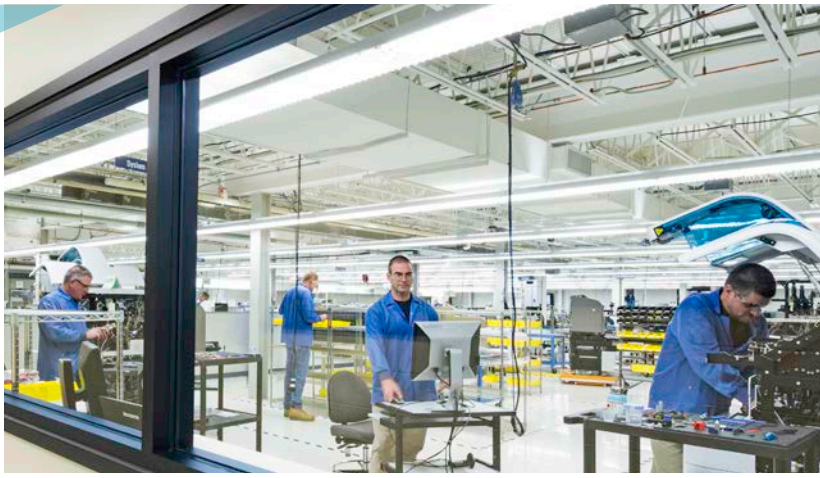
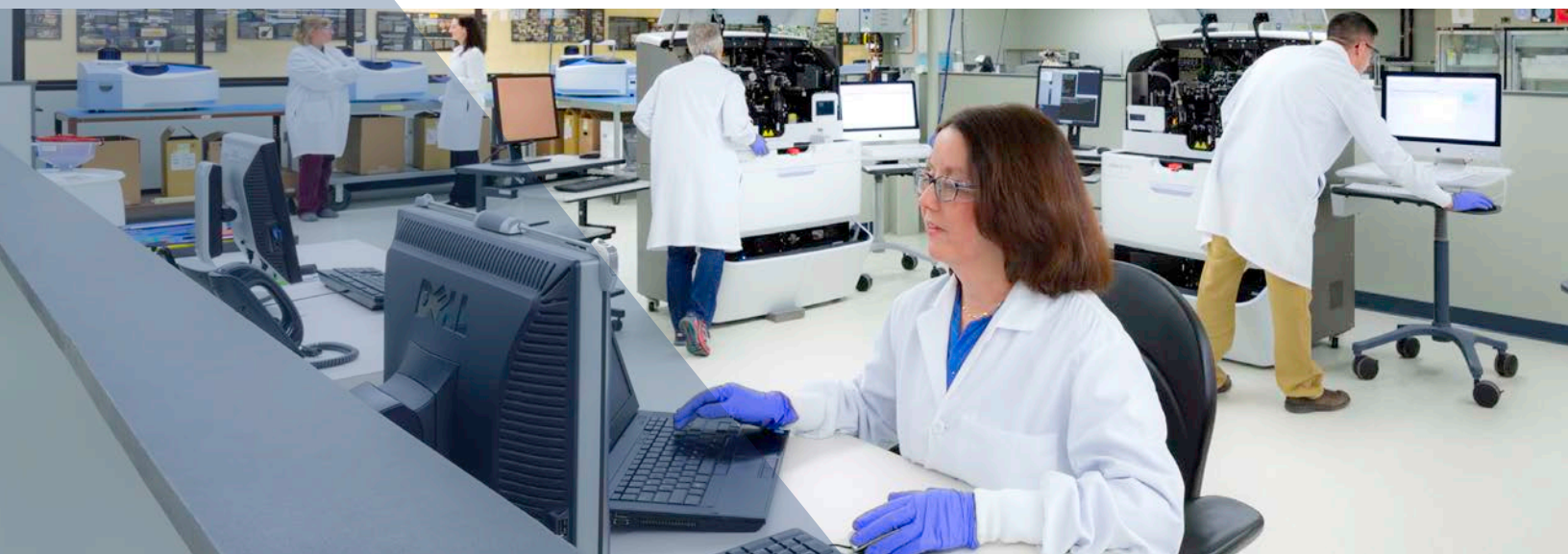
KMC Systems

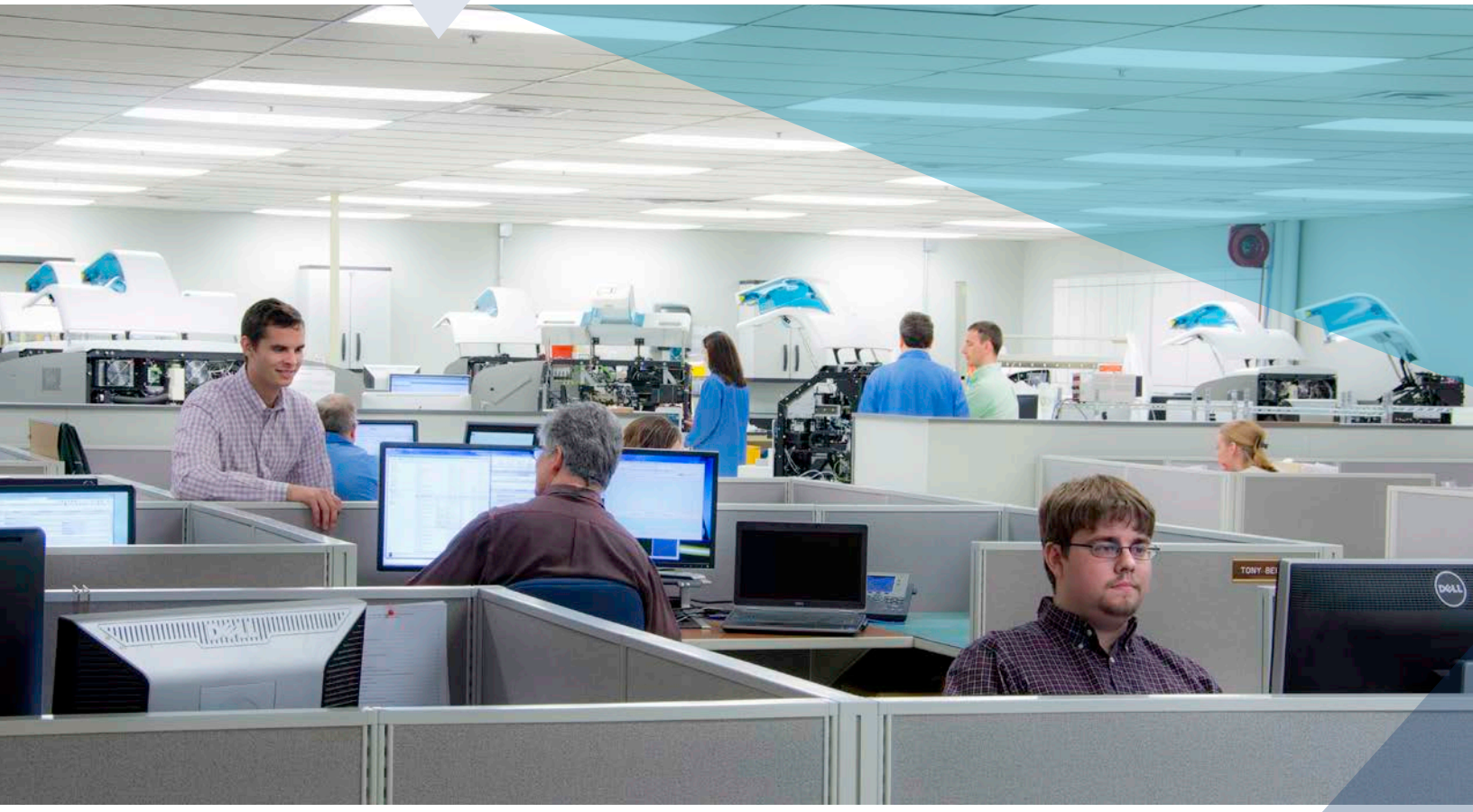
Engineering Services & Contract Manufacturing

Improving Patient Care One Instrument at a Time





Engineering and Design



Since 1980, leading instrument companies have relied on the depth and breadth of KMC Systems' engineering and manufacturing experience to create groundbreaking instruments for the medical and life science markets.

Our engineers work collaboratively with our customers to achieve the best interdisciplinary solution to complex laboratory automation challenges.

Our design services include stringent design controls, technical design reviews, design verification, risk management and analysis. Each of these is completed with you in the loop. Our time proven processes comply with the FDA's Quality Systems Regulation 21 CFR Parts 820, 803 and 806, as well as ISO 13485: 2003 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 the clinical environment. Our Manufacturing Execution System (MES) and Quality Management System (QMS) have evolved over decades of refinement.

Robust QMS

FDA inspected

GMP Compliant

Global sourcing

ISO13485:2003

Wet lab testing

Customized MES

BioSafety laboratories

Cleanroom manufacturing

Incoming parts inspection

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 KMC Systems does. Our robust ISO 13485 environment ensures that Design Controls and Manufacturing Operations are compliant. With current industry standards, KMC's robust Quality Management System is fully automated to adhere to our strict phased gate processes ensuring adherence to industry regulatory requirements. KMC is an FDA registered site for medical device manufacturing.

- IEC 62304
- ISO 14971
- ISO 13485 Medical Device Guidelines
- FDA Current and Good Manufacturing Practices (CGMP)
- Calibration and Metrology
- FDA QSR Parts 820, 803 and 806
- Part 11 compliant software development
- Regulatory Testing (UL, ETL, CE, EMC, EMI)

Connect with us

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KMC Systems

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