

Randy J. Prebula

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Whether describing complex science in straightforward terms to lawyers or translating premarket and compliance regulatory requirements to scientists, Randy Prebula focuses on practical industry experience and a deep understanding of Food and Drug Administration (FDA) regulations to help clients navigate the intersections of science, policy, and law.

As a key resource for medical device, drug, human tissue, and combination product manufacturers, Randy works seamlessly across borders with clients and internal teams to help bring innovative medical products to market and meet patient needs throughout each product's unique life cycle.

As director of the firm's FDA Medical Devices and Technology practice area, Randy helps develop and integrate legal and non-legal professionals into our practice to leverage technical and legal knowledge that provides clients with practical, implementable solutions to meet their regulatory needs. He also helps companies with cutting-edge technologies navigate and optimize the FDA approval process.

He brings a wealth of experience in immunology, biochemistry, and new product development and provides real-world experience in developing, implementing, and maintaining compliant regulatory systems and procedures.

Representative experience

- Assisted Cohera Inc. with premarket approval (PMA) of novel tissue adhesive, TissuGlu.
- Successfully advocated the FDA's downclassification of an imaging device, tissue culture media products, and in vitro diagnostic systems, avoiding the need for a PMA.
- Assisted a company with FDA regulation and U.S. marketing authorization for veterinary wound care products.
- Assisted a biotechnology company with evaluating FDA regulatory requirements for stem cell and regenerative medicine products and medical device sales and distribution projects.
- Assisted clients with Tissue Reference Group advisory opinion requests and Office of Combination Product Requests for Designation (RFD).
- Assisted clients with cell sorter and isolation systems, mesenchymal cells of multiple tissue origins for use, and products intended for reproductive technology applications.

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