelin to design a custom multiphysics structural model, coupling real-time degradation and release performance.

Modeling captures formulation solutions within relevant design space that may have been overlooked by traditional experimental approaches.

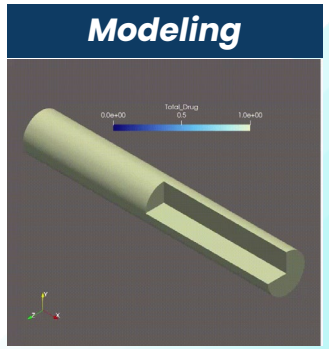


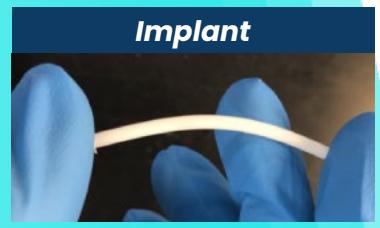










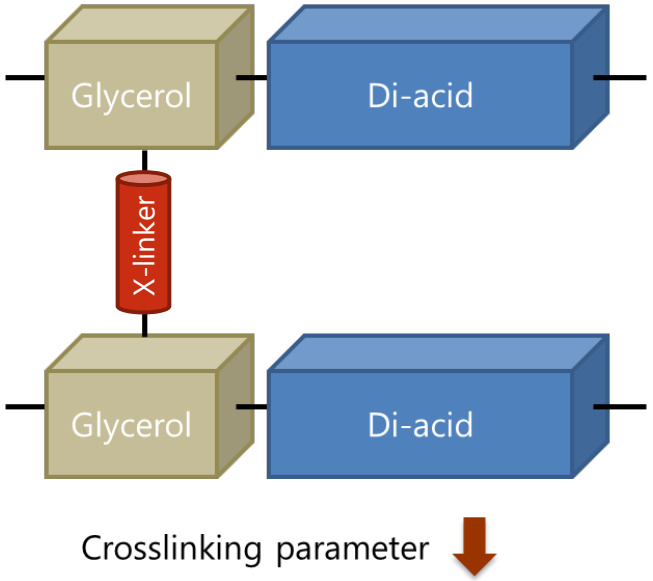


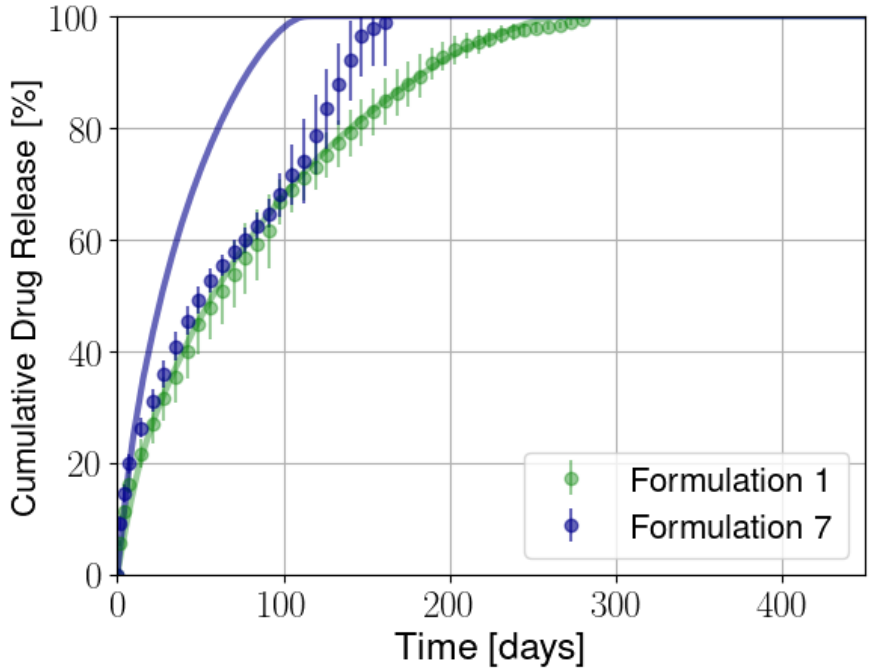
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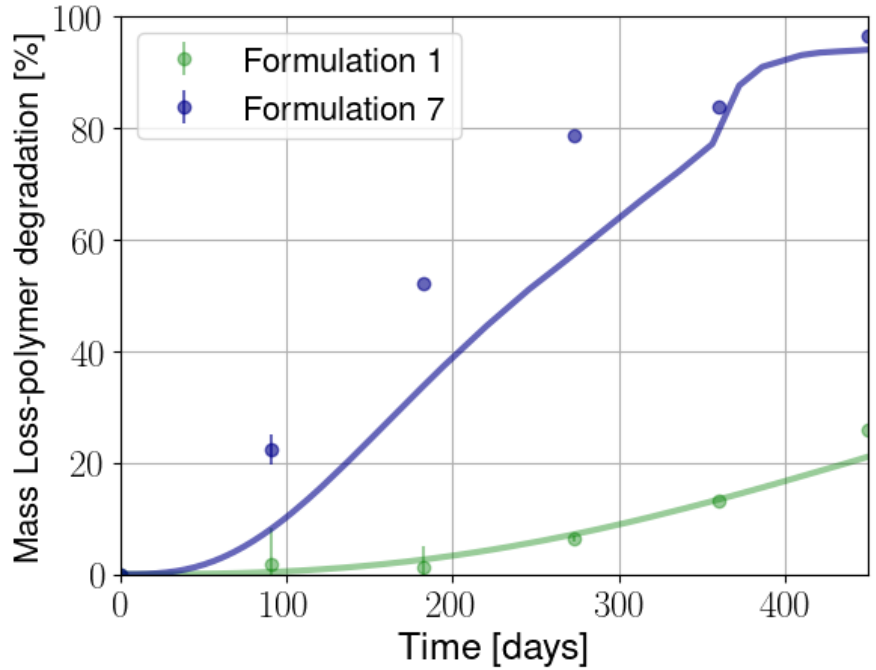
# Capability Demonstration

## Predictive Modeling of API-Loaded Hydralese®**Rx** Implant

**Hard Segment Composition**




- Digital twin can **accurately model degradation and release kinetics** of formulations with varying crosslinking parameters
- PGEU toolbox chemistry enables **preservation of release while accelerating degradation**, translating to a more efficient LAI technology

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Hydralese®Rx

The Hydralese®**Rx** platform offers a flexible alternative to resorbable PLGA-type and non-eroding EVA-type polymer grades, multiple options for customization, supported by a robust QbD-driven framework to enable productive partnerships in drug delivery.

## Stop by Booth 314

- Discuss your next drug delivery project
- See multiple form factors
- Check out our Digital Twin demo

# Questions?



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