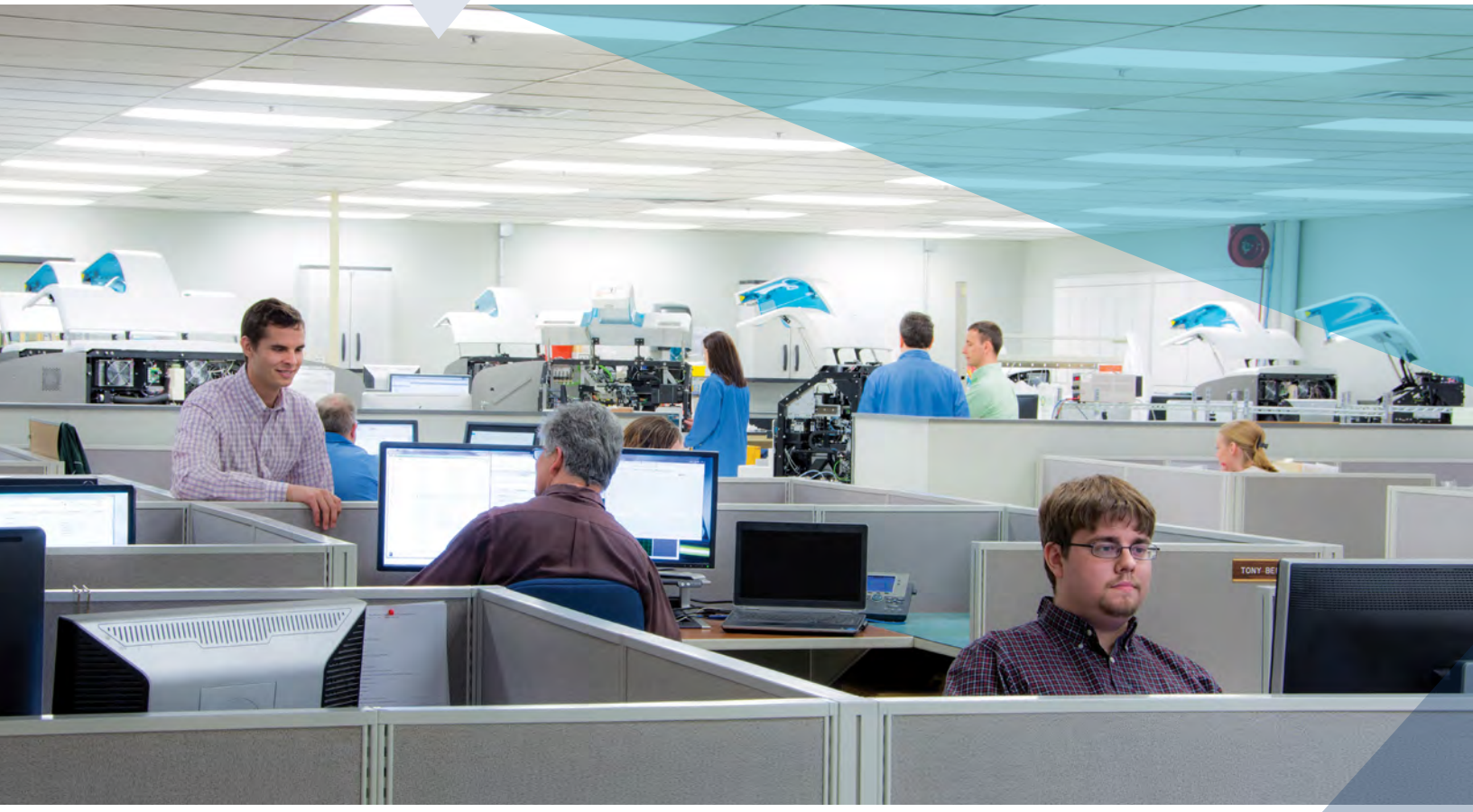
KMC Systems

The Ultimate Partner

Engineering Services & Contract Manufacturing

Engineering Services



Global IVD companies rely on KMC Systems' broad engineering expertise to create groundbreaking instruments for the medical and life science markets. Our engineers work collaboratively with our customers to deliver cost-effective, reliable and timely solutions to complex laboratory automation challenges.

Our engineers are experts in their own fields; working across knowledge domains to achieve the best product development solution to meet your needs.

Our engineering services include stringent design controls, technical design reviews, design verification, risk management and analysis. Our product development life cycle process is time-tested and fully compliant with the FDA's Quality Systems Regulation 21 CFR Parts 820, 803 and 806 as well as ISO 13485 and IEC 62304.

- Optics
- Fluidics
- Robotics
- Motion control
- Software design
- Hardware design
- Thermal control
- Chemistry integration
- Verification & validation
- Sustaining engineering

Contract Manufacturing

Since its inception, KMC Systems has been manufacturing high-value, complex platforms for use in clinical environments. Our robust Manufacturing Execution System (MES) and Quality Management System (QMS) have evolved over decades of refinement.

ISO13485

Robust QMS

FDA inspected

Wet lab testing

GMP Compliant

Global sourcing

Customized MES

BioSafety laboratories

Calibration & Metrology

Cleanroom manufacturing

Our manufacturing team is comprised of skilled assemblers, manufacturing engineers, supply chain professionals and experienced line managers. Complementing those skills, KMC has on-site chemistry capability staffed by medical technologists for full system acceptance testing.

Partner with KMC Systems at any stage of your product's life cycle. We can seamlessly handle your manufacturing needs from prototype to full-scale commercial production based on your market needs.

Quality Assurance

Quality is at the heart of everything that KMC Systems does. Startup firms and industry leaders rely on KMC's talent, expertise and robust Quality Management System to develop and manufacture their complex and compliant instrumentation for the global market. We are FDA registered for medical device manufacturing and ISO 13485, 14971, and IEC 62304 compliant. Our QMS is flexible to meet the unique needs of each project and structured through a phased gate method aligned to satisfy global regulatory requirements.

- ISO 13485 Medical Device
- ISO 14971 Risk Management
- FDA QSR Parts 803, 806, 809, 812, 814, 820
- FDA Current Good Manufacturing Practices (cGMP)
- Part 7 and Part 11 Compliant Software Development
- IEC 62304 Software Development for Medical Devices
- Regulatory Testing (UL, ETL, CE, EMC, EMI)

Partner with KMC Systems

866.742.0442

www.kmcsystems.com

KMC Systems Inc.

220 Daniel Webster Highway

Merrimack, NH 03054

KMC Systems

An Elbit Systems of America Company