

The Audit Findings Nobody Sees Coming

Why organisations lose control of their regulatory position over time

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Defensible Regulatory Scope

Maintained Over Time

Clarity • Control • Continuity

Many organisations assume audits reveal problems.

In reality, audits often reveal problems that have existed for years.

The original regulatory decision may have been correct.

The challenge is that the organisation can no longer explain:

- Why the decision was made
- What information it was based on
- Whether the decision is still valid today

Regulatory positions often survive longer than the rationale behind them.

When auditors question a regulatory decision, organisations often discover that the position still exists, but the original reasoning cannot be reconstructed.

2023 Regulatory Position Established
(MDR applicable, rationale documented)



2024 New market added



2025 Product updated



2026 Regulation amended



2027 Original RA manager left company



REGULATORY POSITION STILL ACTIVE

- ✓ Original rationale missing
- ✓ Assumptions unknown
- ✓ Décision makers gone
- ✓ Scope never reassessed

The regulatory position remains,
The rationale does not.

- Why is this regulation not applicable?
- What evidence supports that conclusion?
- How do you know the conclusion is still valid today?

Most organisations can answer the first question.

Many struggle with the second.

Very few have a systematic answer to the third.

- Why regulatory positions become difficult to defend
 - How regulatory positions evolve over time
- Common governance failures behind audit findings
 - Why regulatory updates require reassessment
- What continuous regulatory governance looks like in practice

Continuous awareness is becoming an operational expectation

Regulatory change assessment is increasingly becoming a continuous operational obligation.

MDR Article 10

IVDR Article 10

ISO 13485 lifecycle obligations

PMS responsibilities

State of the art expectations

Notified Body scrutiny

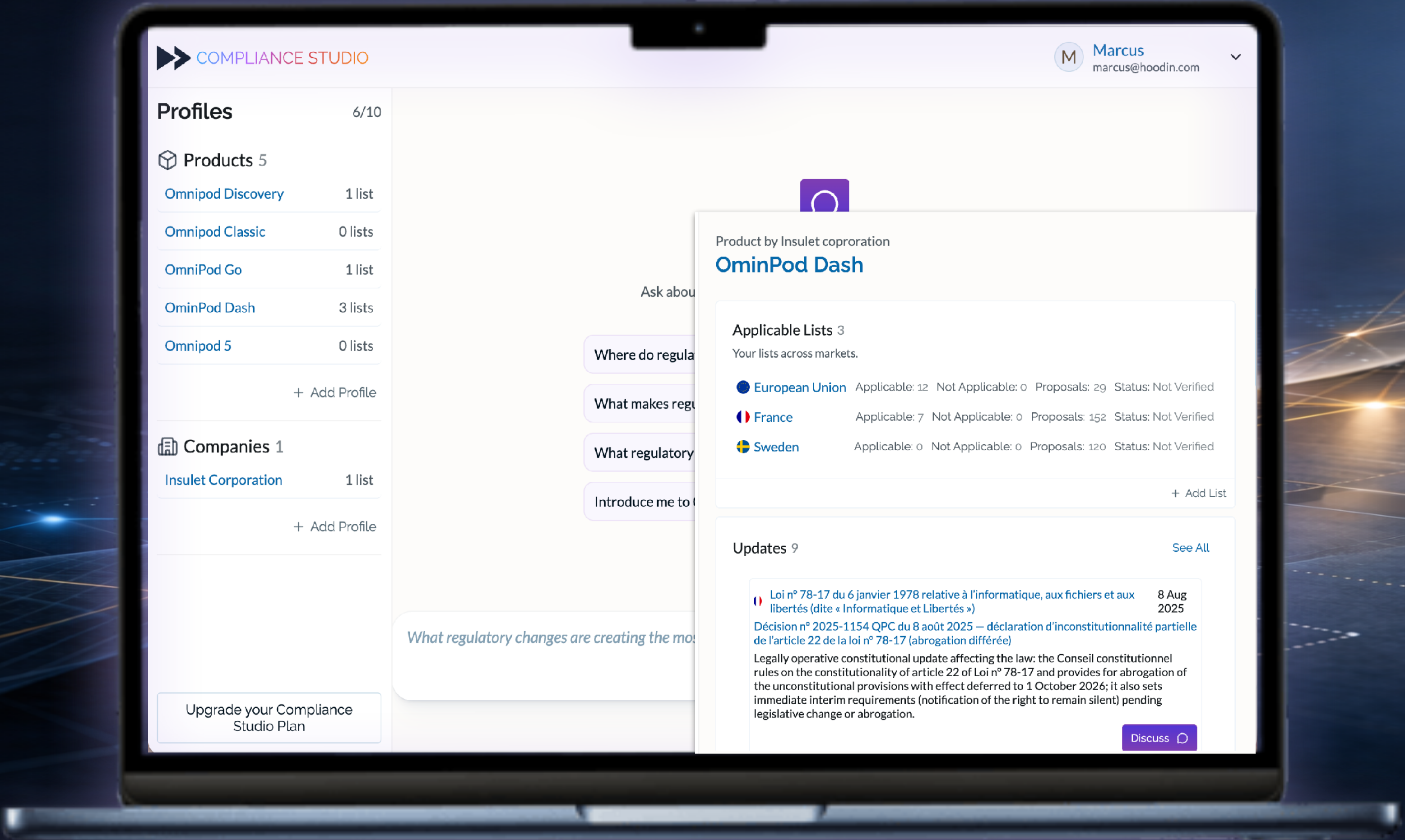
FDA quality system expectations

Generic AI (ChatGPT, Gemini, Claude etc.)

disconnected prompts
isolated outputs
no maintained context
difficult traceability

Vertical AI

maintained regulatory context
applicability reasoning
linked scope
reassessment continuity
governance structure



COMPANY & ACCESS

COMPLIANCE STUDIO

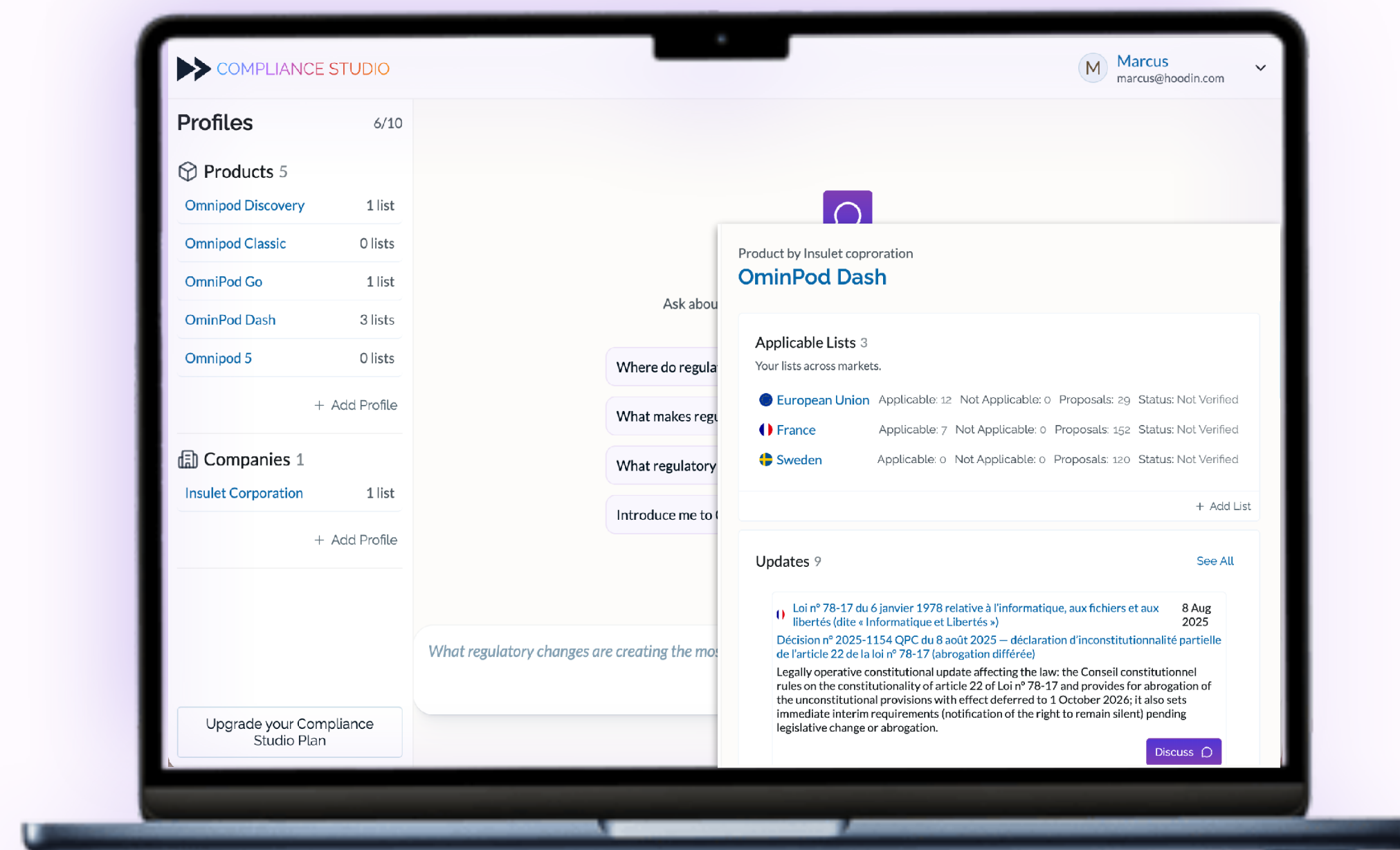
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