

HYBRIDGE

ANNUAL CONFERENCE 2026

Two days
to connect
with experts
shaping
the future
of Hybrid
& 505(b)(2)
ECOSYSTEM.

September 16th – 17th
Palau Macaya | Barcelona

Explore
the full agenda
& make the most
of your event
EXPERIENCE.

From Early Ideation to Market: An
End-to-End Perspective on Inno-
vation Based on Known Molecules

Innovation based on known mole-
cules is becoming an increasingly
strategic area of pharmaceutical
development. The HYBRIDGE An-
nual Conference brings together
experts from Europe and the US to
provide an end-to-end perspective
spanning regulatory strategy,
clinical development, IP, market
access, business development,
and enabling technologies.

Through specialized training and
real-world experience, attendees
will gain practical insights into the
opportunities and challenges of
Value-Added Medicines, 505(b)(2),
and related innovation pathways.

ORGANIZED BY:



PARTNERED BY:



16 SEPTEMBER DAY 1 DEVELOPMENT FRAMEWORK.

9:00 – 9:05 A.M.
WELCOME

9:05 – 9:25 A.M.
INTRODUCTION TO INNOVATION
APPLIED TO KNOWN MOLECULES
THROUGH THE HYBRID & 505(b)(2)
PATHWAY

Setting the scene: definition and market trends,
US and Europe.

ANA GAVALDÁ, PHD. | *Founder of HYBRIDGE and ANNION
PM Managing Partner*

9:25 – 9:55 A.M.
PORTFOLIO OF VALUE-ADDED
MEDICINES / 505(b)(2)

Understanding the value of Value-Added
Medicines: balancing market opportunities
and specific challenges.

ANA CATARINA PINTO, PHD. | *Head of Portfolio Manage-
ment at Bluepharma*

9:55 – 10:40 A.M.
CLINICAL & REGULATORY
REQUIREMENTS (FDA)

Understanding the clinical and regulatory
landscape of 505(b)(2) development.

SPEAKER TO BE CONFIRMED (TBC) |

10:45 – 11:15 A.M.
COFFEE BREAK

11:20 – 12:05 A.M.
CLINICAL & REGULATORY
REQUIREMENTS (EMA)

European Hybrid pathways: clinical and regulatory
considerations.

CHRYSA DAOUSANI, PHD | *Founder-Managing Director/
Senior Consultant at Pharminnova*

12:05 – 12:25 P.M.
NON-CLINICAL REQUIREMENTS

Bridging strategy and check-listing review.

NICOLAY FERRARI | *Owner and Senior Director of Research
at ArendiBio Solutions*

12:25 – 12:45 P.M.
IP

Protecting innovation beyond the molecule: IP
strategies for Value-Added Medicines.

TONI SANTAMARIA | *Chief Intellectual Property Officer at Adalvo*
IRENE CASALPRIM | *Director of Intellectual Property at Adalvo*

12:45 – 1:15 P.M.
BUSINESS STRATEGY TO SUCCEED
WITH THE DEVELOPMENT

Strategic enablement of 505(b)(2) development: a
business-development perspective.

ROSANNE D'ALESSIO | *VP Business Development
at ArendiBio Solutions*

1:20 – 2:20 P.M.
LUNCH BREAK & NETWORKING

2:25 – 2:55 P.M.
MARKET ACCESS EUROPE

Pricing, Reimbursement and Market Access for Hybrid
Medicines in Europe.

JAMES BURT | *CEO at PLG and Board Advisor at Galenicap*

2:55 – 3:25 P.M.
EUROPEAN LEGISLATIVE FRAMEWORK

European legislative framework and policies suppor-
ting value-added medicines.

CONSTANCE MONTAZEL | *Value-Added Medicines Policy Ma-
nager at Medicines for Europe*

3:25 – 4:10 P.M.
MARKET ACCESS US

De-mystifying U.S. managed care for 505(b)(2) deve-
lopers: why early market-access strategy determines
commercial success.

WILL BAINBRIDGE | *Head of Global Commercial Strategy,
Market Access and New Product Planning Consulting
at Premier Consulting*

4:10 – 4:55 P.M.
ROUND TABLE · MARKET ACCESS
Executive round table: market access.

4:55 – 5:00 P.M.
CLOSING FIRST DAY

Building the HYBRIDGE community.

ANA GAVALDÁ, PHD. | *Founder of HYBRIDGE and Annion PM
Managing Partner*

From 5:00 P.M.
NETWORKING EVENT

17 SEPTEMBER DAY 2 INDUSTRY EXPERIENCE.

8:30 – 8:35 A.M.
WELCOME TO DAY 2

8:35 – 9:00 A.M.
EVALUATING INNOVATION BASED
ON KNOWN MOLECULES

Assessing the value of pharmaceutical development
opportunities.

ANA GAVALDÁ, PHD. | *Founder of HYBRIDGE and ANNION PM
Managing Partner*

9:00 – 9:30 A.M.
BUILDING A CO-CREATION ECOSYSTEM

Building a co-creation ecosystem to accelerate ad-
ded-value pipeline growth.

ANA DUARTE | *Senior Portfolio Manager at Farmaprojects,
Polpharma Group*

TECHNOLOGIES THAT CAN ADD VALUE

9:30 – 9:55 A.M.
A Second Life: How Solid-Form Engineering Gives Old
Drugs New Purpose

VÍCTOR M. DÍAZ PÉREZ | *Co-founder and Operations Director
at Solitek Pharma*

10:00 – 10:25 A.M.
Nanomedicine Development: A Robust Strategy for
Targeted Delivery and Controlled Release

ALBA CÓRDOBA INSENSE, PHD. | *Business Unit Director -
DELOS Technology at Nanomol*

10:30 – 11:00 A.M.
COFFEE BREAK

CONTINUATION ON TECHNOLOGIES
11:00 – 11:30 A.M.

Beyond the Molecule: Unlocking Patient-Centric Value
Through Lyophilized ODTs

PAOLO RADDANI | *Chief Executive Officer at Ziblets B.V.*

11:30 – 12:00 A.M.

Value-Added Medicines: Accelerating Repurposed
Drugs from Idea to Clinical Proof of Concept

PHD. HANS PLATTEEUW | *Chief Development Officer · Founder,
Ziblets at Galenicap*

12:00 – 12:30 P.M.
The Device Is the Strategy: Engineering Value into
505(b)(2) Programmes

ARNAU PERDIGÓ | *Chief Executive Officer at Perdigó Medical*

12:30 – 1:05 P.M.
THE INDUSTRY EXPERIENCE

Innovating beyond the generics: 25 years of
Bluepharma's patient-centric journey.

ANA CATARINA PINTO, PHD. | *Head of Portfolio
Management at Bluepharma*

1:00 – 1:30 P.M.
BUSINESS DEVELOPMENT

The paradigm of doing incremental innovation in
Europe vs USA.

DINA FERREIRA | *Chief Scientific Officer at Laboratorios Rubió*

1:30 – 2:30 P.M.
LUNCH BREAK & NETWORKING

2:30 – 3:00 P.M.
BRIDGING EMA & FDA

A two-way road to global approval for 505(b)(2)
and value-added medicines.

CARLOS RODRIGUEZ | *Founder at BCN Lifesciences*

3:00 – 3:45 P.M.
ROUND TABLE · PORTFOLIO STRATEGIES
Executive round table: portfolio strategies
for value-added medicines.

3:45 – 4:30 P.M.
ROUND TABLE · BUSINESS DEVELOPMENT

Executive round table: business development
in value-added medicines.

4:30 – 5:00 P.M.
CLOSING REMARKS

Shaping
the future
of pharmaceutical
INNOVATION.



COMMUNITY
Join the network
shaping the future of innovation
in Value-Added Medicines/
505(b)2 / Hybrid.



INNOVATION
Turn insight into impact across
science, regulation, and com-
mercialization.



REGISTRATION
Be part of the next wave
of pharmaceutical value creation.
Get your ticket at
www.hybridgeglobal.com

