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Cooley

Webinar

A 2025-2026 Survival Guide to Sustainability & Product Compliance

10 December, 2025

complianceandrisks.com

Q&A
Session

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Meet the Team

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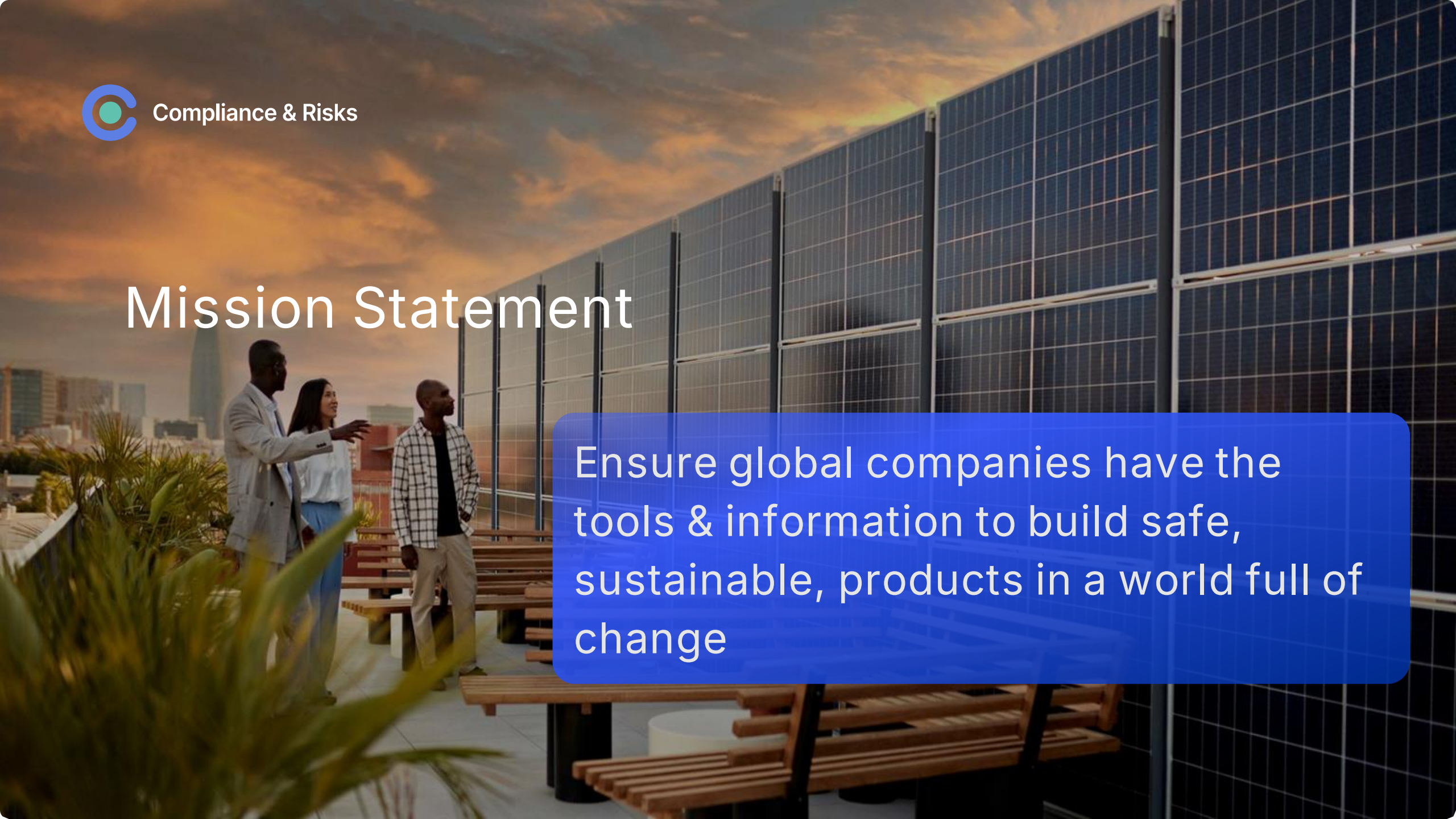
Compliance & Risks
Mission Statement
Ensure global companies have the tools & information to build safe, sustainable, products in a world full of change

Trusted by the World’s Leading Brands

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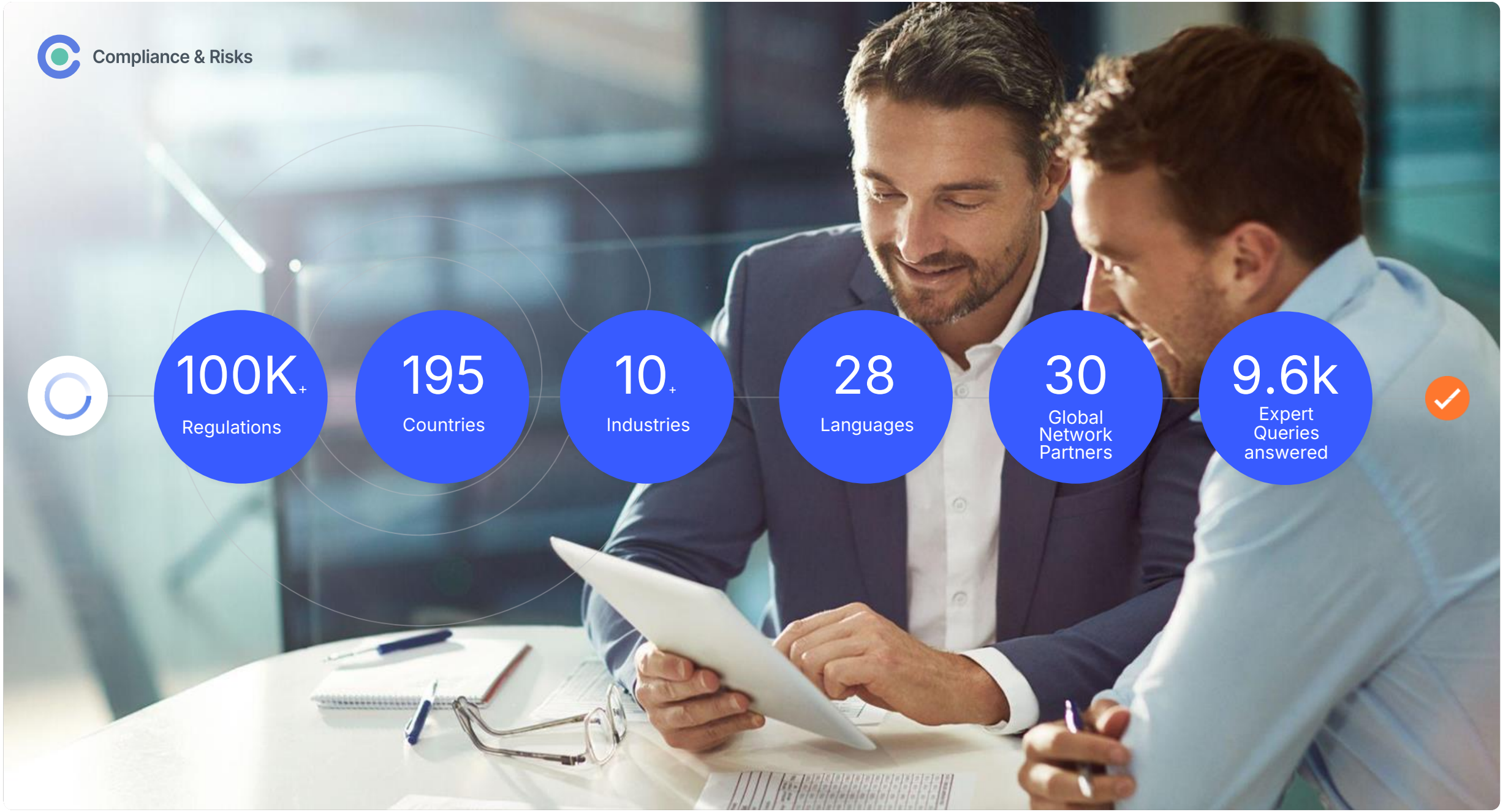
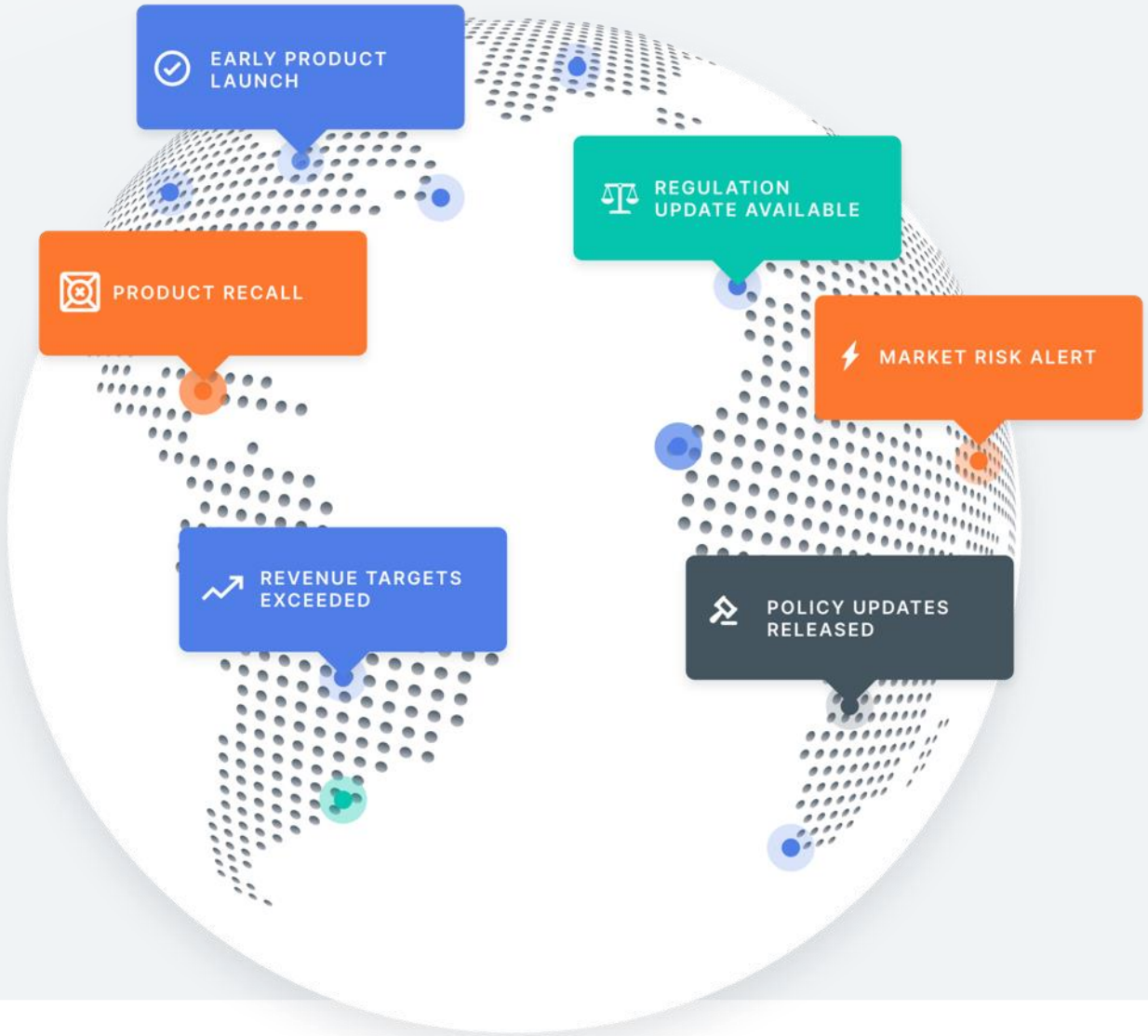


WHAT WE DO

Unlocking Market Access

Keep on top of regulatory changes and their impact worldwide. Early warning alerts, impact probability, productivity workflow tools and so much more.



Agenda

01. EU Sustainability
02. EU GPSR & UK PRAM Act
03. US Deregulation & Fragmentation
04. EU Pharma and Device
05. Regulations

Questions?

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Sustainability Regulation

Taking Stock

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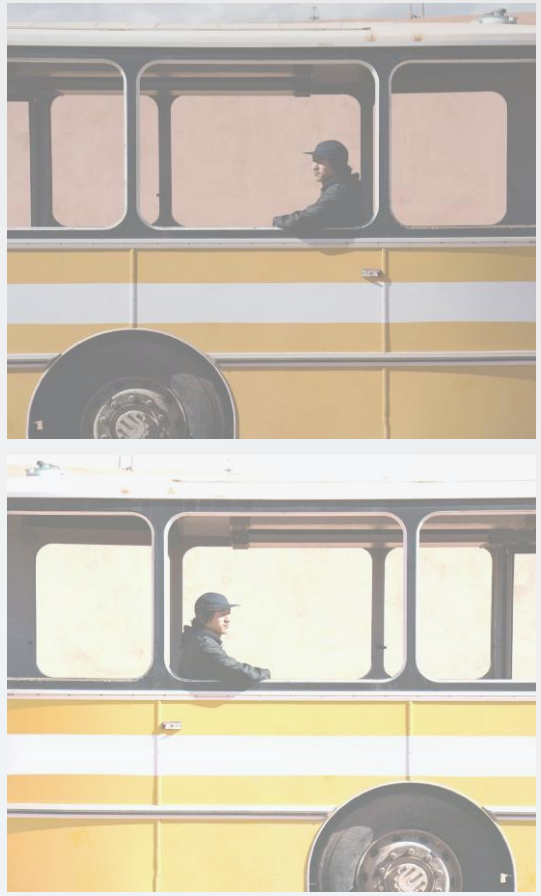
Simplification of EU Sustainability Laws

Key Laws Impacted and Status

Legislation	Application date	Simplification status	*Key takeaways*
CSRD	Delay confirmed. FY27 for Wave 2 EU companies. FY28 for non-EU parents	Proposed (*Omnibus I*), Agreement possible before end of year	Application thresholds likely raised to EUR 450m turnover and (at least) 1000 employees for EU companies. ESRS simultaneously reduced by 60% with generous phase-ins.
CSDDD	Delay confirmed. July 26, 2028	Proposed (*Omnibus I*), Agreement possible before end of year	Application thresholds likely raised to EUR 450m turnover and (at least) 1000 employees for EU companies. Significant changes to scope and deletion of e.g., climate plans expected.
EUDR	Proposed delay to December 30, 2026	Proposed	Needs to be finalized before December 30, 2025.
Batteries Regulation diligence	Delay confirmed, August 18, 2027	Proposed (*Omnibus IV*)	The omnibus IV proposal would exempt *small mid-caps* from due diligence obligations.
CBAM	Maintained, key provisions from January 2026	Confirmed	New 50 tonne *de minimis* threshold.



Others Remain on Course...

Upcoming Compliance Deadlines Unchanged:

Legislations	Applies to companies from...
Ecodesign for Sustainable Products Regulation	Ban on destruction of certain unsold consumer products from July 19, 2026. Reporting on quantities of discarded unsold consumer products also required for most companies in 2026 on FY25 data.
Right to Repair Directive	July 31, 2026
Packaging and Packaging Waste Regulation	August 12, 2026
Green Transition Directive	September 27, 2026
Revisions to Waste Framework Directive (e.g., textile EPR)	June 17, 2027
Forced Labour Regulation	December 14, 2027

Further legislative proposals anticipated:

- Environmental Omnibus (expected to impact EPR, SCIP database etc.)
- Circular Economy Act (due for adoption in Q3/4 2026)

International Developments

Countries Moving in Different Directions

Reporting		USA	*Federal* • SEC climate reporting rules abandoned *California Rules* • SB 251: January 1, 2026, deadline for disclosure of climate-related financial risks postponed • SB 253: GHG emissions reporting requirement under SB 253 continues to apply
		Canada	Canadian Securities Administrators have paused work on mandatory sustainability disclosure rules. Remains possible that the federal government introduces its own disclosure requirements for federally incorporated companies. Forced and child labour reporting continues.
		Mexico	For FY2025 onwards, national filers must now disclose on sustainability KPIs and listed companies must now prepare ISSB aligned reports.
		Australia	New regime on reporting on climate-related financial disclosures continues with additional companies in scope from July 2026 and July 2027. Modern slavery disclosure continues.
		U.K.	Reporting on climate-related financial disclosures and modern slavery disclosure continues. Possible adoption of ISSB-aligned sustainability reporting standards anticipated but scoping remains unclear.
		UAE	From May 2025 onwards, companies must now disclose climate-related risks and GHG emissions.
		Jordan, Qatar, Kuwait	Certain listed companies anticipated to be required to prepare ISSB-aligned reports beginning January 2026 – 2027.
		China	Mandatory sustainability reporting begins for listed companies, extension to private companies anticipated c. 2030.
		Singapore	SGX listed companies must continue to report Scope 1 and 2 GHG emissions but non-STI constituents now benefit from a delay to mandatory ISSB-based climate related disclosures of 3 – 5 years depending on market cap. For large non-listed companies, reporting is delayed to FY2030.
		Japan	Sustainability reporting anticipated for listed companies for the FY ending March 31, 2027.
Due Diligence		*South Korea*	All currently have mandatory human rights and environmental due diligence initiatives under consideration
		Thailand	
		Malaysia	

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EU GPSR & UK PRAM Act

Keeping up with the Regulators

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EU General Product Safety Regulation (GPSR)

The rules started to apply across the EU December 13, 2024

EU GPSR: Key Changes

1	Aligns requirements for non-harmonised and harmonised products (i.e. CE marked)
2	Makes updates to deal with risks of new technologies
3	Makes updates considering circular economy activities
4	Introduces new requirements for online sales
5	Introduces obligations on online marketplaces
6	Introduces mandatory accident reporting
7	New mechanism for consumers + other “interested parties” to report issues
8	Introduces requirements for recalls
9	Expands the role of Safety Gate
10	Stronger enforcement

Guidance now published in addition to existing Q&A and FAQs

EU GPSR: Online Sales

For online sales the “offer” of the product must include:

- Details of the manufacturer
- Details of the Responsible Person in the EU
- Information to identify the product (a picture, its type and any other product identifier). The Commission’s original proposal to also require batch / serial numbers was not included in the final text
- Any warnings and safety information required to be affixed to the product, on its packaging or its accompanying documents

EU GPSR: Methods for Consumers / Other Interested Parties to Raise Issues

1. To manufacturers / importers: required to have publicly available communication channels for consumers to submit complaints, report accidents or product safety issues

2. To online marketplaces: required to designate a single point of contact to enable consumers to "communicate directly and rapidly" with them in relation to product safety issues

3. To Member State authorities: required to enable consumers and other "interested parties" to submit complaints on product safety, unsatisfactory recall remedies etc.

4. To the European Commission: new mechanism for consumers and other "interested parties" to report potentially dangerous products to the Commission via Safety Gate

EU GPSR: Enforcement

Active enforcement by Member States

Yet to see major enforcement action

Software enforcement....?

UK Product Regulation and Metrology (PRAM) Act

What is it?	● Gives government wide-ranging powers to reform the UK product safety framework by laying down new rules via secondary legislation (i.e. regulations)
Why does it matter?	● Enables significant reforms to be implemented in short timeframes, without the usual scrutiny that accompanies primary legislation. Devil will be in the detail of upcoming secondary legislation. ● Powers to make new laws cover product requirements, obligations on online marketplaces, enforcement, information sharing and cost recovery.
Amendment	● An amendment to require the government to consult with stakeholders was included in the final legislation.
Timing	● Passed into law July 21, 2025, main powers to lay down new laws came into force same day ● Consultation is "coming soon"

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US: Deregulation and State Fragmentation

State of the States

Is there Really Deregulation?

- When federal agencies pull back, states fill the vacuum with their own rules
- Absence of federal privacy law forces states to create their own patchwork standards
- Federal restraint on product-lifecycle and sustainability rules pushes states to regulate individually
- Lack of clear federal right to repair standards results in inconsistent state laws
- Active CPSC and focus on tariffs bucks the trend of federal regulatory retreat

State Fragmentation

- Over 1,000 AI-related bills introduced by states in 2025
- Four states with enacted AI laws
- Nearly 20 states with comprehensive privacy laws
- Four states have comprehensive data broker laws, including three with amendments this year
- Seven states have enacted comprehensive packaging EPR laws
- Eight states have or will soon have consumer right to repair regimes

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EU Pharma and Device Regulations in Motion

Future in Flux

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The Latest and the Greatest: Key Regulatory Changes Shaping the Industry in 2025

What	*When*	*Key Takeaways*	
CTR and CTIS	31 January 2025 End of transitional period	Centralized electronic portal and database (CTIS) Single CTA submission to CTIS Two-part assessment (joint Part I assessment)	Stricter timelines Increased transparency
HTAR	12 January 2025 Entry into application	For oncology products, ATMPs and high-risk devices: • 2028: for orphan products • 2030: for all medicinal products	Joint Clinical Assessments: EU wide assessment of the clinical value of new treatments
Amended Variations Regulation + New Guideline	1 January 2025 Entry into application	New classification (e.g. Type 0) Re-classification of certain changes "Super-grouping"	Faster processing for low-risk changes Guidelines: for applications from 15 January 2026
Extension of Transitional periods for legacy IVDs	10 January 2025 Entry into application	The new deadlines depend on the risk class of the device: • 31 December 2027 for Class D devices • 31 December 2028 for Class C devices • 31 December 2029 for Class B devices and Class A sterile devices	
New Information obligations	10 January 2025 Entry into application	Obligation to inform downstream supply chain operators and NCAs, 6 months ahead of any anticipated interruption or termination of supply of medical devices and IVDs that could lead to serious harm to patients or public health	
EUDAMED	26 November 2025	Notice regarding the functionality of the first four modules of the EUDAMED, triggering the six-month transition period From 28 May 2026 use of the four modules will be mandatory	

More to Come: Keeping Up with the Proposals

What	*When*	*Key Takeaways*
Pharma Review	26 April 2023: European Commission Proposal 10 April 2024: Parliament Position 04 June 2025: Council Position 10 December 2025: open-ended trilogue DEAL?	• Data and market exclusivities • Bolar exemption • AMR voucher • Improve the management of shortages • Increase scrutiny on environmental risks
MedTech Reform	08 Sept. - 06 Oct. 2025: call for evidence Xmas 2025– Early 2026: new proposals?	• Lack of internal consensus among stakeholders • Repeated compliance delays • Delay rolling out critical tools • Shortage of device • Decrease in innovation Goals: • Reduce administrative burdens • Improve predictability and cost-efficiency for certification • Proportionality to risk classification • Enable digitalization • International cooperation

Questions?

Lets Talk

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