



Exceptional Manufacturing Flexibility

We can fill a wide range of container sizes and volumes in the clinical and commercial manufacturing of sterile injectables.

VIALS



1/2 mL to 500 mL



5 L to 25 mL

BAGS

SYRINGES



1/4 mL to 50 mL

Additional in-house, on-site capabilities supporting manufacturing & commercial readiness include:

- Formulation development & scale up
- Analytical & microbiological method development & validation
- Extractables & leachables testing
- Full ICH stability study design & execution
- Microfluidization capability for particle size reduction, nano- & microemulsions, liposomes, and nanoencapsulation
- Lyophilization
- Terminal sterilization
- Packaging, labeling & kitting, distribution & warehousing/storage

[Click to get a quote, schedule a meeting or request more information!](#)

CELEBRATING AUGUST



- Best kept secret in the CDMO industry
- US-based, full-service CDMO headquartered in Nashville, TN *(with dedicated in vivo testing facility in Celina, TN)*
- Decades of pharmaceutical commercialization experience across novel, branded & generic drugs
- Strong focus on sterile injectables *(vials, syringes, bags)*
- Expanding high-speed commercial manufacturing capabilities with new facility to be built adjacent to August's current Nashville facility *(open in 2023)*

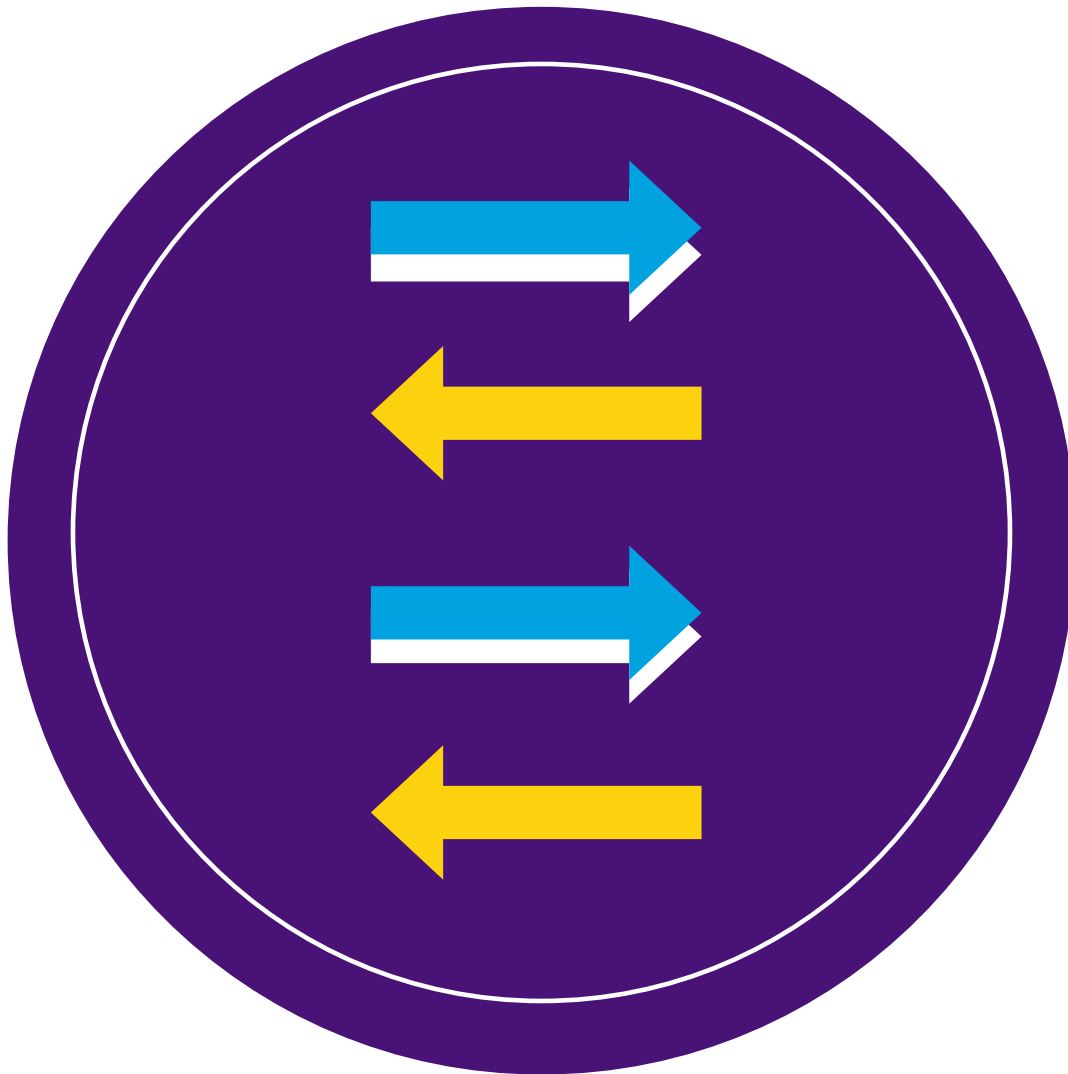
FORMULATION & SCALE UP



- Liquid & Semi-Solid Dosage Forms
 - Oral solutions & suspensions
 - Parenteral solutions & suspensions
 - Topical solutions & semi-solids
- Formulation screening & development
- Manufacturing process development & optimization
- CMC submission readiness, including: specifications, Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs)
- Pilot scale to late stage clinical trial manufacturing (*commercial availability in Q2 2022*)

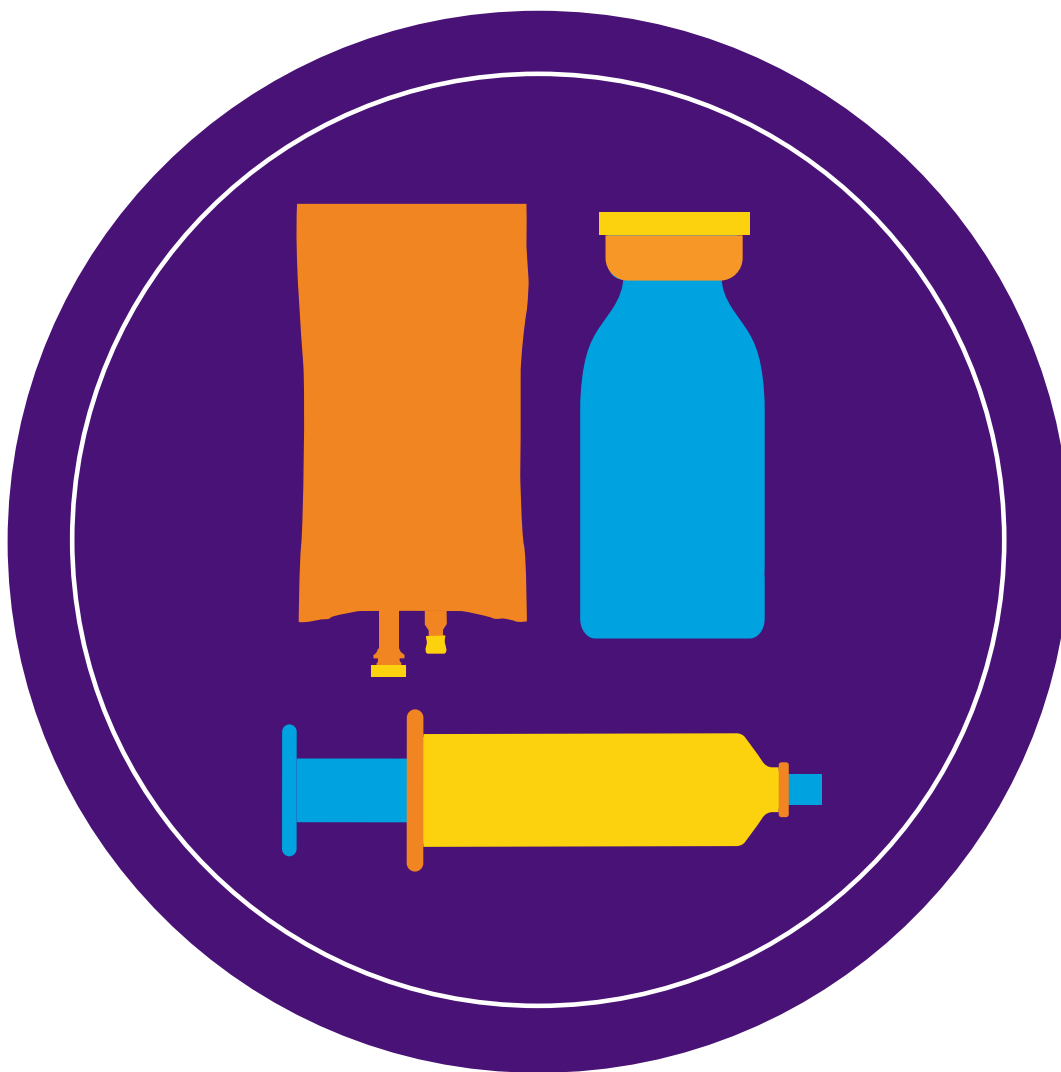


EXTRACTABLES & LEACHABLES



- Route of administration:
 - injectable & inhalable
 - ophthalmic & topical
 - oral & sublingual
 - nasal, otic & transdermal
- Drug materials/dosage forms:
 - solids, semi-solids & liquids
- Product contact types:
 - vials, syringes, IV bags, inhalers, SU disposable bags
- Packaging & contact components:
 - plastics & glass
 - rubber stoppers, plungers, IV sets & other
- Testing will include:
 - VOCs by headspace GC/MS
 - SVOCs by direct injection GC/MS
 - NVOCs by LC/UV/MS

MANUFACTURING



- Automated filling for multiple dosage forms, including: sterile injectables, topicals & oral solutions
- Microfluidization capability for particle size reduction, nano- and microemulsions, liposomes, and nanoencapsulation
- Lyophilization, Terminal Sterilization
- Clinical & Commercial Scale
- Full manufacturing services and process management, including: testing, stability, packaging, labeling & kitting, distribution & warehousing/storage

LYOPHILIZATION



- Forward-looking planning and collaboration through every step of the product life-cycle process, from early-stage development through production
- Cycle development studies to identify optimized freeze-drying performance matrix
- Formulation strengths & components
- Container characteristics
 - Ability to handle complex formulation components
 - Nanoparticles
 - Microparticles
 - Liposomes

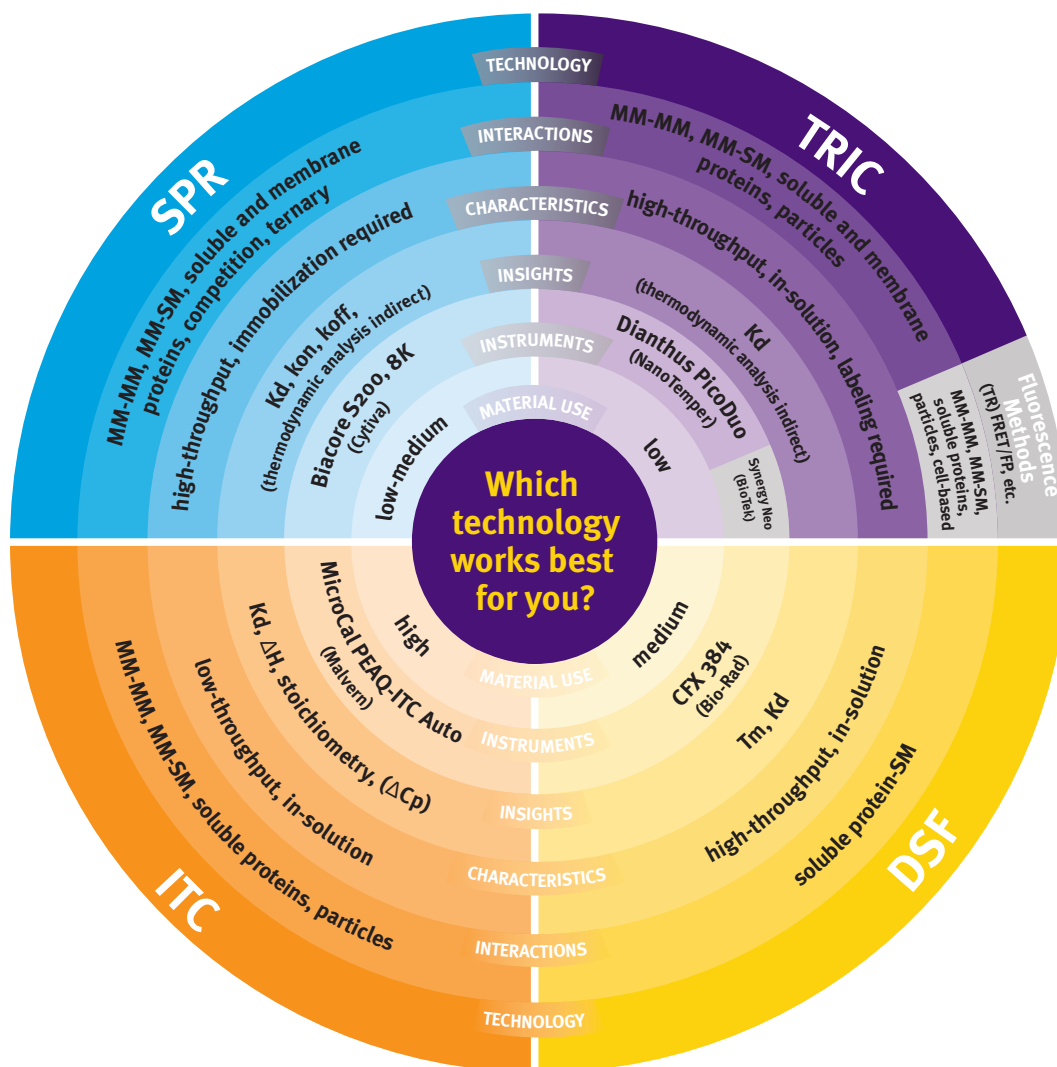


RESEARCH & DISCOVERY SERVICES



- Protein Expression & Purification
- Binding Technologies Toolbox™
 - SPR, TRIC, ITC, DSF, Fluorescence Methods (TR) FRET/FP, etc.
- Cell Culture/Cell-Based Assays
- Antibody Generation/Characterization
- *In Vitro* Testing (Nashville)
- *In Vivo* Testing (Celina)

BINDING TECHNOLOGIES TOOLBOX™



- **TECHNOLOGIES:** SPR, TRIC, DSF, ITC, Fluorescence Methods (TR) FRET/FP
- **INTERACTIONS*:** MM-MM, MM-SM, soluble and membrane proteins, competition, ternary, particles, cell-based, soluble protein-SM

- **CHARACTERISTICS:** High & low throughput, immobilization, in-solution, labeling
- **INSIGHTS:** Kd, kon, koff, ΔH, stoichiometry, (ΔCp), Tm
- **MATERIAL USE:** high, medium, low

*MM = macromolecule; SM = small molecule

IN VIVO TESTING



- Pre-preclinical proof of concept testing
- Immuno-oncology
- Testing for all cancer types; specializing in challenging conditions
(including lymphoma and colon cancer)
- Creation of stable target knockdown or overexpression cell lines
- Organ, tissue and tumor dissection; serum collection and pathological analysis

