

EXECUTING FIELD CHANGE ORDERS: CASE STUDY

Challenge:

FDA product recalls impact hundreds of manufacturers every year and can cause devastating effects on a manufacturer's finances and reputation. It is critical to have the adequate resources, expertise, and systems in place to avoid irreversible brand damage and revenue loss. Fortunately, EMSAR is experienced in helping companies mitigate risk when facing an FDA Recall. EMSAR can help companies in this situation by executing planning & consulting, centralized recall project management, compliance & regulatory reporting, recall execution, and FDA action remediation.

Recently, EMSAR worked with a client that has 50K devices that needed to have a field upgrade applied to them. These devices are located in hospitals across the U.S. and needed to be upgraded within a 12-month timeframe. The client's own workforce was already stretched thin with day-to-day customer requirements and could not handle additional upgrades. Therefore, they hired EMSAR as their trusted partner to manage these upgrades.

Solution

Thanks to years of experience and solid infrastructure, EMSAR was able to provide a flexible workforce to complete the upgrades independent of the client's current workforce. At the outset of the project, EMSAR received a Unit Affected List (UAL) from the client and developed staffing requirements based on locations.

From there, EMSAR assigned call scheduling and management teams to work with the field team to schedule and facilitate the execution of upgrades. EMSAR then created a management portal for the client to monitor progress, increasing visibility of completed and upcoming upgrades.

Your Trusted Partners

Thanks to our established process and proactive approach, EMSAR was able to complete 52,632 upgrades in a 9-month period. The 52,632 units represented 100% of the unit affected list produced by the client. By executing these field change orders in a timely and comprehensive fashion, EMSAR was able to ensure that all equipment was functioning properly and reduced the risks posed for the client when facing an FDA recall. This also allowed the client to keep their internal field service team 100% focused on their normal day-to-day customer needs. In turn, EMSAR was able to safeguard the client's brand and reputation.