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YOU NEED	"WE GOT"
Credible, globally experienced, qualified in-house auditors	Over 75 years collective background and experience, good will, capabilities, network relationships, knowledge of all dosage forms, contacts within the global quality, regulatory and FDA communities
New business opportunities	Relationships with global clients seeking U.S. partners for development, distribution, sales/marketing, investment
In-house capabilities for all regulated products and dosage forms	Expertise in drug products (Rx & OTC), dietary supplement ingredients and products, cosmetics, devices, drugs/devices
Expanded client roster/global client base/access to other markets, etc.	Clients in U.S., North, Central & South America, Europe, China, India, Japan, several of whom we represent as U.S. FDA Agents, and others on a retainer basis
Full electronic submission capability	Via "sister company" for site registrations, drug listings, DMF's, IND's, NDA's, 505(b)(2)'s, ANDA's, 501(k)'s, briefing documents
For foreign companies seeking to enter the U.S. market…	Well-established, experienced global healthcare company, perfect for a foreign company seeking to establish a credible presence in the U.S.
In-house capabilities for FDA submissions	Expertise to prepare or review IND, DMF, NDA, ANDA, 501(k) submissions; and CMC preparation, review and submission
In-house expertise in building and developing Quality Units and Systems	Experience in evaluating and establishing Quality Systems, Standard Operating Procedures, documentation systems and forms
In-house Quality System evaluation	Experience in establishing capabilities to offer remediation of Quality Systems, Vendor Qualification Programs, and CAPA programs
In-house experience with building programs for qualifying all materials, products and dosage forms suppliers	Experience in establishing a Vendor Qualification Program for suppliers of APIs, finished dosage forms, excipients, drug and nutritional ingredients, and

	components
In-house Data Integrity audits	Experience in conducting data-integrity audits and identifying deficiencies
In-house Training Unit for internal and client training	GMP, Pre-Approval Inspection Training and presence on site during FDA inspections
In-house capabilities for global regulatory agency support	Global remediation experience, i.e. FDA, MHRA, CFDA, Anvisa, TGA & CAPA initiatives
GMP Training Modules	Rx, OTC, cosmetics, devices, dietary ingredients and products: 21 CFR Parts 111, 210, 211, 820
In-house due diligence	Expertise for acquisition of or investment in sites, regulatory submissions, products
In-house management of programs	Project development & management experience
Knowledge, Attitude, Skills, Habits, Success	**We got them all and can train your staff**
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