



QuVa's partnership focus is simple. We build valuable and trusting relationships through communicating transparently and being accountable to our customers, so you have the answers you need whether calling on us for a response or when you are being called on for a solution.

We supply products in ready-to-administer presentations that help increase system-wide access, improve safety, simplify processes, save time, and reduce waste.

Engineered to be Accountable

With a proven FDA compliance record, QuVa Pharma is proud to be the 503B service partner of choice for many of the nation's leading hospitals and health systems.

Our 503B expertise is unmatched, with cGMP processes and FDA compliance record being second-to-none in the industry. Every batch undergoes rigorous product testing and is held until all results are confirmed. We NEVER release product at-risk.

While industry leading cGMP processes, full range of Sterile-to-Sterile products and approximately 240,000 sq. ft. state-of-the-art production facilities are the hallmark of our success, QuVa Pharma delivers outstanding customer service by focusing on service with accountability. We partner with our customers to meet their specific needs, anticipate market challenges and communicate regulatory updates to

ensure that safe and effective medications are available as needed.

Expansive Capacity and Scale to Meet Your Demand

As a full-service 503B provider, we have a deep and broad portfolio of essential, ready-to-administer sterile products to support hospital OR, Post Op, ICU, L&D, ER, and General Medicine areas.

Our product presentations span Syringes, IV bags, CADD cassettes, PCA vials, Monoject Barrel syringes, and Pharmacy Bulk bag packages.

Our three FDA-registered, state-of-the-art facilities gives us expansive production capacity and the flexibility to address customers' changing needs. Our scale and strategic supplier relationships enable us to compete as one of the largest Sterile-to-Sterile product suppliers in the industry. We are licensed to distribute in all 50 states, so we can meet your needs wherever you are.

During critical drug shortages, which limit Sterile-to-Sterile production, we can also manufacture from API starting material to provide you supply continuity. We follow the same strict cGMP-compliant processes regardless of starting material, so you can be confident that we never compromise on safety or quality.

Industry-leading FDA Compliance Record

At QuVa Pharma, we pride ourselves on meeting or exceeding FDA guidelines and cGMPs. While other 503B companies are struggling to keep up with regulations, QuVa Pharma has always operated according to strict cGMP standards, as reflected by our unparalleled FDA compliance history.

We take all observations seriously, and promptly address all agency comments with appropriate corrective actions. These actions enable us to further strengthen an already robust quality management system.

Going Above and Beyond Industry Standards.

QuVa Pharma builds in other ways to ensure the integrity of our products:



- ✓ Stability testing on products to establish Beyond Use Date (BUD)
- ✓ Tamper-resistant packaging on syringes, IV bags, and CADD cassettes
- ✓ Container-closure integrity testing on our primary product container
- ✓ UV-blocking overwrap for light-sensitive products
- ✓ Shipment requirements adjusted for extreme weather conditions
- ✓ Availability of Kit Check™ for radio frequency identification (RFID) tracking of pre-filled syringes
- ✓ NEW, intuitive and user-friendly ordering portal that puts you in control of your orders and inventory

Purpose-built to Change 503B Sterile Compounding for the Better.

QuVa was established in 2015. Our leadership team has pharma-grade backgrounds with unmatched expertise in FDA, cGMP, and aseptic manufacturing. They are resolute in the goal of making the 503B compounding industry more safe, efficient and reliable. We saw there was a better way to do business, then we built it, with the right people, processes and facilities.

Our Proven, Industry-leading FDA Record Reflects the Strengths and Consistency of Our Quality Management System, Which Is Based On 7 Pillars:



FACILITY SYSTEMS

Room certification, maintenance, and calibration of equipment.

REGULATORY & PHARMACY

Compliance with all relevant agencies, especially state Boards of Pharmacy and the FDA.

VALIDATION

Proof that processes are under control.

MATERIALS

Supplier qualification and testing before bringing any materials into the system.

PRODUCTION

Sterility assurance, including clean room design, aseptic technique, operations under the hood, all the way to core building airflows.

QUALITY ASSURANCE

An independent quality unit that oversees the production system: reviewing aseptic practices; assembling documents to create a batch record; assuring that the appropriate people are signing off on processes.

QUALITY CONTROL

Final product testing for sterility, potency, and endotoxin is only part of it. In order to have 100% confidence in your product, you have to make sure all of these other systems are integrated and doing their job.

Corporate Headquarters: