9 Touchpoints to Ensure Device Safety Across the Device Lifecycle

- **Device design requirements**: design and test products to ensure safety and eliminate risks.
- **Clinical testing**: such as mechanical and computer testing and animal studies, including human testing for high-risk devices.
- **FDA review**: establishes a reasonable assurance of safety and effectiveness for the device.
- **Complaint handling**: companies must investigate complaints and file adverse event reports with FDA for serious injuries, deaths, and device malfunctions.
- **FDA regulatory action**: FDA may seize products that pose safety concerns or prevent unsafe products from entering the U.S. DA may bar companies from distributing products that pose safety risks. Companies and their CEOs are subject to civil and criminal penalties if they violate product safety requirements.
- **FDA inspections**: FDA inspects companies to confirm that they meet safety requirements like proper device design, adverse event and recall reporting, and effective corrective and preventive actions.
- **Recall reporting**: companies must report to FDA when they fix devices or pull them from the market.
- **Recalls and removals & Unique Device Identifier**: companies regularly fix devices or pull them from the market to prevent possible safety concerns, even where there has been no actual harm. Each device must have a unique identifier to facilitate recalls and adverse event reporting.

Patient safety is the medical device industry’s #1 priority.

There are many protections in place to ensure that medical devices are safe. Please find a few of them below: