Webinar

How to demonstrate Compliance driven by Global Regulations & Standards

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The Domino Effect →

GDPR fines jump as EU regulators raise pressure on business

Data protection penalties climbed 40% in the past year, according to research

The New York Times

Toyota to Pay a Record Fine for a Decade of Clean Air Act Violations

Toyota's $180 million settlement with the federal government follows a series of emissions-related scandals in the auto industry.

RTE

WhatsApp Ireland hit with record fine of €225m by DPC

The Data Protection Commission (DPC) has fined WhatsApp Ireland €225m for infringements of data protection rules. It is the largest fine...

2 Sept 2021

The National

Big technology companies face hefty fines as EU agrees on new law governing content rules

Social media services, such as TikTok and Facebook-owned Instagram, are also affected by the new rules. Non-compliance will be severely punished...

News | EP Lab | July 28, 2021

St. Jude Medical Pays $27 Million for Allegedly Selling Defective Heart Devices
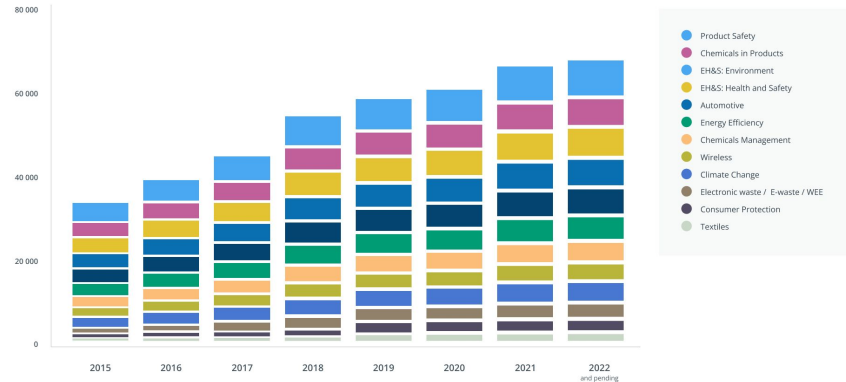
Bloomberg.com

US to Toughen Enforcement of Russia, China Export Violations

The US plans to increase the penalties for companies violating rules that limit export of products that threaten national security,...

6 days ago

60% Growth in Regulations in the past 5 years

Legend:
- Product Safety
- Chemicals in Products
- EH&S: Environment
- EH&S: Health and Safety
- Automotive
- Energy Efficiency
- Chemicals Management
- Wireless
- Climate Change
- Electronic waste / E-waste / WEE
- Consumer Protection
- Textiles

Chart axis: 80 000, 60 000, 40 000, 20 000, 0
Years: 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022 and pending

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Times have changed...

"We use excel & macros to document & maintain our regulatory requirements and supporting evidence.

It has got so complex over the years & we're at a point where we are unable to grow our business with our current processes. We need a better way"

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A sense of uncertainty & a lack of control..

"We need a single source of truth to be able to prioritise long term projects coming down the line with day to day emerging issues.

We have to be compliant or our products are taken off the market & we are fined."

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Lots of Manual Reporting for Audits & Under Resourced Teams...

"We are trying to get common understanding of what our compliance requirements are outside the expert teams to the rest of the organisation.

Customers also come with questions about our compliance proof & we have to respond to them"

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Compliance Teams are always putting out fires...

"Today is all about putting out fires. We want to get to a level of pure governance covering our blind spots.

We can't sell the same product for 10 years as regulations change all the time"

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Market Access impacts & Demonstrating Compliance

1. Vast increase in Reg changes - Complex Requirements
2. Documentation of Information - Data Silos & Manual Processes
3. Inefficient Processes - Lack of Confidence & limited oversight
4. Managing Change in Time - Preventing Stop Ship
5. New Market Expansion - Unable to easily determine the changes required
6. Limited oversight leading to surprises & non compliance - Expiry of Evidence Documentation

Compliance & Risks

Trying to keep on top of it all...

Google Alerts

Events & Trade Shows

Industry & Associations

Mailing List, Webinar & Whitepaper

Paperwork & File Sharing

Consulting & Legal Services

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Hidden Cost of Compliance →

- Large, unmanageable spreadsheets to keep track of changes
- Disjointed processes & data siloes with 'dumb' documents
- Redesigning and retesting products
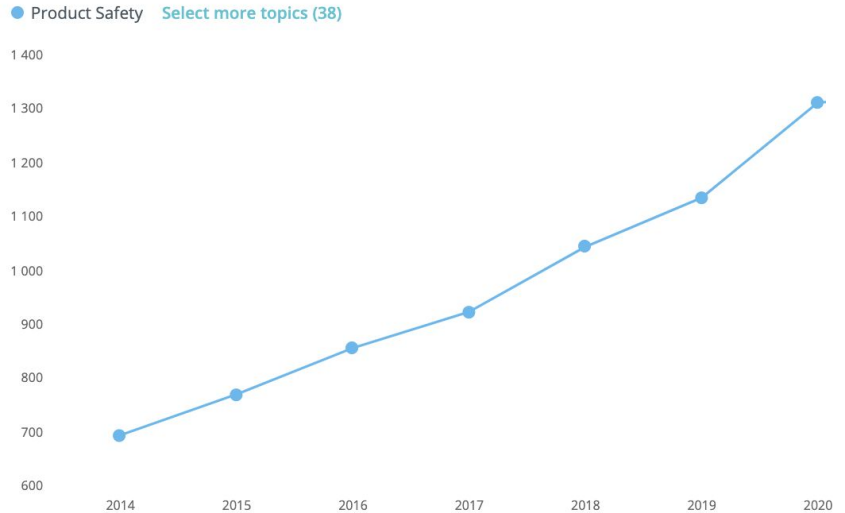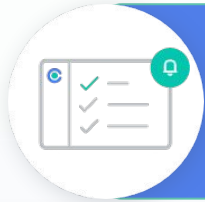- Stop-ship in the field and rework on the production line

MANUALLY CHECKING 000'S OF PRODUCTS

BRAND DAMAGE

NON COMPLIANT   ACCIDENT

REVENUE IMPACT

UNHAPPY CUSTOMERS   PRODUCT RECALL

Alert!
1 Market Risk

Alert!
1 Market Risk

● PRODUCT REQUIREMENTS   ● MARKET RISK

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Selling Product X in Market Y →

1. Demonstrate Compliance

2. For what is Required

3. As Driven by Regulations & Standards
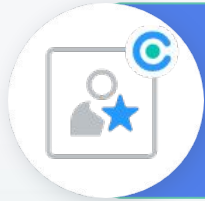
Regulations by topic over time ⓘ [Cumulative] Trend

● Product Safety   Select more topics (38)

1 400
1 300
1 200
1 100
1 000
900
800
700
600

2014   2015   2016   2017   2018   2019   2020

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Powerful Enterprise Technology

Extensive Global Regulatory Content

Team of Subject Matter Experts

Holistic Market Access Solutions...

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Manage everything in One Place...

- **Design & Build** new products with confidence

- Continually **monitor requirement changes & keep ahead of proposed changes** before they happen

- Keep all **compliance evidence** up to date & **live linked** back to their Regulations, Standards & Requirements

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C2P - The Key to Unlocking Market Access

EVIDENCE → Procure & link evidence records to relevant requirements to prove compliance

REQUIREMENTS → Capture, analyze & manage in the platform "live" linked to regulations & standards. Build customized sets of requirements covering your products & countries

STANDARDS → Contextual linking to regulations & requirements Searchable versions & equivalences of standards

REGULATIONS → Stay in control of the evolving regulatory landscape with access to 70,000+ proposed & enacted regulations & documents

EVIDENCE

REQUIREMENTS

C2P

STANDARDS

REGULATIONS

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Live-Linking Regulatory Changes To Compliance Requirements

Managing Compliance Requirements effectively has always been challenging.

- Manuals and guidelines are often static, require regular updating and can be overwhelming to maintain.
- No visibility on which requirements need to be reviewed
- No easy way to navigate between regulations & requirements

The result?
A disjointed, sometimes, misaligned compliance process working against the needs of product engineering.

SORT BY DATE

C2P Alert   15/02/2020
9 Requirements to revi... Inbox - Google
Hi Damien, The following West Coast Future
requirements may need to be r....

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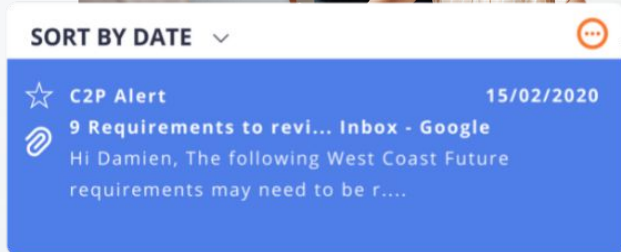
Building a Compliant Product

Product Model	Attribute(s)	Market(s)	Requirements Sample Data		Evidences Sample Data		Status
		EU	Product shall have valid CE marking	Draft			
	Product Packaging		Product shall be manufactured using Quality Management System	✓			
			Product shall be compliant to EMC	Draft			
	Commercial Use		Product shall have instructions for user statement	✓			
			Product shall be constructed to comply with product safety standard	✓			
Espresso XPR Series	Pressure Equipment		Lead restriction in EEE subject to the RoHS Directive	Draft			
	External Energy Supply		. . .				

EU

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Achieving Market Access

Product Model	Attribute(s)	Market(s)	Requirements Sample Data		Evidences Sample Data		Status

Espresso XPR Series

Attributes:
- Product Packaging
- Commercial Use
- Pressure Equipment
- External Energy Supply

Market: **EU**

Requirements		Evidences	
Product shall have valid CE marking	✓		
Product shall be manufactured using Quality Management System	✓	Certificate of Registration	Draft
Product shall be compliant to EMC	✓		
Product shall have instructions for user statement	✓	User Manual English	✓
Product shall be constructed to comply with product safety standard	✓	Safety File E345343	Draft
Lead restriction in EEE subject to the RoHS Directive	✓		
2.4 GHz Radiofrequency Emissions in the EU	✓	2.4GHz Emission Test Report	Draft
. . .			

Achieving Market Access

Product Model	Attribute(s)	Market(s)	Requirements Sample Data	Evidences Sample Data	Status
	Product Packaging	EU	Product shall have valid CE marking ✔	CE Declaration ✔	
			Product shall be manufactured using Quality Management System ✔	Certificate of Registration ✔	
	Commercial Use		Product shall be compliant to EMC ✔	TUVr EMC Report No. 134567 ✔	
Espresso XPR Series			Product shall have instructions for user statement ✔	User Manual English ✔	Compliant ✔
	Pressure Equipment		Product shall be constructed to comply with product safety standard ✔	Safety File E345343 ✔	
			Lead restriction in EEE subject to the RoHS Directive ✔	Lead Restriction Test Report ✔	
	External Energy Supply		2.4 GHz Radiofrequency Emissions in the EU ✔	2.4GHz Emission Test Report ✔	
			Chemical Restriction on Mercury in Batteries ✔	Mercury Test Report ✔	

European Union

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Changes to Requirements

Product Model	Attribute(s)	Market(s)	Requirements Sample Data		Evidences Sample Data		Status
Espresso XPR Series	Product Packaging Commercial Use Pressure Equipment External Energy Supply	EU	Product shall have valid CE marking	⚠️	CE Declaration	⚠️	Compliance at Risk ⚠️
			Product shall be manufactured using Quality Management System	✅	Certificate of Registration	✅	
			Product shall be compliant to EMC	✅	TUVr EMC Report No. 134567	✅	
			Product shall have instructions for user statement	✅	User Manual English	✅	
			Product shall be constructed to comply with product safety standard	✅	Safety File E345343	✅	
			Lead restriction in EEE subject to the RoHS Directive	✅	Lead Restriction Test Report	✅	
			2.4 GHz Radiofrequency Emissions in the EU	✅	2.4GHz Emission Test Report	✅	
			Chemical Restriction on Mercury in Batteries	✅	Mercury Test Report	✅	

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Expiring Evidence Documentation

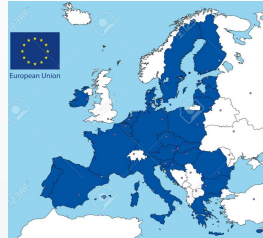| Product Model	Attribute(s)	Market(s)	Requirements Sample Data	Evidences Sample Data	Status

Espresso XPR Series

- Product Packaging
- Commercial Use
- Pressure Equipment
- External Energy Supply

EU

Requirements	
Product shall have valid CE marking	✅
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2.4 GHz Radiofrequency Emissions in the EU	✅
Chemical Restriction on Mercury in Batteries	✅

Evidences	
CE Declaration	✅
Certificate of Registration	🕐❗
TUVr EMC Report No. 134567	✅
User Manual English	✅
Safety File E345343	✅
Lead Restriction Test Report	🕐❗
2.4GHz Emission Test Report	✅
Mercury Test Report	✅

Non Compliant ⚠️

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TECHNOLOGY - C2P

Enterprise Saas Technology

The Key to Unlocking Market Access

Live Demo

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Q&A

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Abbott   FUJITSU   BOSE   TESLA   KOHLER

BURBERRY   XEROX   Thermo SCIENTIFIC   SONY   GARMIN

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