

Webinar Series: *Achieve Market Access*

From a Tidal Wave of Regulation to a Compliant Product

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UNLOCKING MARKET ACCESS

Unlocking Market Access

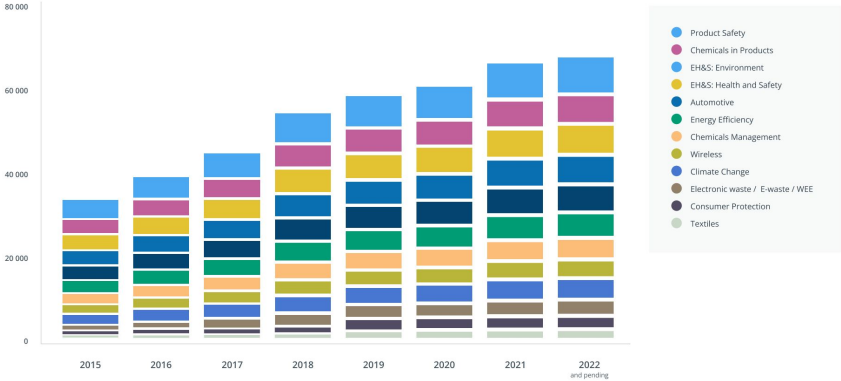


GROWTH IN REGULATIONS

A Tidal Wave of Regulations hitting Product Manufacturers...



60% Growth in Regulations in the past 5 years



GROWTH IN REGULATIONS

What are the exact Regulations my Product needs to comply with?

- National regulations
- Product specific safety standards
- Mandatory standards
- Documentation
- Global regulations
- Voluntary standards
- Substance regulations
- Testing
- Labelling
- Certifications
- ESG obligations
- Harmonized standards
- REACH
- Chemicals in your products
- Cybersecurity



Trying to keep on top of **it all...**

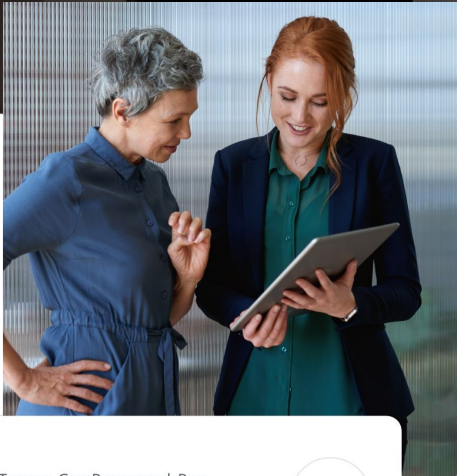


'Can I sell Product X in Market Y?'

1. Identifying the right Compliance Sources
2. Clarify what applies to my Products across Markets
3. Assess Relevance & Deep Dive into exact Product Requirements



Key Challenges



Readily identify the right regulations..

"We need to be able to readily identify emerging product-related regulatory issues around the world, and to manage them in an efficient manner"

Not enough time..

"Usually, there is not enough time to understand the regulations and act on our products to be compliant to all those regulations"

Quickly tailor to our products..

"Our compliance teams should be able to quickly tailor the regulatory content to our specific needs"

REGULATION

(Proposed) Texas: GenProposed Reg
Sources Sep 8 with Deadline for comments
- preview copy

Sep 8

ACHIEVE MARKET ACCESS

1. Identifying the right Compliance Sources...

*"We are struggling to do this as our existing setup is somewhat **piece-meal and dispersed among different systems and providers.***

*This makes it **difficult to understand if we are seeing all of the regulatory information that we need.***



2. Establish what Applies to my Products Across Markets

*“We need to cross-identify all **Regulations & Standards** for my **Product X** in **Market Y** of interest.*

*But the challenge is that I need the time and **skills** to navigate through an **overwhelming amount of information.**”*

“Working across multiple industries we need to interpret the applicability of regulatory changes to our product portfolio & develop systems to ensure we are compliant.”



ACHIEVE MARKET ACCESS

3. Assess Relevance & Deep Dive into Exact Product Requirements

"I need to be able to easily manage & maintain an assessment process."

But the challenge is that there is no streamlined coordinated process for our team's work.

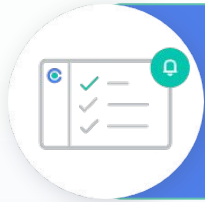
There is no organised way of keeping the corporate memory; And often we are not sure about our final decision"

*"It may not be obvious, but **companies** spend a significant amount of time assessing the same law, which wastes time and resources"*



A Smarter Way to Manage Product Compliance

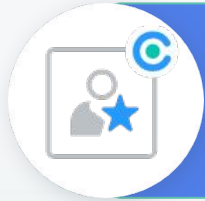
Holistic Market Access Solutions



Powerful Enterprise
Technology - C2P



Curated Global
Regulatory Content

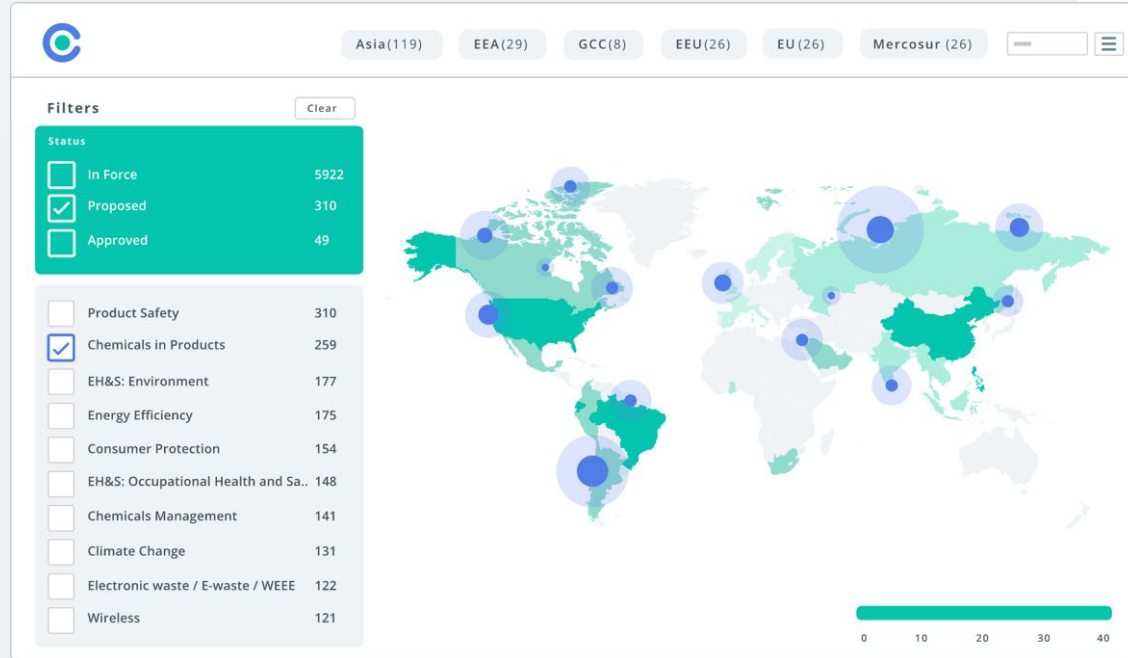


Team of Subject
Matter Experts

Holistic Market Access Solutions...

Manage everything in One Place...

- Design & Build new products with confidence
- Continually monitor reg changes & keep ahead of proposed changes before they happen
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements



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



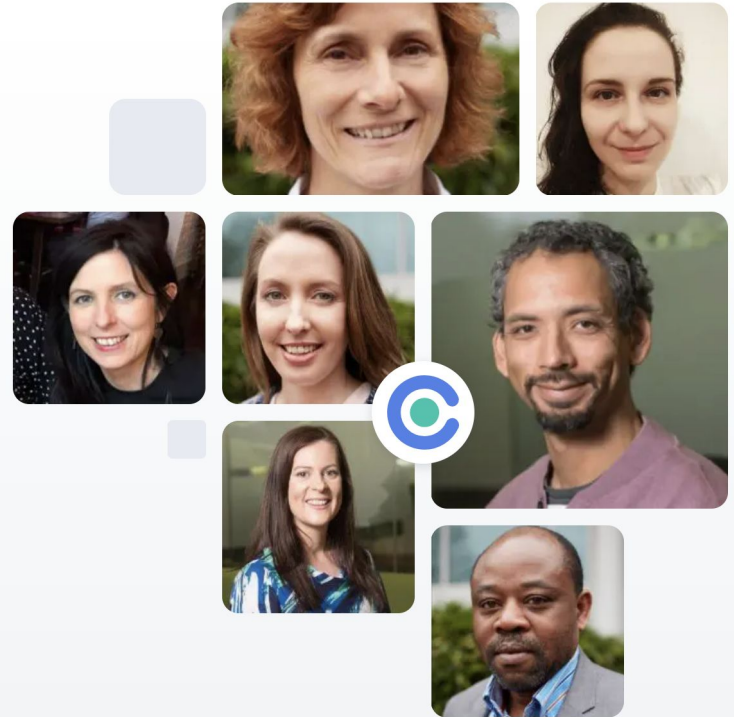
Stay in control of the evolving regulatory landscape with access to 70,000+ proposed & enacted regulations & documents



SUBJECT MATTER EXPERTISE

Global Regulatory Expertise

- 40+ Subject Matter Experts around the globe gathering necessary compliance information
- Almost 30 languages spoken to understand the local complexity
- Extensive Knowledge Partner network
- Expertise across products, geographies & policy areas



TECHNOLOGY - C2P

1. Relevance Increase

- Eliminate noise
- Tailor C2P to your products
- Filtered alerts

The screenshot displays the Compliance & Risks (C2P) interface. At the top, there are navigation tabs for 'Filter', 'My alerts (52,525)', 'C&R (68,485)', and 'All library (76,798)'. A search bar is located on the right side of the top navigation bar. Below the navigation bar, there is a sidebar on the left with various filter categories: 'Last updated', 'Responsible', 'Content areas (65 content areas)', 'Product category', 'Geography', 'Status', 'Requirement type', and 'Workflow Tags'. The main content area shows search results for 'All results' under the 'Regulations' tab. The results are sorted by 'Best Match' and show 30 results per page. The first result is a regulation: '(In force) EU: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006'. Below this, there are several product categories listed: 'WCA Coffee Machines · WCA Air Con Units · All WCA Products', 'Brewing Chambers · Ceramics FCM', and 'West Coast Refrigerator Division'. The second result is another regulation: '(In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU', with product categories 'WCA Electric Heaters · WCA Air Con Units' and 'High risk · Karl's In Progress'. A 'Help' button is visible in the bottom right corner.

TECHNOLOGY - C2P

2. Search & Filter Regulations

- Easy navigation through regulatory content
- Intelligent search engine
- Easy to filter information

The screenshot displays a dashboard interface for regulatory compliance. At the top, there is a green header with a circular logo on the left and three navigation buttons: 'Trends', 'Heatmap', and 'Assessment Report'. Below the header, a white panel contains search and filter controls. On the left, there is a 'Date Created' dropdown menu and a text input field containing 'All time'. To the right of these are two checked checkboxes: 'Exclude supporting' and 'Exclude not in force'. Further right are buttons for 'Filter Results', 'Excel' (with a download icon), and 'Print' (with a printer icon). Below the filter panel is a table with four columns: 'CONTENT AREAS', 'RESPONSIBLE', 'TOTAL', and 'ASSESSED'. Each row in the table includes a small circular icon with a green arrow, a text description of the content area, the name of the responsible party, the total number of items, the percentage assessed, and a progress bar. The progress bars are labeled with the total count '1070/1145'.


CONTENT AREAS	RESPONSIBLE	TOTAL	ASSESSED
Global Chemicals & Substances (generic applicability to any product)	Meg (WCO Textiles) O'Keeffe	1145	93%
Textiles - Global	Anne (WCO Textiles) St-Laurant	1203	90%
Packaging - Global	Meg (WCO Textiles) O'Keeffe	1203	25%

3. Regulatory Summaries

- Readily available
- Extracted from regulatory text to give quick insight
- Essential metadata for faster decision-making
- Local language documents summarised into English

Overview

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. ... [show more](#)

 Understanding REACH
European Chemicals Agency (ECHA), 2007

Scope

Products Covered 20 of 22

- Aerosols
- All Products
- Barometers
- Cosmetics
- Electronic Components
- Fire Fighting Foam
- Home Textiles
- Implantable Medical Devices
- Jewellery
- Lamps
- Leather Products
- Manometers
- Medical Devices
- Paints

Requirement Types

- Chemical Restriction
- Labelling
- Permits / licenses / approvals
- Providing consumer information
- Providing product information
- Registration
- Reporting
- Retention/Destruction of records
- Substance data sharing
- Testing

Topics

- Business-to-consumer (B2C) selling
- Chemicals in Products
- Chemicals Management
- Distributor relations
- EU REACH
- Globally Harmonised System (GHS)
- Intellectual Property
- Research & development (R&D)
- Supplier relationship management

[Help](#)

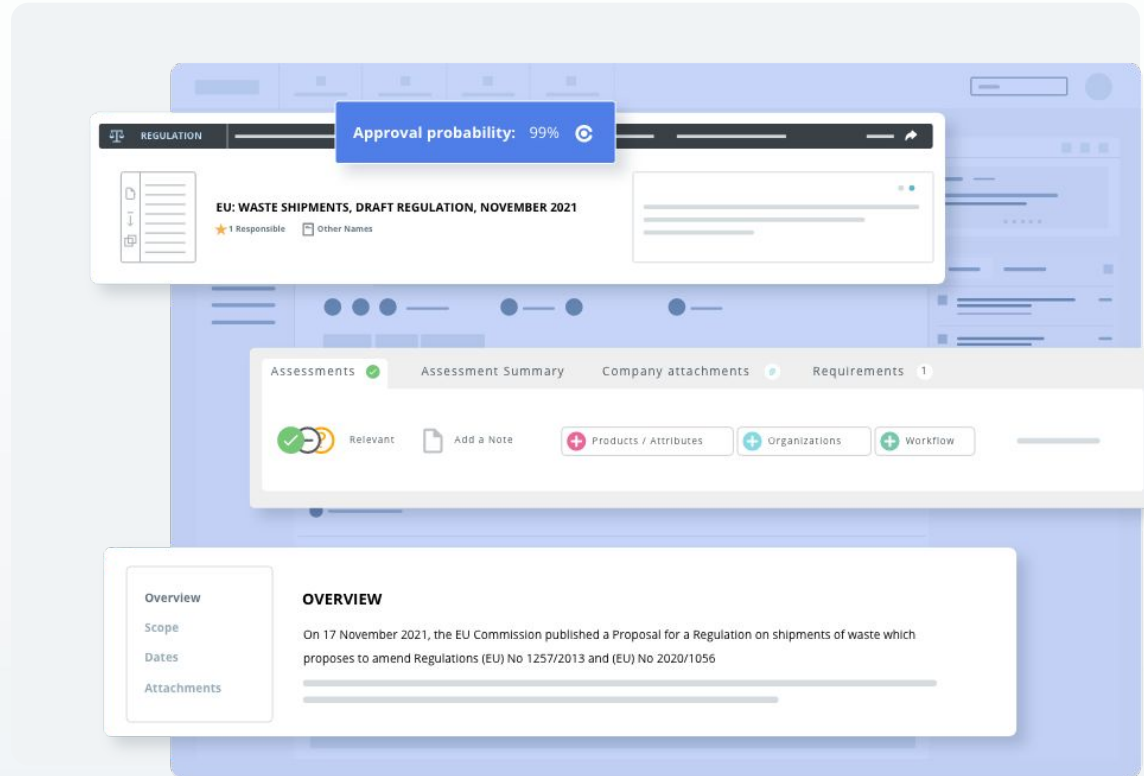
4. Integrate Internal Documents

- Include internal policies
- Add internal documents and integrate them with C2P

The screenshot displays a document management system interface. The top navigation bar includes 'Zen industries', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main content area is divided into a left sidebar with filters (e.g., 'Last updated', 'Responsible', 'Content area') and a central search results pane. The search results pane shows a list of documents with columns for 'All results', 'Regulations', 'Standards', and 'Supporting'. The first document is 'Ecuador: Approving Technical Regulations for Electric 16227, 2016'. The right sidebar contains an 'Add document' form with sections for 'Document details', 'Main attachment', 'Publication reference', 'Summary', 'Scope details', 'Markets', 'Topics', and 'Products'. The 'Document details' section includes fields for 'Type', 'Title', 'Status', and 'Issuing organisation'. The 'Main attachment' section has an 'Attach' button. The 'Publication reference' section has a 'Paste URL of reference' field. The 'Summary' section has a 'Placeholder text' field. The 'Scope details' section has a blue box with the text 'Scoping increases the data intelligence of your document.' The 'Markets', 'Topics', and 'Products' sections each have a 'Select or search' dropdown menu.

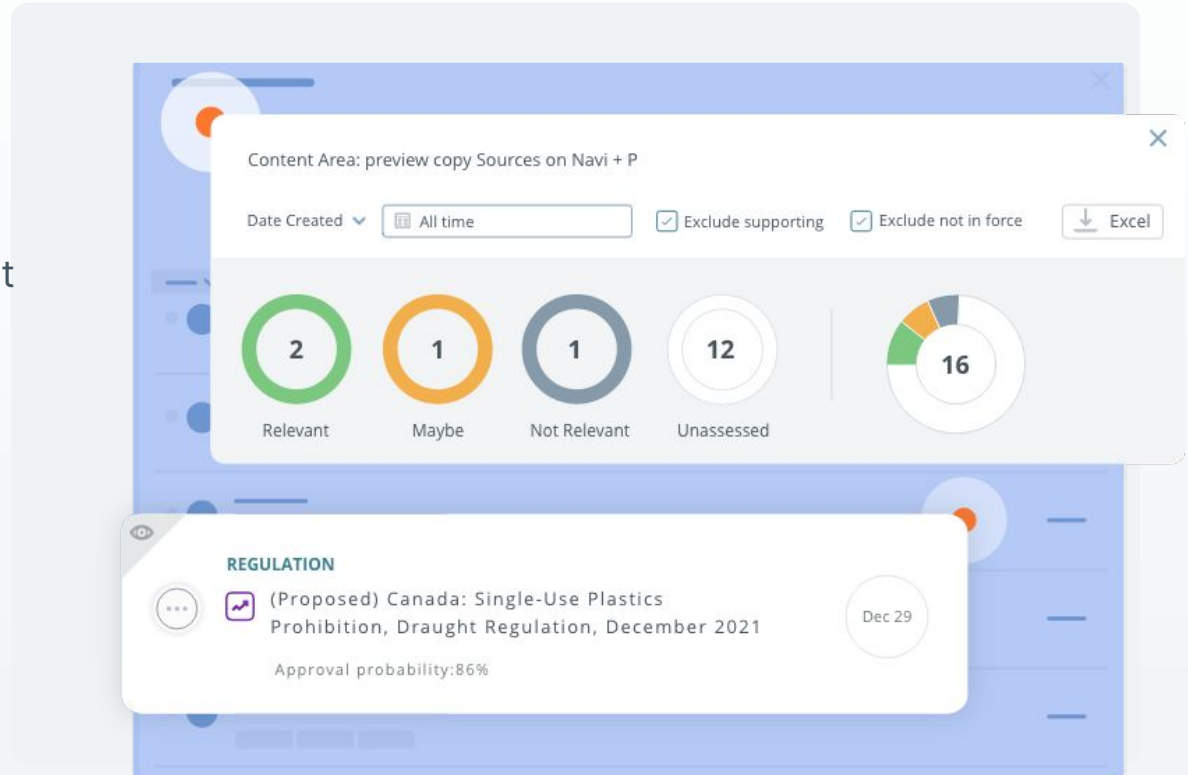
5. Probability Analysis

- Know what's coming beforehand
- Draft regulations included
- AI powered probability of approval



6. Assessments

- Earmark the regulations that need to be actioned on
- Maintain your corporate memory with a uniform criteria



7. News & Analysis

- Clarity on [implications](#) of a [new/revamped regulation](#)
- [Analysis](#) from our team of experts

Expert Commentary preview 6 of 30

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The New Blue: EU Updates Key “Blue Guide” to Products Laws

TB



Tracey Bischofberger and Edward Turtle of Cooley LLP

The European Commission has published its revised 2022 Blue Guide (available [here](#)). The Blue Guide is a key guidance document for EU product rules and the Commission [describes](#) the revision as “a substantial update”. In this blog, we provide a quick summary of some of the headline changes.

Background

The Blue Guide is a key European Commission guidance document for EU product rules and applies to a wide range of products covered by Union harmonisation legislation (i.e., generally, CE-marked products). These include radio equipment, electrical and electronic equipment, medical devices, toys, machinery and PPE, amongst many others. More information can be found in our [bitesize introduction](#) to the Blue Guide.

The Blue Guide’s broad scope and detailed guidance also make it influential in other areas. Whilst not legally-binding, it provides meaningful interpretation guidance on many areas of product regulation, and in practice is relied upon heavily by market surveillance authorities. The Blue Guide was first published more than two decades ago, in 2000, and was updated in 2014 and 2016. The latest revision has been a while in the

TECHNOLOGY - C2P

8. Ask Our Experts

- Get a **second opinion**
- **Direct** access to our team of subject matter experts

Welcome to Ask Our Experts

This is your team's direct line to our experts, who can address your questions about regulations, standards including purpose, applicability, requirements, and more.

- Our Ask Our Experts service is free if your question can be answered within 30 minutes.
- If responding to your question requires longer than 30 minutes, an expert will get back to you and inform you.



Hi, is conformity to the standard TIS 3061-2563 mandatory for placing on market in Thailand?



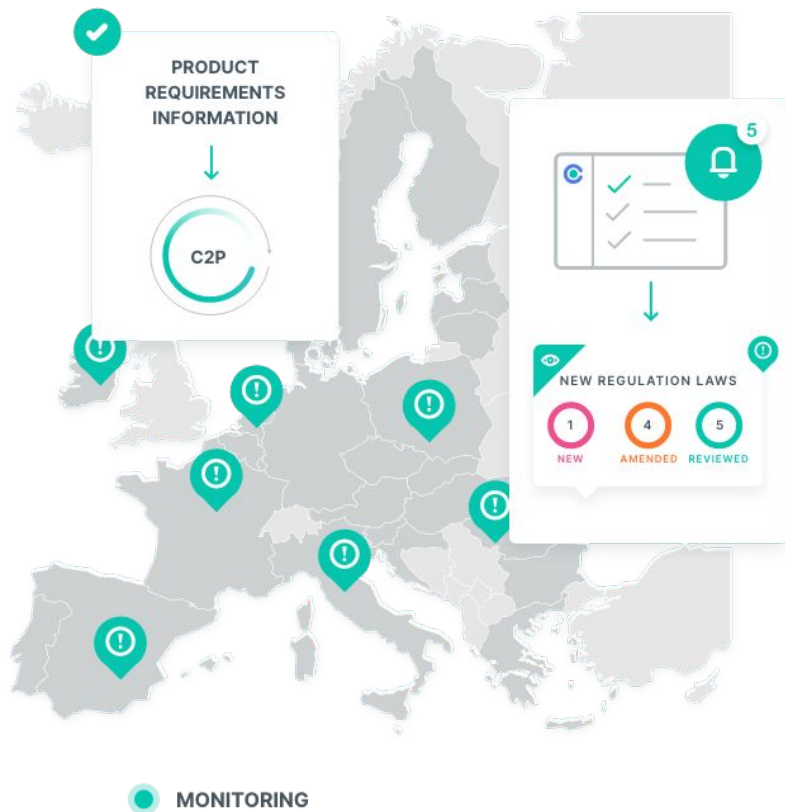
Thank you. Are there any relevant regulations I should be aware of relating to this?



I did not find any Ministerial Regulations requiring compliance with the requirements of this standard.

Ask the first question for your company

Ask our Experts



WHY C2P?

Greater ROI for the Compliance Team

- Optimize your compliance process with C2P & reduce Time-to-Market
- Improve your team's efficiency by focussing on decision making rather than on bookkeeping & firefighting

Q&A