EXPERTISE AND INNOVATION IN FORMULATION DEVELOPMENT

Vici Health Sciences

OUR GOAL IS TO DELIGHT OUR CUSTOMERS THROUGH EXPERTISE AND INNOVATION IN FORMULATION DEVELOPMENT. WE ARE PASSIONATE ABOUT SOLVING OUR CUSTOMER'S PROBLEMS.

These problems may be high-cost, project delays, poor customer service, or low-quality R&D. Work with us to boost your company growth through new product development.

WE ARE EXPERTS AT

- Formulation development
- Analytical method development
- Manufacturing process development and tech transfer
- CRO management for BE studies
- CMC regulatory documentation
- Regulatory filings

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CONTRACT DEVELOPMENT

We have proven expertise in finding innovative, low-cost, high-quality solutions to technical and logistic problems and we pass the savings on to you. Being US-based, we are your ideal one-stop R&D partners. Being a small, flat organization, speed and attention to your project are guaranteed. We can manage all aspect of product development and work with local and international manufacturing partners to have your product concept developed, manufactured and FDA approved in record time.

FORMULATION DEVELOPMENT

Developing high quality stable and bioequivalent formulations

- Solid and liquid oral dose formulation development
- Injectable formulation development
- Complex formulations
- Extended release formulations
- Tablets, capsules, oral solutions and suspensions, ODT, extended release suspensions, chewable, powers for reconstitution, injection formulations in vials or ampules

ANALYTICAL METHODS

Low-cost, HPLC method development and testing

- HPLC based method development
- Assay, dissolution, stability indicating methods, degradation products, cleaning methods, content or blend uniformity
- Preservative assay, preservative efficacy, water content, particle size
- Analytical testing for formulation development support
- In-process, release, or stability testing
- GLP/GMP
- Method qualification, method verification, method transfer

STABILITY STUDIES

Solving stability problems and performing R&D stability studies

- Solving problems with product stability
- All ICH stability conditions
- Developing stable products with desired shelf life

CLINICAL STUDIES

- Manufacturing clinical trial material for pilot bioequivalence studies or Phase I clinical trials
- US-based or international CRO selection, pricing negotiations, quality audits, protocol review
- Managing all aspects of bioequivalence or pharmacokinetic clinical studies

MANUFACTURING TECH TRANSFER

- Managing all aspects of working with CMO, from identification through product approval
- Manufacturing process development and optimization at R&D scale
- CMO identification, selection, contract negotiations, audits
- Tech transfer and process development at CMO
- Solving manufacturing problems such as lack of process control, blend and content uniformity failure, or batches failing to meet release specifications

REGULATORY DOCUMENTATION AND FILING

- Product development report in the CTD formatQbD, risk assessment, FMEA
- Pre-IND, IND documentation and filing
- FDA controlled correspondence
- Writing all CMC sections of an ANDA or 505(b)(2) NDA filing
- Managing all aspects of ANDA or 505(b)(2) filings and approval through our preferred regulatory services provider

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PATENTS

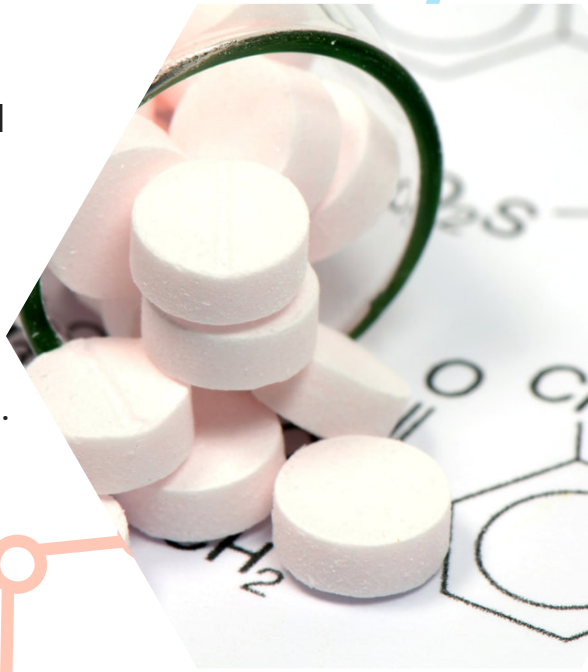
- Developing and filing for patents around your products for enhanced exclusivity
- Non-infringing Para IV ANDA product development
- Consulting on all formulation, clinical, API related, dosing related patent issues

FULL-SERVICE R&D

- Vici offers all services that an internal R&D department offers parent companies
- Partner with us to receive all the benefits of having your own internal R&D group without the cost or headache associated with creating and maintaining an internal R&D group

PRODUCT OUT-LICENSING

Vici has proven expertise in producing drug leads and is working to expand its commercial development partnerships for products developed in-house.



Our development pipeline contains many exciting unique barrier-to-entry oral product ANDA opportunities. Our target is to successfully develop and out-license 10 ANDA products a year. We're actively developing these products while seeking funding, manufacturing or distribution partners. **Contact us with your partnership ideas** and we can work out a mutually beneficial profit-sharing agreement for these products.

ANDA

The ANDA pathway is used for the development and approval of generic medicine. Working for our clients, Vici has developed and filed ten (10) ANDAs, eight (8) of which have been approved. Four additional products are on track for ANDA filing by Q1 2020.

505(B)(2)

The 505(b)(2) NDA pathway allows companies to create new dosage forms, of previously approved molecules, that offer improved convenience, safety, or efficacy at a fraction of the cost of traditional NDAs. Vici is currently developing two products targeting CNS diseases that are on track for 2020 FDA filing.

WE ARE HERE TO HELP

We believe in building long term, lasting relationships with our customers, and each employee is committed to providing quality and transparent information to promote growth and understanding.

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