



**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.

