Hogan Lovells

Unique Device Identifiers

Handling the U.S. Food and Drug Administration's (FDA) rules regarding unique device identifier (UDI) obligations requires regulatory and technical knowledge. Do you understand your requirements? The lawyers at Hogan Lovells advise clients regarding the specifics of the UDI rule, including applicable exceptions, strategies for implementation, and timing.

The FDA's rules and expectations are nuanced. And we know them well. We help you develop procedures to address UDI implementation across your business and find ways to make UDI implementation useful from a business perspective. As this area evolves, we keep up with complex requirements to ensure compliance and help you avoid missteps that could cost time and money.

Representative experience

Work with a Fortune 50 company to develop governing procedures for implementation to ensure compliance and add business value.

Obtained compliance extension to ensure device availability for critically ill population and exceptions to labelling requirements due to technological constraints.

Advise companies on nuanced implementation for convenience kits and private label distributions.

Contacts

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Practices

Medical Device and Technology Regulatory