



Regulatory Readiness Support for a Class IIa Therapeutic Medical Device (TGA)

CASE STUDY



Background



- ◆ A medical device manufacturer developing a therapeutic vaping device for smoking cessation sought regulatory support to prepare for interaction with the Australian Therapeutic Goods Administration (TGA).
- ◆ The device fell within the medical device regulatory framework and required structured alignment with the Essential Principles, including clinical justification and documented safety and performance evidence.
- ◆ The manufacturer had invested significantly in product development and supporting documentation but was cautious about initiating a full Clinical Evaluation Report (CER) without first validating regulatory expectations.



Key Regulatory Challenges



1

Clinical Evidence Uncertainty

Determining whether existing published literature and available data would be sufficient to justify safety and performance, or whether additional clinical investigation might be expected.

2

Proportionality of Clinical Strategy

Avoiding unnecessary over-commitment to a full CER prior to regulator feedback, while still demonstrating regulatory rigor.

3

Essential Principles Alignment

Ensuring that existing documentation could be clearly mapped against the Essential Principles in a regulator-ready manner.

4

Preparation for Regulator Dialogue

Structuring evidence and rationale to support confident discussion with the TGA, without triggering avoidable follow-up requests.

Elexes' Approach

1 CER Proposal Development

Rather than drafting a full CER, Elexes developed a CER Proposal Document designed specifically for regulator engagement.

This includes:

- A defined clinical evaluation methodology
- A structured literature review framework, including intended databases and search logic
- Clear inclusion and exclusion principles for clinical evidence
- A benefit–risk narrative approach focused on safety and performance
- Explicit boundaries around scope, avoiding unsupported claims or assumptions

This allowed the manufacturer to present a credible, transparent clinical strategy to the TGA while retaining flexibility based on feedback.



Elexes' Approach

② Essential Principles Compliance Checklist

In parallel, Elexes conducted a one-on-one Essential Principles mapping exercise, involving:

- Review of existing technical, quality, and safety documentation
- Direct mapping of evidence against each applicable Essential Principle
- Identification of confirmed compliance areas and documentation gaps
- Delivery of a structured Essential Principles checklist suitable for internal review and regulator discussion



This exercise established a clear baseline for compliance readiness.



Results and Impact

- ◆ The manufacturer gained a regulatory-ready clinical strategy proposal
- ◆ Essential Principles alignment was documented in a structured, defensible format
- ◆ Regulatory risk was reduced prior to submission or notification activities
- ◆ The manufacturer was positioned to engage the TGA with clarity and confidence
- ◆ Future regulatory steps could be planned based on regulator feedback, not assumption





Broader Applicability

This engagement demonstrates Elexes' capability in supporting:

- 1 Therapeutic vaping and inhalation-based medical devices**
- 2 Medical devices relying on literature-based clinical justification**
- 3 Early-stage TGA regulatory planning and readiness**
- 4 Manufacturers seeking proportional, risk-based regulatory strategies**

The same approach is directly transferable to other therapeutic delivery devices, patient-operated medical devices, and Class IIa products requiring structured Essential Principles alignment.

