Webinar Series: Guide to Successful Market Access

Demonstrate Compliance to Unlock Global Market Access

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Compliance & Risks

Guide to Successful Market Access

Unlocking Market Access

Compliance & Risks

Guide to Successful Market Access

Achieve Market Access

1. Achieve Market Access

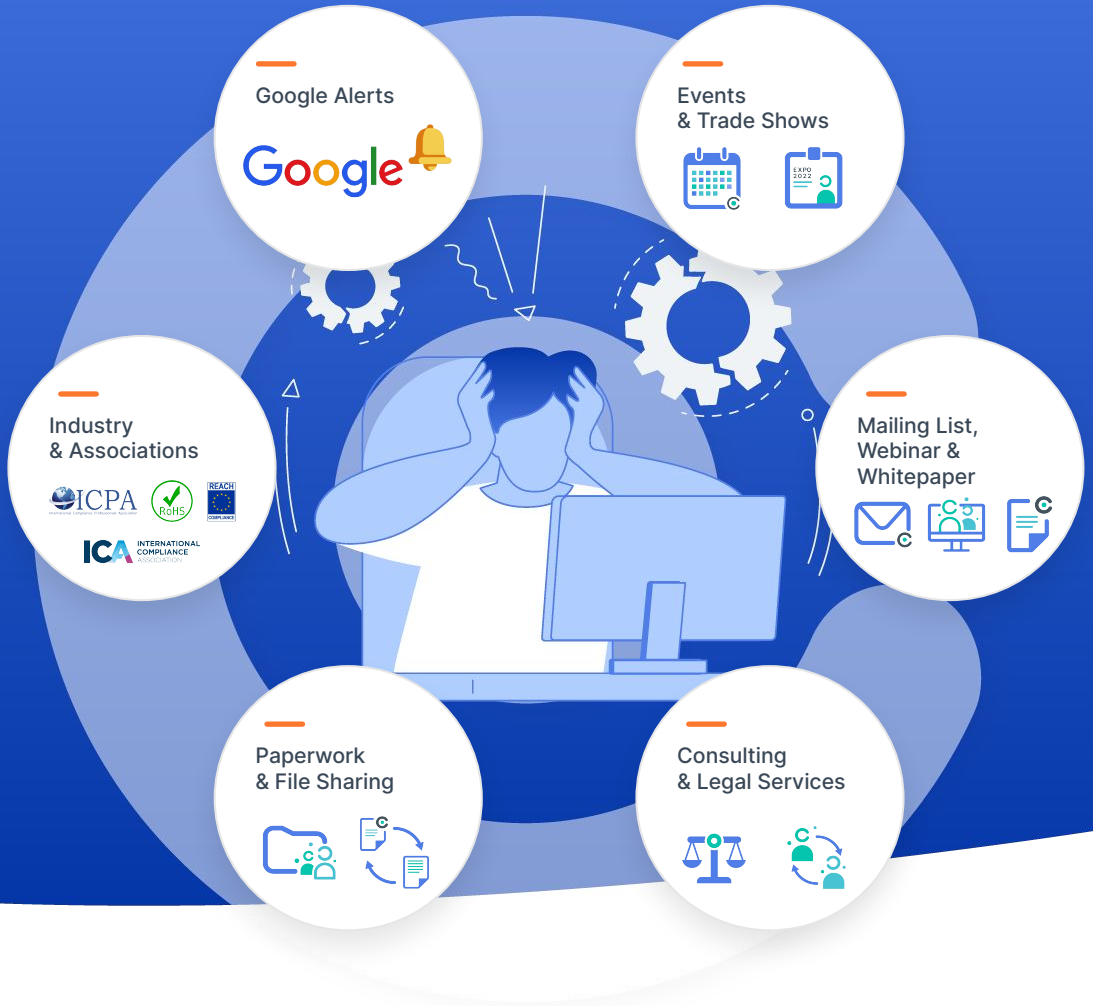
- *From a Tidal Wave of Regulation to a Compliant Product - July*
- *Interpreting The Impact Of Relevant Regulations On Your Products- August*
- *Demonstrating a Compliant Product to unlock market access for your product - September*

Coming up next...

2. Maintain Market Access

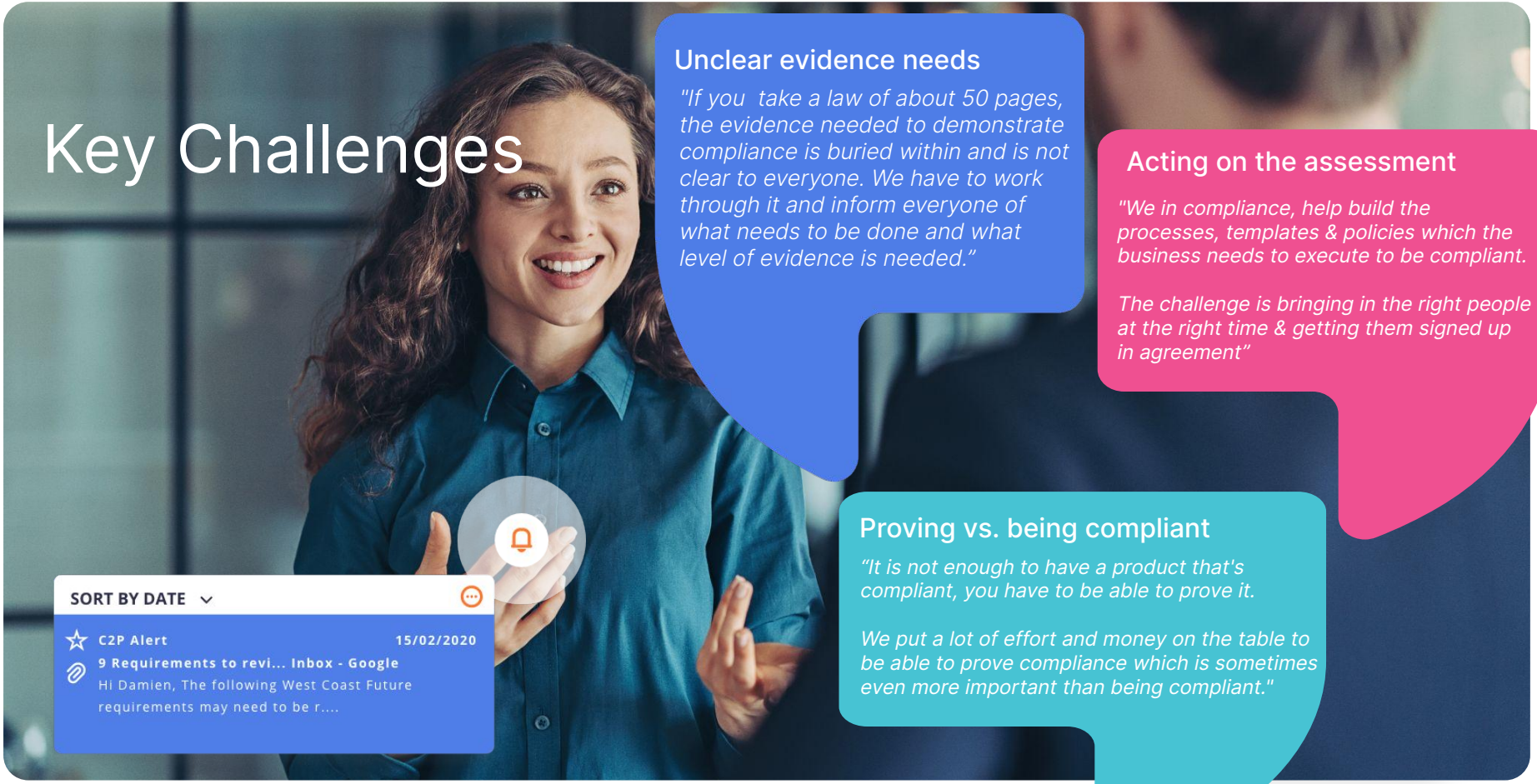
3. Expand Market Access

Trying to keep on top of it all...



Compliance & Risks

Key Challenges



Unclear evidence needs

"If you take a law of about 50 pages, the evidence needed to demonstrate compliance is buried within and is not clear to everyone. We have to work through it and inform everyone of what needs to be done and what level of evidence is needed."

Acting on the assessment

"We in compliance, help build the processes, templates & policies which the business needs to execute to be compliant.

The challenge is bringing in the right people at the right time & getting them signed up in agreement"

Proving vs. being compliant

"It is not enough to have a product that's compliant, you have to be able to prove it.

We put a lot of effort and money on the table to be able to prove compliance which is sometimes even more important than being compliant."

Demonstrate Compliance to Unlock Market Access

Holistic Market Access Solutions

Compliance & Risks

How can I accurately demonstrate compliance?

C&R's market research highlighted the key steps to demonstrate compliance for each product

1. Determine the required evidence for each requirement
2. Make a compliance recommendation for each product & gain agreement from key stakeholders & decision makers
3. Communicate compliance requirements for implementation
4. Compile a library of evidence documentation
5. Report on evidence of compliance to internal & external stakeholders

Poll #1

Choose the step that you have found the most challenging in your experience at your organization.

ACHIEVE MARKET ACCESS

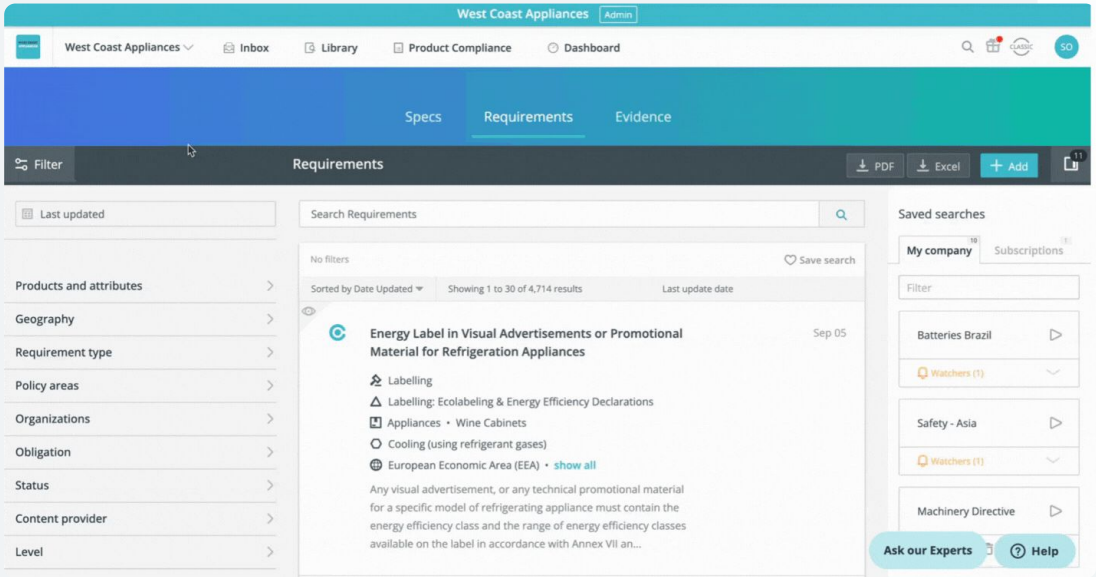
1. Determine the required evidence for each requirement

“The evidence needed varies hugely. It can depend on the nature of the evidence being requested or the governing body that is setting the regulations and measuring the compliance.

We make products that go into military equipment, and some of those products are considered classified under DFAR which basically carries with it some very strict and rigorous evidence requirements for meeting the DFAR compliance requirements."

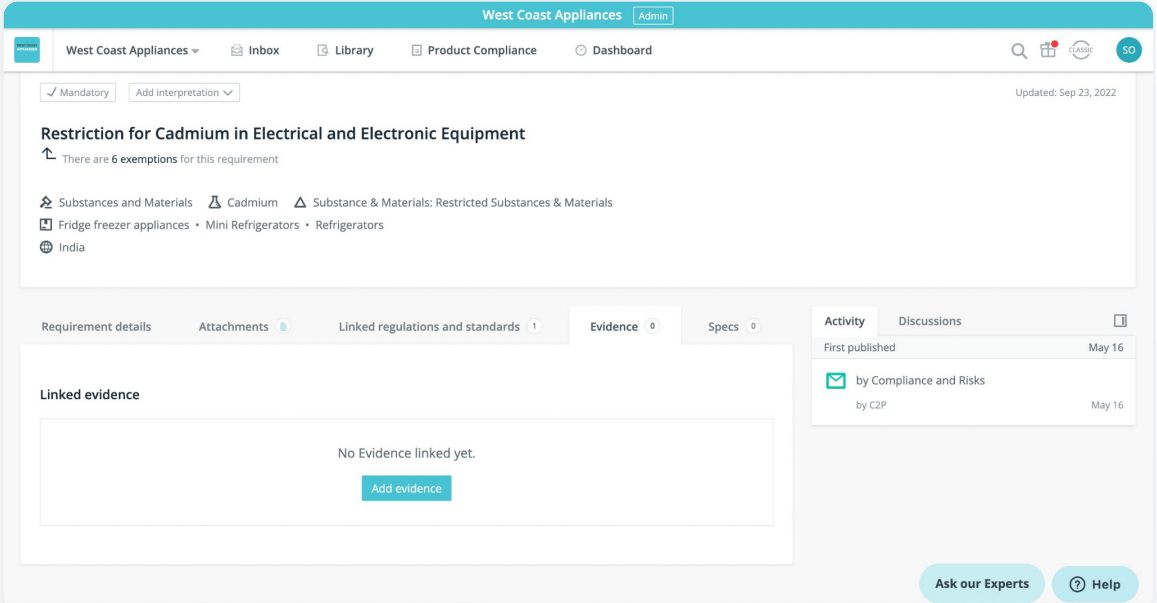
1. Identify deliverables

- Our SME's extract deliverables from each regulation
- Clear action for each requirement



1. Define draft evidence

- Create draft evidence records for each requirement
- Collaborate with advisors & stakeholders on the level of evidence needed



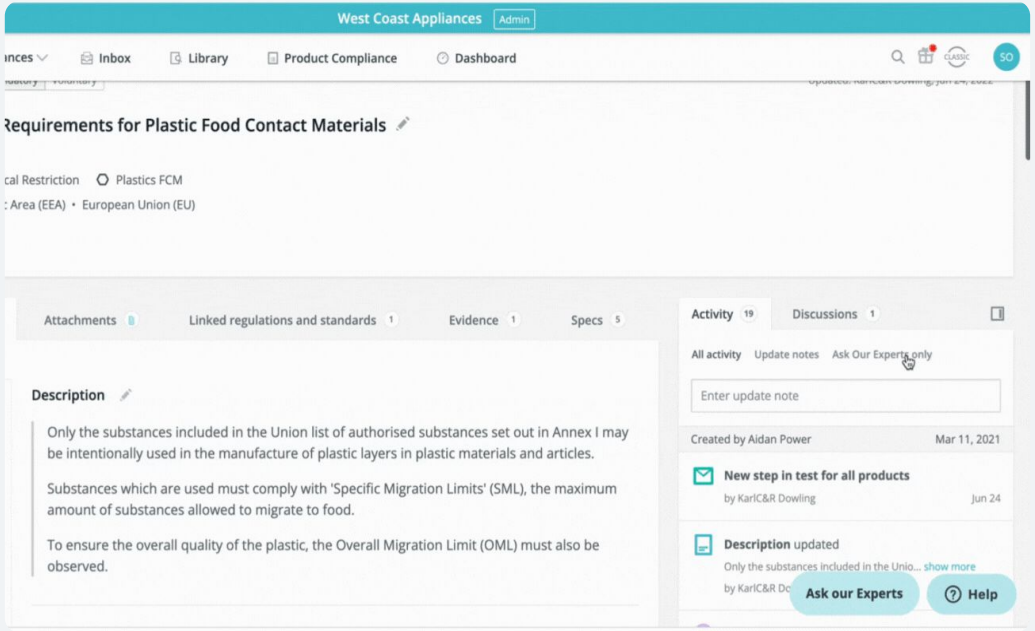
2. Make compliance recommendation & gain agreement

"Harmonization is a key factor. Wherever I can do something to bring the different regions and countries on the same ground, regulating the same thing the same way, is our primary goal.

Diversity in regulations kills the entire compliance effort because you multiply resources required, the budget needed for fulfilling the different certification testing."

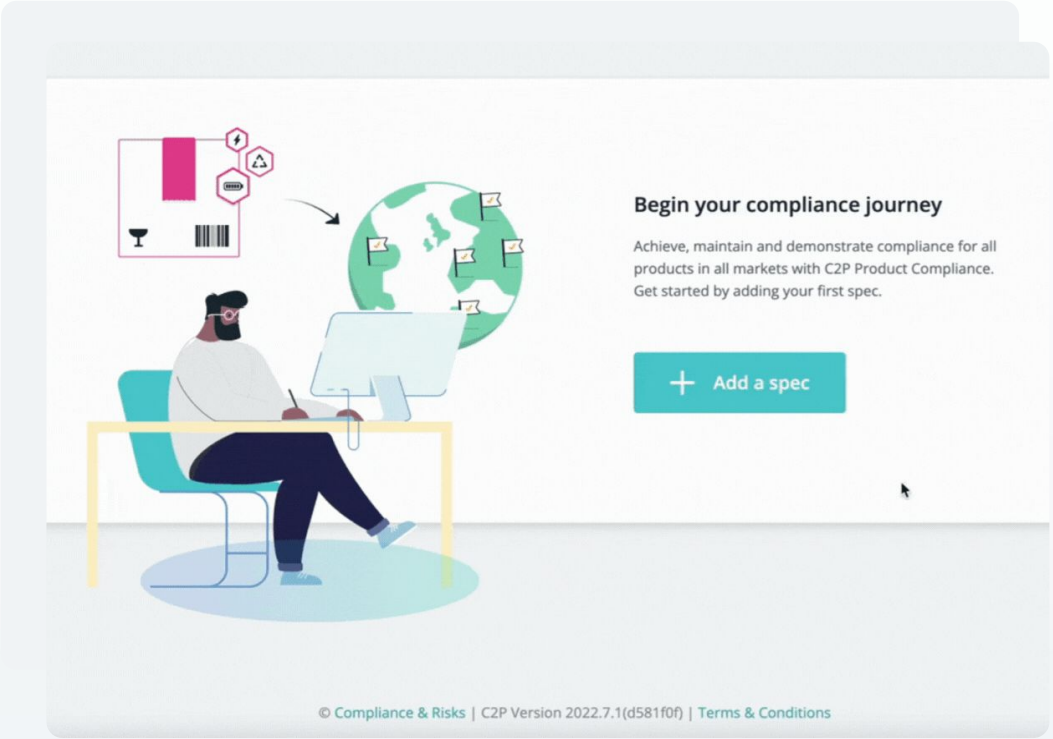
2. Collaborate on requirements

- Assess the same regulation to produce unambiguous decisions
- Harmonise your compliance approach across all teams, products & markets
- Reduce unnecessary work



2. Product Compliance Specifications

- Easily create a product focused outcome
- All relevant requirements & evidence need to be compliant
- Produce reports to gain agreement & start implementation

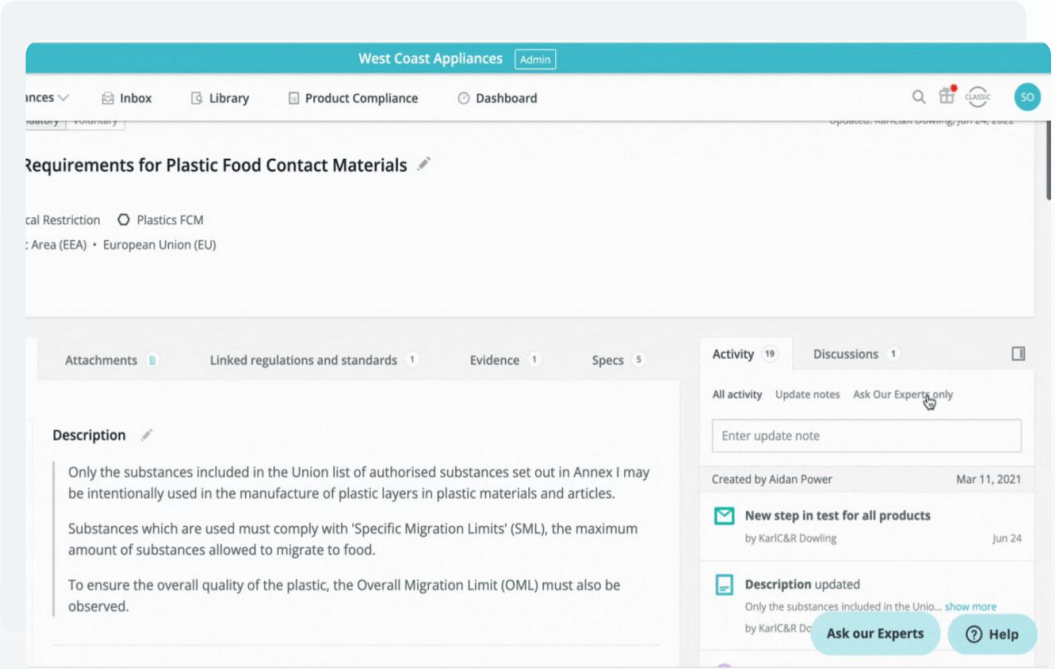


3. Communicate compliance requirements for implementation

"We in compliance, help build the processes, the templates, the policies that allow us to be compliant, and then the business needs to execute. ***The challenge is bringing in the right people at the right time, getting them signed up that,*** *yes, in fact, we need to do all of this. You need to build it in as part of your process at the beginning, as opposed to afterwards."*

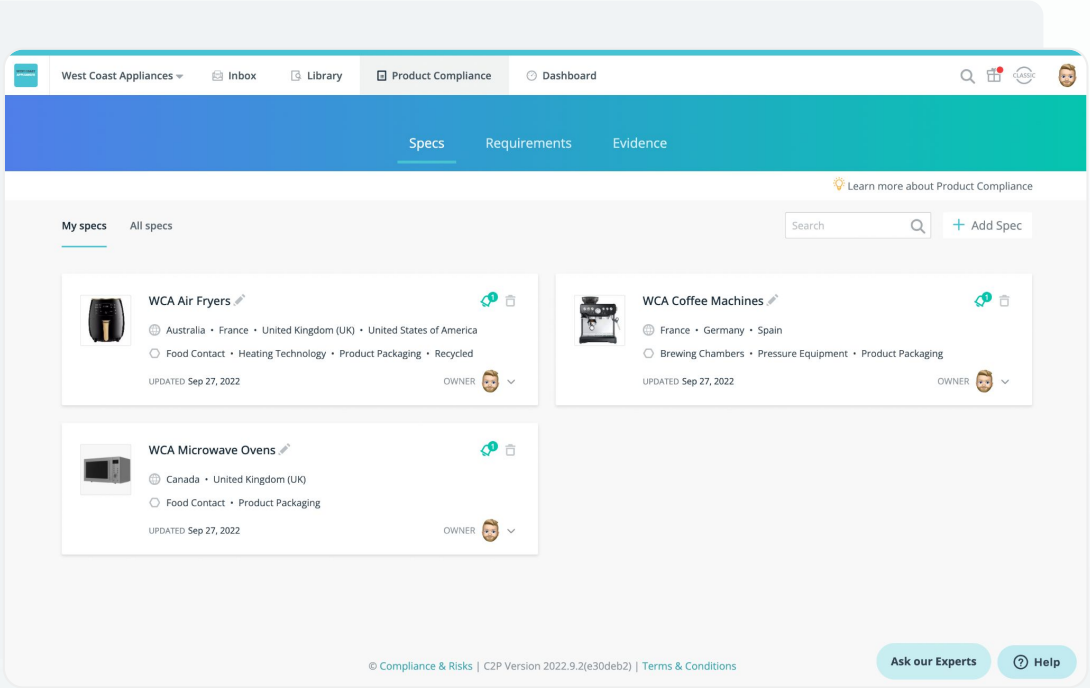
3. Collaboration & Decision Making

- Task management & discussions
- Fast and effective collaboration between stakeholders
- Record activity provides transparent decision making



3. Watching for updates

- Watch your Product Compliance Specs
- Get alerts on new or updates requirements
- Insights into any changes during implementation



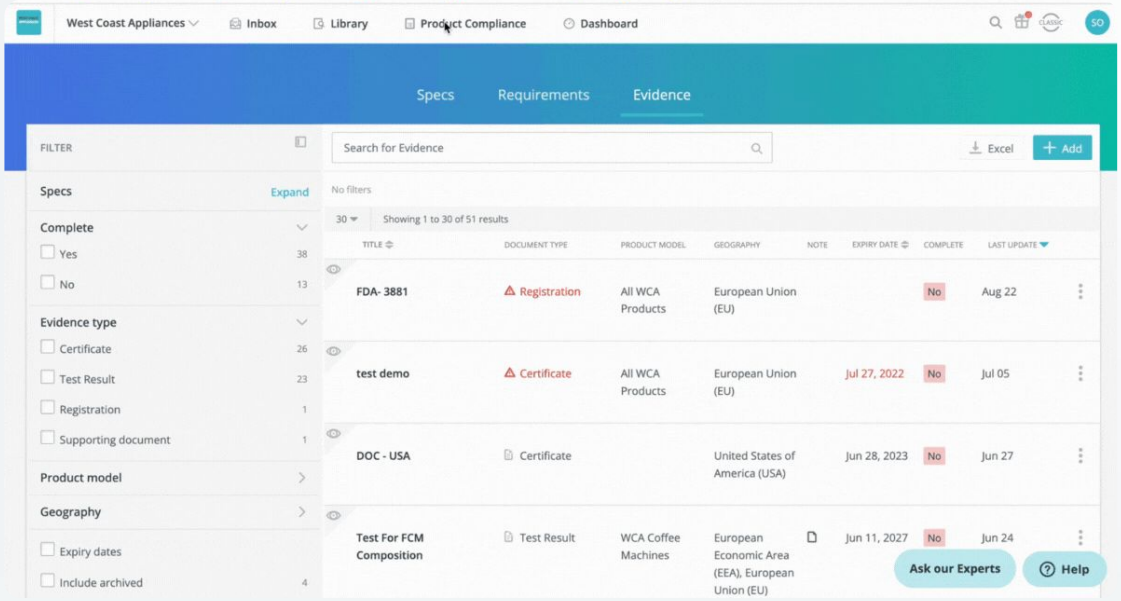
4. Compile a library of evidence documentation

“We don't use any management system to structure our folders, it is a bit haphazard e.g. folder by model, energy efficiency certs, etc. random folder names.

This makes it very difficult to locate the exact documents because we don’t know if a document is about to expire, or will expire or should expire.”

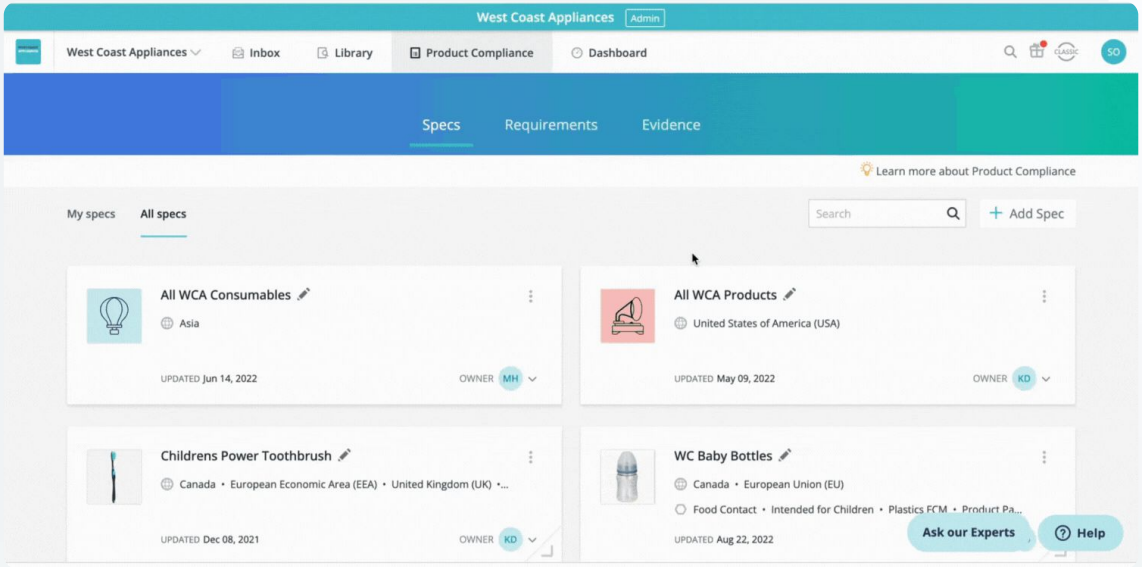
4. Documenting evidence records

- Single place for all evidence documentation
- Linked to requirements
- Track evidence expiration



4. Missing evidence for each product

- Evidence scoped to products & requirements
- Identify gaps in evidence
- Confidence all products are complaint



ACHIEVE MARKET ACCESS

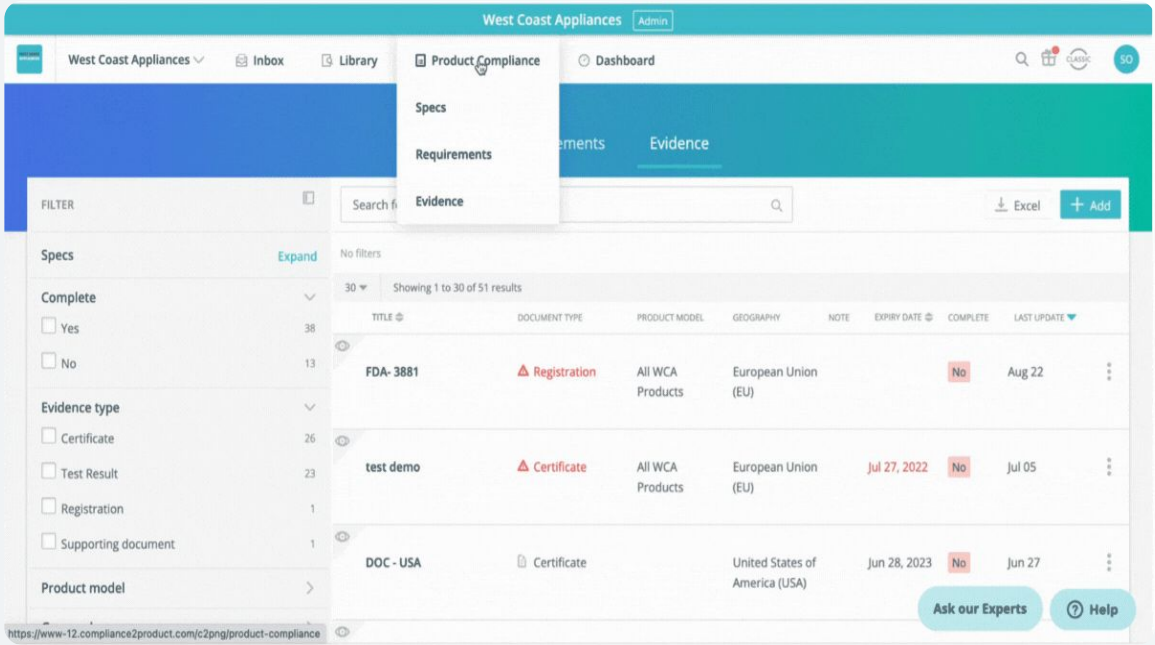
5. Report evidence to key stakeholders

"Providing too little or too much evidence information of the compliance of a product can open the company up to potential liability issues, or further questions from regulatory bodies.

Therefore, we need to ensure our reporting is accurate and is key for maintaining audit deadlines."

5. Demonstrating compliance

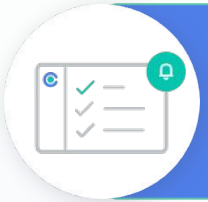
- Provide stakeholders access to evidence records
- Provide access to auditors
- Quickly respond to requests to prove compliance



A Smarter Way to Manage Product Compliance

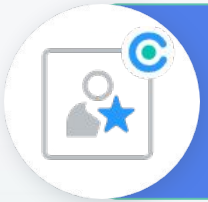
Holistic Market Access Solutions

Compliance & Risks



Powerful Enterprise Technology

Extensive Global Regulatory Content



Team of Subject Matter Experts

Holistic Market Access Solutions...

“Can I sell product X in market Y?”

→ Achieve market access

“Can I continue to sell product X in market Y when there is a change?”

→ Maintain market access

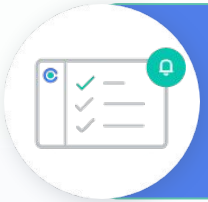
“What do I need to do to sell product X into a new market?”

→ Expand market access

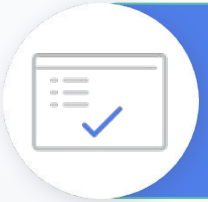
Accelerate the ability to

Achieve, Maintain & Expand Market Access for all products in all markets

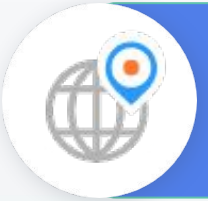
Achieve your business objectives, by ...



Demonstrating Compliance



For what is required



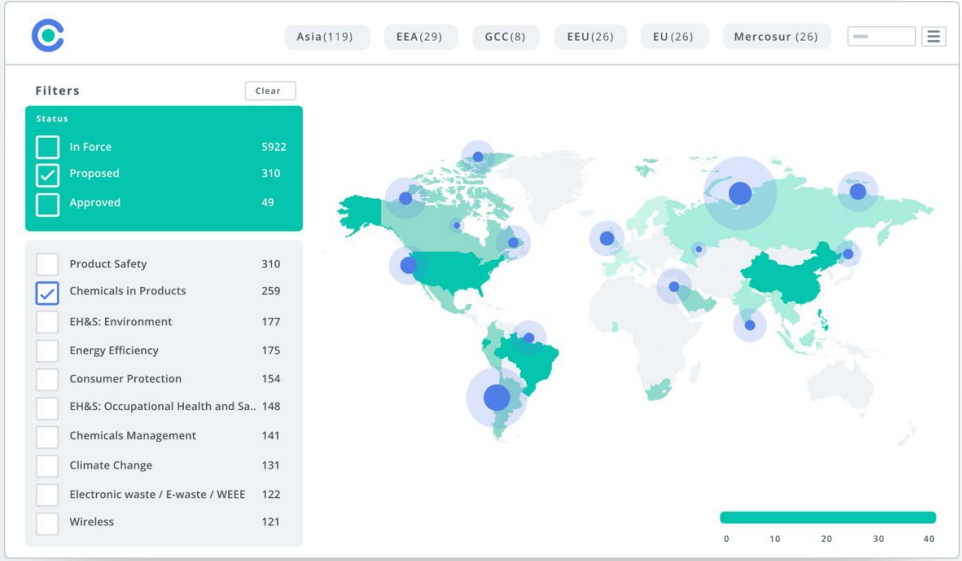
Driven by Global Regulations & Standards

TECHNOLOGY - C2P

C2P

The Key to Unlocking Market Access

- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration

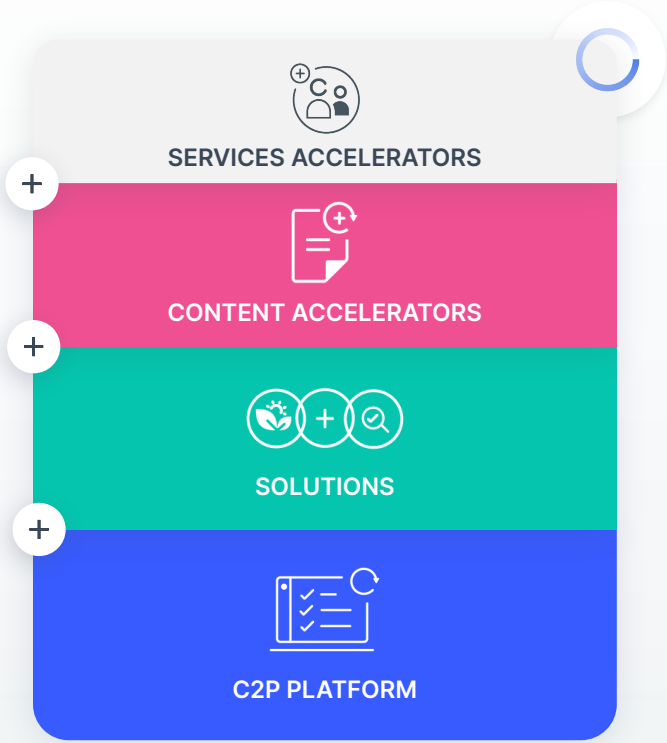


TECHNOLOGY - C2P

Tailored to meet your needs...

- Comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence

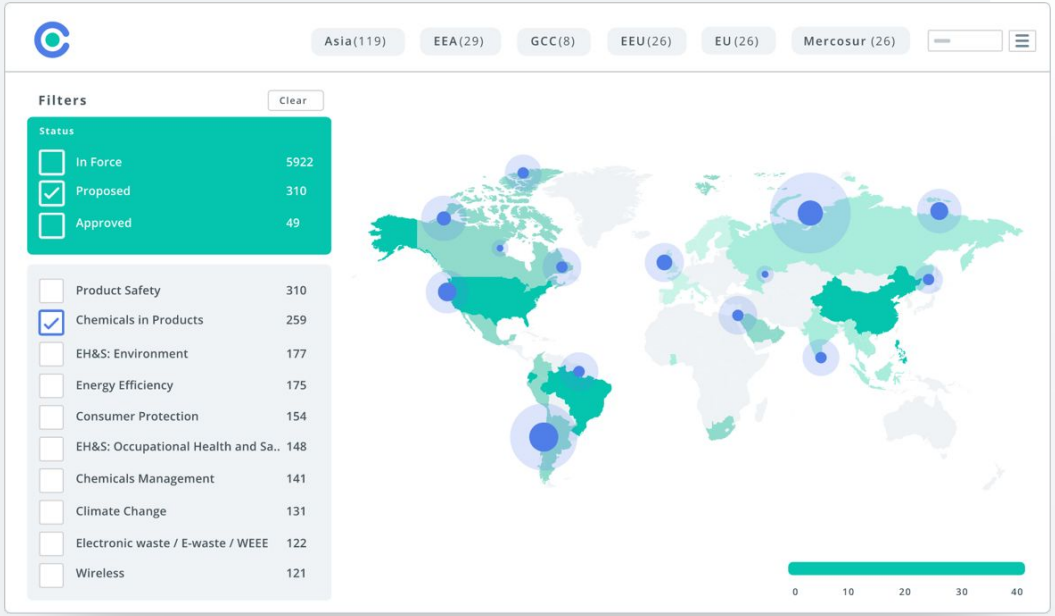
- Add-on packages to accelerate market access through:
  - Use-case specific solutions
  - Global regulatory content
  - Professional services



TECHNOLOGY - C2P

Manage everything in One Place...

- Design, build, and collaborate on new products with confidence
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements
- Continually monitor regulatory changes & keep ahead of proposed changes before they happen
- Integrate with other systems to enable streamlined business processes



WHY C2P?

Why Invest in a Technology Platform?

- Accelerate time-to-market for products
- Reduce non compliance risks that impact your ability to meet business goals and cause reputational damage
- Enable business continuity by digitizing your compliance process and building corporate memory
- Improve efficiency and enable your team to focus on business critical initiatives rather than manual tasks
- Save time with access to Compliance & Risks' extensive Knowledge Partner network

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3. Expand Market Access

Q&A