CHATA Biosystems, LLC

THE COMPOUNDING INDUSTRY AND THE CHATA SOLUTION

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Traditional pharmaceutical compounding

Pharmacy began as a compounding task. Alchemists, wizards, and shamans mixed herbs, soils, and flora to create salves and elixirs to cure tribal ills. It pretty much continued that way until some standardization and production recipes arose in the 19th-century. But, mass manufacturing has yet to put the compounding pharmacist out of business.

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Today's traditional compounding pharmacies prepare medications for patients as custom-ordered. These patients cannot swallow pills, suffer allergic reactions to one ingredient or another, or have some problem that stands in the way of taking the medication as usual. Others take medications and biologics intravenously. And, some medications are prescribed by veterinarians for their four-legged patients.

But, cost savings and heightened demands have increased the manufacturing volume and product diversity of the compounding pharmaceutical industry. High performing and FDA registered laboratory solutions are approaching the volume of the drug manufacturers themselves. When asked how their spending on outsourcing R&D or manufacturing would change in the next 12 months, 44% of drug manufacturers indicated their budgets will increase by 10.4% over the previous year. More manufacturers have come to recognize that outsourcing relieves them to focus on their core strengths.

Economics rule the opportunity

Various economic pressures demand that drug manufacturers (Big Pharma) find new, cost-effective, and often external laboratory solutions. These pressures drive drug companies to reduce internal R&D capabilities and manufacturing flows in favor of outsourcing. They look to outsourcing providers to perform their traditional functions, solve their problems, and enhance their quality and productivity. Customer patients, doctors, hospitals, and communities want guaranteed quality, lower costs and global availability. And, the compounding industry savors and develops that intimate end-user connection.

The Pharma industry is looking to outsourcing providers to enhance quality.

New pharmacy business model

The new healthcare paradigm is moving towards the consumption of pharma product and away from medical services. According to a report by The Physicians Foundation, "Physicians will need to redefine their roles and rethink deliver models in order to meet rising demand." The changes in technology, financials, and appetite for risk readies the drug compounding industry for a dynamic shift in purpose and performance.

Healthcare markets in developed and developing worlds and government programs like Medicare and the Affordable Care Act press drug manufacturers to step up innovation, laboratory solutions, and reduced pricing. This has led to "a worldwide shortage of biotech manufacturing capacity" that will limit availability and keep new products in the Phase II and III development pipeline.

This problem is good news for the compounding industry because people will look for cheaper ways to get access what has already been invented if big pharma is no longer making new drugs. So, the pipeline problem should increase compounding industry business, which in turn, will boost the need for outsourcing support solutions under the new exacting FDA quality regulations.

So, bio-pharmaceutical outsourcing has become one certain option to navigate the market pulls. The promise of secure processing, quality assurance, increased productivity, and cost-effectiveness offers a market checks and balance attractive to manufacturers and customers.

Not without risk

In 2013, tainted injectable drugs led to a meningitis outbreak that resulted in the death of 64 people. In another incident, 715 people were sickened by a tainted steroid medication. While pharmacy compounding is subject to state regulation, the FDA has had little oversight. This lead to the Drug Quality and Security Act, which allows the compounders that do mass-produce, drugs the choice to register with the FDA as "outsourcing facilities," subject to federally monitored quality controls and oversight. Outsourcing compounders are not required to register, but they are doing so in increasing numbers to show they value quality and to prove their dedication to protecting the consumer.

Outsourcing benefits on the laboratory side

Prominent registered compounding laboratories are designing strategies to improve their pharmacy operations by increasing their technical resources, investing in more focused research and development, and improving their human resource talent. As a result, there is every reason to believe that outsourcing of laboratory solutions can help increase drug maker productivity and integrity of lab results.

- Outsourcing laboratory solutions provides the chance to trade higher fixed costs for reduced variable costs. It reduces the need for large capital investment and allows institutions access to expertise and high-end clinical technology as needed. Lab outsourcing simply provides huge cost savings by ensuring the best quality assurance laboratory standards with the least amount of provider oversight and resource allocation.
- Laboratory outsourcing provides experts in critical chemical and analytical testing as dedicated consultants who work with institutions to deliver desired outcomes.
- Outsourcing allows companies to focus internal efforts on lab management, product development, and improved performance by saving money, ensuring sustainability, and supplementing the workforce of companies that operate in-house labs.

Strategic outsourcing:

Pharma outsourcing partners with compounding manufacturing suppliers to the benefit of both. The outsourcing server offers best state-of-the-art services to allow the drug manufacturer to better face the marketplace.

Tactical outsourcing:

Cost reduction and the desire to reduce in-house problems - lack of laboratory bench space, time, or qualified personnel - drive tactical outsourcing which relieves companies on issues of facility management and security.

Decisive outsourcing factors for the compounding industry

Decision makers must consider several factors when reviewing their outsourcing options:

- Mutual trust: Outsourcing contracts are essentially based on trust and people. Cost savings is not the key factor in selecting the outsource partner. What can go wrong will go wrong, so in dealing with the life and death issues of medications, the partners need to share clear and contracted understanding of how problems will be resolved.
- Off-shoring: Some outsourcing options are low-cost opportunities in foreign countries. Time zones, language barriers, and culture gaps invite problems with communication and team work.
- Quality performance: CROs (contract research organizations) and CMOs (contract manufacturing organizations) partner with drug manufacturers to produce their product at reduced cost as a result of specialized laboratory solutions and reduced labor burden.
- Due-diligence: The risk in any outsourcing arrangement is keeping both partners aligned in performance, quality, and regulatory due-diligence. Contracts must provide clarification of parties and roles, including shared understanding for quality and regulatory expectations.
- Supply chain logistics: Successful quality performance requires a sustained transition in which both parties provide mutually interested proactively involved project teams. Outsourcing risks counterfeiting and product degeneration. Suppliers must demonstrate transparency, visibility, and controls conducive to strict due-diligence and regulatory audits. When outsourcing also means off-shoring, the risk of weakness or failure escalates.

Outsourcing checklist:

Any outsourcing partnership must follow time spent on a thorough checklist of compatibility:

- Capability: Any judgment on the capability of the outsourcing service has to review the company's experience in similar work, staff expertise in aligned laboratory solutions, and their track record for execution and delivery.
- Capacity: They must be equipped and staffed to move and adapt with agility to, perhaps, new expectations and regulatory requirements.
- Quality: Quality is not a mere description in 21st-century manufacturing. It is a development and manufacturing process that requires constant monitoring and self-improvement.
- Regulatory Compliance: Compliance issues mount and multiply with the Congress's Drug Quality and Security Act (2013), and each agency has its own process, administrative, and archiving requirements.
- Financial Considerations: The cost of service in outsourcing is largely a function of continuity and long-term stability.
- Culture: Outsourcing performance depends on developed and sustained mutually profitable relationships between the partner companies.

Comprehensive service solutions

Chata Biosystems works to solve a comprehensive array of compounding supplier issues thereby assuring trust and quality assurance:

- Chata products match precise client specifications including the traceability of chemical components and solvents. The manufacturing of products, such as USP dissolution media and USP water, in larger quantities and shipping as needed assures the same lot can be used longer and decreases batch variance.

- Chata provides a full certificate of analysis complete with lot traceability with each product to decrease the client lab time spent on solution preparation and internal documentation releasing facility space and utility. This allows manufacturers and QC labs struggle to maximize outcomes with minimized resources.
- Chata bridges manufacturing gaps that result from outages or shutdowns. as a primary or secondary supplier of USP purified water and other packaged solutions.
- Chata produces reliable solutions with documentation that can meet or exceed FDA requirements or customer needs.

Custom laboratory solutions - without purchase orders

Chata Biosystems provides outsourcing suppliers with a catalog of services and products, such as USP dissolution media, USP water, and custom HPLC mobile phases water. They provide bulk eluents for production columns, preparatory buffers, non-parenteral excipient formulations, bulk sterile USP purified water, and more. A simple three-step online order system lets clients order custom laboratory solutions with ease and without purchasing orders.

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