

# Regulatory Policy - Global

## Document Control

<b>Policy Name:</b>	Regulatory Policy	<b>Version:</b>	1
<b>Effective Date:</b>	13Dec2022	<b>Scope:</b>	Global
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<b>Approved by:</b>	Mark Hewlett	<b>Policy Owner:</b>	Mark Hewlett



2San is committed to supply high quality, regulatory certified products across the categories of Clean, Protect, Test. 2San is headquartered in the UK and operates internationally across North America, Europe, Australia, Canada, and New Zealand and their respective regulatory authorities.

Our approach to regulatory is centred around:

- I. **Proactive** actions to ensure regulatory compliance, implemented through planned procedures, and regular coordination with jurisdictional in market representatives
- II. Appropriate **Reactive** processes in place should a regulatory issue occur
- III. **Engagement** with the regulatory bodies and building relationships to sustain future collaboration

2San partner with jurisdictional representatives to manage in-market products with varying regulatory responsibilities: *Distributor, Importer, Sponsor*. Central coordination by 2San Global, allows us to monitor regulatory commitments and respond to the needs of individual markets as required.

The *New Product Development* process considers regulatory risks in its preliminary stages and integrates Regulatory as a key indicator. 2San has chosen a risk-based approach to onboarding of suppliers to control regulatory exposure when a new product is bought to market. Early regulatory assessment is introduced to ensure that the risks are fully understood by 2San and appropriate actions can be taken in collaboration with partners and authorities.

Regulatory Forum is held fortnightly to ensure wider coordination of regulatory activities and discuss global risks centrally. This also provides an opportunity for leadership involvement, and Corporate Risk Management escalation where required.

Continuous improvement is central focus for innovation within 2San, and it is a future ambition to bring additional regulatory roles in-house as we mature as an organisation.

Every 2San employee is committed to:

- I. ***Remain compliant with all relevant standards and regulations within the required markets***

It is the responsibility of the 2San leadership team to engage with employees to ensure:

- I. ***Decisions are made via a risk-based approach***
- II. ***Regulatory responsibilities are understood across the global organisation***



Signed:

Date 13Dec2022

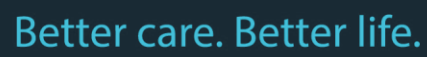
Position: Global Head of Quality & Regulatory

Signed:

Date 13 Dec 2022

Position: CEO

Reference Number	Title
GBL-SOP-001	Supplier Management Procedure
GBL-SOP-010	Recall Procedure
TBC	New Product Development



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We look forward to working with  
you to achieve a **safer and more  
secure** environment.

Better care. Better life.