

The background is a dark purple color with several large, overlapping circles in shades of purple and orange. The circles are scattered across the frame, with some partially cut off by the edges.

teknova:

THE RISE OF MODULAR MANUFACTURING

Scalable Solutions to Accelerate Novel Therapy Development

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Vice President, Operations

PHACILITATE | ADVANCED THERAPIES WEEK
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We make solutions possible

Accelerating the discovery, development, and commercialization of novel therapies, vaccines, and molecular diagnostics that aim to help people live longer, healthier lives



Producer of **complex research and clinical-grade reagents** fundamental to the life sciences industry



Modular manufacturing supports emerging therapeutic modalities, like cell and gene therapy



Production platform delivers **high-quality, custom products** with short turnaround times



Well-established, respected brand with **~3,000 customers** and a **>95% retention rate***



Ability to seamlessly scale with customers from **discovery through commercialization**

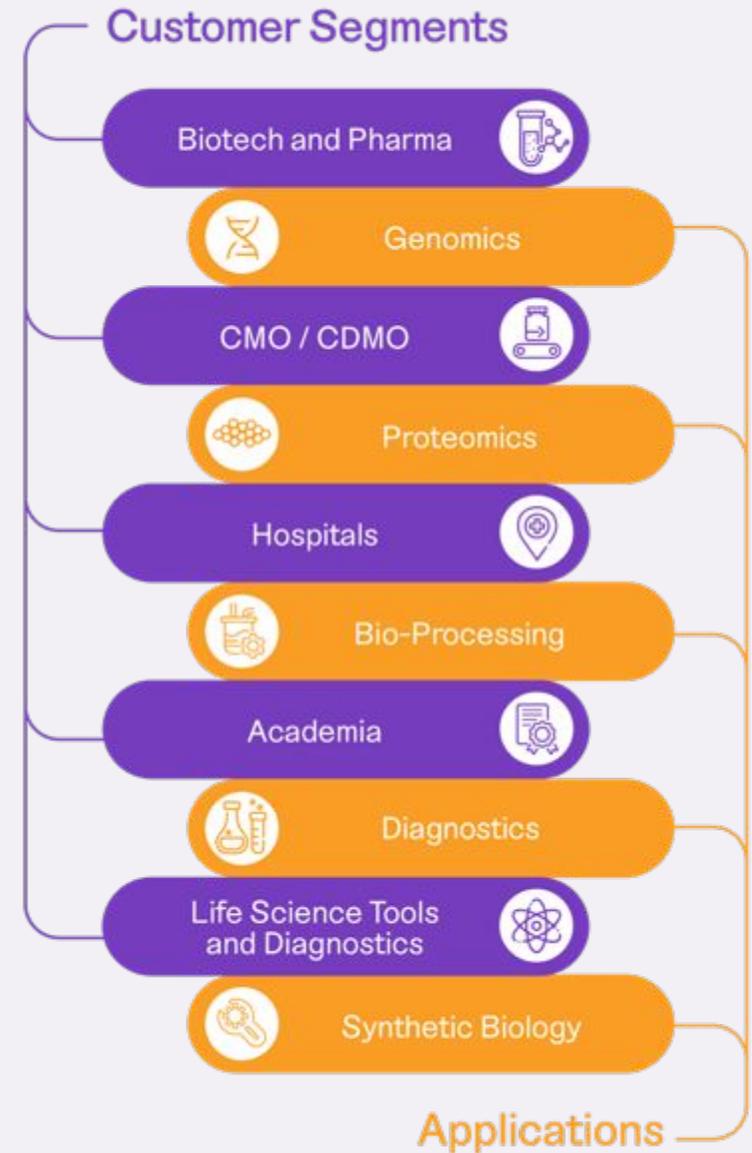


Extensive online catalog of **1,400+ lab essentials products** available

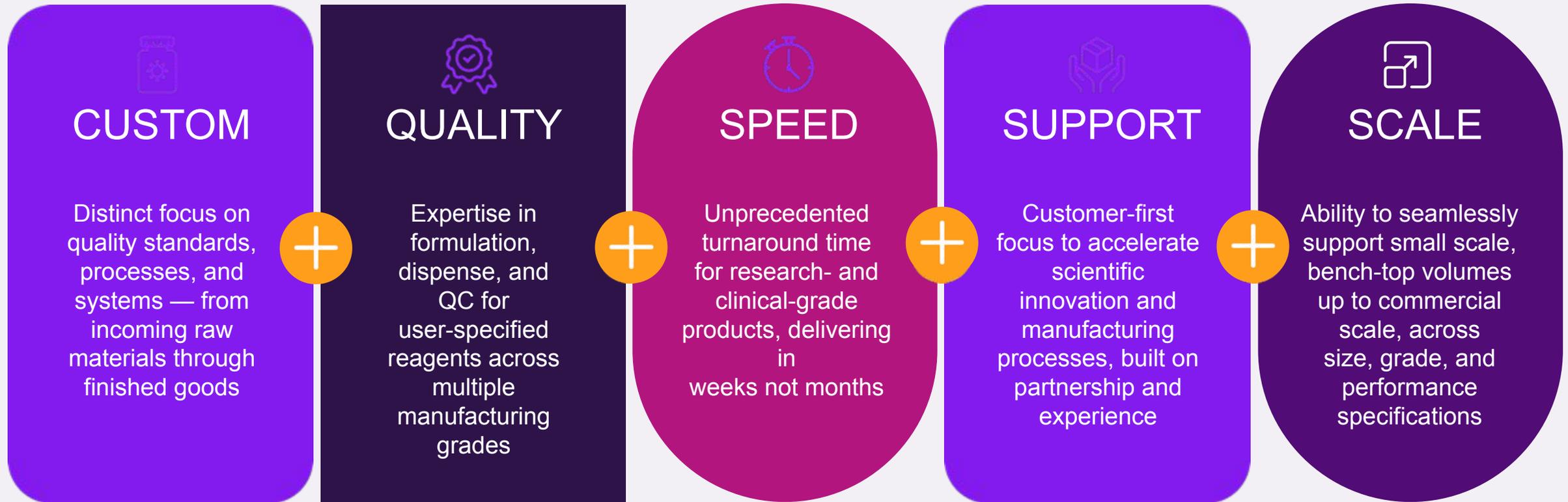


* Among customers with >\$10K in annual revenue, representing ~15% of total customers and ~90% of FY:2024 revenue

Our products are fundamental to the life sciences industry



What makes Teknova different



Emerging therapeutics and diagnostics require a new approach to address today's unique bioprocessing needs

Agile and adaptable production of custom research- and clinical-grade reagents



Compliant, yet flexible, state-of-the-art manufacturing facility



Trusted, experienced partner that thrives in changing environments

Agile and adaptable production of custom research- and clinical-grade reagents

WHAT TO LOOK FOR:

- Flexible manufacturing infrastructure offering a wide range of customization options
- Fast turnaround production scaling from low minimums for custom orders to large-volume capacity
- Manufacturing grades and processes designed to seamlessly scale and adapt



Flexible manufacturing infrastructure delivers optionality, speed, and confidence to scale

Customization Options

Wide range of options supports bioprocessing scale-up and diagnostics

- ✓ Formulation
- ✓ Format
- ✓ Raw Materials
- ✓ Concentration
- ✓ Fill Volume
- ✓ Documents and Labels
- ✓ And more ...

Small Batch Sizes

Custom and GMP formulations manufactured as low as 25 L batches



Express•Tek™ Production

RUO

≤1 week
vs. ~3 weeks

RUO+

≤2 weeks
vs. ~4 weeks

GMP

≤6 weeks
vs. ~8 weeks

Manufacturing Grades

RUO → RUO+ → GMP

Adherence to compliance standards

Cost-effective options that maintain comparable quality levels

Risk reduction while optimizing scalability

Compliant, yet flexible, state-of-the-art manufacturing facility

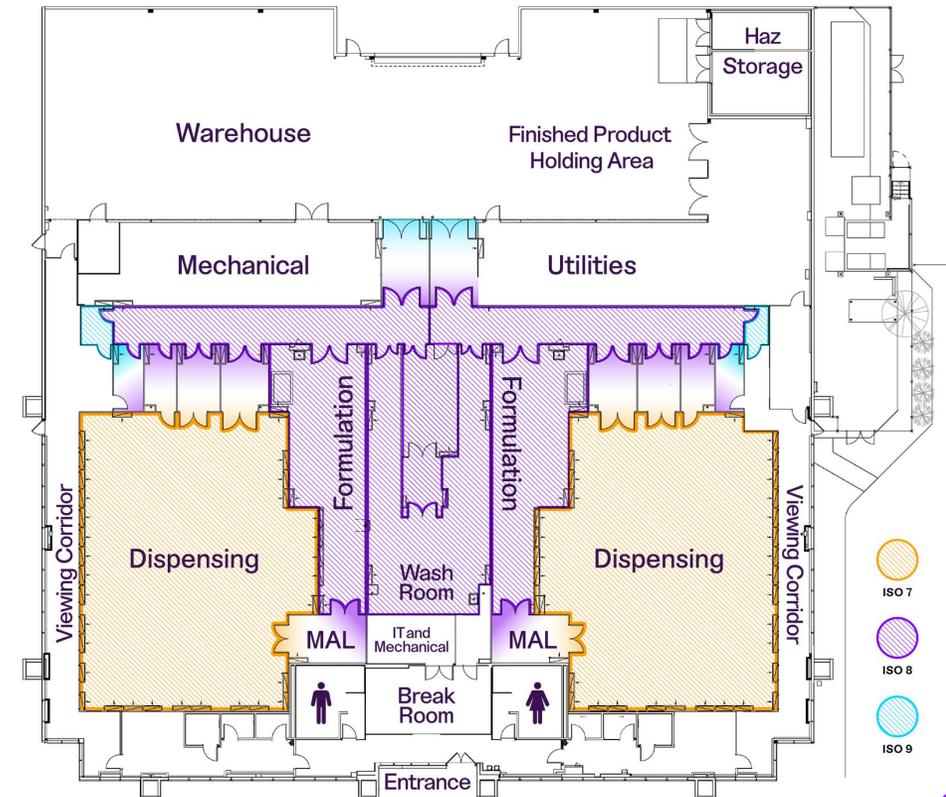
WHAT TO LOOK FOR:

- Facility designed specifically to support modularity, scalability, and redundancy
- Robust quality management systems (QMS) that scales across manufacturing grades
- Validated multiple production scenarios to ensure manufacturing flexibility and speed
- Ability to add on performance- and quality-based testing options for the life of the product



Facility designed specifically to support modularity, scalability, and redundancy

- ✓ Multiple manufacturing suites with separate, dedicated air handling systems for redundancy and flexibility
- ✓ Unidirectional flow for both people and materials
- ✓ Endotoxin-controlled and animal-free facility
- ✓ Contamination control strategy that enables end-to-end sterile manufacturing, supporting single-use system requirements
- ✓ Cleanroom design that allows for simultaneous automated and manual dispensing across multiple dispensing stations, supporting large variety of custom formats and sizes (e.g., tubes, bottles, bags)



Commitment to a robust microbial contamination control strategy validated across facilities, processes, and equipment

FACILITY QUALIFICATION

- Air balancing and exchange rates
- Airflow visualization (smoke) studies
- Containment testing
- HEPA filter certification
- HVAC
- Recovery testing
- Temperature, relative humidity, and differential pressure testing

UTILITY QUALIFICATION

- Clean steam
- Compressed gases
- Water system

EQUIPMENT QUALIFICATION

- Autoclaves, depyrogenation ovens, and parts washer
- Environmental monitoring (in-situ) equipment
- Filter integrity tester
- Formulating and filling equipment
- Single-use systems (SUS)

PERSONNEL QUALIFICATION

- Aseptic training
- Gown selection, frequency, and type of personnel monitoring
- Gowning training, qualification and disqualification processes

METHOD QUALIFICATION

- Cleaning and disinfection: facility and equipment
- Environmental Monitoring Performance Qualification (EM PQ)
- Material transfer
- Quality Control (QC) test method

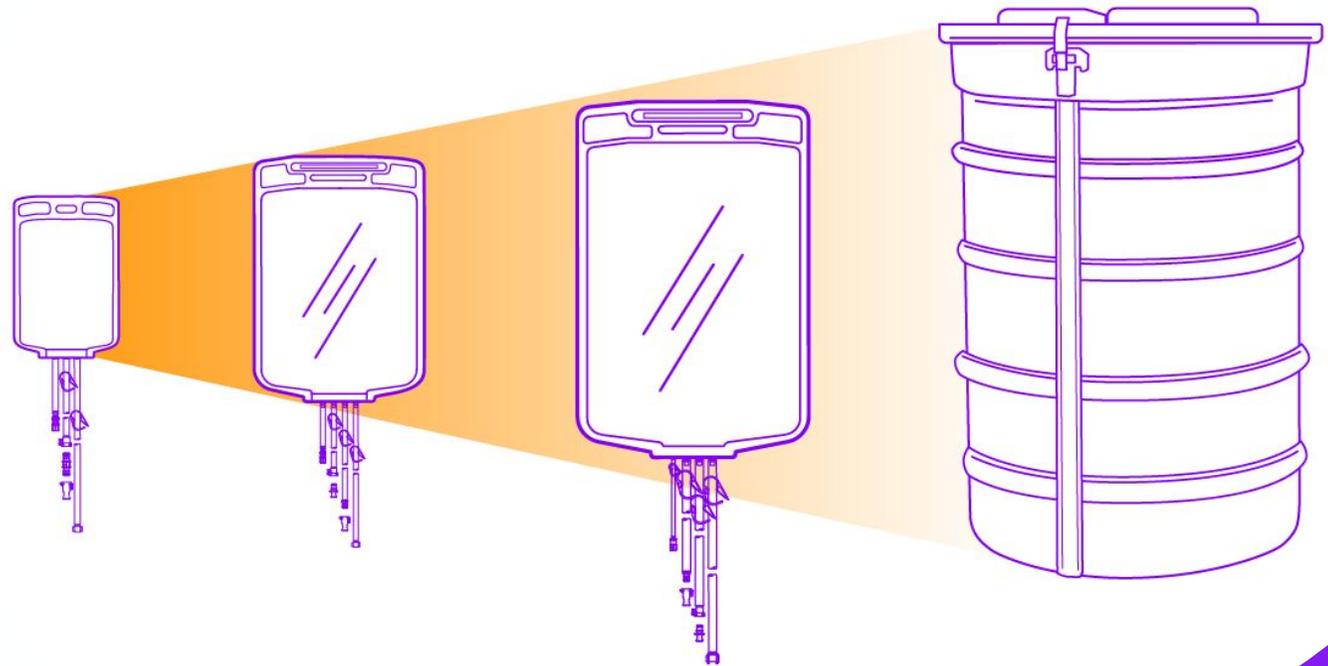
PROCESS QUALIFICATION

- Defined occupancy rates
- Defined personnel, material, equipment, product/waste flows
- Maximum hold times for equipment, consumables, and product
- Worst case interventions

Robust quality management systems (QMS) that scales across manufacturing grades

QMS must also validate how to control multiple manufacturing processes

Bracketed validation that collectively validates a range (or “bracket”) of products, equipment, fill volumes, processes, and personnel over the course of a specific timeframe in a cleanroom environment



Ability to add on performance- and quality-based testing options for the life of the product

- Rigorous USP-compliant testing and documentation on incoming raw materials and finished goods ensures reproducible and scalable results
- Maintenance of retention samples for the life of each product enables further testing if questions or issues arise
- Custom stability programs are essential to quantify effectivity over time, meet regulatory requirements – even extend the shelf life of custom GMP-grade products or raw materials

Raw Materials	Purity Identification	Endotoxin Performance
Agar Plates	Growth Performance Sterility	
Microbial Culture Media	Performance pH	Conductivity Sterility
Buffers and Reagents	pH Conductivity Osmolality Density	DNase, RNase, Protease Endotoxin PCR Sterility
Water System	CONTINUOUS MONITORING Conductivity Total Organic Carbon WEEKLY TESTING Endotoxin Bioburden Total Organic Carbon	MONTHLY TESTING DNase, RNase, Protease, Mycoplasma, Ammonium, Calcium, Magnesium, Sulfates, Chlorides, Osmolality, Nitrates, and Particulates

Trusted, experienced partner that thrives in changing environments

WHAT TO LOOK FOR:

- Specialized technical, operational, and quality experience in the manufacture of complex buffers and reagents
- Expertise in addressing key considerations at critical bioprocessing inflection points, such as process development, scale-up, and tech transfer



Specialized experience in the manufacture of complex buffers and reagents

Established practice leveraging cross-functional problem-solving to support changing manufacturing needs

- Manufacturing science and technology (MSAT) support for tech transfer and specialized consultation
- Floor-level production guidance based on manufacturing processes and product requirements
- Manufacturing and process engineering to drive efficiency and novel solutions
- Quality leadership with pharmaceutical experience to ensure compliance to certification and customer requirements



Five takeaways when evaluating custom reagent manufacturing partners

- 1 Certified manufacturing platform that supports agility, speed, and a **seamless transition from RUO to GMP**
- 2 Support a wide range of **customizable options**, from product specifications, manufacturing, to QC
- 3 Current track record in **developing innovative solutions** to address key barriers in your workflow or pipeline
- 4 **Compliant yet flexible manufacturing platform**, from facility design to use of bracketed validation methods
- 5 Credentials for relevant experience, **strong problem-solving ability**, and a consultative approach



teknova:

MODULAR MANUFACTURING
PLATFORM



Save time, resources,
and money



Simplify tech transfer: Minimal
rework and repeatable results



Scale faster, with confidence

teknova:

Thank you!

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COME VISIT US AT
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