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Pharma, Medtech, Biotech:

Regulatory Updates, AI Risks, & Enforcement Trends

November 12, 2026 • Lido House, Newport Beach, CA



Welcome



Mark Gardner

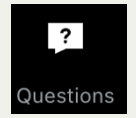
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Today's discussion

Legal and business issues facing established medical product companies and new innovations.

Questions

Attendees may submit questions for the closing Q&A via the GoTo Webinar questions feature.



Continuing education

For CLE and RAPS RAC credit info: office@gardner.law

In-person attendees must sign in

Today's session will be recorded

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Agenda

1:00–1:30	Hot topics: Regulatory, compliance, and privacy.
1:30–2:05	Regulatory strategy, evidence, and product decisions.
2:05–2:40	Commercialization and marketplace risk.
2:40–2:50	Refreshment break.
2:50–3:25	Managing a more complex compliance environment.
3:25–4:10	Ask the Experts: Audience Q&A.
4:10	Networking reception.

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Opening Briefings

Regulatory, Privacy, and Compliance Updates

1:00–1:30 p.m. PT

Presenters

Nathan Downing • Regulatory
Paul Rothermel • Privacy
Amanda Johnston • Compliance

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Opening briefings



Regulatory

Nathan Downing

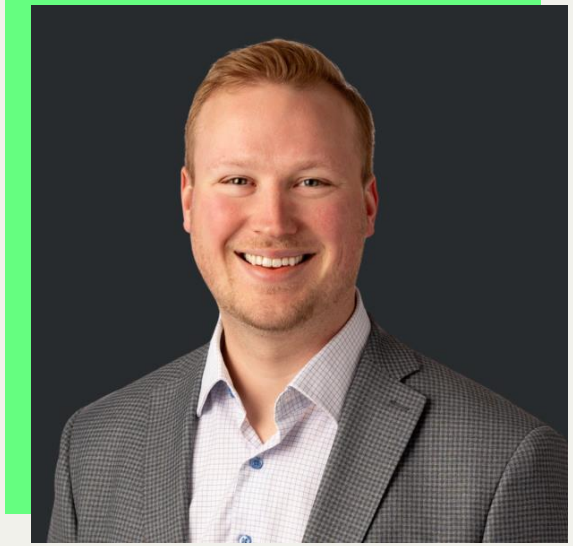
Managing Attorney, Gardner Law



Compliance

Amanda Johnston

Partner, Gardner Law



Privacy

Paul Rothermel

Managing Attorney, Gardner Law

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Regulatory updates

FDA's Proposed Guidances for FY 2027

AI, QMS, and PCCP finalization show FDA's focus in efficiency and addressing rapidly changing areas.

AI in FDA operations

FDA announced Elsa 4.0 in May 2026 and continues integrating AI into staff workflows with human review.

FDA Communications

Communication with FDA remains an area where focus is needed.

FDA Updates



- Overall focus
- Resource considerations
- Enforcement updates

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Latest on Drugs

Drug Development Updates

- Clinical trial updates
- Focus on generic drugs
- Programs to speed development
- Other considerations



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Latest on Medical Devices

- Wellness products and associated FDA guidance
- Digital health updates
- Regulation of generative AI
- Other issues to watch



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FDA engagement and the record

01 **Clear questions**

Identify the decision, proposed approach, and evidence supporting it.

02 **Traceable evidence**

Connect study results and risk analyses to intended use and product claims.

03 **Consistent submissions**

Use consistent terminology and explicit references across the record.

04 **Documented follow-up**

Record FDA feedback, unresolved issues, and the basis for the next step.

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DOJ fraud enforcement priorities

August 2026 priorities

DOJ’s National Fraud Enforcement Division identifies health care and corporate misconduct as priorities.

Medical products exposure

The memorandum highlights kickbacks, deception of regulators, and deceptive marketing of unsafe products.

Detection and corporate response

DOJ emphasizes data analytics and rewards voluntary self-disclosure, cooperation, and remediation.

Commercial programs and compliance

01 **Discounts and customer value**

Assess discount structure, documentation, and reporting obligations.

02 **HCP engagement**

Review purpose, compensation, attendee selection, and repeat attendance.

03 **Reimbursement support**

Define the service, who benefits, and the boundaries of field-team involvement.

04 **Auditing and monitoring**

Test actual conduct against program rules and follow through on exceptions.

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2026 US privacy law: key areas of focus

State laws expand, enforcement intensifies, and AI and health data draw scrutiny

Expanding state footprint

24 states now have comprehensive laws. Oklahoma and Louisiana take effect Jan. 1, 2027, Alabama May 1, 2027, Vermont Jan. 1, 2028.

Tighter scope and sensitive data

Connecticut amendments (July 1) lower thresholds to 35,000 consumers, narrow exemptions, and add neural and biometric data.

Risk assessments and ADMT

California risk assessment rules began Jan. 1, 2026; ADMT requirements follow Jan. 1, 2027. Vermont adds profiling rights.

Enforcement and health data

California data broker actions and sectoral audits, active FTC cases, Maryland's health data sale ban, and breach notice deadlines.

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Operational considerations

What companies should do now to stay ahead of 2026 requirements

Map data and vendors

Inventory personal and health data, uses, and third-party flows to determine which state laws apply and where exemptions no longer hold.

Reassess scope and notices

Recheck applicability thresholds, sensitive data categories, consent flows, and privacy notices after state amendments.

Risk assessments and AI governance

Stand up documented risk assessments and review ADMT and profiling uses ahead of California's 2027 requirements.

Prepare for enforcement

Honor opt-outs and authentication rules, tighten breach response timelines, and train teams to handle regulator inquiries and audits.



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Build

Regulatory Strategy, Evidence, and Product Decisions

1:30–2:10 p.m. PT

Moderator

Nathan Downing • Gardner Law

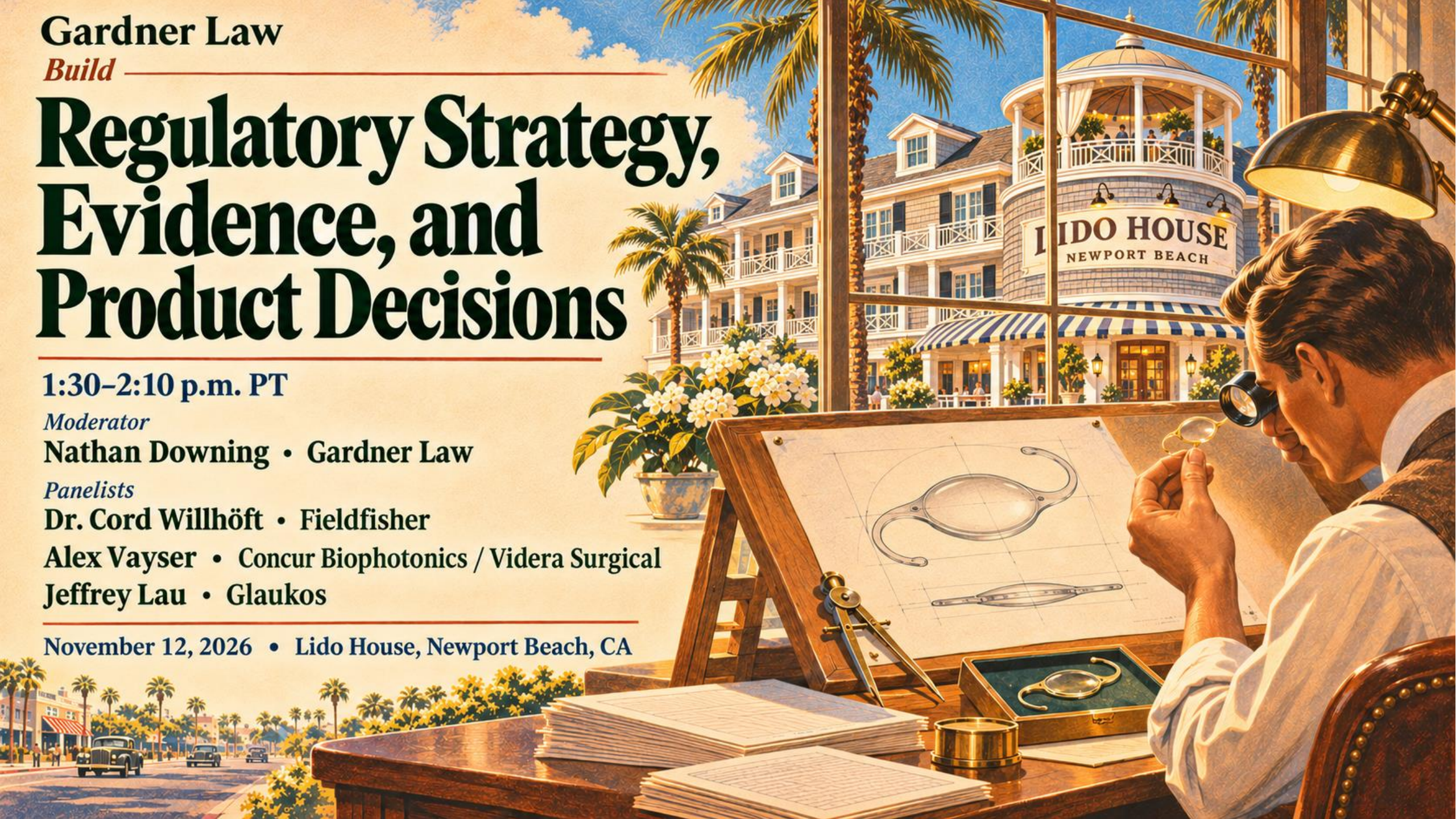
Panelists

Dr. Cord Willhöft • Fieldfisher

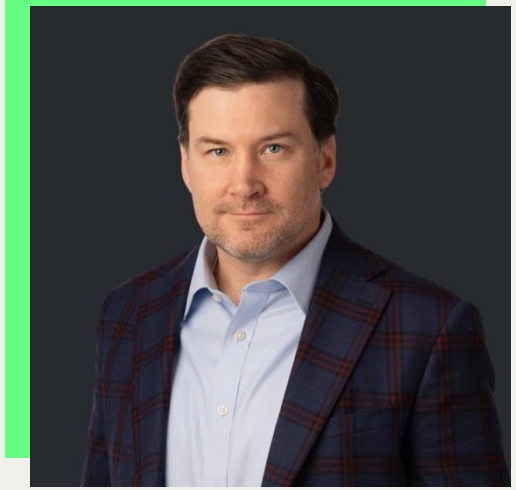
Alex Vayser • Concur Biophotonics / Videra Surgical

Jeffrey Lau • Glaukos

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Regulatory strategy, evidence, and product decisions



Nathan Downing

Moderator
Managing Attorney

Gardner Law



Dr. Cord Willhöft

Partner, Co-Head,
Life Sciences & Healthcare

Fieldfisher



Alex Vayser

Founder & CEO

Concur Biophotonics



Jeffrey Lau

Associate General Counsel

Glaukos

Current U.S. and EU Regulatory Challenges

01 **Panelist Introductions**

What is your role, and what does your work focus on?

02 **Current Challenges**

What is the toughest issue your team faces right now when working with FDA or navigating the EU regulatory system?

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Changing Expectations and Time to Market

03 Innovative Products

How are recent FDA and EU developments changing what teams need to show for AI-enabled devices, digital health technologies, or combination products?

04 Time to Market

Where could QMSR, real-world evidence, or digital review tools shorten time to market? What looks promising in the EU, and where do delays persist in either market?

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Regulatory Engagement and Product Strategy

05 **Working With Regulators**

When do you approach regulators, and how do you use their feedback to resolve an obstacle or explore a new option?

06 **Strategy for a New Product**

When you build a legal and regulatory strategy for a new medical product, which decisions do you make first, and why?

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Launch

Commercialization and Marketplace Risk

2:10–2:50 p.m. PT

Moderator

Paul Rothermel • Gardner Law

Panelists

Sameena Habib • Medtronic

Chase Leavitt • Mobia Medical

Brian Kelly • Advanced Bionics

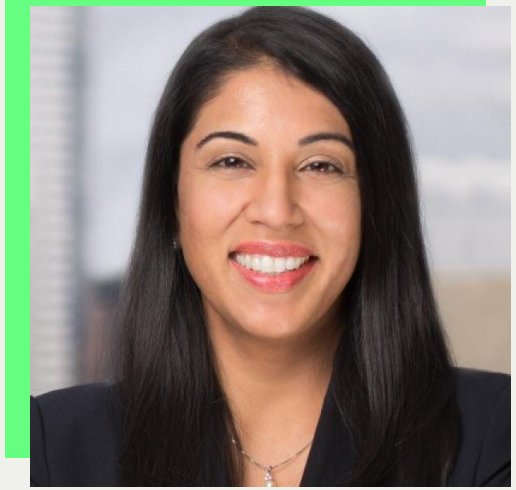
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Commercialization and marketplace risk



Paul Rothermel
Moderator
Managing Attorney
Gardner Law



Sameena Habib
Global R&D AI & Data Counsel
Medtronic



Chase Leavitt
General Counsel

Mobia Medical



Brian Kelly
VP, Chief Compliance Officer
Advanced Bionics

Commercialization: launch risks

01 **Overlooked risks**

Which legal and compliance risks are addressed too late?

02 **One question**

What should commercial leaders ask before any new initiative?

03 **Training and oversight**

How can companies better train and oversee commercial teams?

04 **A seat at the table**

How can legal and compliance shape marketing and launch plans?

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Working with limited resources

01 **Prioritizing risk**

Where should limited legal and compliance resources go?

02 **Outside expertise**

How do you spot new-initiative risks and identify when to call outside counsel or specialists?

03 **Translating advice**

How does the GC turn specialist advice into action? How can specialists provide practical advice for their GC or business teams?

04 **AI guardrails**

How is AI changing lean legal support? What guardrails are needed?

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Refreshment break

The program resumes at 2:50 p.m. PT.

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Grow

Managing a More Complex Compliance Environment

3:05–3:45 p.m. PT

Moderator

Amanda Johnston • Gardner Law

Panelists

Shannon Treviño • SpyGlass Pharma

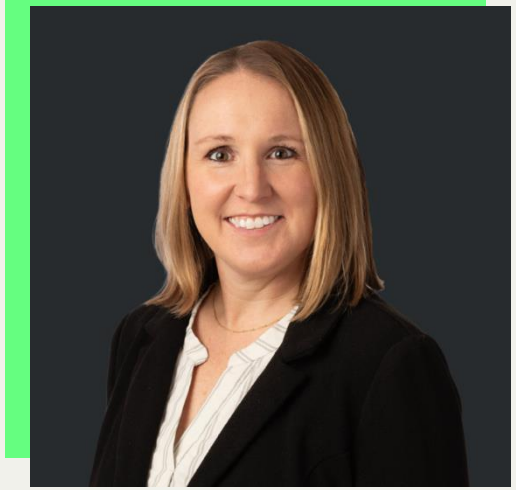
Karyl Haskell • OrthAlign

Liana Edgar • HeartFlow

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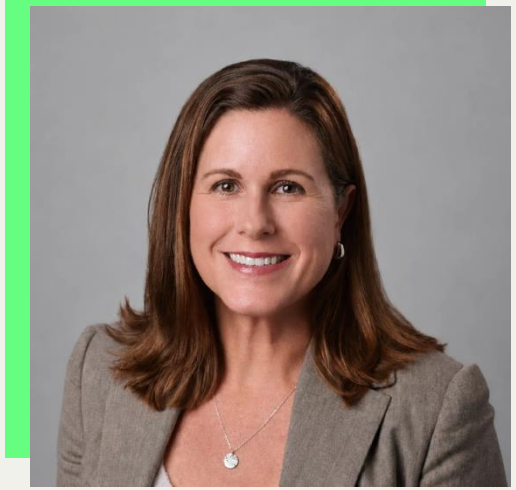


Managing a more complex compliance environment



Amanda Johnston

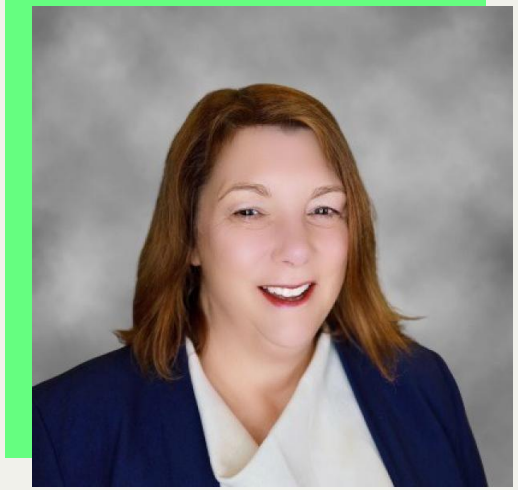
Moderator
Partner
Gardner Law



Shannon Treviño

General Counsel

SpyGlass Pharma



Karyl Haskell

VP, Regulatory Affairs
& Quality Assurance
OrthAlign



Liana Edgar

Corporate Counsel

HeartFlow

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precise · alignment · simplified

Heartflow

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Compliance as the Business Grows

01 **Outgrowing Existing Processes**

What signals that a company has outgrown its compliance processes?

02 **Investment and Priorities**

How do you secure investment in people or systems when budgets are tight?

03 **Commercial Pressure**

Where does commercial growth create pressure, and what helps?

04 **HCP Relationships**

What becomes more complicated as HCP engagements grow?

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Testing Controls and Taking Action

05 **Auditing and Monitoring**

What have audits or monitoring revealed that you might have missed?

06 **Coordination and Ownership**

How do you bring the right functions together and establish ownership?

07 **Enforcement Developments**

Which developments change your priorities and get leadership's attention?

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Data, AI, and Lessons Learned

08 **Privacy and Data Practices**

What privacy challenges arise as data use expands, and what has helped?

09 **AI in Products and Daily Work**

How is AI changing compliance in products and in everyday work?

10 **One Earlier Investment**

What compliance investment would you encourage a company to make earlier?

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Ask the Experts

Regulatory, Privacy, and Compliance Q&A

3:45–4:15 p.m. PT

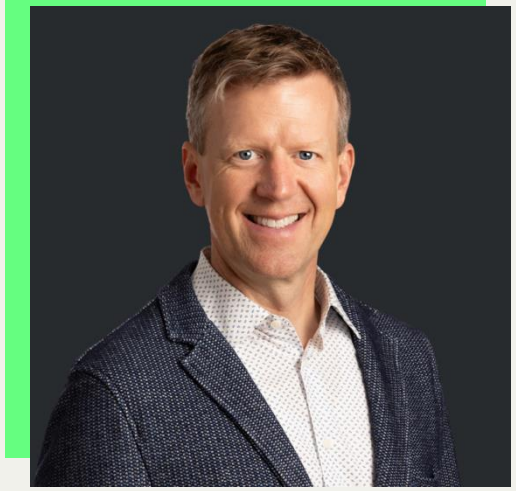
Moderator
Mark Gardner • Gardner Law

Panelists
Melissa Hoffman • Edwards Lifesciences
Christopher Shurland • Asahi Intecc USA
Sara Kerrane • Glaukos

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Ask the Experts



Mark Gardner

Moderator
Founder & Managing Partner

Gardner Law





Melissa Hoffman

VP, Lead Counsel, TMTT

Edwards Lifesciences





Christopher Shurland

Managing Counsel

Asahi Intecc USA





Sara Kerrane

VP, IP, Regulatory
& Litigation Counsel

Glaukos



Early Legal Input and Evidence Strategy

01 **Current Business Challenges**

What is the biggest legal challenge your business faces today?

02 **Earlier Legal Involvement**

What do you wish business teams brought to legal sooner?

03 **Evidence and Product Claims**

What do we need to prove, and which claims must the evidence support?

04 **Regulatory Pathway Tradeoffs**

When might a faster pathway limit future commercial options?

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AI Use and Legal Risk

01 **Validation and Business Context**

How do teams test AI outputs for accuracy and business nuance?

02 **Confidentiality and Privilege**

What risks arise from AI meeting records and legal memoranda?

03 **Regulatory Submissions**

How should human review address AI-generated issues and responses?

04 **Employee Relations and Investigations**

When do inaccurate AI-generated accounts increase the review burden?

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Relationships and Decisions Under Uncertainty

01 **Avoidable Mistakes**

Which commitments need review before the business makes a promise?

02 **Trust and Access**

How can legal build relationships that bring issues to the team earlier?

03 **Moving Forward Without Clear Rules**

When do internal guidance and SOPs help, and when do they add complexity?

04 **Practical Takeaways and Audience Q&A**

What is one action attendees can take back to their teams?

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Thank you

Networking reception

Thank you to our speakers and everyone joining us.



Questions about credits or program materials?
office@gardner.law

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Drug Development Considerations

Opportunities

Challenges

Unique issues—peptides as a case study



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Medical Device Definition
21 USC § 321(h)(1)

"The term *device* … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

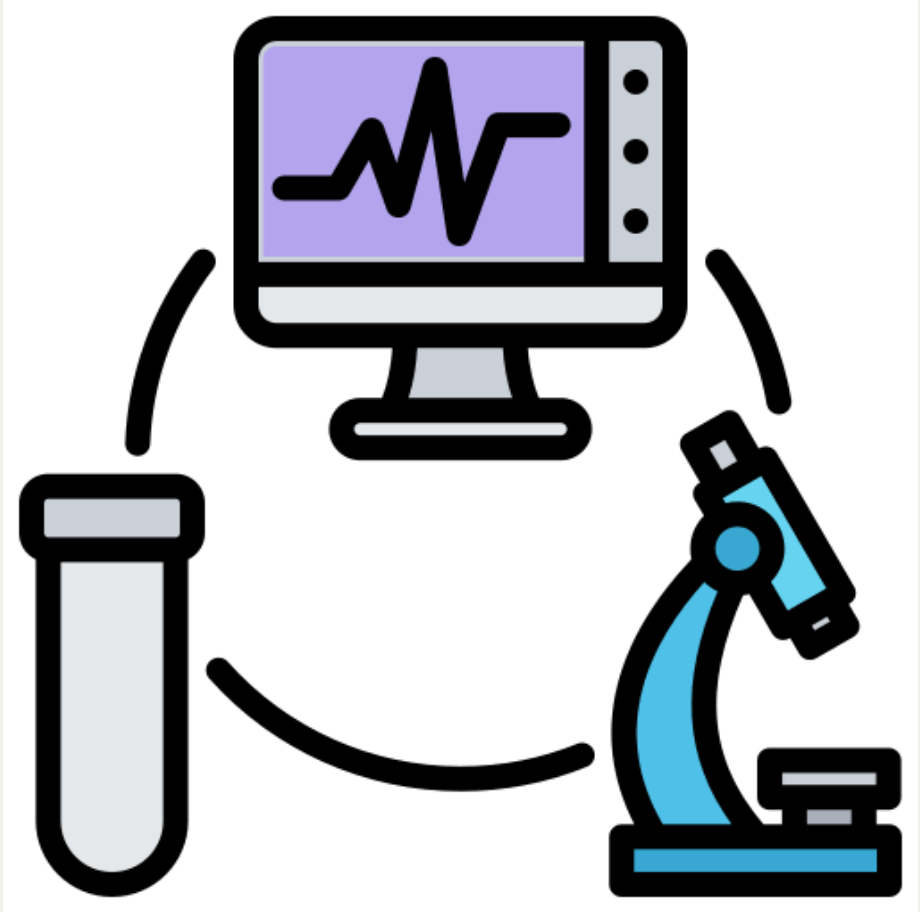
(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,

(C) or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man… and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

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Medical Device Development Considerations

- Opportunities
- Challenges
- Working with CDRH



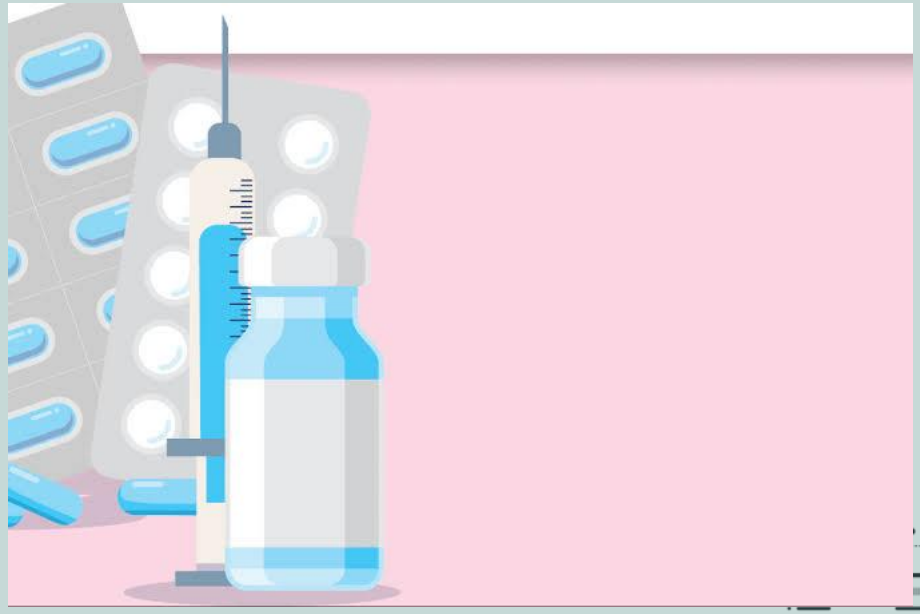
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Latest on Biologics

Major growth in approvals for cell and gene therapies

Biosimilar updates

Peptides and their regulatory status



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Latest on Vaccines

Promising technology in areas such as cancer will require FDA support

FDA's role in regulating messaging and the public's perception

Focus on post-market monitoring



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How to Bring a Medical Product to Market in a Changing Environment

Fully assess intended use

Develop regulatory and testing strategy

Navigate FDA



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Appeal Options

Varies by product type

Understand informal options

Formal appeal options at FDA

Article III courts



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FDA Communication Strategy



Early Touchpoints



Address Issues



Appeals

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FDA Communication Considerations



SHOULD YOU RISK ASKING A QUESTION



KNOW WHAT YOU KNOW … AND WHAT YOU DON’T



DO NOT FEAR FDA

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Conclusion



Keep up with a changing FDA



A regulatory strategy is an imperative



Closing thoughts

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Regulatory strategy in practice

01 **U.S. and EU requirements**

Where do differences in regulatory expectations change the product strategy?

02 **Evidence and intended use**

How should teams align clinical evidence with the claims they want to make?

03 **Data and product decisions**

When should privacy, cybersecurity, and data governance enter the discussion?

04 **Investment and diligence**

Which unresolved regulatory issues create the greatest transaction risk?

Federal Anti-Kickback Statute: liability framework

42 U.S.C. § 1320a-7b(b) · Criminal statute governing remuneration tied to Federal health care program business

01 **Prohibited conduct**

Knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or reward referrals, purchases, orders, leases or recommendations involving items or services payable by a Federal health care program. “Remuneration” is construed broadly and can include cash, free services, gifts, rebates, below-market benefits or other value.

02 **Intent and causation**

The government must prove knowing and willful conduct, but a person need not know the AKS or specifically intend to violate it. Under the judicial “one purpose” approach used in several circuits, an improper inducement purpose may suffice even when an arrangement also has legitimate purposes. Circuit-specific causation rules matter for derivative FCA claims.

03 **Safe harbors**

42 C.F.R. § 1001.952 protects arrangements that satisfy every applicable element. Failure to fit a safe harbor does not itself establish an AKS violation; the arrangement is assessed under the statute based on remuneration, referral nexus, intent and the totality of facts. OIG advisory opinions bind only HHS and the requestor.

04 **HCP arrangement risk factors**

Need and selection tied to business potential; compensation above FMV or not set in advance; vague or duplicative services; payment for unused work; excessive frequency; sales control of selection or approval; benefits extending beyond legitimate training, consulting or research purposes; weak documentation of performance. FMV is relevant but does not negate improper intent.

05 **Consequences and compliance response**

Felony exposure includes fines and imprisonment; related consequences can include exclusion, civil monetary penalties and FCA liability. Controls should connect a documented need, objective selection, written scope, compensation methodology, deliverables, payment evidence, transparency reporting and post-payment monitoring. Escalate exceptions rather than treating approval as a one-time event.

Key authorities: 42 U.S.C. § 1320a-7b(b), (g); 42 C.F.R. § 1001.952; HHS-OIG GCPG (2023). Safe-harbor noncompliance is not per se illegality.

False Claims Act and industry guidance

The FCA creates civil liability; OIG and AdvaMed materials provide nonbinding compliance frameworks.

01 FCA liability

31 U.S.C. § 3729 covers knowingly presenting a false claim, using a material false record or statement, conspiracy, and reverse false claims. “Knowingly” includes actual knowledge, deliberate ignorance and reckless disregard; no specific intent to defraud is required. Materiality asks whether the matter has a natural tendency to influence, or is capable of influencing, payment.

02 Remedies and enforcement

Liability includes treble damages plus a per-claim civil penalty adjusted for inflation. DOJ may sue, and private relators may bring qui tam actions in the government’s name. A six-year limitations period applies, subject to the alternative government-knowledge rule and an outside ten-year limit. The government proves civil FCA elements by a preponderance.

03 AKS-to-FCA linkage

The AKS states that a claim including items or services resulting from an AKS violation constitutes a false or fraudulent claim for FCA purposes. That statutory linkage does not eliminate disputed issues concerning causation, knowledge, materiality or whether the underlying arrangement violated the AKS. Claims analysis must be tied to the governing circuit and facts.

How guidance should be used

01	**HHS-OIG GCPG**	Voluntary and nonbinding. Identifies seven compliance-program elements, governance expectations, risk assessment, reporting, auditing and corrective-action practices. “Should” reflects guidance, not a legal mandate.
02	**AdvaMed Code of Ethics**	Voluntary industry code for medtech-HCP interactions, including consulting, training, education, grants, charitable support and third-party programs. The November 2025 update adds data-use, privacy and responsible-data guidance.
03	**Practical legal effect**	Guidance does not create FCA or AKS liability by itself. It can inform program design, contractual guardrails, training and monitoring, and may become relevant evidence concerning knowledge, intent, reasonableness or remediation depending on the facts.

Key authorities: 31 U.S.C. §§ 3729-3731; 42 U.S.C. § 1320a-7b(g); HHS-OIG GCPG (2023); AdvaMed Code of Ethics, effective Nov. 1, 2025.

Compliance program expectations: binding law vs. evaluative guidance

Appendix · Managing a more complex compliance environment

01

Binding law

AKS, FCA, Open Payments, HIPAA, FTC Act/HBNR, CCPA and product-specific FDA requirements create enforceable obligations. Safe harbors and exceptions define protected pathways but are not the only lawful structures.

02

Agency guidance

HHS-OIG's General Compliance Program Guidance is voluntary and nonbinding. DOJ's ECCP describes questions prosecutors use to evaluate program design, resourcing and effectiveness.

03

Risk-based controls

The defensible question is not whether every control is "best in class," but whether controls are tailored to the company's actual risk profile, implemented in good faith and tested in practice.

Key authorities: 42 U.S.C. § 1320a-7b(b); 31 U.S.C. §§ 3729-3733; 42 U.S.C. § 1320a-7h; HHS-OIG GCPG (2023); DOJ ECCP (2024).

When growth outpaces the compliance operating model

Program maturity should track risk, complexity and information flow, not headcount alone.

01 **Risk assessment no longer maps to the business**

New products, channels, geographies, patient programs, distributors or data uses are launched without a documented reassessment of legal and operational risk.

02 **Compliance lacks authority, access or resources**

DOJ asks whether compliance has sufficient stature, autonomy, funding, personnel and timely access to data. OIG emphasizes direct access to leadership and the board.

03 **Approvals become informal or inconsistent**

Material exceptions move through email, policy ownership is unclear, and similar arrangements receive different answers because facts and rationale are not captured.

04 **Controls are not tested after launch**

Training completion and policy publication are inputs. Effectiveness requires monitoring actual conduct, identifying root causes and updating controls based on findings.

Investment case

Tie the request to a defined risk and control gap: volume handled, cycle time, exceptions, data access, repeat findings, coverage gaps and the cost of manual work. Identify the minimum viable control, owner, implementation date and test metric.

DOJ ECCP framing: Is the program well designed? Is it adequately resourced and empowered? Does it work in practice?

Commercial growth and HCP relationships: the core legal framework

The AKS analysis is intent-based and fact-specific; failure to fit a safe harbor is not itself a violation.

01	**Purpose and selection**	Document the legitimate need, objective selection criteria and why the HCP's expertise is required. Avoid selection tied to current or potential business.
02	**Services and compensation**	Use a written agreement with defined services. Compensation should be set in advance and consistent with FMV; FMV does not eliminate improper-intent risk.
03	**Execution and evidence**	Require contemporaneous deliverables, attendance or activity records, invoices and business-owner certification. Monitor repeat engagements and unused work product.
04	**Related obligations**	Assess Open Payments reporting, state gift/marketing laws, privacy and promotional controls. Claims tainted by kickbacks can create FCA exposure under the statutory linkage.

Practical trigger for escalation: compensation, selection, frequency, business influence or deliverables do not align with the documented rationale.

Authorities: AKS, 42 U.S.C. § 1320a-7b(b); personal services safe harbor, 42 C.F.R. § 1001.952(d); Open Payments, 42 U.S.C. § 1320a-7h; FCA, 31 U.S.C. § 3729.

Testing controls, investigating concerns and documenting remediation

A credible program produces evidence that controls operate, findings are escalated and corrective actions are completed.

01

MONITOR

Targeted review of high-risk activities and leading indicators

02

TRIAGE

Preserve information, assess materiality and identify immediate safeguards

03

INVESTIGATE

Use appropriate independence, scope, privilege decisions and documented facts

04

REMEDIATE

Address root cause, discipline consistently, repay or disclose when legally required

05

RETEST

Confirm that corrective action changed behavior and reduced recurrence

What to measure

- approval cycle time and exception rate
- repeat HCPs / repeat attendees / missing deliverables
- hotline substantiation, retaliation indicators and closure time
- corrective-action aging and recurrence
- access to transactional data and trend analysis

DOJ evaluates whether monitoring is risk-based, investigations are independent and timely, root causes are addressed, and remediation is tested.

New data uses require a layered privacy analysis

HIPAA is only one layer; identify the entity, data, purpose, recipient and technology before selecting the rule set.

01

HIPAA

Applies to covered entities and business associates. Determine permitted use/disclosure, minimum necessary, authorization, BAA and security obligations.

02

FTC / HBNR

FTC Act prohibits unfair or deceptive practices. The Health Breach Notification Rule can apply to qualifying health apps and connected products outside HIPAA.

03

California CCPA

Covered businesses face notice, rights and contracting obligations. Final regulations effective Jan. 1, 2026 add risk assessments and phased ADMT/cyber-audit duties.

04

Contract + state law

Provider data-use restrictions, consent promises, state consumer-health laws, TCPA/communications rules and security terms may be independently relevant.

California timing: risk-assessment obligations began Jan. 1, 2026; ADMT requirements for significant decisions begin Jan. 1, 2027; audit certifications phase in 2028-2030.

AI governance: product risk and enterprise-use risk are different workstreams

Governance should cover the model, data, intended use, human role, validation, change management and accountability.

01 Product / regulated function

For AI-enabled device software, assess device status, intended use, validation, cybersecurity, labeling, postmarket monitoring and whether a change requires a new submission or fits an authorized PCCP.

02 Enterprise and workforce use

Inventory tools and use cases; address confidentiality, privilege, access controls, training data, inaccurate outputs, record retention, vendor terms and prohibited or high-risk uses.

03 Compliance program oversight

DOJ asks how the company assesses emerging-technology risk and whether compliance has access to data and technology comparable to the business functions it monitors.

04 California privacy overlay

CCPA risk assessments can be triggered by specified AI-related processing. ADMT rules apply to covered uses that replace or substantially replace human decision making for significant decisions.

Minimum governance record

approved use case • data sources • validation limits • required human review • change owner • monitoring metric • incident/escalation path

FDA's January 2025 AI-device lifecycle document remains draft guidance and is not for implementation; distinguish it from binding statutory and regulatory requirements.

The earlier investment: a scalable compliance operating system

The highest-value investment is usually a repeatable decision and evidence process, not a larger policy library.

1 INTAKE

Standard facts and routing for HCP, commercial, reimbursement, privacy and AI requests

2 DECISION

Named approver, documented rationale, conditions and escalation thresholds

3 EVIDENCE

Agreement, approval, FMV support, deliverables, payment, data flow and completion record

4 MONITOR

Risk-ranked testing, trend metrics, exception review and corrective-action tracking

Implementation sequence

1. Choose the two highest-volume, highest-risk workflows.
2. Define minimum facts, decision rights and evidence required.
3. Automate routing and reminders only after the workflow is stable.
4. Test a sample at 60-90 days; revise based on exceptions and user behavior.

Design principle: controls should be proportionate, auditable and usable by frontline teams; complexity that cannot be followed consistently is not an effective control.