Enabled compliant rebranding for ~10,000 medical device labels – delivering high-quality redlines across MedSurg and Dental Portfolios during a large healthcare spinoff's brand transition

Wound Care Leader

Situation

Supported a global healthcare company during its separation from a legacy multinational parent by delivering large-scale medical device label redlines across the MedSurg and Dental business units.

The work involved implementing transactional rebranding updates alongside regulatory and MDR-driven changes, while maintaining compliance with global medical device labeling requirements. The scope covered 10,000+ labels and required close coordination with the client's Regulatory Affairs team to ensure accuracy, consistency, and inspection-ready quality under aggressive timelines.

Our approach

Portfolio: 10,000 Labels | Global Medical Device Labeling

- Established a structured redlining framework to consistently apply rebranding updates resulting from separation from a legacy healthcare conglomerate, while preserving approved content and regulatory intent
- Conducted detailed label-by-label reviews to identify and implement transactional, regulatory, and MDR-related changes without introducing unintended regulatory risk
- Partnered closely with a dedicated Regulatory Affairs team member to manage feedback cycles, resolve technical questions, and align on interpretation of regulatory requirements
- Implemented quality control checkpoints to ensure traceability, and consistency across large label volumes
- Managed daily coordination, tracking, and delivery to maintain momentum and meet tight timelines across workstreams

Impact and outcomes

- **10,000+ Label Redlines Delivered:** High-quality, inspection-ready redlines completed across MedSurg and Dental portfolios
- **Compliant Rebrand Execution**: Successfully captured required rebranding changes associated with a corporate separation while maintaining alignment with global labeling regulations and MDR expectations
- **Regulatory Risk Mitigation:** Ensured regulatory and MDR-driven updates were incorporated accurately, minimizing downstream review cycles and rework
- **Seamless RA Collaboration:** Worked in collaboration with the client's Regulatory Affairs organization, enabling efficient decision-making and consistent quality across all labels
- **Scalable, Repeatable Process:** Established a redlining approach capable of supporting large-volume labeling updates under tight timelines and regulatory scrutiny