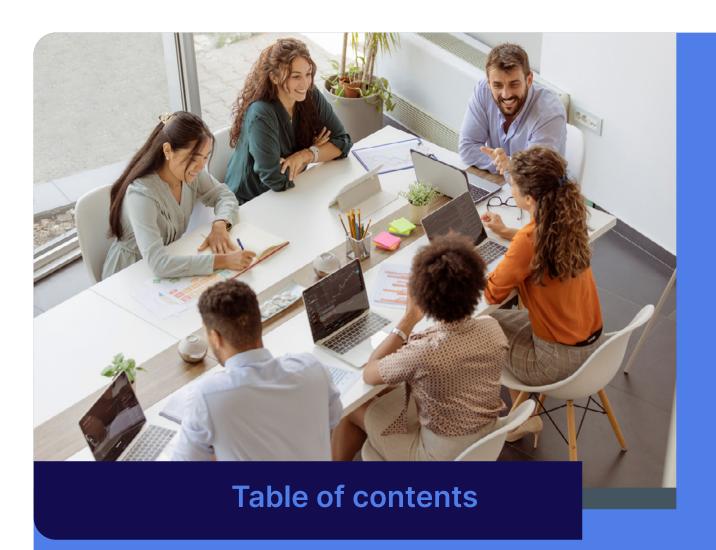


HOW TO GUIDE

Building a Business Case for a Product Compliance Solution



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Introduction

Implementing a product compliance Software-as-a-Service (SaaS) solution can significantly enhance an organization's ability to manage regulatory requirements, streamline processes, mitigate risks, and achieve uninterrupted market access for your business. (See Image 1, Source, Compliance & Risks).

For most compliance departments, the level of digital maturity remains low but the amount or regulatory activity and macroeconomic conditions warrant a necessity to change the status quo.



Gartner's research identifies three critical opportunities for legal leaders looking to pursue technology:

- Establishing (or strengthening) foundational systems of record
- 2. Enabling core workflows with digital investments (beyond sending emails or Excel spreadsheets)
- Transitioning largely analog risk management methodologies into the digital realm

However, gaining agreement from stakeholders and securing the necessary resources for such an investment requires a well-constructed and persuasive business case. In this guide, we will explore the key steps and considerations involved in building a strong business case for a product compliance SaaS solution, helping you secure the support needed to move forward.



Image 1: Global Regulatory Monitoring using C2P, A Regulatory Compliance SaaS Solution. Source: Compliance & Risks

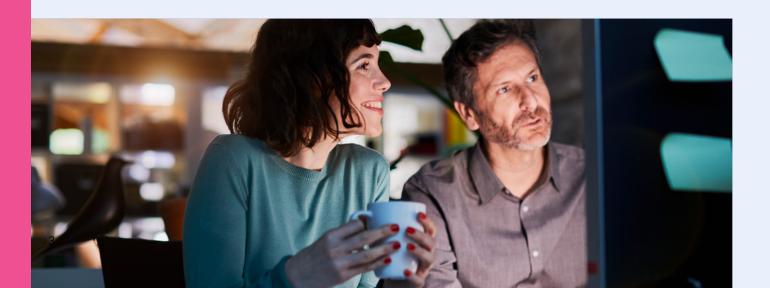
Understand Your Current Challenges & Pain Points

The true cost of outdated compliance processes is more than just fines and penalties. (See Image 2 below, Source: Compliance & Risks). To build a compelling business case, start by clearly understanding the challenges and pain points your organization currently faces in managing product compliance.

Consider factors such as regulatory complexity, manual processes, resource limitations, risk exposure, and the potential consequences of non-compliance. Quantify the impact of these challenges in terms of costs, productivity, and reputational risk relevant to your business.

Few of the challenges we have heard from our customers and market research

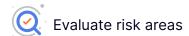
- Manually checking thousands of products
- Large, unmanageable spreadsheets
- Disjointed processes & data silos
- Redesigning and retesting products
- Stop-ship in the field & rework on the production line



How Do You Quantify The Consequences of Non-Compliance?

Here are a few ways you can quantify the consequences of non-compliance





How much revenue is generated annually by your best-selling product in a market? What if this was disrupted for a month, year, etc?



Image 2: Market Access Risks due to non-compliance, Source: Compliance & Risks

What We Have Been Hearing...

Here are a few quotes from our customers about their challenges from before they implemented a SaaS solution.

How do we scale with lean teams?

How do we operationalize the need to keep up with regulations, and reduce the legal costs that are building up?

Compliance Head Leading e-Commerce Giant

We need more resources..

We as a business are always dealing with significant levels of change. Around the time of Brexit, it became obvious we were reaching a tipping point and we needed to add more resources to allow us to maintain our effectiveness.

Compliance Director
Luxury Fashion & Beauty Brand

How do we get all of the compliance requirements to the product teams in the most efficient means possible?

Quality Assurance Director Global Medical Device Manufacturer

Regulations are too complex and significantly changing..

I need to ensure our products meet current, stringent environmental compliance legislation, as well as be prepared for regulatory changes coming down the line.

Environmental Program Manager National Instruments



The cost of non-compliance is too high...

Sending non-compliant products to our customers could result in costly order changes and delays at customs borders.

Sr. Regulatory Compliance Specialist FoxGuard



Benefits Of A Product Compliance SaaS Solution

A Product Compliance SaaS solution provides an array of benefits. Identify and outline the specific benefits that a product compliance SaaS solution can offer for your business.

These may include:





Identify Market Expansion Opportunities

Regulatory Insight

Gain valuable insights into compliance standards and regulations, helping you understand the specific requirements for entering new markets.

Market Access Assessments

Conduct thorough assessments of market access by evaluating regulatory landscapes and requirements in various regions or countries. Analyze certification needs, labeling requirements, and product restrictions to identify markets with the most potential for compliant products. This assessment guides strategic market entry decisions, focusing on regions that offer the greatest opportunities.

Competitive Advantage

By highlighting their compliance achievements, businesses can differentiate themselves in the market, build trust with customers, and attract new opportunities that require compliant products or services.



Risk Mitigation

Showcase how a SaaS solution can enable proactive monitoring, real-time alerts, risk assessments, and mitigation strategies. Discuss how this can help minimize the potential for penalties, legal actions, and reputational damage.

We have reduced our exposure to the risks and cost of regulatory noncompliance through regular reliable compliance information & early alerts on changes.

Officer for Sustainability Management
Miele

C2P has resulted in substantial time savings and we are confident that we have no gaps in coverage.

Manager of Environment Health & Safety at Kodak Alaris

The regulatory alerts system is really invaluable in terms of reducing the workload as we expand the business into more and more countries around the world.

Compliance Director
Leading e-Commerce Giant

Scalability & Adaptability

Emphasize the solution's ability to scale and accommodate future regulatory changes, business growth, and evolving compliance requirements. Discuss how this ensures long-term sustainability and reduces the need for additional investments in the future.

4

Streamlined Workflows

Highlight how the solution can automate manual processes, reduce data entry errors, and improve efficiency in compliance management. Quantify the time and cost savings that can be achieved if possible.

C2P gives us confidence in the accuracy of the changes, and gives us the ability to automate our work, enabling us to keep lean teams.

Compliance Director Leading e-Commerce Giant Our regulatory team has leveraged the workflow capabilities built into C2P, replacing a manual process with streamlined tools.

Jay Mathewson, Manager of Environment Health & Safety Kodak Alaris

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Regulatory Expertise & Intelligence

Emphasize the value of having access to up-to-date regulatory information, including changes, updates, and interpretations relevant to your industry.

Explain how this can improve compliance accuracy and reduce the risk of non-compliance.

I didn't need 15 different services giving me the same updates...Now I just use one, C2P.

Quality Assurance Director Global Medical Device Manufacturer 6

Reporting & Analytics

Highlight the solution's reporting capabilities, including generating comprehensive compliance reports, audit trails, and performance metrics. Demonstrate how these features can enable better decision-making and demonstrate compliance to stakeholders and regulators.

C2P cuts through mountains of regulations to ensure we get the most relevant information we need to do our jobs.

Senior HSE Manager Kodak

A centralised compliance management system customised to our needs.

Officer for Sustainability Management Miele

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Onboarding Support, Guaranteed Support & Issue Resolution

Guaranteed service often includes dedicated customer support teams that offer timely assistance, answering questions and resolving issues promptly. Having access to knowledgeable experts ensures you can overcome challenges swiftly and effectively, maintaining compliance without significant disruptions.

Guaranteed service often comes in the form of Service Level Agreements (SLAs) that outline specific performance standards and commitments from the SaaS provider. SLAs typically define metrics such as uptime percentages, response times, and issue resolution times. By adhering to SLAs, SaaS providers demonstrate their commitment to delivering high-quality services and provide businesses with contractual reassurances.

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Corporate Memory, Business Continuity & Disaster Recovery

Unforeseen events such as natural disasters or system failures can disrupt business operations, including compliance processes. Product Compliance SaaS solutions often include robust business continuity and disaster recovery measures. These measures ensure that critical compliance data is backed up, secured, and accessible, minimizing the risk of data loss and ensuring continuity even in adverse circumstances.

C2P secures the preservation of our corporate compliance knowledge in one place

Environmental Program Manager National Instruments

A centralized compliance management system customized to our needs

Officer for Sustainability Management
Miele



Free Trials

Free trials offer an excellent opportunity to prove your business case to success. You can involve all the key stakeholders in trialing the solution and hence offer them with hands-on experience, real-time compliance testing, gather feedback and is a low-risk evaluation option.

Smooth integrations

Having a Product Compliance SaaS solution that integrates well with the rest of the internal and external solutions being used by your organization makes it easy for the relevant stakeholders to be on board to invest in it. You could also highlight the fact that smoother integrations would mean that Product compliance and Supply chain compliance can also be worked upon simultaneously, which is a fantastic additional value.

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Data Protection & Tighter Security Protocols

One of the key areas we see IT teams enquire about is data protection and security. Emphasis on the certifications the SaaS solution holds to ensure your compliance data stays safe and secure helps strengthen your business case.



By leveraging these advantages, you can effectively showcase the value and suitability of the solution, making a strong case for its adoption and facilitating informed decision-making regarding compliance management.

Cost-Benefit Analysis

One of the most critical aspects of building a business case is conducting a comprehensive cost-benefit analysis. This analysis should compare the costs associated with implementing a product compliance SaaS solution against the expected benefits.

Consider the following factors:

Implementation Costs

Include costs such as software licensing fees, implementation services, data migration, and training.

Ongoing Costs

Account for recurring costs, such as subscription fees, regulatory content maintenance and support, software updates, and any required integrations.

Time and Resource Savings

Quantify the time and effort saved by automating manual processes and streamlining compliance workflows. Consider the productivity gains and the potential for reallocating resources to higher-value & strategic activities.

Risk Mitigation

Estimate the potential cost savings associated with mitigating the risks of non-compliance, including fines, legal actions, and reputational damage.

Return on Investment (ROI)

Calculate the expected ROI by comparing the projected benefits against the total costs over a specific timeframe. Present this information in a clear and concise manner to demonstrate the financial viability of the investment.



C2P Saves me 20-25% of my time on a weekly basis. It provides timely awareness of regulatory changes. We have not missed any regulatory changes in our space. That is extremely important and is why we feel comfortable with C2P.

Quality Assurance Director Global Medical Device Manufacturer

Engage Stakeholders

To gain agreement for the product compliance SaaS solution, it is crucial to engage and address the concerns of all relevant stakeholders. Tailor your communication to each stakeholder group, emphasizing the most relevant benefits to their roles and responsibilities.

- Procurement
- IT
- Legal
- Product
- ESG/Sustainability
- Sales

Address any potential concerns, such as data security, system integration, and user adoption. You can provide evidence of successful implementations in similar organizations or industries to build credibility and alleviate doubts.



Present a Detailed Implementation Plan

A well-defined implementation plan is essential for demonstrating the feasibility of the project.

Outline the plan for deploying the product compliance SaaS solution.

Discuss the support and training that will be provided to ensure a smooth transition and user adoption.

- 1. Key steps
- 2. Milestones
- 3. Timelines
- 4. Dependencies
- 5. Resource Requirements
- 6. Potential Risks





Highlight Industry Trends & Competitive Advantage

To strengthen your business case, provide an overview of industry trends and the competitive landscape. Discuss how adopting a product compliance SaaS solution aligns with industry best practices and positions your organization as a leader in compliance management.

Highlight any potential competitive advantages gained by having an automated, scalable, and efficient compliance solution in place.

Here are all the regulatory industry trends published by Compliance & Risks



ESG



Product Safety



Medical Devices



Apparel



Household Appliances



Consumer Electronics

Measure Success & Continuous Improvement



Lastly, emphasize the importance of measuring success and continuous improvement. Define key performance indicators (KPIs) that will be tracked post-implementation to evaluate the effectiveness of the product compliance SaaS solution.

Highlight the ability to make data-driven decisions, improve compliance processes, and adapt to changing regulatory landscapes.

C2P Product Compliance SaaS Solution

Compliance & Risks has developed an innovative technology platform, called C2P, that helps the world's leading brands comply with global regulatory changes. C2P helps compliance teams accelerate their ability to achieve, maintain and expand market access for all their products in international markets.

C2P is purpose-built to be tailored to a company's specific needs with comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence.

Add-on packages help accelerate market access through use-case-specific solutions, global regulatory content, a global team of subject matter experts and professional services.

See Figure 3 below, a screenshot from C2P Product Compliance Solution, showcasing the timeline of upcoming regulatory changes.

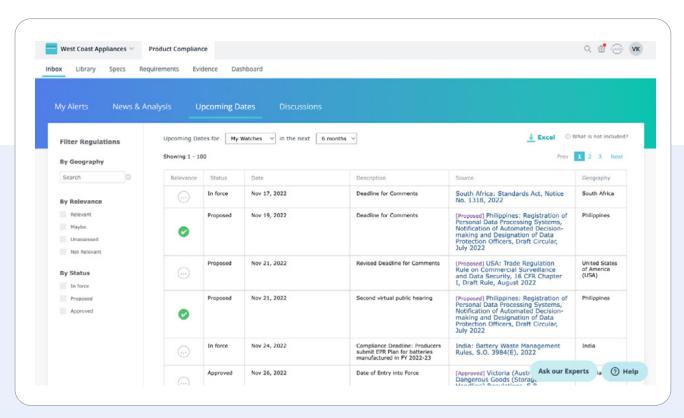


Figure 3: Timeline of upcoming regulatory changes (Source: C2P Product Compliance Solution)

There are 5 key areas that C2P Product Compliance Solution helps companies with:

- Identify relevant regulations and standards
- Interpret the regulations and standards for your products
- Communicate the regulatory requirements to the teams who need to implement them
- Determine the evidence needed to prove compliance against each of these requirements
- Monitor changing regulations and standards globally to ensure compliance at all times

C2P serves as a single source of compliance information for the teams and helps in driving a 'Zero surprises' compliance policy for the business. (See Figure 4 below, a screenshot from C2P, with live linking between regulations, standards, requirements and evidence).

To learn more about how C2P can help with your product compliance requirements, talk to us today.

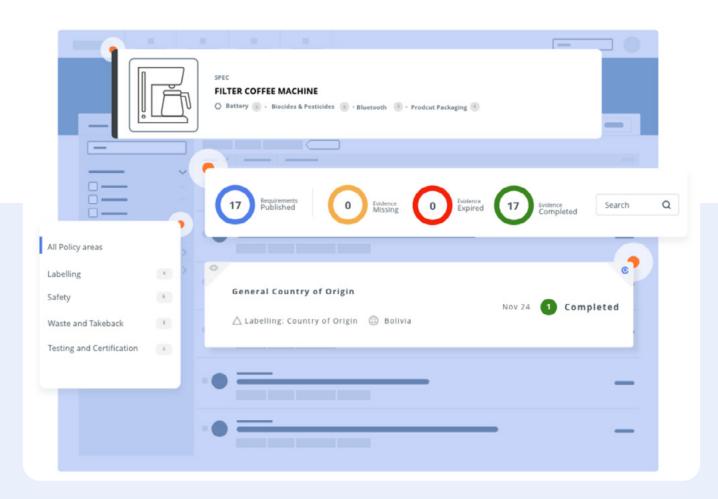


Figure 4: Product compliance management system (Source: C2P Product Compliance Solution)



Conclusion

Building a solid business case for a product compliance SaaS solution requires a thorough understanding of your organization's challenges, the benefits of the solution, and a comprehensive costbenefit analysis.

Engaging stakeholders, addressing concerns, and presenting a detailed implementation plan are critical to gaining agreement and securing the necessary resources.

By demonstrating the value of the solution in terms of efficiency, risk mitigation, and competitive advantage, you can position your organization for success in managing product compliance effectively.

Need help in putting together a business case yourself? We would love to help. Talk to us today.

Our numbers



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