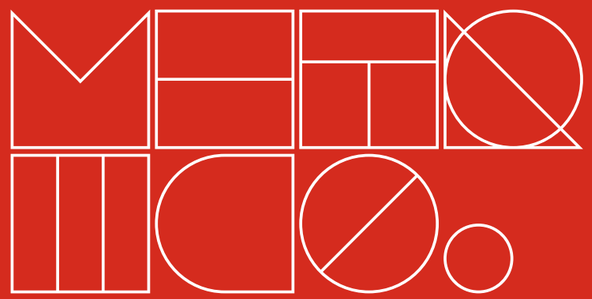
Proactive Problem Solvers

metrics contract services

Welcome to our digital brochure. Throughout this brochure you will see various interactive links to our website, videos and ways to reach out to our team.



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Meet Metrics

Say hello to our team

Metrics Contract Services is a science-led CDMO engineered around customers. We harness complexity and deliver confidence to companies developing novel oral solid dose products.

With a track record that spans over 25 years, we support pharmaceutical companies from initial concept to global commercialization.

Our skilled scientists and expert operators provide pharmaceutical development, analytical testing and commercial manufacturing to over 100 customers worldwide from our facility in Greenville, NC - all under a single FDA registration.

We specialize in smaller batches, ideal for orphan drug development and niche patient populations. Our strong compliance record and best-in-class equipment make us the ideal partner for your novel oral solid dose product.

Metrics Contract Services is a division of Mayne Pharma Inc.

1994

Metrics Founded

Starting as a Contract Laboratory, Metrics' rich analytical heritage begins.

1997

Product Development and Clinical Trial Supplies Expansion

Expanding our core service offering to support our customers across the clinical journey.

2000

Metrics opens current site at 1240 Sugg Parkway

Adding GMP manufacturing suites and 50,000-square-foot laboratory capacity.

2007

Quality and Commercial Expansion

Metrics begins commercial manufacturing and expands its quality control labs.

2009

High Potency Handling

Metrics commissions dedicated high potent manufacturing facility.

2012

Metrics is acquired by Mayne Pharma

A transformational acquisition that materially enhances Mayne Pharma's scale, market access, and capabilities and provides Metrics with a global footprint and expanded client resources.

2014

$5M Investment

Metrics invests in pre-clinical and development labs.

2015

$80m expansion to quadruple manufacturing capacity and grow development spaces

Additional 126,000-square-foot facility to support and accelerate organic growth.

2018

Commercial Manufacturing Facility Expansion Complete

Metrics Contract Services is now able to offer clients a comprehensive 'concept to commercialization' solution under one FDA site registration.

2020

$10m Commercial and High Potency Expansion

Metrics adds three further high potency suites, for added flexibility to meet the demand for small and moderate commercial batch sizes.

Formulation Development

Our team of experienced formulation scientists delivers materials for all phases of clinical development through to commercial supply.

We advance formulations with the end goal in mind, and our collaborative approach ensures that your goals are met and your products reach the market as quickly as possible.

We have successfully developed a wide range of novel OSD forms for hundreds of companies, from large pharmaceutical organizations to virtual biotech companies.

In our state-of-the-art 93,000 square foot facility, we have the capability to handle controlled substances (CI-CV) as well as potent APIs with OELs down to 30 ng/m³.

Our batch sizes range from 100g to 450kg, which allows for efficient scale-up from early clinical batches to registration and drug product commercialization.

We specialize in:

- Bioavailability enhancement
- Controlled and modified release technologies
- Poorly soluble APIs
- Potent APIs
- Taste masking and pediatric dosage forms
- Multi-particulate drug delivery systems

OSD technical formulation expertise:

- High shear wet granulation
- Dry granulation
- Milling and micronizing
- Fluid bed coating and drying (extrusion and high shear)
- Wurster granulation and coating
- Tablet and capsule film coating
- Pellet (bead) layering and coating

Clinical Manufacturing

Early Phase

We deliver tailored and timely solutions to guide you to and through your first clinical study.

Adapting to the needs of your Phase I & First-in-Human studies, we offer Clinical Trial Material batch sizes from benchtop to pilot scale and can work at miniature scale to conserve API.

We are well-versed in handling highly potent compounds, using hard-wall isolation technology for batch sizes up to 8kg (Xcelodose® 600S located in our highly potent processing area). And we house manual or automated bottle packaging lines to support your clinical trial preparations.

Tailored approaches

- API-in-Capsules – Using our Xcelodose® 600S encapsulator, we can fill API directly into a capsule with high precision and accuracy over a dosage range of 1mg to 250mg.
- Blend and fill – Based on the physical and chemical properties of your product, we develop a blend of ingredients to help with manual or semi-automated capsule filling.
- Tablets – We may suggest a tablet formulation as the best approach to developing a Phase I dosage form.

Comprehensive analytical support services:

- Method Development or Optimization
- Phase-Appropriate Method Validation
- Clinical Trial Material Product Release Testing
- Stability Study Support Testing

Late Phase

Whether we are scaling up a Phase I program or supporting your product's transfer to Metrics, our scientists develop products at the Phase II and III stage with Quality by Design (QbD) and commercialization in mind.

Our experiments identify the parameters, and the Design of Experiments (DoE) confirms the ranges for formulation and the manufacturing process.

Process Development

Through collaboration, our veteran scientists initiate studies to determine which process is most suitable for the drug product. We evaluate the use of techniques including:

- High-shear wet granulation
- Dry granulation
- Milling and micronizing
- Fluid bed coating and drying (extrusion and high shear)
- Wurster granulation and coating
- Tablet and capsule film coating
- Pellet (bead) layering and coating

Proactive problem solvers first and foremost, our team will troubleshoot and optimize your process efficiently.

Batch Size and Scale-Up

Throughout Phase II and Phase III, Metrics considers your scale-up and commercialization requirements. We offer various sized equipment to accommodate each phase and enable easy scale-up which conform to SUPAC requirements. Clinical Trial Material batch sizes range from 100g to 450kg.

Commercial Manufacturing

We are engineered to take your novel oral solid drug product from initial concept to global commercialization.

Our team has the expertise, flexibility and access to a state-of-the-art facility that can handle challenging projects requiring custom processes and solutions. Our scientific excellence is supported by robust operational readiness with best-in-class equipment and a strong compliance record.

We offer turn-key services including full testing, regulatory support, supply chain support, packaging, stability, CMC support and serialization.

Our clinical, analytical, development and commercial services are co-located on one site under a single FDA registration, ensuring efficient transfer and scale-up from clinical phase production through to commercial manufacturing.

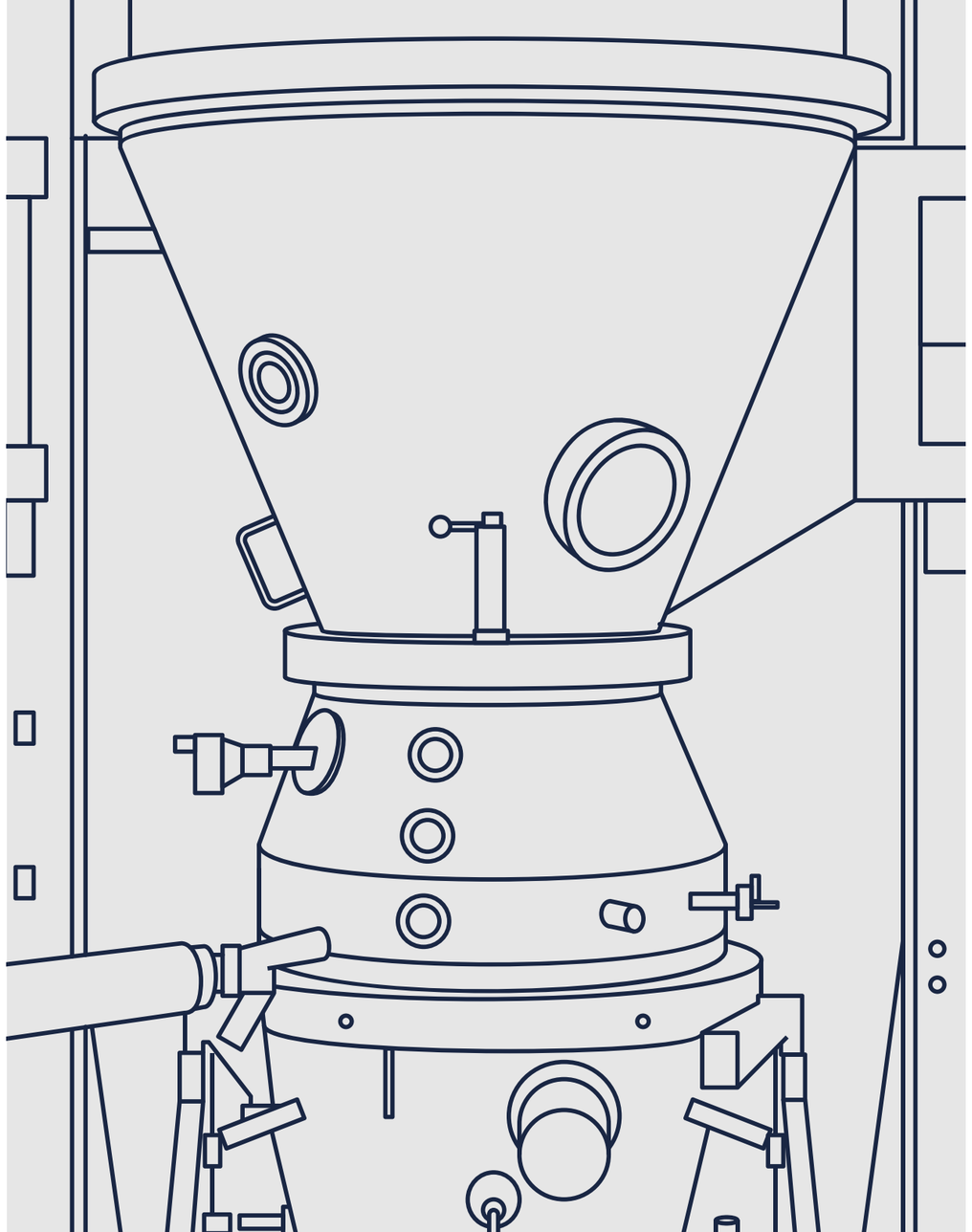
Services include:

- Production of immediate and modified release and multiple-unit pellet systems (MUPS) oral solid dosage forms
- Production of registration and process validation batches
- Technical transfer of products into a world-class manufacturing facility by an experienced technical services group
- Commercial batch sizes up to 450kg
- Dedicated Quality Control Laboratory

Quality

Throughout our partnership, you will be supported by experienced commercial quality assurance, operations, quality control, supply chain, and warehousing teams.

A dedicated account management group backed by our operators works diligently to complete your project according to specifications and bring a superior quality product to market.



Specializing in highly potent compounds

Specifically designed for containment, our facility can readily manage commercial-scale manufacturing of highly potent compounds.

Cross contamination risks are mitigated by rigid control of flows of personnel, materials and equipment, interlocked airlocks, and 100% outside air in processing rooms.

Commercial manufacturing equipment:

- Bin blending for direct blend manufacturing
- Dry granulation by roller compaction
- High-shear granulation – multiple units including integration with fluid bed drying
- Fluid bed processing – drying, top spray granulation, Wurster processing (both aqueous and organic solvent capable)
- Extrusion-spheronization
- Tablet compression
- Tablet coating using a perforated coating pan (both aqueous and organic solvent capable pan coating)
- Encapsulation: powders and beads
- Tray drying ovens
- Automated solid dose bottle packaging lines compliant with serialization (Drug Quality and Security Act {DSCSA}) requirements.

Analytical

We provide a unique, science-led CDMO partnership with comprehensive capabilities. Exceptionally trained with a vast understanding of diverse analytical techniques, our team of over 150 analytical chemists is dedicated to solving your complex challenges.

Using over 25 years' experience to your advantage, we also provide scientific, quality, and regulatory guidance to support the direction of your drug development project.

Method Development

We have a proven track record of creating methods for testing both drug substance and drug product. Combining our experience and technical understanding, we develop methods efficiently to keep your clinical and commercial journey on schedule.

We offer traditional methodologies such as HPLC Assay, HPLC Related Substances, Dissolution (Immediate or Controlled Release), and Content Uniformity, as well as specialized development for techniques such as GC, GC-MS, or LC-MS.

We have experience handling:

- Potent compounds
- Light-sensitive
- Temperature-sensitive
- DEA Scheduled CI-V controlled substances

Dosage forms include:

- Tablets
- Capsules
- Injectables
- Suspensions
- Topicals

Method Validation

Our team works with you to develop phase appropriate validation for your methodology in line with current global regulatory requirements.

Depending on the method, our scientists challenge the method on:

- Accuracy
- Precision
- Linearity
- Stability
- Specificity of Solution
- Robustness

Supporting your regulatory submission, our reports generated during method development and method validation are prepared to ensure you can use them directly or with minor modifications.

Routine Testing

An integral part of your team, we have the expertise to handle sample analysis for virtually any of your pharmaceutical products. We perform routine testing of samples for release of drug substance or drug product, from experiments conducted during development, or samples pulled from stability studies.

Our laboratories offer extensive capacity and are designed to handle multiple testing techniques simultaneously allowing us to provide agile analytical support and ensure quick turnaround times to meet your schedule.

- Chromatography
- Trace Metals
- Particle Size Characterization
- Thermal Analysis
- Microbiology
- Raw Materials
- Dissolution and Drug Release
- Karl Fischer Moisture Titrations

Method development and validation . Greenville, NC

Our Facility

Located in Greenville, North Carolina, our single-campus facility provides you with a true “concept to commercialization” solution under a single FDA registration.

Specifically designed for containment and scale-up, our Greenville campus provides a flexible space to proactively solve challenges and progress our customers’ products through the clinical and commercial journey. We specialize in handling potent compounds and small to medium batch sizes, ideal for orphan or targeted drug development. Pairing scientific excellence and robust operational readiness, we maintain a strong FDA record and 95% schedule adherence.

Facility Overview

Pre-Commercial Pharmaceutical Development

- 16 manufacturing suites (11 designed to handle potent compounds) and 2 packaging lines that allow us to support a large variety of development programs
- We can handle controlled substances (CI-V) as well as potent APIs with OELs down to 30 ng/m³
- Batch sizes ranging from 100g to 450kg

Commercial Manufacturing

- A 126,000-square-foot facility with 16 manufacturing suites (with a further $10m, 3,760 square-foot expansion, operational by February 2021)
- An estimated annual production capacity of 1-2 billion oral solid dose units (combined tablet and capsule production)
- Commercial batch sizes ranging up to 450kg
- Compliance with U.S. FDA and other international regulatory agencies
- Flexible rooms to accommodate high potent handling capabilities
- A dedicated Quality Control laboratory

Analytical Testing

- Over 150 exceptionally talented analytical scientists
- 25,000 square feet of analytical laboratory space
- Services include Method Development, Method Validation, Sample Analysis, Release Testing, Stability Study Storage and Testing, Physical Characterization, Trace Metals Analysis, and Microbiology
- A wide range of analytical instrumentation including – HPLC, UPLC, GC, LC-MS, Dissolution Apparatus and more

Stability Storage

- 17,000-square-foot stand-alone Stability Center of Excellence that features:
- 7,000 sq-ft of space for most International Conference on Harmonization (ICH) storage conditions
- 100-percent back-up power generation providing 1,200 kilowatts of electricity, fueled by an uninterrupted supply of natural gas
- Integrated system redundancies for HVAC, chillers and humidifiers
- 100-percent seamless and sealed construction inside and outside units
- Specialty climatic mapping and tolerances that include each ICH stability zone for temperature and humidity
- Sufficient square footage to double the number of chambers initially installed, providing room to grow for years

Investment

Between 2015–2020, we invested over $100 million into our Greenville, NC facility.

These investments evidence our aspirations and commitment to increasing our novel oral solid manufacturing capabilities and providing our clients with quality services from initial concept through to global commercialization.

$80 million - Commercial Manufacturing

Our 126,000-square-foot facility officially opened in 2018. Leveraging best-in-class containment, it meets or exceeds the quality and safety standards of major drug regulatory authorities globally and has the capacity to manufacture more than 1 billion oral solid doses annually.

Specifically designed for containment, the facility can readily manage the commercial-scale manufacturing of potent compounds and offers solvent-capable, fluid-bed processing and film coating.

Each of the site's 16 production suites was engineered to meet stringent demands for mitigating cross contamination, while also offering flexible space and delivering a broad range of capabilities and services.

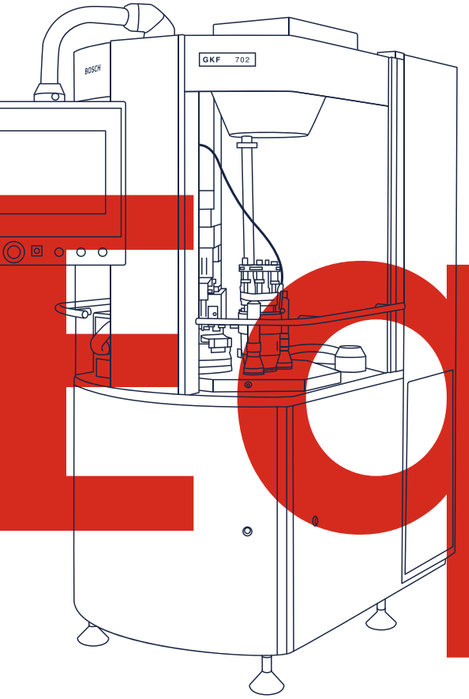
Features include:

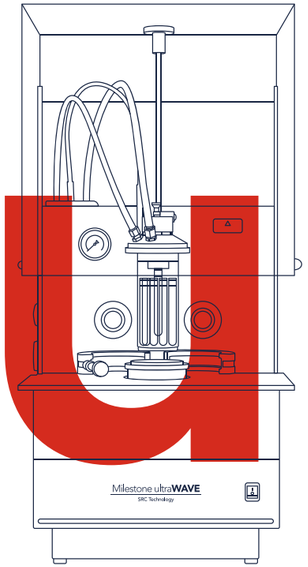
- 100-percent HEPA-in and HEPA-out filtered air
- Strategically placed airlocks for gowning, material and equipment
- Segregated product corridors
- Dedicated quality control laboratories
- Commercial scale up to 450kg per batch

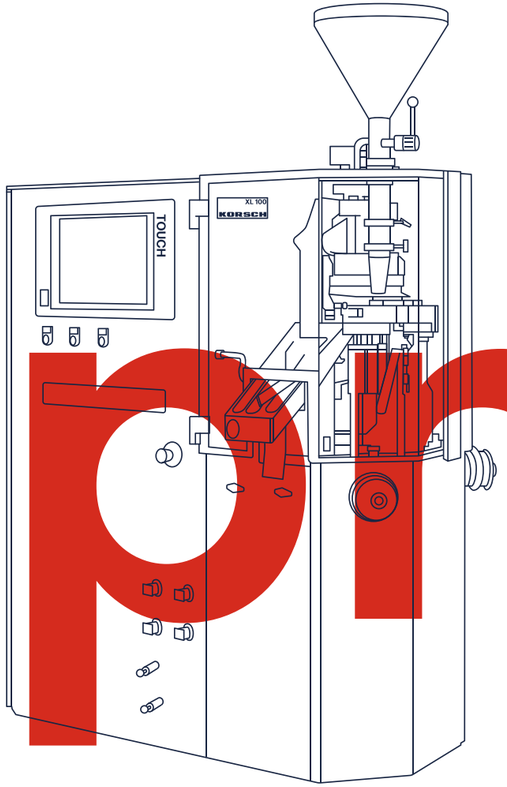
The facility allows Metrics to offer clients a comprehensive "concept to commercialization" solution under one FDA site registration.

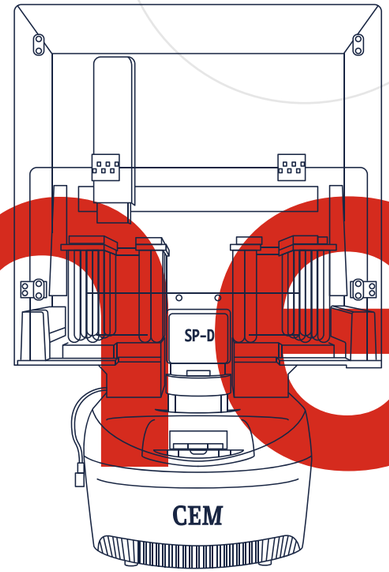
Equipment

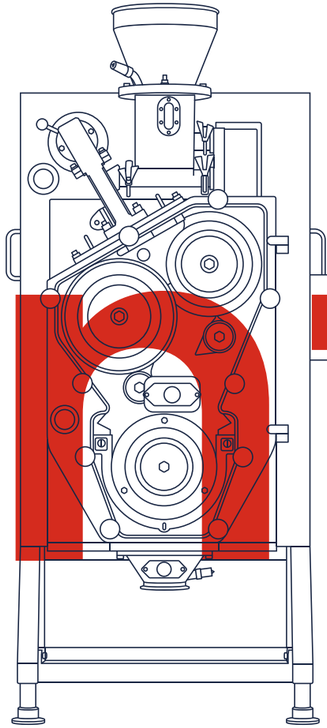
View our full equipment list











At Metrics Contract Services, we are continually investing in our capabilities and equipment. We aim to use best-in-class equipment that meets the needs of clients both now and in the future.

BoschGKF 702, Milestone ULTRAwave, Korsch XL100, CEM Discover SP-D Microwave, Gerteis Mini Pactor

Pre-Commercial Pharmaceutical Development Facility

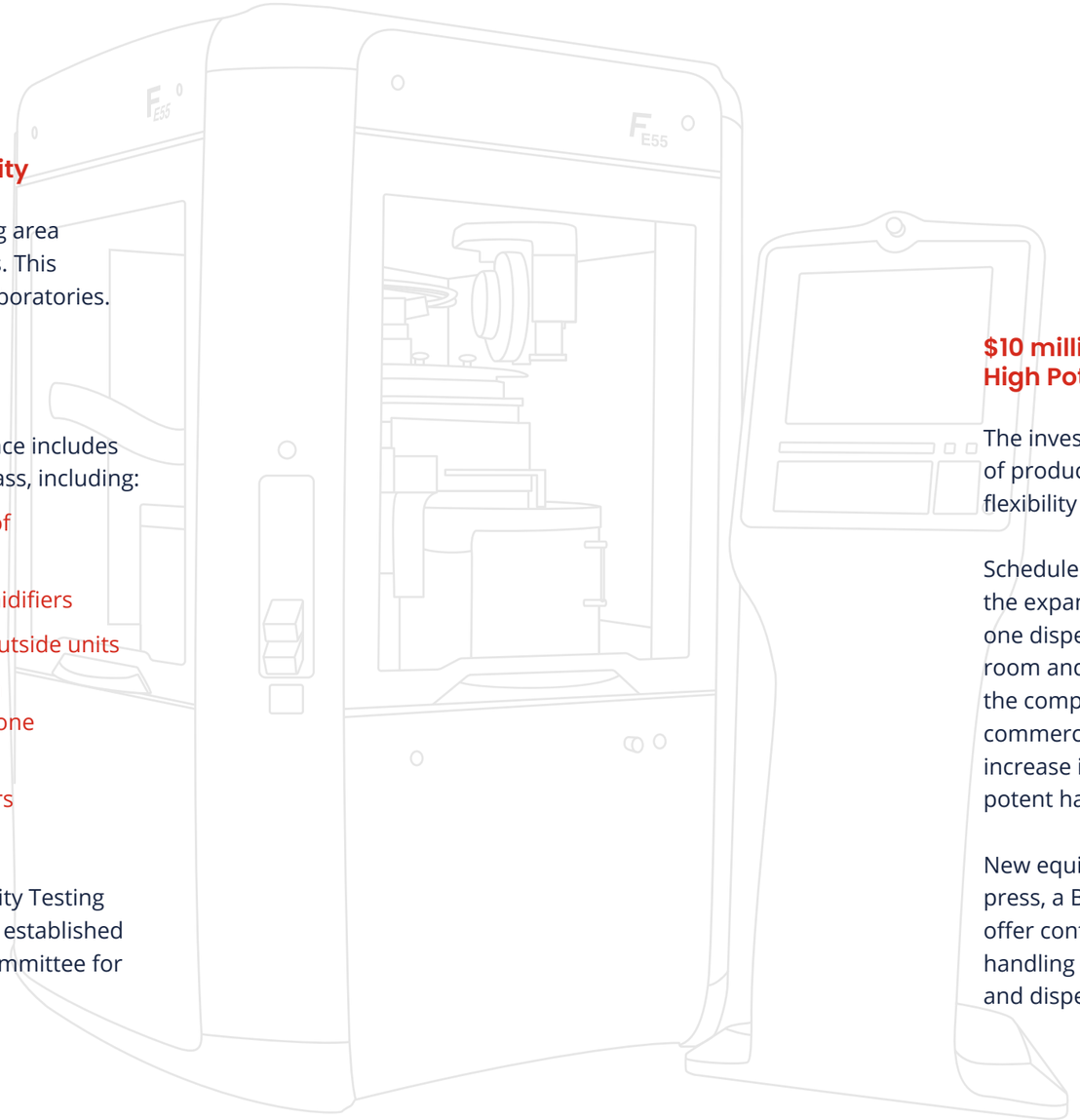
We repurposed space in our former commercial manufacturing area to expand pre-commercial capacity to better service our clients. This repurposing adds 10+ new processing rooms and expanded laboratories.

$3 million - Stability Center of Excellence

Our 17,000-square-foot stand-alone Stability Center of Excellence includes features that establish the stability storage facility as best-in-class, including:

- 100% back-up power generation providing 1,200 kilowatts of electricity, fueled by an uninterrupted supply of natural gas
- Integrated system redundancies for HVAC, chillers and humidifiers
- 100-percent seamless and sealed construction inside and outside units
- Specialty climatic mapping and tolerances that include each International Conference on Harmonization (ICH) stability zone for temperature and humidity
- Sufficient square footage to double the number of chambers initially installed, providing room to grow for years

Systems used in the Center meet ICH Guidelines Q1A for Stability Testing and Q1B for Photostability Testing, and comply with guidelines established by the FDA, the WHO and the European Medicines Agency's Committee for Proprietary Medicinal Products.



$10 million - Commercial and High Potency Expansion

The investment will add 3,760 square feet of production space, providing added flexibility and capacity.

Scheduled for completion in Febuary 2021, the expansion consists of three new rooms: one dispensing/flex room, one tablet press room and one flex room to accommodate the company's growing portfolio of commercial services following sustained increase in demand from clients for high potent handling capabilities.

New equipment includes a Fette FE55 tablet press, a Bosch 720 encapsulator, which both offer containment capabilities for the safe handling of potent products, and a weigh and dispense isolator.

metrics contract services

Visit our resource hub

Say hello...

T: 252-752-3800 Send us a message or visit metricscontractservices.com for more information

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