

Leading a Culture of Compliance

LIVE
WEBINAR



Integrating Ethical Behaviors Throughout the Organization



with Shelly M. Gallup
&
Mark A. Pfister

 Webinar Start Countdown



M. A. Pfister
Strategy Group



WEBINAR REMINDERS

a few points to mention

- **Purpose:** Share knowledge regarding **compliance trending, non-compliance impact, compliance culture responsibility and a compliance culture framework for leaders to form high-performance teams.**
- **Questions:** Write your questions in the Q&A section. Our goal is to answer all questions at the close of the presentation. Otherwise, we will follow-up with you via email afterwards.
- **Materials:** Yes, this entire webinar is being recorded and you will receive a link via email shortly. This link will also include the ability to view & download the presentation deck in its own separate file.
- **International Board Director Competency Designation:** IBDC.D certification holders will receive 1 CPE credit by attending (be sure to follow proper CPE credit submission guidelines).



YOUR SPEAKER



Shelly M. Gallup

Non-Executive Director, Quality Assurance, & Regulatory Affairs Expert

SGallup Consulting

- Owner of SGallup Consulting, a regulatory affairs consulting agency providing regulatory strategy & compliance advisory services.
- She is the Co-Director of Educational Programs for Orange County Regulatory Affairs Discussion Group (OCRA-DG), with focus on Medical Devices.
- She is currently the Sr. Vice President of Regulatory Affairs & Quality Assurance for Prismatic DentalCraft, Inc. / Glidewell Dental.
- Holds an International Board Director Competency Designation (IBDC.D)

YOUR HOST



Mark A. Pfister

Non-Executive Director, CEO, & Chief Board Consultant

M. A. Pfister Strategy Group / IBDC.D

- Governance & Strategy expert, Non-Executive Director, & Chief Board Consultant having consulted & advised hundreds of public, private, nonprofit, & PE Boards.
- His book, *Across The Board: The Modern Architecture Behind an Effective Board of Directors*, is a bestseller with circulation in over 70 countries.
- He is the creator of the International Board Director Competency Designation (IBDC.D), a globally-recognized Board Director education & certification program.





LEADING A CULTURE OF COMPLIANCE

Agenda

Compliance Trending

Non-Compliance Impact

Compliance Culture Responsibility

Compliance Culture Framework

Summary Points



COMPLIANCE TRENDING

DEFINE "CULTURE OF COMPLIANCE"
INCREASING/DECREASING IN 2025





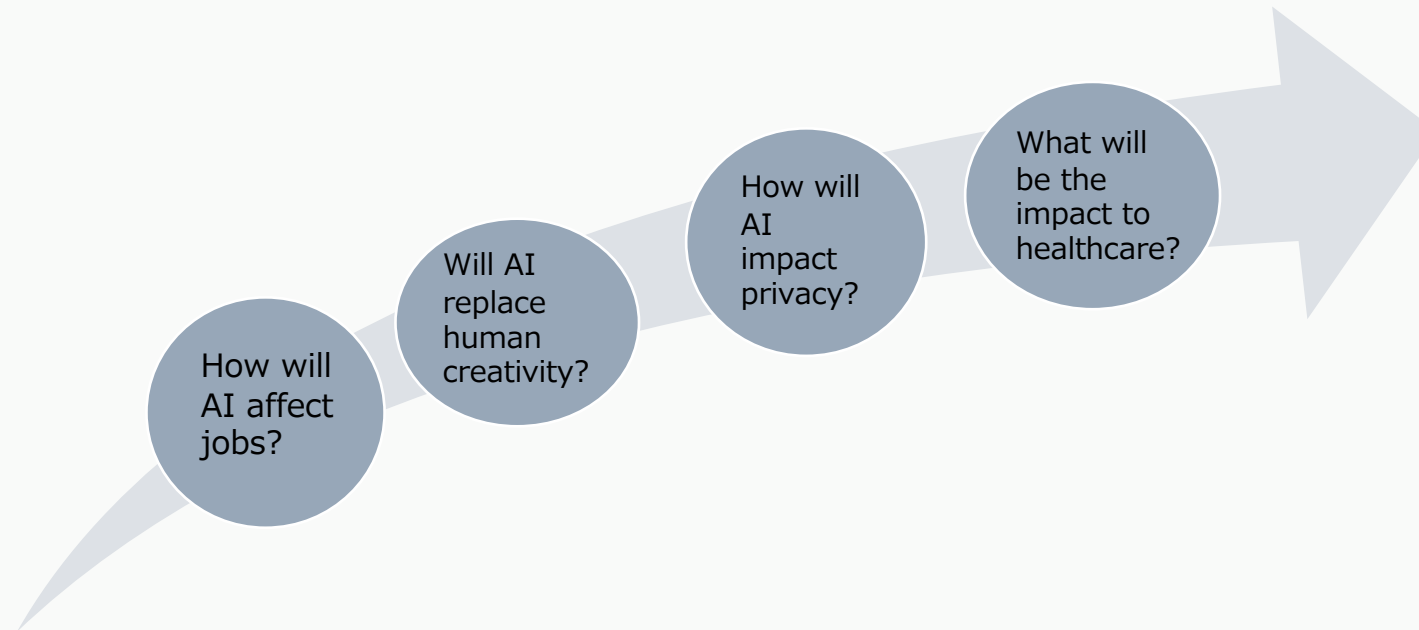
What is “Culture of Compliance”?

A behavior in the workplace that aligns with external laws, internal policies, and increasingly, ethical values.

Compliance Trending



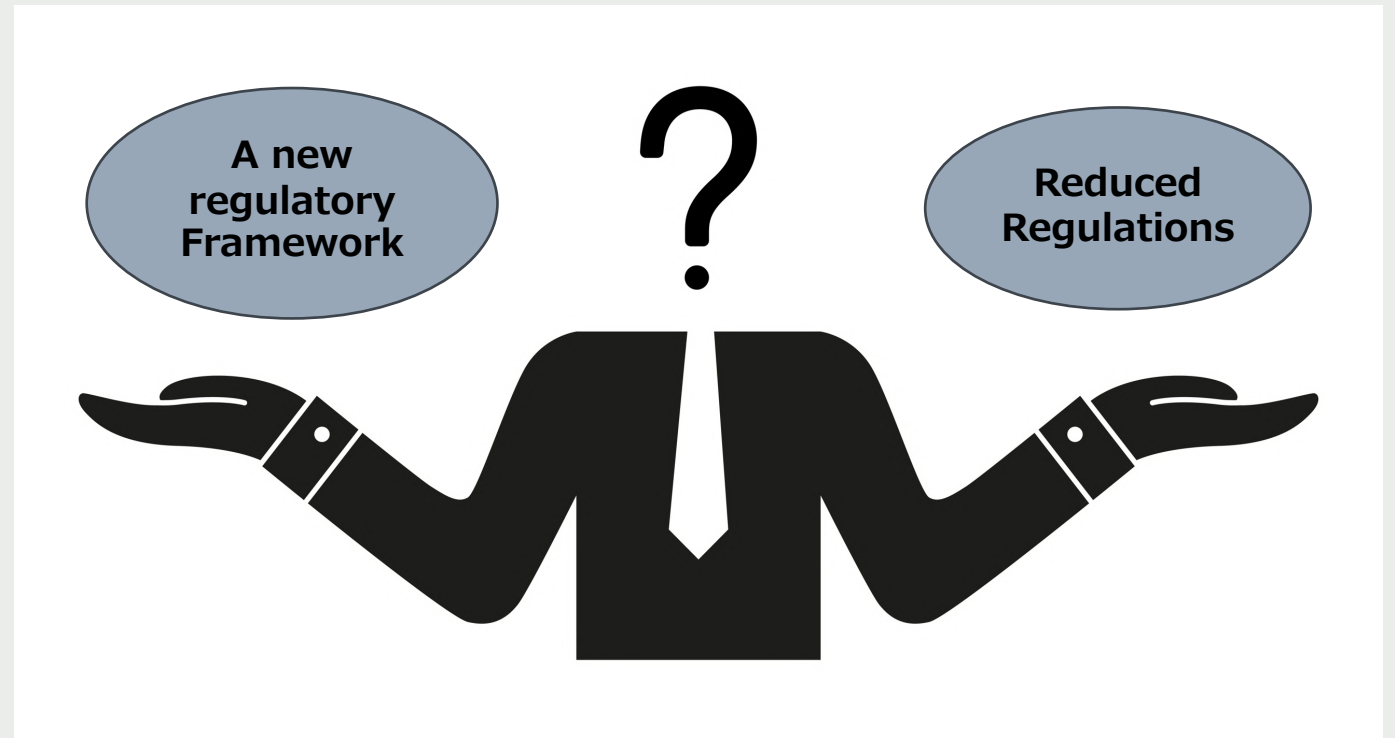
1. Artificial Intelligence – AI regulation will intensify.



Source - [Top 5 Compliance Trends Expected in 2025: Insights for Future Planning](#)

Compliance Trending

2. **Cryptocurrency** –There is a lot of speculation as to what will happen in the crypto market in 2025.

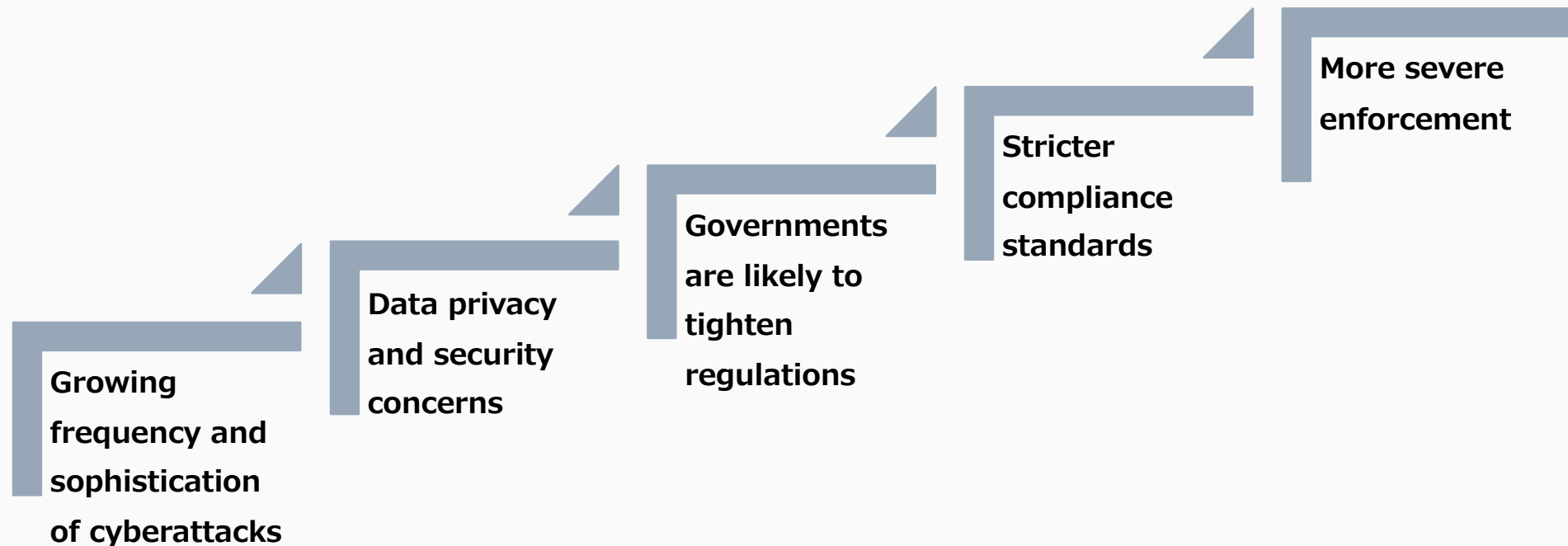


Source - [Cryptocurrency investors hope for smoother regulations after November](#)
[How SEC Regs Will Change Cryptocurrency Markets](#)
[Donald Trump is reportedly set to pick the crypto enthusiast Paul Atkins to lead the SEC - Fast](#)
[CoSEC Chair Gary Gensler to step down Jan. 20, make way for Trump replacement \(cnbc.com\)mpany](#)
[What the Fed's 'Policy Mistake' Means for Crypto Markets - YouTube](#)

Compliance Trending

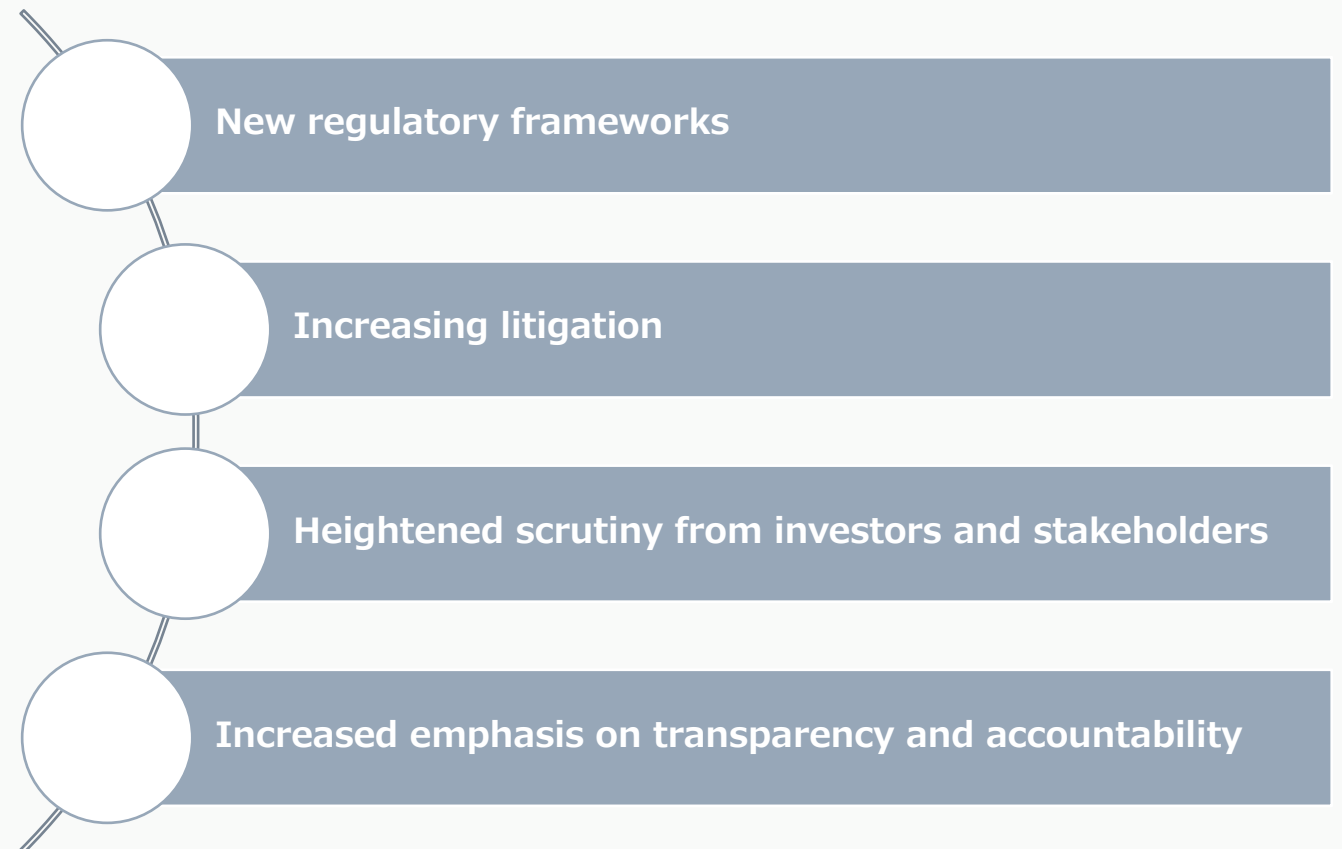


3. Cyber Crime – Expect an increase in regulatory scrutiny around the world in 2025.



Compliance Trending

4. Environment, Social, Governance (ESG) – 2025 will be a pivotal year for ESG and sustainability.



Compliance Trending

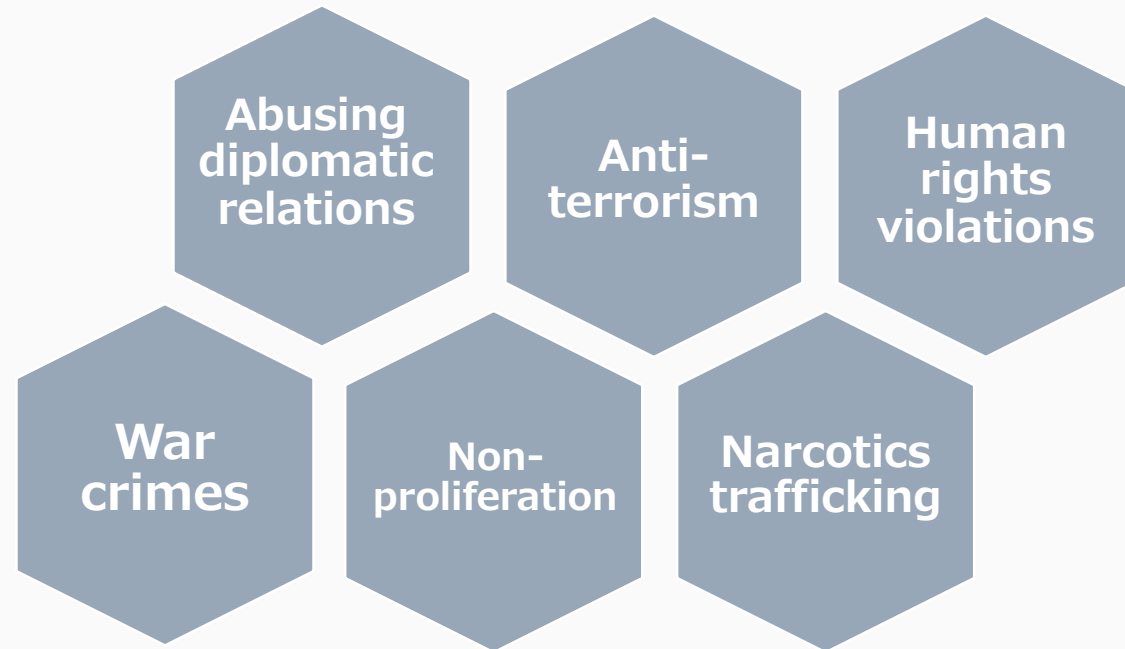
5. Supply Chain –
Supply Chain Compliance is expected to increase, and the adoption of breakthrough technologies will be a key focus.

Source: [Future of Supply Chain Management and Trends in 2025](#)



Compliance Trending

6. Sanctions – We can expect tightened restrictions on Iran, Venezuela and Cuba, while the Russia sanctions remain uncertain.



Source - [OFAC Consolidated Frequently Asked Questions | Office of Foreign Assets Control](#)
[Trump 2.0: International Trade, Sanctions and Economic Policy](#)



Compliance Trending

7. Financial Crimes – U.S. regulators are warning bankers about intensified focus being put on financial crime.

Beef up efforts

- Fight Money Laundering

Enforce

- Know-your-customer rules

Source - [US Regulators Warn Bankers About Intensified Focus on Financial Crime](#)

NON-COMPLIANCE IMPACT

PAST FAILURES

IMPACT TO BUSINESS



PAST FAILURES

TD Bank

Cumberland
DRW

Volkswagon

Meta

Boeing 787
Dreamliner

Masimo
Rad-G

Past Failures

- Sources

[Office of Public Affairs | TD Bank Pleads Guilty to Bank Secrecy Act and Money Laundering Conspiracy Violations in \\$1.8B Resolution | United States Department of Justice](#)

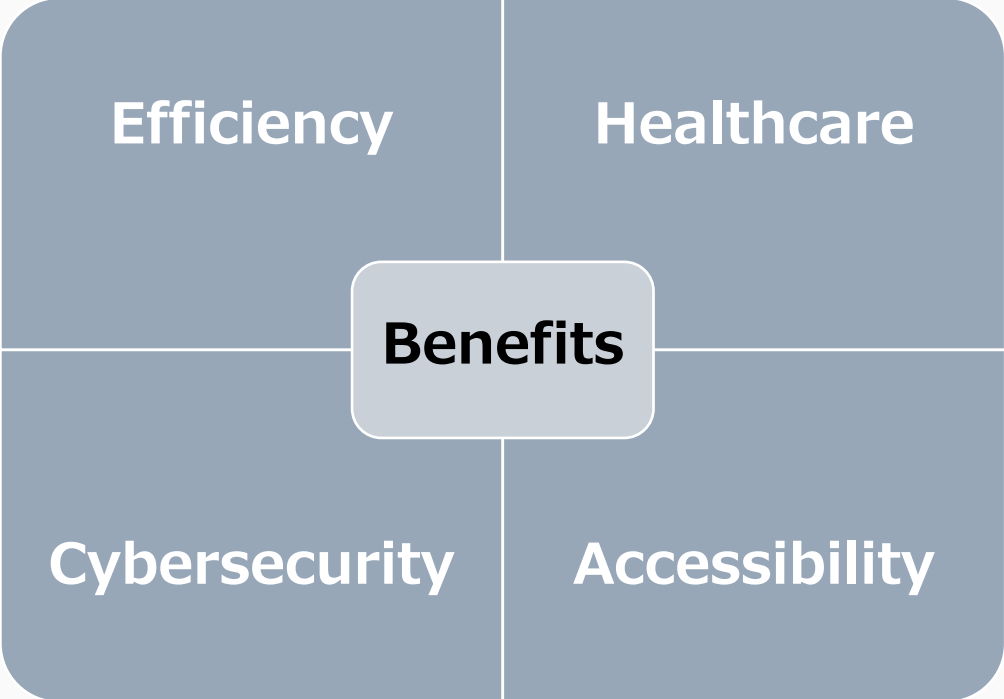
[SEC.gov | SEC Charges Cumberland DRW for Operating as an Unregistered Dealer in the Crypto Asset Markets](#)

[Volkswagen To Spend Up To \\$14.7B To Settle Allegations Of Cheating Emissions Tests And Deceiving Customers On 2-Liter Diesel Vehicles](#)

[Biggest data breach fines, penalties, and settlements worldwide 2024 | Statista](#)

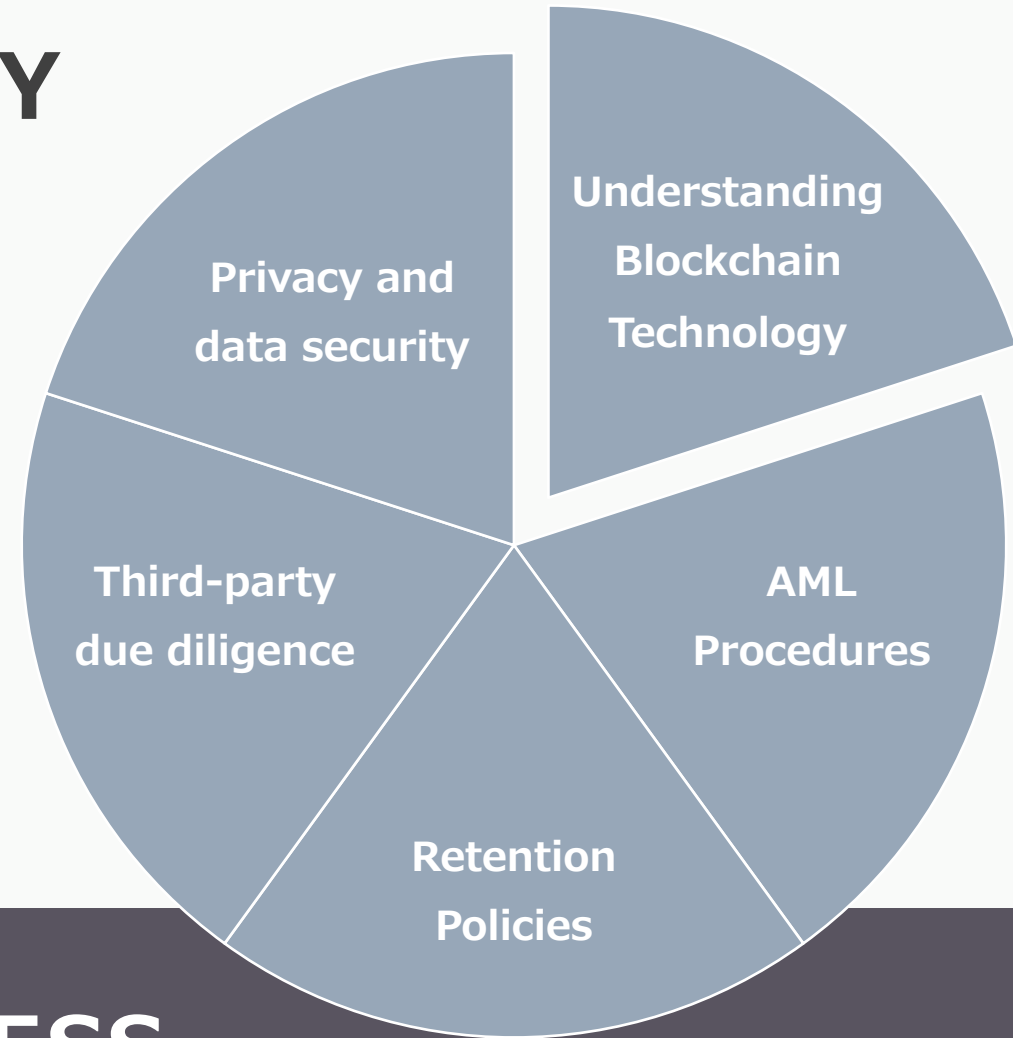
[Masimo Recalls Certain Rad-G Pulse Oximetry Devices](#)

ARTIFICIAL INTELLIGENCE



IMPACT TO BUSINESS

CRYPTOCURRENCY – Areas of Concern/Risk



IMPACT TO BUSINESS

CYBERCRIMES

Data breaches

Ransom
-ware

Malware
Attacks

Cyber
Attacks

Cyber
Crime

Cyber
Threat

IMPACT TO BUSINESS

Source - [The Latest Cyber Crime Statistics \(updated October 2024\) | AAG IT Support](#)

3 pillars of ESG



ICONS: ANASTASIA MALACHI/GETTY IMAGES

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IMPACT TO BUSINESS

Image Source - [What is ESG \(Environmental, Social and Governance\)? | Definition from TechTarget](#)

SUPPLY CHAIN

Supply chain compliance significantly impacts a business by ensuring adherence to legal and ethical standards throughout the entire supply chain.



Ethical Standards

- Underline the importance of human rights, fair labor practices, and environmental sustainability

Legal Standards

- Require firms to comply with multiple national and international laws and regulations

IMPACT TO BUSINESS

SANCTIONS

Firms that lack governance, oversight, skills retention, resourcing, screening capabilities, customer due diligence, know-your-customer procedures, and breach reporting can be impacted economically.



SANCTIONS

7 Ways Economic Sanctions Disrupt the Business Sector

- 1 Restricted Market Access
- 2 Increased Operational Costs
- 3 Supply Chain Disruptions
- 4 Financial Market Volatility
- 5 Loss of Revenue
- 6 Reputation Risk
- 7 Innovation and R&D Challenges

IMPACT TO BUSINESS

FINANCIAL CRIMES

Financial crimes can have a significant impact on businesses.



IMPACT TO BUSINESS

COMPLIANCE CULTURE RESPONSIBILITY

WHO'S RESPONSIBILITY IS IT TO
ENSURE A CULTURE OF COMPLIANCE
WITHIN A COMPANY?

WHAT IS THE PURPOSE?



Who is Responsible?

Everyone in the Company!

Set the Tone from the Top.

- The Board
- CEO
- Compliance Officer
- Senior Leadership
- Managers
- All Employees

Compliance culture ensures safety, integrity and ethical behavior across all organizational levels.

What is the Purpose?

The purpose is to protect your business.

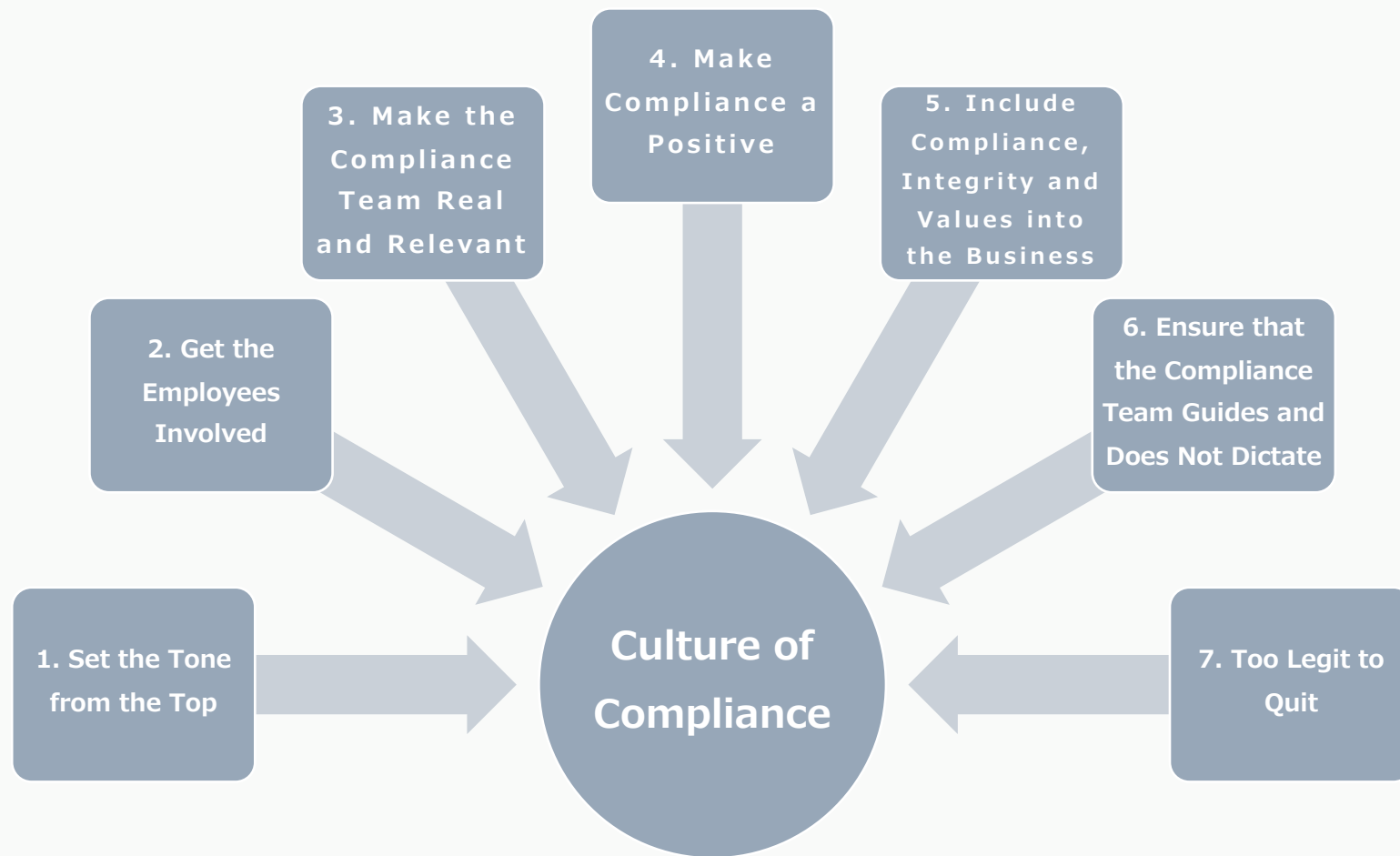
The ROI of a Culture of Compliance is significant!

Compliance is a legal requirement that is crucial for success and sustainability in a competitive world where reputation is everything.

COMPLIANCE CULTURE RESPONSIBILITY

COMPLIANCE CULTURE FRAMEWORK

ELEMENTS/BUILDING BLOCKS FOR A CULTURE OF
COMPLIANCE



COMPLIANCE CULTURE FRAMEWORK

SUMMARY POINTS

“Compliance” is Not a
Bad Word

Non-Compliance is
Expensive

Reputation is Everything

Compliance is
Everybody’s
Responsibility

Compliance fosters trust
within an organization
and among stakeholders

THANK YOU

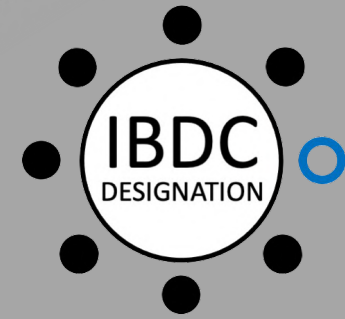


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1:1

Group

On-Demand

<https://www.pfisterstrategy.com/exceptionalboarddirector>



CULTURE OF COMPLIANCE

are you prepared?

Understand
the importance
of Values &
Culture

Protect legal
and
reputational
risks

Follow the
framework

Q&A

Contact Shelly at sgallupconsulting@gmail.com

Contact Mark at mark@pfisterstrategy.com

Board Director Education + Certification Details <https://www.pfisterstrategy.com/exceptionalboarddirector>



SHELLY M. GALLUP

Non-Executive Director, Quality Assurance, & Regulatory Affairs Expert

Biography

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With a strong focus in Strategy, Governance & Risk/Compliance, Shelly Gallup is a high-achieving Quality Assurance & Regulatory Affairs Expert in the Medical Device and In-Vitro Diagnostic industry. She has demonstrated success in managing positive interactions with regulatory agencies, both domestically and internationally, bringing product to market. Throughout her career, Ms. Gallup has developed a wealth of knowledge related to the lifecycle management of products at all levels of risk, in cardiovascular, anesthesiology & respiratory therapy, dental, general & plastic surgery, pain management, point-of-care (POC) and self-test kits. She prides herself on enabling people to think differently and initiating meaningful shifts in what individuals consider to be important and directing those minds toward the goal with discipline and transparency.

The overarching theme throughout her career has been her increasing responsibility in leadership positions, passion on self-development and developing others through mentoring and coaching, her ability to build trust with cross-functional players and creating value for shareholders and stakeholders through creative, out-of-the-box regulatory strategies. Ms. Gallup influences those around her through her values, vision, passion, purpose and inspiration. As stated by Stephanie Goddard, CEO, Glidewell, *“Ms. Gallup exemplifies values-based leadership through her consultative and collaborative approach, ensuring every decision aligns with both her core principles and the organization’s strategy. Her confident demeanor and approachability inspire trust and drive positive outcomes across all levels of the organization.”*

Ms. Gallup is a certified Regulatory Affairs Professional and serves as an expert Quality Assurance and Regulatory Affairs Executive, consulting for a start-up company on global regulatory registrations and impact to quality assurance, in their initiation and sustaining phases, as well as identify gaps requiring remedial focus to bring them into compliance. She has a deep knowledge and experience in product lifecycle & business operations, strategic planning, governance, risk management, leadership development, product development, and auditing. Even more to her credit, Ms. Gallup has received a “Bold Moves & Rising Stars” spotlight in the Spring 2024 edition of The LEAD Magazine.

She currently holds an Executive position as the Senior Vice President of Regulatory Affairs and Quality Assurance for Prismatic Dentalcraft, Inc./Glidewell Dental. She simultaneously serves as a consultant/advisor for Multiphze, LLC and as the Co-Director of Educational Programs to the Orange County Regulatory Affairs – Discussion Group (OCRA-DG) Board of Directors. She has previously held a position as the Sr. Director of Regulatory Affairs at Innova Medical Group, LLC, and Director of Regulatory Affairs at Sekisui Diagnostics. She holds a B.A. in Chemistry from California State University, San Bernardino, an MBA from University of Phoenix, and completed Becoming an Exceptional Board Director Candidate program – Education & Certification Course. Ms. Gallup is a highly respected and skilled Leader that has successfully led numerous global government regulatory meetings and discussions that resulted in more effectively bringing product to market. Her solution driven recommendations and strategies often roll up to the Board level at the companies that she serves.

Ms. Gallup has established herself as Mentor to a multitude of Quality Assurance & Regulatory Affairs Professionals in the Medical Device Industry. She prides herself in creating development plans and providing guidance throughout the careers of those she mentors.

She has demonstrated her expertise in compliance via a webinar presentation of *Leading a Culture of Compliance, Integrating Ethical Behaviors Throughout the Organization*.

Ms. Gallup is a proficient Board Director and Regulatory Affairs & Quality Assurance Executive with experience across multiple industry verticals. She has the ability to serve effectively on the following committees: Strategy, Governance, & Risk/Compliance.

She holds an *International Board Director Competency Designation (IBDC.D)* through M. A. Pfister Strategy Group, is certified under *Regulatory Affairs Certification (RAC – Devices)* through Regulatory Affairs Professionals Society (RAPS) Institute, earned a *Medical Product Development Certificate* through UC Irvine, and holds a *Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals* through RAPS Institute.



M. A. Pfister
Strategy Group



MARK A. PFISTER

Non-Executive Director, CEO, and Chief Board Consultant

Biography

mark@pfisterstrategy.com



With a strong focus in Strategy, Governance, and Technology / Cybersecurity, Mark A. Pfister is CEO & Chief Board Consultant of M. A. Pfister Strategy Group, an executive advisory firm that serves as a strategic advisory council for executives and Boards in the public, private, nonprofit, and private equity (PE) sectors. He is also Founder & CEO of the International Board Director Competency Designation (IBDC.D) education and certification program, a Board Director certification course recognized globally, and was previously Chairman & CEO of Integral Board Group, a specialized Board services and consulting company. Mr. Pfister is a 'Board Macro-Influencer' and his success has been repeated across a wide range of business situations and environments. He prides himself on being a coach and mentor to senior executives and Directors. In Board Director circles, Mr. Pfister has earned the nickname 'The Board Architect.'

The overarching theme throughout his career has been his aptitude in leadership positions, passionate focus on people, unique governance models, and ability to create value for shareholders and stakeholders through innovative business strategies and operational excellence. Michael Lorelli, Executive Chairman of Rita's Franchise Company, has said, "Mark's unusual combination of excelling at a macro and micro grasp of business, genuine interest in Governance, and ability to coach and mentor a Management Team make him a terrific Independent Director."

Mr. Pfister is a certified project management professional and frequently serves as an expert Project Executive, consulting on global programs/projects in their initiation and operational phases, as well as programs requiring remedial focus to bring them back on track. He has deep knowledge and experience in Board design & operations, strategic planning, business transformation, technology implementations, decisioning processes, certification & continuing education programs, executive coaching, and governance models.

Mr. Pfister was CEO of Pro4ia, Inc., an international consulting and professional services company specializing in a wide range of technology solutions utilizing formal Project Management as a proven and repeatable delivery method. With a Fortune 50 client list, Pro4ia was Citibank's Nominee for Crain's Magazine 'Entrepreneurship of the Year' Award in 2005. He simultaneously served as CEO of Onit, Inc., a national sourcing company specializing in placements for all levels of technology skill sets. Mr. Pfister was also the Regional Program Office Leader for American Express leading some of the largest technology transformation initiatives in the company's history. He served as a Licensed Engineering Officer in the U.S. Merchant Marine, holds a B.S. from the State University of New York Maritime College in Facilities Engineering, and completed Harvard Business School's Executive Education Program for Board Directors.

Mr. Pfister is the creator of the 'Board as a Service' (BaaS) engagement model, an industry he is credited with inventing. He is a Master Speaker and conducts international speaking tours, lectures, and seminars focused on effective leadership, strategy, Board architecture, becoming an exceptional Board Director candidate, professional project/program management, and entrepreneurship.

His popular book, 'Across The Board: The Modern Architecture Behind an Effective Board of Directors,' an Amazon best-seller with circulation in over 70 countries, has influenced an entire new generation of Board Directors.

Mr. Pfister is a proficient Board Director and CEO with experience across multiple industry verticals. He is typically the Chair, or a member of the Strategic Planning Committee, Governance Committee, Technology & Cybersecurity Committee, and has deep Nominating Committee experience. Mr. Pfister's experience as an internationally renowned Board Consultant, having guided and coached hundreds of Boards, Board Committees, and Board Members across public, private, nonprofit, and private equity (PE) verticals, additionally offers up unique and informed viewpoints to the companies he serves.

He holds an *International Board Director Competency Designation* (IBDC.D) through M. A. Pfister Strategy Group, is a certified *Project Management Professional* (PMP) through the Project Management Institute, earned a *Global ESG Board Certification* (GCB.D) through Competent Boards, holds a *Certified Cyber Intelligence Professional* Board Certification (CCIP) through the McAfee Institute, and previously held an *Executive Masters Professional Board Certification* through the American College of Corporate Directors (ACCD).

