



Offering a Rigorous Strategic and Tactical Approach combining Intellectual Property Analysis and Review Step-by-Step, Drug Formulation Development CRO Integral BioSystems LLC is helping Pharmaceutical Companies with “Difficult-to-Formulate” Drugs and Integrated IP-Drug Development for Repurposed Drugs

**Healthcare
CRO
Innovative Drug Delivery**

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**Shikha P. Barman
CEO**

BIO: Integral BioSystems CEO and CTO, Shikha Barman, Ph.D. has approximately 20 years of work experience in the pharmaceutical and biotech industries in areas of drug delivery, pharmaceutical development and tissue engineering. Her interests have always been entrepreneurial, selecting the start-up venture over established companies choosing to accept high risk in exchange for exponential professional growth usually experi-

enced in innovative product development. Also an artist, Dr. Barman has always been fascinated by the creativity of targeted drug delivery with the goal of improving and modulating drug targeting, absorption, cell permeability and solubility. Notably, her initial major contributions at her first job Focal, Inc. were inventive contributions toward design and development of a platform technology of PEG-based photocrosslinkable, biodegradable tissue sealants, the entire line of which was acquired by Genzyme BioSurgery. She has also contributed to core IP for other companies that she held positions in: Zycos, Inc., Sontra Medical Corporation, Inotek Corporation and Follica, Inc. Her roles have been increasingly multi-factorial with each successive company that she worked in, with cross-functional job responsibilities in CMC, pharmaceutical development, preclinical and toxicology.

She founded Integral BioSystems, LLC with Boston-area patent attorney Dave Karasic with the joint objective of creating an integrated drug development firm, offering innovative drug delivery solutions to hard-to-develop drugs. Dr. Barman has a M.S. and a dual-degree Ph.D in Polymer Science and Plastics Engineering from University of Massachusetts-Lowell, MA and a B.S. / M.S. in Chemistry from Auburn University, AL.

About Integral BioSystems LLC:

Integral BioSystems was founded in 2009 as a niche drug delivery and intellectual property consulting company, but quickly evolved into a drug

formulation development CRO with fully equipped laboratories and scientific staff in 2012. Based in the greater Boston area, Integral BioSystems merged expertise with a Bedford, MA based firm Patents Etcetera to offer drug development services that starts with a focused IP strategy, particularly for APIs suitable for repurposing. In this regard, this integrated and unique approach allows companies to review and develop solid and focused IP strategy around the proposed drug product, prior to incurring massive drug development expenses. The strategic IP exercise teaches whether the drug product should be developed as a generic or a 505(b)(2) NDA with market exclusivity afforded by patent protection. Whether innovative or generic, Integral BioSystems provides drug formulation and development services leading to technology transfer.

In addition to offering contract IP and formulation development services to pharmaceutical companies, Integral BioSystems has internal programs developing platform delivery systems, with the purpose of out-licensing/partnering with pharmaceutical companies with difficult-to-develop drugs.

Integral BioSystems, LLC is based in Bedford, MA.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Dr. Barman, would you tell us about Integral BioSystems?

Dr. Barman: Integral BioSystems is an integrated IP-drug delivery CRO offering a focused step-by-step IP review of the drug formulation strategies to be utilized/or utilized to develop the product. The IP review and analysis includes assessments on patentability of formulation approaches for an established drug, guiding the thought process toward minimizing risks for obtaining patent protection. Many companies leap headfirst into the drug development process, without these key assessment check-points leading to the expenditure of big dollars with a possibility of patent rejection by the USPTO and other IP authorities. With a focused strategy in hand, we proceed with drug formulation development, fast-tracking the program to technology transfer to a GMP facility. Additionally, at Integral, we come up with innovative solutions to formulating drugs that are “undruggable” due to its unacceptable physiological properties such as low cell permeability or absorption which leads to high, often-toxic doses, low solubility, or high drug efflux ratios. We come up with focused strategies with the goal of enhancing the efficacy of a drug. Our niche and focused expertise in drug formulation development attracts pharmaceutical companies that value a rigorous quality approach as opposed to the “quick” and “good-for-now” strategy. The latter often leads to CMC issues later, sometimes grinding a program to a halt. We follow a rigorous approach to drug development and advise our clients accordingly. This plans for success.

CEOCFO: How do you decide what you want to work on, both on your own in development and in partnership? Is there a common thread?

Dr. Barman: There is definitely a common thread. We invest in drug delivery projects that are platform technologies and would be applicable to a wide spectrum of clinical applications. The drug delivery platform would seek to address a long-standing clinical need. For example, a drug delivery system that can deliver precise quantities of drug to the retina sustained over a year, solves a long-

standing clinical issue of the need for multiple, repeated injections into the eye! If developed, this delivery system would become the “holy-grail” carrier system for a variety of drugs and a whole host of retinal diseases (macular degeneration, diabetic retinopathy) that can lead to blindness. Integral BioSystems’ strategy is to partner with pharmaceutical companies to enable its delivery systems into a variety of drug products. In order to develop the full potential of the platform, Integral BioSystems offers non-exclusive licenses, although philosophically, any business transaction is negotiable!

CEOCFO: What is the competitive landscape and why should people be looking to you as a partner as opposed to some of the others?

Dr. Barman: As expected, the landscape is competitive. We offer a rigorous strategic and tactical approach

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- Shikha Barman, Ph.D.

to drug development that combines intellectual property analysis and review step-by-step. This unique combination of integrated drug development differentiates Integral BioSystems from other companies offering contract services. For example, drug development companies are not patent firms; our company offers both, as a combined service—critical to drug development. This is especially important in times where large pharmaceutical companies are losing market exclusivity on their blockbuster drug products. Most of our clients are attracted to us, for these unique services. Most of our clients are aware of our innovative drug delivery programs and approach us with difficult issues with their drug. For example, a company approached us with a highly unstable, but potent API. Of the course of a co-development program, Integral BioSystems developed a stable

dosage form they could take to the clinic.

CEOCFO: Your website shows that you offer a systematic, step-wise development plan. How does your approach maybe differ or what is better about it than the others are? What do you bring to the table from your many years of experience to assure success?

Dr. Barman: We offer a systematic step-wise drug development plan, mapping the path from the lab to the clinic. However, I agree that other companies offering drug development services most likely offer a systematic plan, as well. We have differentiated ourselves by offering innovative approaches to develop “difficult-to-formulate” drugs. Additionally, companies that approach us specifically request integrated IP-drug development, especially for repurposed drugs. So, this business strategy for service differentiation is quite successful. For these clients, we apply our combined expertise in drug delivery, drug development and IP to develop and propose a potentially patentable, innovative drug product.

CEOCFO: Could you give me an example of where that innovation comes into play?

Dr. Barman: Yes, of course. An ophthalmic pharmaceutical company approached us to develop a drug development strategy for a well-known drug with an established mechanism of action. The drug has been never used as an ophthalmic. We developed an IP strategy that ultimately resulted in a drug product that was platform, and can potentially be used in number of different clinical applications and not just ophthalmics! We, along with our client, were extremely pleased with this outcome. This led to repeat business for us, from this client. Thus, we are already demonstrating that this rigorous IP-drug development works. I predict that this will be the path to well-focused drug development programs. We will see more of this, in the future.

CEOCFO: How do you reach potential customers?

Dr. Barman: It is always difficult to obtain that first client. Reputation and well-honed C.V.s of the key players offer credibility to any program. Ultimately though, a combination of various approaches has worked for us. These are networking through colleagues and professional contacts, memberships, advertising through trade shows, post card mailings, well-focused newsletters all can contribute to branding and gaining visibility. For companies offering science-based services, I recommend trade-shows, peer-reviewed publications and scientific white papers. These all synergistically add value to a company's image as a service provider. Additionally, it is critical to establish and maintain credibility with our current clients by the quality of the services we offer them. Lastly, it is important to offer reasonably priced services. My philosophy is to build up the "bottom line" with repeat business from a client who trusts our work.

CEO CFO: Why should investors and people in the business community pay attention to Integral BioSystems?

Dr. Barman: Investors and persons in the business community primarily operate on three assessment tools: a sound, well-thought out rigorous approach, a unique and differentiated product that addresses a well-defined problem and potential market value of that product. We pass all three criteria. In terms of our contract services in Integrated IP-Drug Product development, it is to be noted that this approach is what attracts the client to Integral BioSystems for the first time. Both drug companies and investors recognize the value of this approach to create potentially patentable products with market exclusivity. Notably, the number of patent applications rejected by the USPTO has risen exponentially in recent years, which leads to a lengthy appeal process and millions of dollars lost. In terms of our innovation-based drug delivery sys-

tems, our programs are geared toward the development of platform technologies, rather than "one-off" products. Platform technologies have traditionally been attractive to investors, due to its potential for multiple products and large pay-offs.

CEO CFO: Final thoughts?

Dr. Barman: My vision is to build this company into a R&D "incubator", generating a platform system that can be "spun-off" into new entities formed around each application. Integral BioSystems will retain the IP to the core technology, while the spin-offs will focus on a particular clinical use of the platform. The IP aspect of our business is key to the patenting aspects of the platform. We plan to expand our contract research service offerings, with top-notch facilities and talented scientists and patent agents.



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