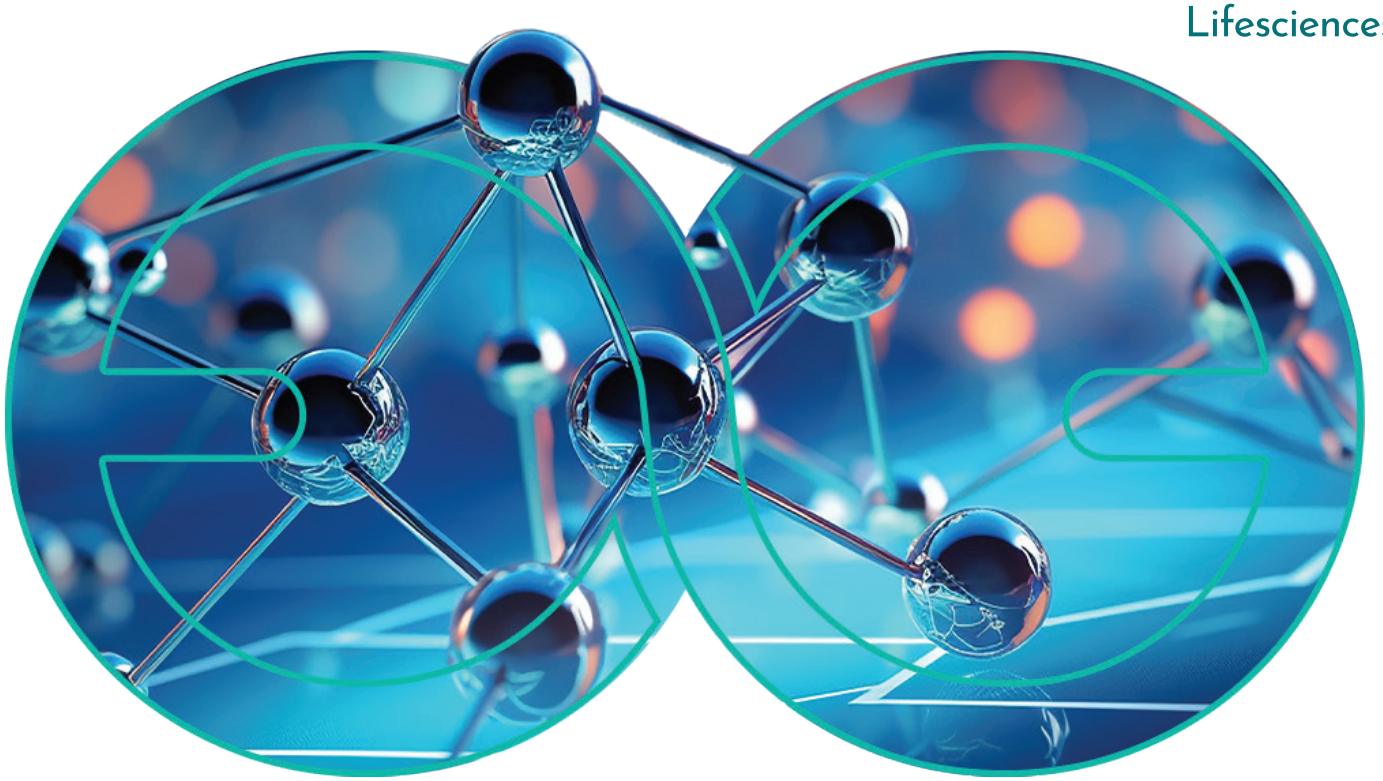
Veeda™ Lifesciences



Beyond the Hurdles: Veeda Lifesciences Approach to 505(b)(2) Regulatory Success

Sponsors Striving to bring Complex Drugs to Market through Traditional Pathway often Grapple with Issues like

- The need for sophisticated planning to meet stringent regulatory requirements
- Expertise in demonstrating therapeutic equivalence, safety & efficacy endpoints
- Challenges in addressing time-intensive, costly development cycles
- Lack of clear regulatory guidelines for approval
- Identification of targeted markets and indications to address unmet patient need

A Suite of Solutions: Partnering for Success with Trusted Expertise

- **Tailored Study Design:** Crafted to meet the unique requirements of each project
- **Experienced Teams:** Investigators and staff prioritizing participant safety while ensuring accurate and efficient dosing procedures
- **Accelerated Timelines:** Validated methods delivered in 4-6 weeks
- **Strategic Guidance:** Secure timely approvals for even the most complex studies

Real-World Success: Veeda's Role in Overcoming Regulatory Barriers

	Challenge	Solution	Outcome
Approval for Rectal Gel Dosage Form	During the SEC meeting, DCGI requested preclinical safety data for the new dosage form	We conducted a 28-day repeat-dose toxicity study showing that the rectal gel's bioavailability was comparable to the tablet form & confirmed its safety in healthy subjects	Based on this robust data, approval for the clinical trial was granted in the follow-up SEC meeting
Ethical Clearance for Animal Toxicity Study	DCGI requested ethical clearance for an animal toxicity study to support the test formulation	We provided Ethics Committee clearance for the animal toxicity study, addressing requirements raised during the initial DCGI meeting	Following deliberations in subsequent SEC meetings, the strong supporting data and scientific justification led to trial approval
DCGI Approval for a Fixed-Dose Combination (FDC) Test Product	Demonstrating the safety of the FDC product to meet regulatory standards	Comprehensive preclinical safety data specific to the FDC product was presented to address regulatory concerns	The FDC product received approval after successfully meeting all requirement

Features of the 505(b)(2) Pathway Driving Industry's Interest

	Studies	Market Exclusivity	Timing for Approval	Cost of Drug Development	Clinical Trials, Non-clinical/ Toxicology Data
505(b)(1)	Full	5 years	8–15 years	$500 m – 2b	Yes
505(b)(2)	Partial	3–5 years	2–5 years	$3 m – 7 m	Maybe

Veeda Lifesciences Capabilities in Supporting 505(b)(2) Applications

Pre-Clinical Studies

- In vitro studies
- In vitro PD studies
- In Vivo PK/PD studies
- In Vivo Toxicology studies:
  - Repeat dose toxicity studies (14/28/90 days etc.,)
  - DART studies
  - Genotox studies

Clinical Studies

- Single & Multiple dose BA/BE
- Dose Proportionality
- Pharmacokinetics/Pharmacodynamics
- Food effect
- Safety/ efficacy studies
- Drug Interaction
- Single Ascending Dose/ Multiple Ascending Dose

Proficiency in **More Than 10 Therapy** Areas Including Psychiatry, Endocrinology, Respiratory, Dermatology and others

Veeda Lifesciences Proficiency in Navigating Regulatory Approvals through the 505(b)(2) Pathway:

- Completed **14** Complex Studies
- Successfully Executed **45** Studies
- Database of **89,000+** Volunteers
- Collaborated with **25+** Global Sponsors

Wide Experience across Different Formulations

- Capsule
- Solution
- Tablet
- Oral Solution
- Oral Suspension
- Granules Sachet
- Sublingual Spray
- Rectal Suspension
- Ophthalmic Solution
- ODT (Orally Disintegrating Tablet)

Studies Successfully Submitted to Global Regulatory Bodies such as: **ANVISA, Canada, DCGI, USFDA, NPRA**

Veeda Lifesciences Advantage

- Skilled personnel with focus on Continuous Professional Development
- High Customer Centricity and Satisfaction
- Extensive Scientific Competence to service a Diverse client base
- One of the largest Independent Full Service CROs in India
- Robust Quality & Regulatory Compliance
- One stop solution for complex studies

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