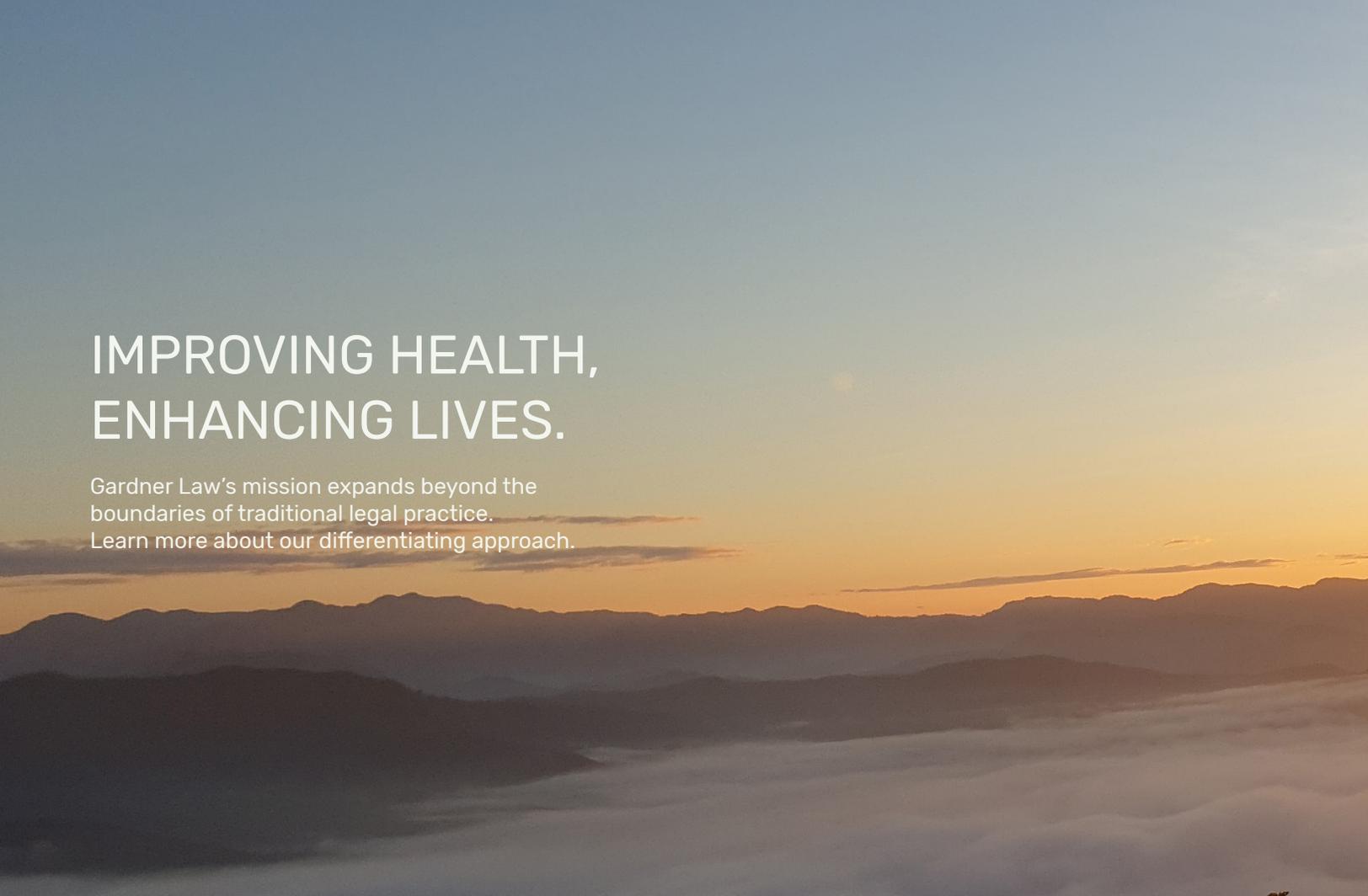




GARDNER

AN FDA LAW FIRM



IMPROVING HEALTH, ENHANCING LIVES.

Gardner Law's mission expands beyond the boundaries of traditional legal practice.
Learn more about our differentiating approach.





The right partner for FDA-regulated companies

Gardner Law provides expert counsel to FDA-regulated companies in regulatory, compliance, privacy, litigation, and commercial matters. Our industry and government experience enables us to deliver actionable advice, empowering clients to make informed decisions. We prioritize responsiveness, ensuring timely support. Our attorneys possess deep regulatory knowledge gained through experience at leading organizations.

Legal Practice Areas:

- Regulatory
- Compliance
- Privacy
- Litigation
- Commercial



SECTORS

Gardner Law specializes in FDA-regulated legal matters, offering expert transactional and litigation counsel across diverse industries. Our overarching mission is to positively impact lives and promote better health. This is the driving force at Gardner Law.



Medical Device



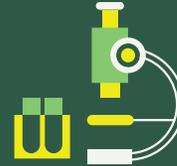
Drug



Digital Health



Vaccine & Biologics



Laboratory



Supplements



Veterinary



Cosmetics



Food & Beverage

A woman with long blonde hair, wearing a black blazer, is seated at a desk in an office cubicle. She is looking down at a laptop on the desk, with her hands resting on the keyboard. The cubicle is separated by dark grey metal frames and frosted glass panels. In the background, a brick wall and an arched window are visible. The lighting is soft and focused on the woman.

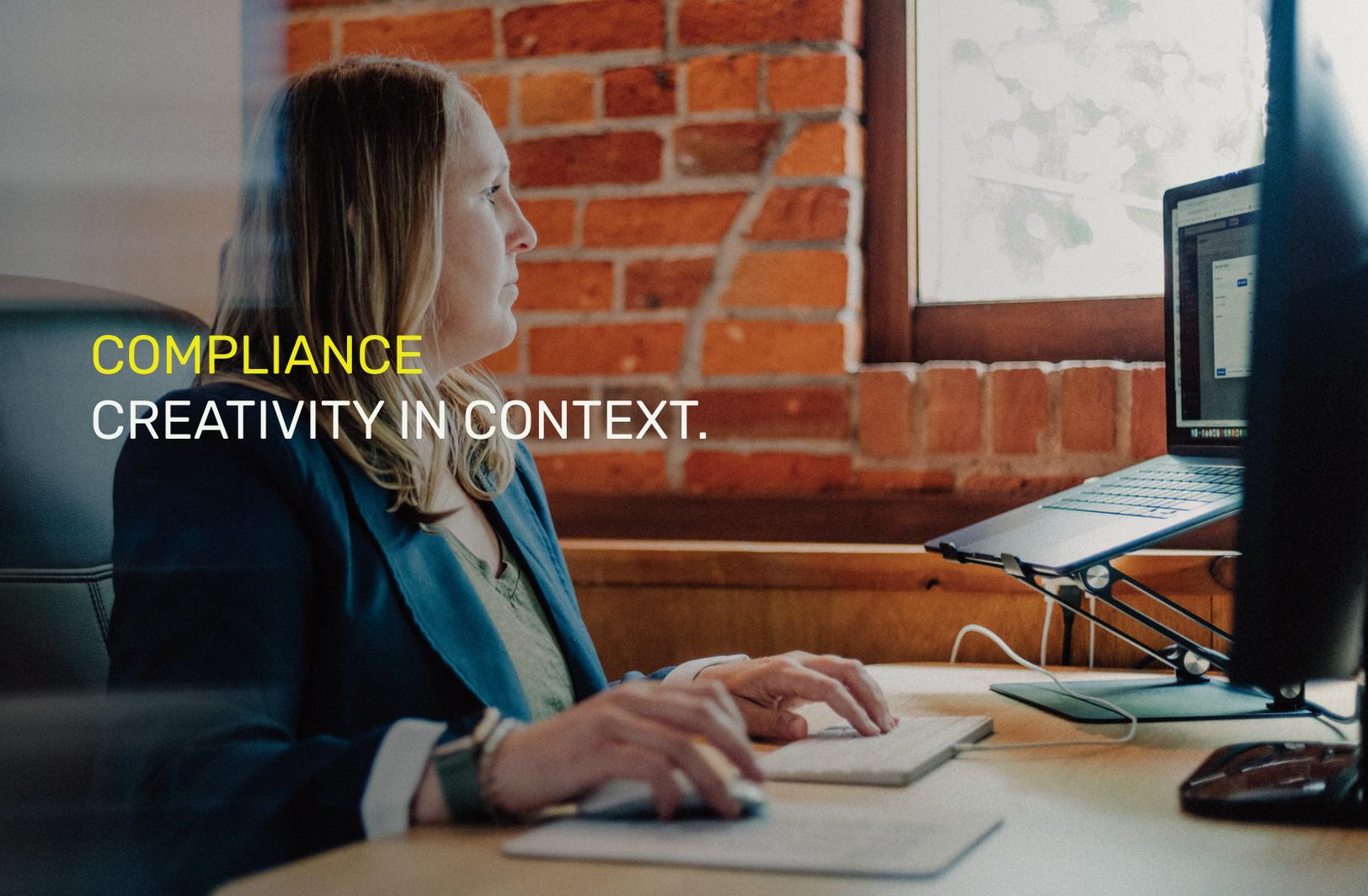
REGULATORY
THE HUMAN FACTOR.



At Gardner Law, we prioritize empathy and clear communication in our counsel to FDA-regulated companies. Our firm possesses recognized expertise in navigating complex FDA regulations, guiding clients through potential pitfalls. With specialized experience, we provide exceptional strategic guidance, ensure timely submissions, and negotiate effectively with regulators.

Representative Matters:

- Advertising and Promotion Review
- Regulatory Strategy
- FDA Pathway Assessment
- Clinical Trial Agreement Review, Drafting, and Negotiation
- Research Practices and Negotiating with FDA
- FDA Pre-Submission Meetings
- Quality System Policies and Procedures
- Recalls
- Warning Letters, Untitled Letters, Notice of Violation Letters, 483s, Import Holds, Clinical Holds
- Medical Device Submissions (IDE, 510(k), PMA, De Novo, HDE, EUA, OTC)
- Drug and Biologics Submissions (IND, NDA, ANDA, 505(b)(2), BLA, EUA, OTC)
- Food and Dietary Supplement Safety
- Labeling Negotiation with FDA
- CGMP Compliance
- Mock Inspections and Preparation
- OUS Regulatory Support

A woman with blonde hair, wearing a blue blazer, is seated at a desk in profile, looking towards the right. She is using a laptop and a mouse. The desk is light-colored wood. In the background, there is a red brick wall and a window with a view of greenery. A large monitor is visible on the right side of the desk.

COMPLIANCE
CREATIVITY IN CONTEXT.



Gardner Law provides compliance counsel with a focus on practical solutions and risk mitigation. Our attorneys possess a deep understanding of the Anti-Kickback Statute, False Claims Act, Physician Payments Sunshine Act, Stark Law, and Foreign Corrupt Practices Act, among others, and are adept at developing effective strategies that translate into actionable steps for our clients. Our team is committed to finding creative and compliant ways to achieve your business objectives.

Representative Matters:

- Compliance Officer Secondments
- Design, Implement, Monitor, and Audit Compliance Programs
- Compliance Investigations
- Due Diligence for Buyers and Sellers
- Address Violative Practices
- OIG Advisory Opinions
- Sales and Marketing Program Evaluation
- Outsourced Transparency Reporting
- Risk Assessment
- Compliance Monitoring and Auditing
- Draft, Review, and Negotiate Contracts
- Reimbursement Support Services Audit
- AdvaMed, PhRMA, and OIG Safe Harbor Compliance
- Seizures
- Civil Money Penalties
- Fair Market Value (FMV) Analysis
- Compliance Committee Operation
- Draft, Implement, and Train on Compliance Policies and Procedures
- Training

PRIVACY
THE ART OF ARTICULATION.





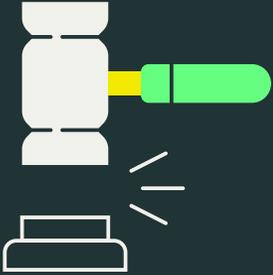
Privacy and cybersecurity law continues to change rapidly. Understanding privacy and cybersecurity requirements is paramount to any business. Our privacy-focused attorneys have the experience and know-how to help you navigate the impact of privacy laws and regulations. Complying with applicable requirements is a science, but explaining them clearly is an art.

Representative Matters:

- Privacy Officer and DPO Secondments
- Privacy and Cybersecurity Program Audits
- Privacy and Cybersecurity Counsel
- Privacy Impact Assessments and Security Assessments
- Privacy and HIPAA Compliance Programs
- DPAs, SCCs, Transfer Impact Assessments
- Privacy Policy Drafting, Implementation, and Training
- Data Transfer Agreement, Informed Consent, and Privacy Notice Drafting
- Business Associate Agreements
- Websites and Mobile Applications
- Patient Authorization and Consent Drafting
- Privacy Compliance for FDA Complaint Handling

A man in a blue and white checkered shirt stands on the left, smiling and holding a grey folder. He is talking to a woman with blonde hair, wearing a black top, who is sitting at a wooden desk. She is looking up at him. On the desk are two laptops, one silver and one black. A man in a grey suit is partially visible on the right, looking towards the woman. The background features a brick wall and large glass windows with wooden frames. The text "LITIGATION STRATEGIC SOLUTIONS." is overlaid on the image in yellow and white.

LITIGATION
STRATEGIC SOLUTIONS.



We partner with our clients to resolve disputes and achieve the best possible outcomes. Our experienced attorneys understand that every dispute is unique, and we tailor our approach to protect client interests. Whether it involves disputes with competitors, regulatory enforcement actions, arbitration, or litigation, we are equipped to represent our clients in various forums and proceedings. With a deep understanding of the legal landscape and a proven track record of success, we provide strategic guidance and aggressive advocacy to help our clients achieve the optimal outcomes efficiently and effectively.

Representative Matters:

- FDA Litigation
- Consent Decrees
- Seizures
- Civil Monetary Penalties (CMPs)
- Recall Litigation
- Product Liability Litigation
- DOJ and OIG Investigations and Prosecutions
- Government Fraud Prosecutions
- False Claims Act and Anti-Kickback Statute Cases
- Civil Investigative Demands
- Search Warrants
- Injunctions
- Expert Witness Testimony
- Subpoenas
- FTC and NAD Litigation
- Labeling Class Actions
- Arbitration and Mediation

A man and a woman are sitting at a wooden desk in a modern office. The man, on the left, is wearing a blue checkered shirt and is looking towards the woman. The woman, on the right, has long brown hair and is wearing a dark blazer over a light blue top. She is smiling and looking back at the man. Both have laptops open in front of them. The background features a large window with white curtains and a green plant. The lighting is warm and natural, suggesting a bright day.

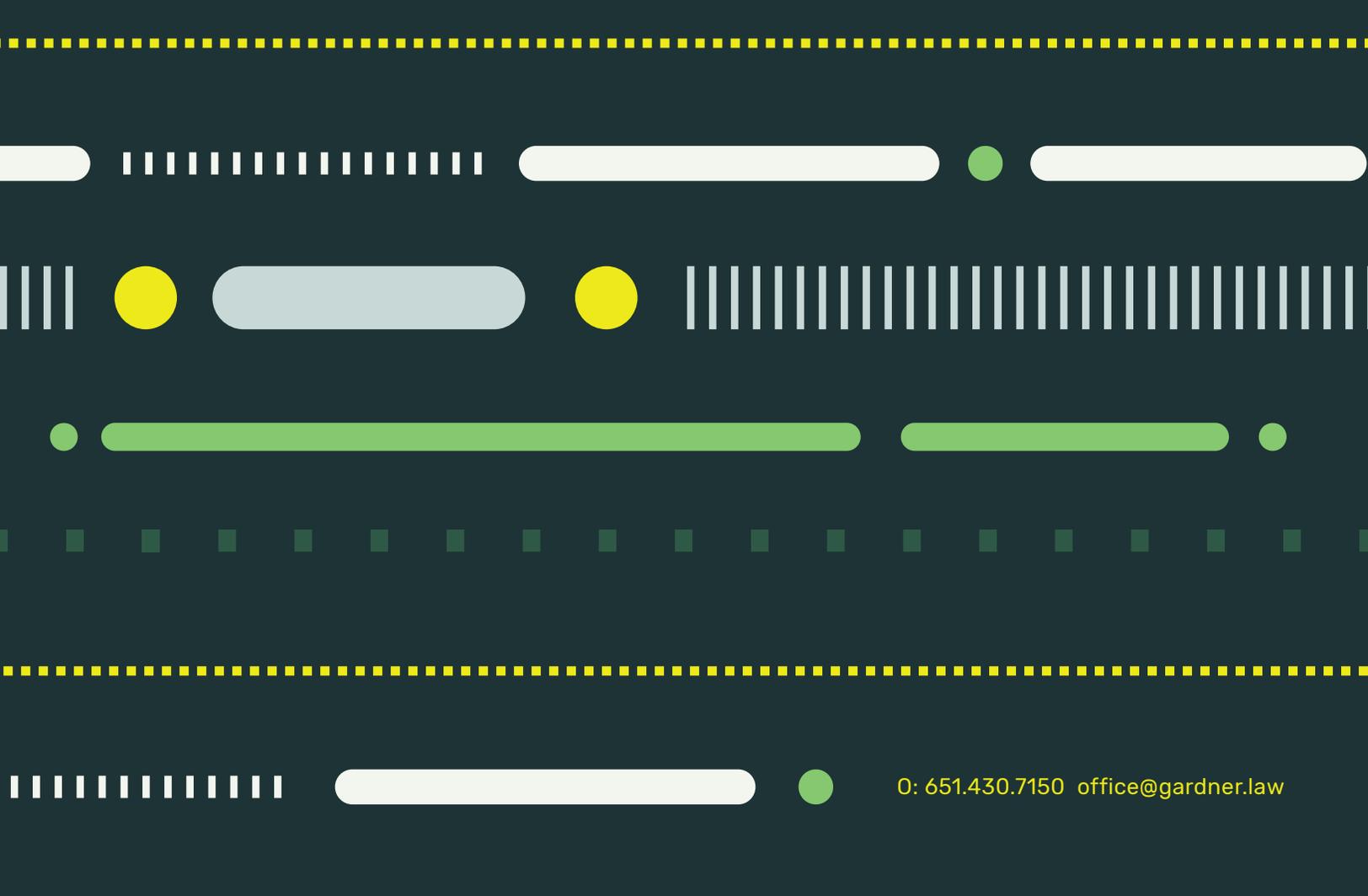
COMMERCIAL
DEAL-MAKING WITH
DISCIPLINE.



At Gardner Law, we provide comprehensive legal support for commercial transactions involving FDA-regulated products, technologies, and services. We help FDA-regulated companies structure and execute transactions that move business forward. Whether negotiating sales agreements, navigating M&A, licensing IP, or advising on supply and sourcing arrangements, our attorneys bring deep regulatory knowledge and commercial acumen to every deal. We understand the nuances of doing business in regulated industries and provide counsel that balances legal risk with business reality—helping clients close deals with confidence, clarity, and compliance.

Representative Matters:

- Mergers, Acquisitions, Divestitures, and Joint Ventures
- Procurement and Supply Agreements
- Licensing and Technology Transfer Agreements
- Co-Promotion and Co-Marketing Agreements
- Distribution and Reseller Agreements
- Manufacturing, Technical, and Quality Agreements
- Clinical Trial and Research Agreements
- Research, Educational, and Charitable Grant Agreements
- Equipment Placement, Loan, and Product Sale Agreements (Including Rebates and Discounts)
- Master Service Agreements, SOWs, and Consulting Agreements
- Confidentiality and Release Agreements
- Risk-Share and Value-Based Agreements
- Privacy and Data/Use Sharing Agreements



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