

CASE STUDY

Rapid Engineering Scale-Up To
Avoid FDA Consent Decree

EXECUTIVE SUMMARY

A Chicago-based Medical Device company specializing in infusion technology faced intense regulatory pressure to avoid an imminent consent decree—a legally binding agreement with the FDA requiring immediate corrective action. To meet aggressive remediation timelines and satisfy FDA obligations, the company urgently needed to scale its Systems and Electrical Engineering teams across multiple product lines.

Kirk stepped in as a trusted recruiting partner, placing **25 engineers within the first 12 months** and ultimately over **50+ technical professionals**, helping the company navigate a critical turning point and avoid further regulatory risk.

BUSINESS CHALLENGES

The company was close to falling under an FDA consent decree, a serious regulatory action that required immediate improvements across design controls, documentation, risk management, and system architecture. Failing to meet deadlines risked further penalties, product delays, and reputational harm.

The most urgent challenge came when leadership from the Consumables Engineering team reached out to Kirk. They needed to hire and onboard **15 Systems Engineers within 4 weeks**, ensuring all new hires were trained and ready to contribute immediately to a fast-moving remediation program. The roles spanned entry to principal-level, and included two key technical leaders.



OUR APPROACH

ONSITE PARTNERSHIP:

1

Kirk embedded himself onsite with engineering leadership. By immersing in the team's daily operations and understanding their urgency, he was able to quickly align on expectations and priorities. Within hours, half of the positions were lined up with interviews. Within weeks, all roles were filled—meeting the tight onboarding deadline.

2

HANDS-ON COLLABORATION

By working directly with functional managers, Kirk helped refine role clarity, define technical gaps, and ensure the right balance of leadership and execution on the incoming team.

3

ADAPTABILITY UNDER PRESSURE

This effort required more than recruitment—it demanded speed, accuracy, and the ability to scale fast while maintaining quality. Kirk worked side-by-side with hiring managers to prioritize candidates based on technical depth, regulatory understanding, and leadership potential.

THE RESULTS

Over the course of the project, this evolved into a deeper partnership—resulting in the successful hiring of 50+ engineers across:

- Systems Engineering (Risk, Architecture, and Design History Files)
- Electrical Engineering (Analog, Test)
- Project and Program Management (HW/SW/Systems)
- Embedded Software Development

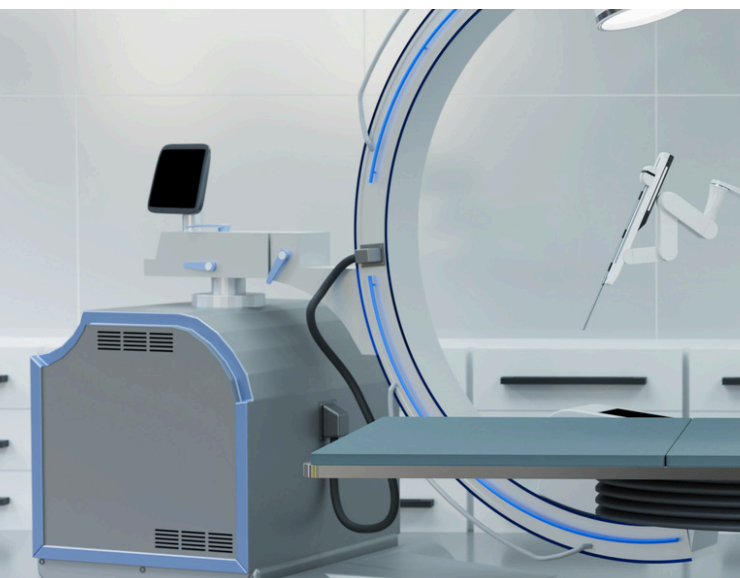
**15 Systems
Engineers
onboarded in
under 4 weeks**

**50+ roles filled
over the course
of the
engagement**

**Critical
compliance
deadlines met to
avoid consent
decree**

**Established strong
technical
leadership and
scalable systems
support**

**Helped stabilize the
product lines and
regain FDA
confidence**



Kirk is hands down the best recruiter I've worked with in my career. He jumped in during a mission-critical window and helped us hire 15 Systems Engineers in under a month. His speed, precision, and understanding of our technical needs kept us on track to hit aggressive milestones that otherwise could've slipped."

C.V. – Systems Engineering Manager

CONCLUSION & BUSINESS IMPACTS

This engagement is a powerful example of how embedded recruiting support can make a strategic impact during a company's most high-pressure moments. By serving as an extension of the internal leadership team, Kirk helped deliver rapid results when the stakes were high—ensuring deadlines were met, compliance was restored, and the foundation was laid for future growth.

Preferred Partner for Engineering and Regulatory Talent within Medical Device and Life Sciences

WHAT WE DO

We are leaders in Full-Time Direct-Hire Employment, specializing in connecting Medical Device companies with the best engineering and regulatory talent. We are changing the way companies "Digest Recruiting" and are here to make an impact—one hire, one company, one career at a time.

We'll help you find qualified specialists in your desired industry to carry out all of your company's needs.

SCREENING

We focus on finding and attracting job-seekers who may not realize a better opportunity is just a phone call away.

ALIGNING

We truly care about the people we're choosing to work with and take the extra time to learn about your vision of success, so we can build the roadway there together.

RELATIONSHIPS



WEBSITE
talentfactorymedical.com



PHONE
847.796.0997



EMAIL
kirk@tfrecruiting.com

We are leaders in Full-Time Direct-Hire employment, specializing in connecting medical device companies with the best engineering and regulatory talent.

KIRK PETYO

MANAGING PARTNER, TALENT FACTORY

