

## The Stokes Difference

We receive many inquiries from our clients and others seeking information about our services and how we differ from other pharmacies. As a leader in the compounding industry, we felt it was important to take a moment and share our approach and philosophy to help clarify our standards and practices.

### ***Understanding Compounding***

Compounding is the art and science of mixing individual ingredients together to make a specific medication for a patient. When an individual pharmacist compounds specifically for their patients, they are known as 'compounding pharmacists,' likewise for technicians. Any licensed pharmacist, regardless of experience or training, can compound a medication and be referred to as a 'compounding pharmacist.'

Modern pharmaceuticals have their genesis in compounding. The traditional mortar and pestle, which are often used as symbols of compounding and pharmacy, can trace their history to more than 1500BC. Over the centuries, the process of compounding medications has matured to the point where commercial manufacturing dominates pharmaceutical production. However, thousands of compounding pharmacies around the nation and the world still choose to take the time and care required to compound medications to meet the needs of their patients.

### ***A Higher Standard: Quality, Not Quantity***

At Stokes Pharmacy, we are fastidious in our approach to ensure that the highest standards of compounding are practiced. Excellence by design encompasses everything we do:

- Our staff actively participates in rigorous and concise training plans where they master the concepts and theory of compounding. Part of that process includes making training preparations and proving their skills and abilities along the way.
- Our staff is certified to make specific compounds and receives advanced training on specialized compounding equipment.
- Equipment is subjected to a robust qualification process to ensure it not only meets its design qualification (DQ), but also meets installation qualification (IQ), operational qualification (OQ) and any performance qualifications (PQ) required.
- Preparations compounded at Stokes are consistent from lot to lot. Additional standards of practice designed and practiced at Stokes add additional assurance of consistent preparations.
- We have dedicated suites to physically separate distinct compounding processes to prevent contamination, confusion and inefficiency.
- We have developed robust operating procedures that are able to prevent, detect and investigate quality deviations throughout the compounding process.
- We utilize a highly developed microbiology performance qualification system developed at Stokes to monitor, identify, categorize and remedy quality events whether part of materials, environment, personnel or products.

At Stokes, we work daily with controlled substances, diverse and potentially dangerous chemicals, as well as common excipients. We must not only ensure that our compounds are safe and consistent, but we must also protect our own employees who regularly handle these ingredients. We do so by:

- Investing heavily in physical protections such as chemical hoods in every area of the pharmacy where powders are utilized.
- Specialized training programs on material handling to prevent cross-contamination.
- Installing specially designed air handlers, which influence airflow patterns to keep our preparations and staff safe.
- Employing a facility-wide environmental monitoring system that tracks metrics such as temperature, humidity and air pressure differentials. This advanced system sends alerts immediately in the event any area falls out of specification.

### ***Raising the Standards***

With a combined 150 years of experience in pharmacy compounding, our team of chemists and pharmacists have an exacting approach to developing formulations that meet not just USP regulations but also our own self-imposed strict criteria. Our team understands the critical components, mechanics, and chemistry behind the formulations. Once a formulation has passed our testing and is approved, our process ensures that every time the formula is prepared it will be made in the same manner yielding the expected quality results. At Stokes, formulations are continuously being improved by testing formulas and processes both internally and externally to ensure we exceed our customers' expectations as well as our own. Our chemists and pharmacists are trained to understand the subtleties involved in meeting these complex requirements.

We invest a great deal of time and resources into obtaining the finest chemicals, equipment and processes for our compounds. We evaluate all of our chemicals to ensure they meet or exceed regulatory requirements and routinely send chemicals, intermediates and finished preparations out for independent analysis. While this adds cost to the compound, it is often a necessary and overlooked step in the formulation development or batch process.

Additionally, Stokes invests in building quality into each step of the compounding process. This is commonly known as quality by design (QbD). This means that Stokes must take a systematic approach to ensure each process is properly defined, controlled and produces the expected result. This approach is used ubiquitously at Stokes.

*We are also a technology leader:*

- We use barcoding for accuracy in compounding from the raw chemicals through to the final packing slips and invoices.
- All compounding is performed by computer guidance, minimizing human errors.
- We use compounding software that connects directly to hardware such as scales and sensors that self-document, adding another level of assurance to a well-controlled process.
- We are investing heavily in our own software to more efficiently handle the complex requests we receive from our customers.

### ***The Difference is Clear***

Occasionally, compounding pharmacies will undercut Stokes pricing on compounds because they do not invest as much into the development of their preparations, facility, training or compliance and can therefore pass on those savings. When a customer orders a compounded medication, it is critical that they understand that they are paying for more than the preparation itself. They are paying for the process, the experience and the expertise that makes the preparation superior in quality, potency and purity. Stokes provides quality – and at times slightly more expensive- preparations because we employ superior processes and staff equally committed to excellence.