

Defensible Regulatory Governance in Practice

What it actually means. And how to achieve it.

Enabled by Vertical AI

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Defensible Regulatory Scope

Maintained Over Time

Clarity • Control • Continuity

Regulatory decisions must be reconstructable

Most organisations cannot demonstrate reconstructability consistently, **on demand** and **over time**

Why this happens

- > Decisions are not structured at the point they are made
- > Rationale is incomplete or not linked to the decision
- > Evidence is stored separately from the decision
- > Ownership and review are not consistently defined
- > Regulatory updates do not trigger systematic reassessment

Defensible regulatory governance requires that every decision:

- ✓ What requirement applied (exact reference)
- ✓ How applicability was determined (interpretation)
- ✓ What decision was made (applies / not applicable)
- ✓ What evidence supports the decision
- ✓ Who is accountable and when it was reviewed
- ✓ How the decision has been maintained over time

Regulatory decisions exist

BUT THEY ARE:

- > Distributed
- > Implicit
- > Depended on context



SPREADSHEETS

Data and assessments



DOCUMENTS

Requirements, interpretations, justifications



RISK FILES

Hazard analysis, risk evaluations



EMAILS

Discussions, clarifications, decisions



REGULATORY DECISIONS



PEOPLE

Knowledge in people's heads

RECONSTRUCT THIS!

Time-consuming. Inconsistent. Not defensible.

Why this is required

Regulatory frameworks require demonstrability

A regulator must be able to:

- ✓ Identify applicable requirements
- ✓ Understand how decisions were made
- ✓ Verify supporting evidence
- ✓ Confirm decisions are maintained over time

(MDR / IVDR • FDA QSR • ICH Q10 • GMP)

Take one product

Give yourself one hour

Can you prove your decisions?

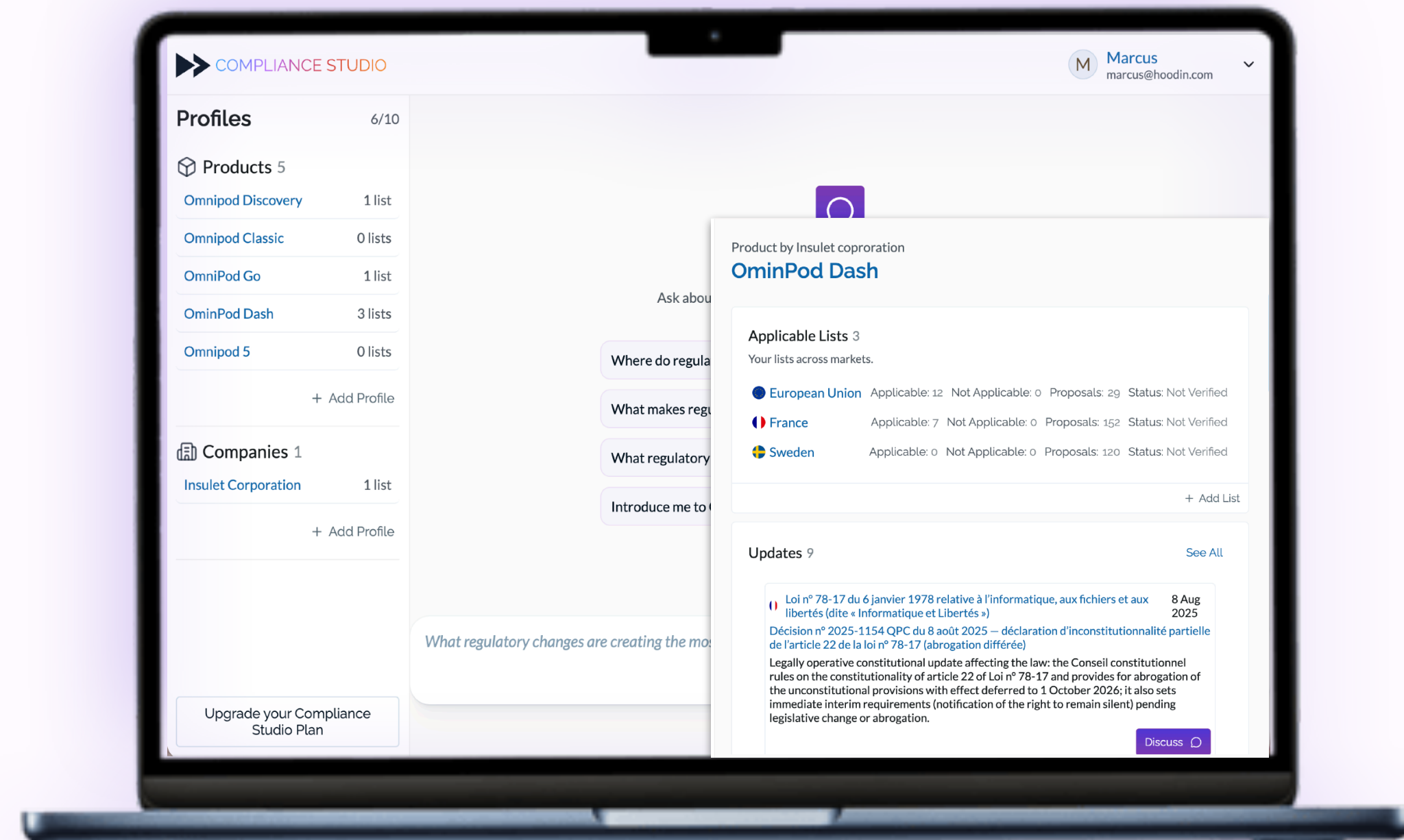


Founded to solve regulatory intelligence and applicability management for life sciences.

Over the past five years the team has built the regulatory infrastructure that powers Compliance Studio.

Core foundation

- 20,000+ regulatory instruments collected and structured
- 500+ life science professionals trained in regulatory applicability management
- 2,500+ professionals in the regulatory community
- 15 senior regulatory and QA experts in the advisory network
- Tailored regulatory AI knowledge architecture developed since 2022



Try Compliance Studio

Join thousands of regulatory professionals

Access here: www.hoodin.com

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