One Health Compliance

Regulatory strategy & Problem-solving.

Expertise, presentation & solutions

Human Health | Animal Health

Medical devices & Diagnostics

From uncertainty to a clear strategy: expertise in medical devices, diagnostics and care or wellness products for human health and animal health.

Content

About
One Health Compliance

Whether visible or not, regulatory uncertainty always has an impact. The difference is when you act.

Our mission

One Health Compliance supports companies developing and commercialising medical devices, in vitro diagnostics, and care or wellness products for human and animal health, in their regulatory strategy and compliance challenges.

Even with an internal regulatory team, blind spots remain: an evolving regulatory framework, a borderline product that is difficult to qualify, an unexplored market, a non-conformity quietly taking hold.

The consequences often appear late but hit hard: delayed market access, unexpected costs, missed funding opportunities, stalled R&D projects.

Our role: to be the partner who removes uncertainty, anticipates risks, and identifies the opportunities that regulatory complexity can cause you to miss. Because a solid regulatory strategy, built at the right time, means: time saved, resources preserved and projects that succeed.

What makes us unique

Dual human–animal expertise, rare worldwide

We are **one of the only consultancies in the world** with expertise in regulatory requirements for medical devices and in vitro diagnostics in both human and veterinary medicine. This cross-expertise opens **opportunities: transposing an innovation** from the veterinary field to human health, or vice versa, while anticipating all regulatory and clinical impacts from the outset.

An integrated strategic vision: regulation, R&D, marketing, innovation

Beyond compliance, we act as a strategic partner serving **your business objectives.** Our expertise integrates directly with the challenges of marketing, R&D and innovation so that regulation becomes a **project accelerator,** not a friction point.

Resolving uncertainties, quickly

Regulatory grey areas, borderline products, urgent non-conformities, investment decisions to secure: we specialise in **the rapid identification of concrete, actionable solutions.** Where uncertainty blocks, we bring clarity and an action plan.

A recognised European reference: Animal Health Europe and Health for Animals have called on One Health Compliance for reference work on the regulation of veterinary medical devices.

Our founder

“I founded One Health Compliance in 2017 with a deep conviction:

regulation is not a constraint to be worked around. It is a tool for protection, structuring and differentiation. It requires demonstrating the real value of a product, identifying its contribution relative to existing alternatives, and targeting the right market with the right evidence. When properly mastered, it becomes a genuine development accelerator.

With nearly **20 years of experience** in regulatory affairs, quality, clinical and R&D, I **have supported companies of all sizes** in obtaining CE markings and regulatory approvals for market entry in **France, Europe and internationally.** What drives me most in this profession is solving complex problems: turning regulatory uncertainty into clear decisions, unblocking stalled projects, identifying opportunities where others see only constraints.

As a pharmacist, I believe deeply that our role is to do everything possible to ensure that **solutions with real clinical benefit** reach those who need them quickly and safely whether patients or animals. That is what drives and motivates me every day. ”

— **Sandra Dejean,**
Doctor of Pharmacy, Certified
ISO 13485 Lead Auditor

At One Health Compliance, we step in where uncertainty remains to turn grey areas into clear decisions, and hidden risks into **concrete opportunities.**

Founding history

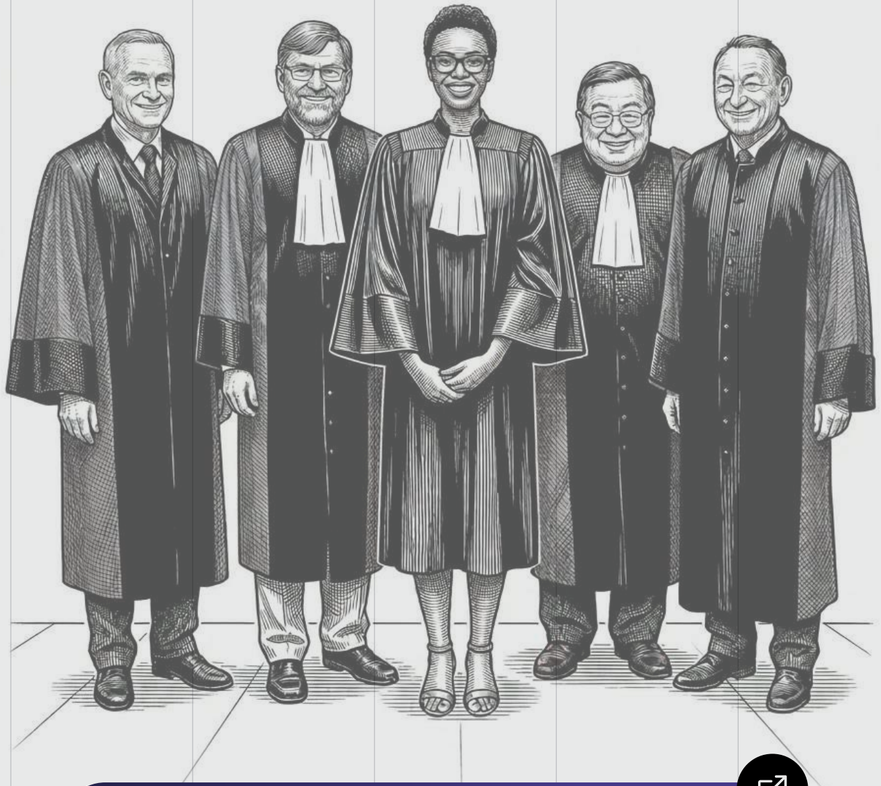
“ **My dual human–animal expertise originated in a question asked more than ten years ago by an equine veterinarian:** could a medical device designed for humans be used on a horse?

Faced with the regulatory uncertainty surrounding this question, **I made it the subject of my thesis.** In exploring this field, I realised that **many companies did not dare venture into animal health** held back by unfamiliarity with the market and the absence of clear regulatory benchmarks.

But the One Health concept also works the other way: **innovations developed for animal health can benefit human health.** The COVID crisis illustrated this vividly: the veterinary industry was able to produce rapid diagnostic tests quickly and at scale, making a direct contribution to the human pandemic response.

It is this circularity between the two fields that I wanted to place at the heart of One Health Compliance: supporting companies in both directions, from human to animal, but also from animal to human.

I then adapted the One Health concept to my profession: removing those barriers and supporting companies that want to explore and conquer this market, with the same rigour and ambition as in human health. ”



Veterinary expertise
Thesis Award
French National Academy of Pharmacy · 2016

We work with

One Health Compliance supports a diverse range of clients, united by a common need: **moving forward with clarity in a complex regulatory environment.**

Startups and SMEs developing medical devices, diagnostics, or care and wellness products – for humans, animals, or both – who need a regulatory partner to structure and accelerate their project.

R&D, marketing and innovation teams seeking an external perspective to unblock a situation, secure a decision or explore a new market.

International companies wishing to understand and meet French and European requirements for their health products.

Investors, whether from the veterinary industry seeking innovative projects or business angels in human health, looking to evaluate the regulatory potential and risks of an opportunity before committing.

&

Any company facing a **regulatory qualification question,** particularly on borderline products where answers are never straightforward.

Enhanced expertise, tailored to your project's needs

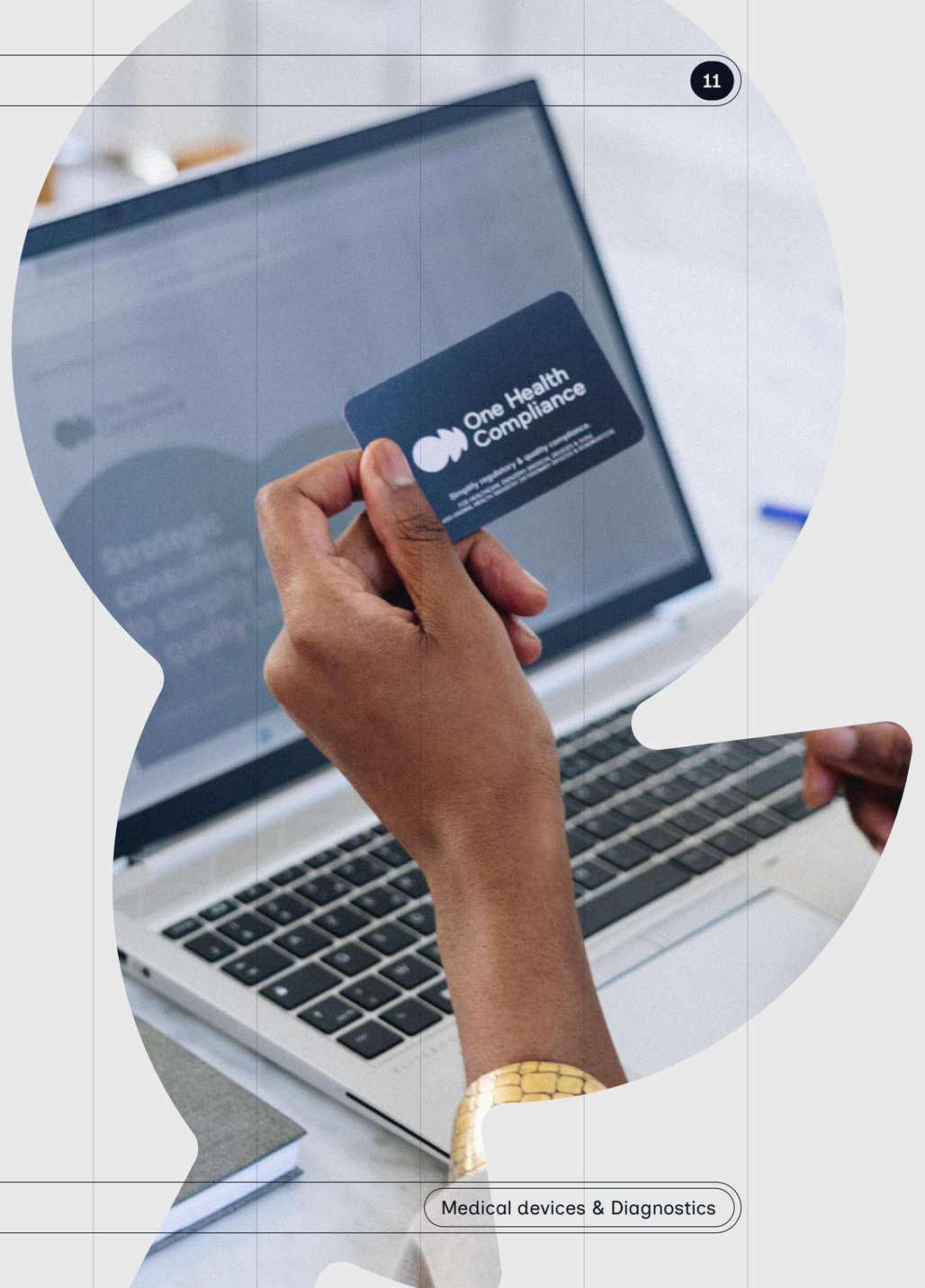
“ Every project has its own specificities. When your situation calls for it, I bring in carefully selected experts recognised for their excellence in their field: clinical trial expertise, biostatistics, marketing specialised in the equine sector, and other profiles as needed.

These collaborations are built on trust, continuity and high standards. I remain your dedicated point of contact and project manager throughout the mission, ensuring the cohesion, quality and efficiency of the whole. ”

The first step takes just 15 minutes.

Book a discovery call directly with Sandra Dejean to discuss your project and challenges.

Book my 15-minute call



Key figures

20 years
of hands-on experience across all project stages

30%
of projects concern animal health

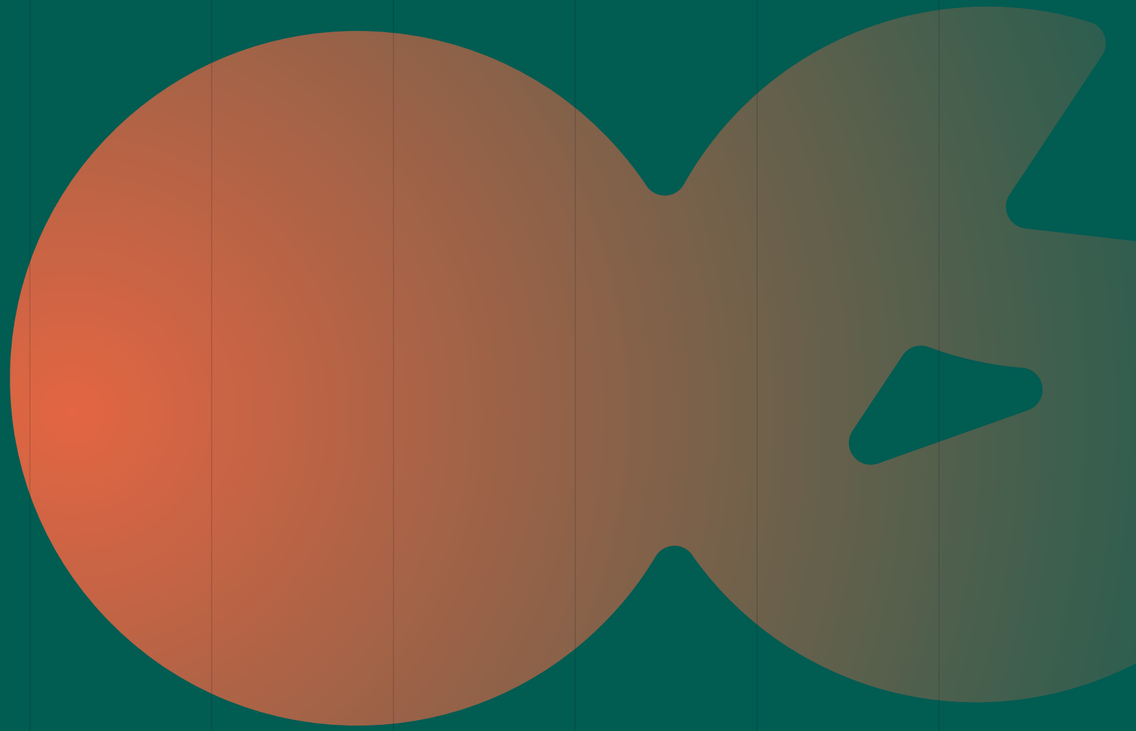
25%
of clients are based internationally

European reference
Reference work conducted for Animal Health Europe and Health for Animals on veterinary medical devices and diagnostics regulation

13 countries & regions
Regulatory approvals obtained on 4 continents

32 countries
covered in a single regulatory strategy project

100%
of responses to authorities accepted



Our solutions

→Technical Day → Project Audit → Problem-Solving Workshop

There is no one-size-fits-all solution to regulatory complexity. That is why One Health Compliance has developed three complementary solutions, each tailored to a specific project situation and always personalised to your context, constraints and objectives.

Solution 1

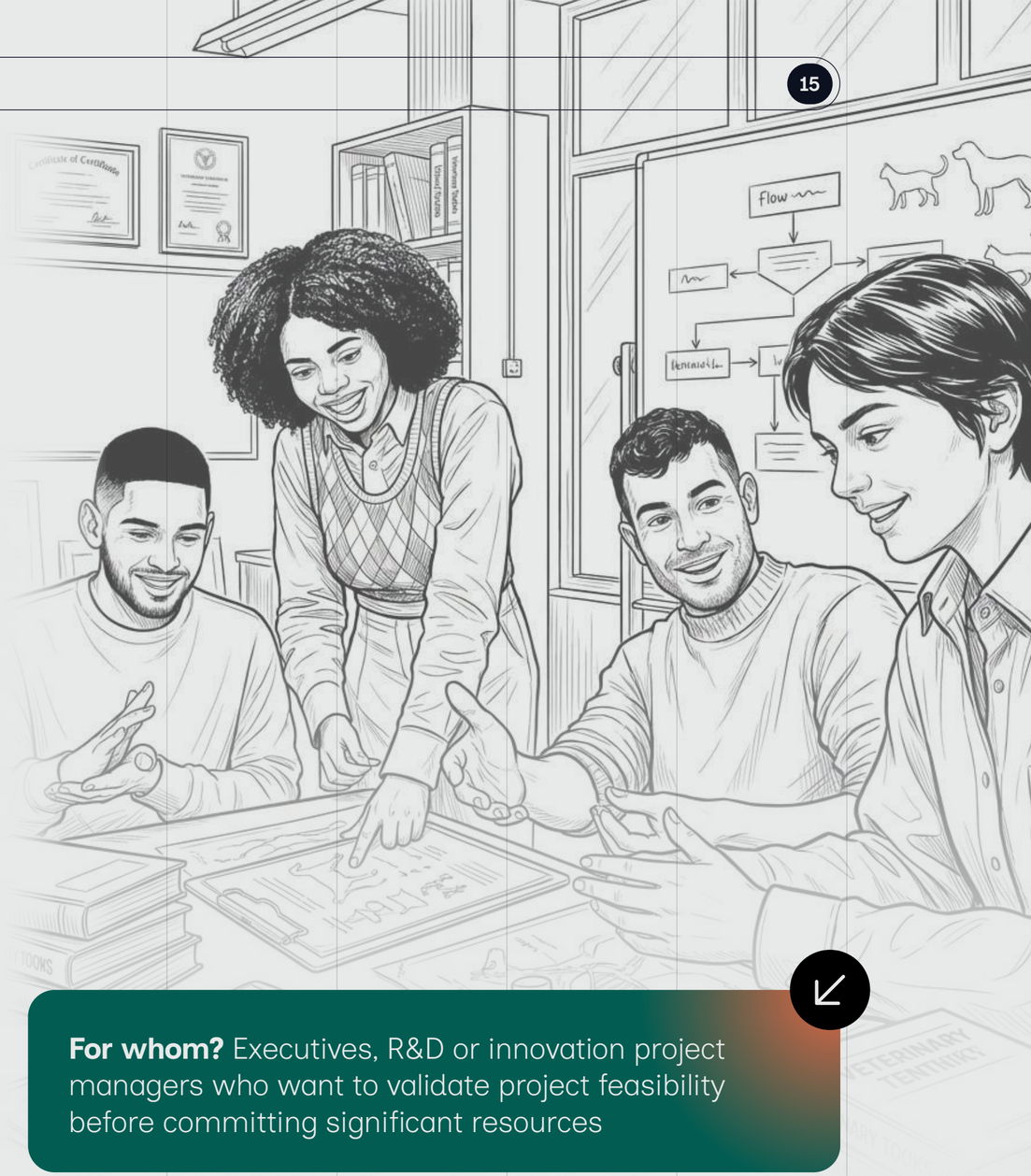
Technical Day

You have a promising idea or concept. Before investing, you need to know what you are getting into.

The Technical Day is a **rapid, structured decision-making tool** designed for projects at the **idea or proof-of-concept stage.** In a single day, in a small group, we review together all the parameters that will condition the success of your project.

What you get:

- A clear view of regulatory, technical, quality, clinical and strategic considerations to anticipate.
- An assessment of the impact on your timeline and resources.
- Concrete recommendations to manage financial and business risks.
- Information needed to decide with confidence: proceed, adapt or pivot.



For whom? Executives, R&D or innovation project managers who want to validate project feasibility before committing significant resources

Solution 1

Technical Day

Process

Example of a completed project: Mid-sized company – Adaptation of a human health technology for veterinary use.

Initial Situation

Technology already commercialized for human use.

Strategic question

Veterinary feasibility (horses, dogs, cats)?

Technical Day

One Health Compliance

- In 1 day
- In small groups
- Critical project parameters reviewed

Topics covered during the day

Veterinary regulations
Applicable requirements under different scenarios.

Existing data
Review of the reuse of human data.

Impact on planning & costs
Estimated timelines and resources.

Risks & opportunities
Market launch strategy.

Results

- Action plan
- Regulatory roadmap
- Estimated budget

Concrete impact: Meeting internal deadlines · Informed GO/NO GO decision.

Solution 2

Project Audit

Your project is underway. You want to make sure you are on track or identify what is blocking before it becomes too costly.

The Project Audit is an in-depth, structured analysis in 4 phases, drawing on Sandra Dejean's **ISO 13485 Lead Auditor** expertise and 20 years of hands-on problem-solving. It can be conducted **at any stage of your project lifecycle,** including in the context of a **funding process** or **due diligence.**

What you get:

- A precise mapping of critical and non-critical issues in your project.
- A prioritised, actionable action plan or remediation plan.
- Strategic options with their respective advantages, disadvantages and associated risks.

For whom? Executives, investors, R&D or marketing directors who want to secure a project, overcome an obstacle, or prepare for a fundraising round.

Solution 2

Project Audit

Process

Example of a completed project: A startup developing an AI-powered disease detection tool - regulatory strategy and partnerships.

Initial Situation

- Innovative project
- Goals: Market launch in Europe and the United States
- Partnership options to be evaluated

Project Audit
by One Health Compliance

Phase 1
Preparation
- Scope definition (context, resources)
- Business objectives
- Collection of available data on the AI product

Phase 2
Assessment
- Classification
- CE and FDA labeling requirements
- Impact of partnership scenarios

Phase 3
Alignment Workshop
- Strategic options
- Benefit/risk by scenario
- Priority decisions

Phase 4
Debriefing
- CE Roadmap
- FDA Roadmap
- Partnership recommendations

Results
- Clear EU + US Strategy
- Informed partnership choice

Tangible Impact: Accelerated Project · A structured regulatory strategy that secured new funding.

Solution 3

Problem-Solving Workshop

You are facing an urgent regulatory problem. You need concrete solutions, fast.

Drawing on **20 years of problem-solving expertise,** One Health Compliance can deliver **an action plan within days.** The workshop brings your project team together in a **collaborative, structured format** moving from problem identification to solution selection **without losing time.**

What you get:

- A clear identification of problems, their root causes and your company's constraints.
- Resolution options evaluated and compared (timeframes, feasibility, advantages, risks).
- A selected, operational action plan with milestones and responsibilities.
- Implementation support and, if desired, guidance to prevent recurrence.

For whom? Any team facing an urgent non-conformity, a regulatory blockage or an imminent inspection.

Solution 3

Problem-Solving Workshop

Process **Example of a completed project:** Large company – Project stalled for 1 year due to issues with the clinical evaluation strategy

Critical situation

- New medical device
- Stalled for 1 year
- Clinical study deemed too long and costly

Problem-Solving Workshop
by One Health Compliance

Step 1
Identification of the problem
- Analysis of the bottleneck
- Regulatory constraints
- Available internal data

Step 2
Identification of options
- Analysis of the clinical evaluation strategy
- Alternatives to pre-CE marking clinical investigation

Step 3
Selection of the action plan
- Equivalence strategy validated
- Compliant
- No premarket clinical study

Step 4
Implementation
- Drafting of the clinical evaluation report and clinical follow-up plan
- Technical documentation

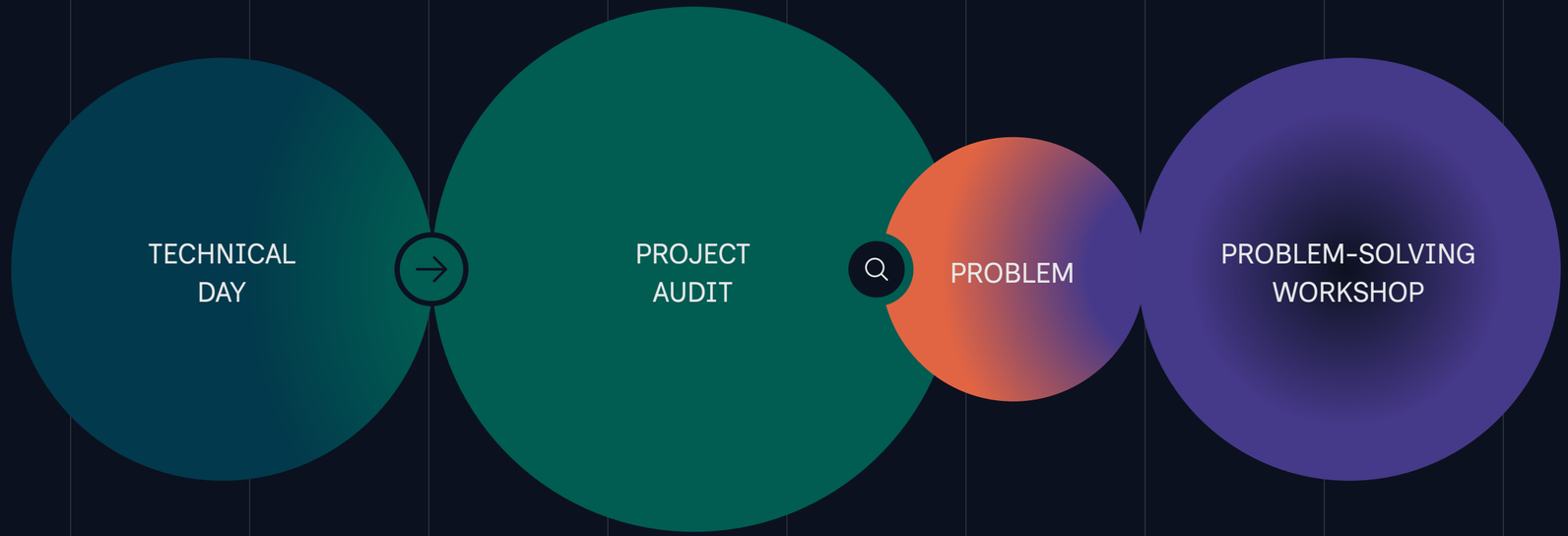
Results
- Project unblocked
- CE marking obtained
- Product marketed

Tangible impact: One-year bottleneck resolved · Clinical trial costs avoided · Unmet clinical need addressed.

These three solutions can be combined

The Technical Day can precede a Project Audit. An Audit can reveal a problem requiring a Problem-Solving Workshop.

One Health Compliance supports you on all or part of the journey according to your needs, stage of development and resources.



Case Studies

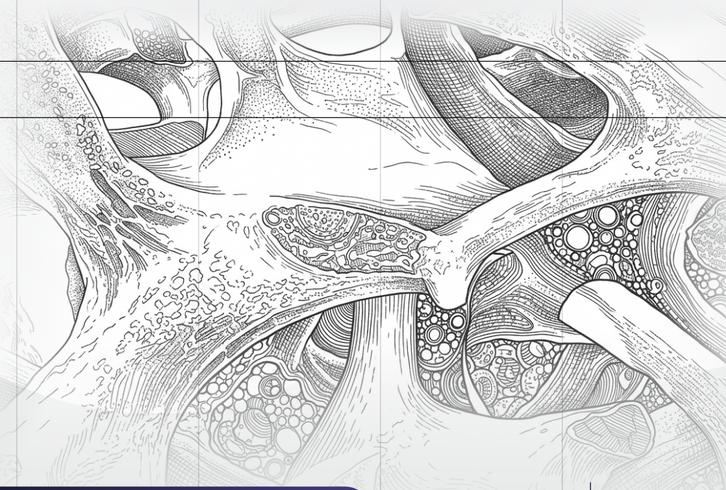
→ Securing a Funding Round → Humain → veterinary → Quickly mitigate risks → Unblocking under urgency → CE renewal

These case studies illustrate the diversity of situations in which One Health Compliance intervenes and how strategic regulatory expertise can unblock, accelerate or secure a project.

Case 1

Securing a startup during a funding round.

French startup | Biomaterial in dermatology



Biomaterial

Context

A startup in the process of structuring and fundraising was developing two topical products based on an innovative biomaterial.
With no defined regulatory qualification, no internal regulatory team, and investors to convince, the company needed clarity...and fast.

Challenge

The absence of regulatory visibility directly threatened the project's viability: incorrect claims, unsuitable testing, delays at submission, cost overruns. Errors at this stage could have jeopardised the fundraising round.

The One Health Compliance solution

Definition of clear, concrete regulatory strategic scenarios understandable by non-specialists with impact analysis for each option, associated regulatory and quality roadmap, and prioritised decision criteria to move forward quickly.

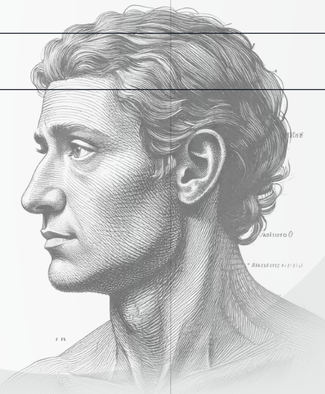
Results:

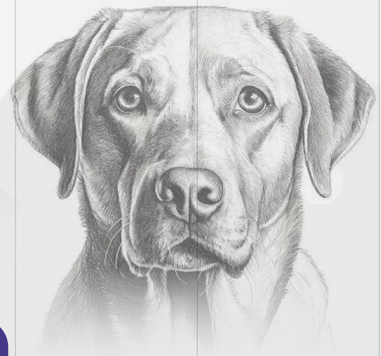
- Fast, secure decision-making
- Decision-support tool directly usable for investor discussions

Case 2

From human to veterinary market.

Large international company | Molecular diagnostics





Context

A large international company wanted to assess the feasibility of extending its molecular diagnostic platform already approved in human health to the veterinary market (companion animals and horses), across 32 countries including Europe and the United States.

Challenge

Speed was critical: the project had to be presented to the executive committee for a GO/NO GO decision. The company needed a complete regulatory strategy integrating the specificities of each target market, the potential for reuse of existing human data, and options for early discussions with authorities.

The One Health Compliance solution

Delivery of a tailored regulatory strategy covering 32 countries, with country-by-country requirements mapping, optimisation of synergies between human and veterinary data, and recommendations for early interactions with authorities (including the USDA).

Results:

- The executive committee had all the elements needed to make its decision on time

Case 3

Quickly mitigate risks for a clinical study.

Canadian Startup | Innovative medical device

Context

A Canadian startup was submitting a clinical study application in the EU for an innovative medical device. During initial review, the competent authority issued a non-validation, questioning the product's classification with a direct risk to the CE marking and the market launch timeline.

Challenge

Resolving the situation quickly without jeopardising the overall project strategy. The team, unfamiliar with European requirements, needed clear, operational guidance.

The One Health Compliance solution

Rapid situation analysis, definition of a response strategy compliant with European requirements, leveraging of existing internal data, and direct management of certain activities to meet deadlines.

Results:

- The clinical study application was validated by the competent authority
- The project resumed without impact on the timeline

Case 4

Unblocking a US regulatory approval under urgency.

Large international company | Veterinary diagnostic

Context

A very large international company had already planned the commercialisation of a veterinary diagnostic in several countries when an unexpected blockage from the US authority arose at the last minute: a regulatory requirement had not been anticipated, directly threatening the launch timeline.

Challenge

Finding an urgent solution in a particularly complex context: European requirements do not provide for an official marketing authorisation for this type of product, making the US authority's request seemingly impossible to satisfy.

The One Health Compliance solution

Identification of an unexpected strategic option: obtaining an attestation from a competent authority in a European Union country, to be presented to the U.S. authority.

One Health Compliance obtained the signature of an official document previously drafted and argued, and then sent a well-substantiated response letter to the U.S. authority.

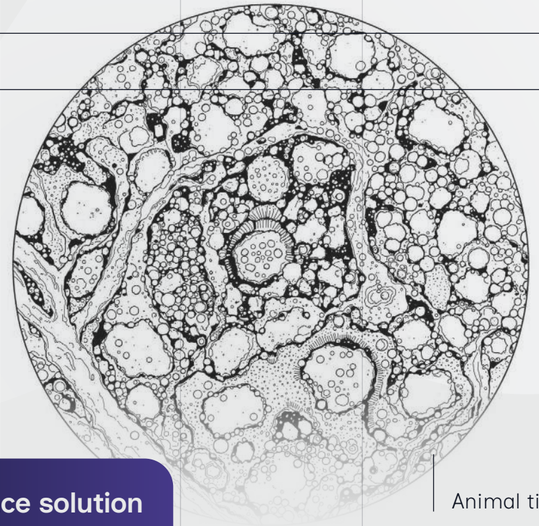
Results:

- The US authority accepted the submitted documentation
- The registration process was not expanded
- The client launched commercialisation as planned with no delay

Case 5

CE renewal of an animal-derived implantable device.

French SME | Implantable device commercialised for over 30 years



Animal tissue 400x

Context

An animal-derived implantable device commercialised for over 30 years required CE marking renewal in a context of significantly strengthened regulations. The notified body raised numerous questions about risk management related to the animal origin and the maintenance of clinical benefit.

Challenge

Reconstructing traceability and the formalisation of design choices for an ageing product with no structured documentation while demonstrating compliance with new requirements and preserving market access.

The One Health Compliance solution

Deployment of a reverse engineering approach to reconstruct the design history, formalise risk analyses, and gather key data from animal-derived biomaterial suppliers. Assembly of a complete file including applicability reports, specific risk management, and clinical benefit review.

Results:

- File accepted by the notified body
- CE marking maintained and commercialisation continued

Let’s take action

A project to launch, a situation to unblock, a decision to secure? Let’s talk.

The first step takes just 15 minutes.

Book a discovery call directly with Sandra Dejean to discuss your project and challenges.

Book my 15-minute call

Prefer to write or call?

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Based in France · Operating across Europe and internationally

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