End-to-End TGA Approval for a Therapeutic Nebulizer Device

Elexes

PROBLEM STATEMENT

- A MedTech company developing a therapeutic nebulizer device intended to deliver medications for respiratory therapy sought to obtain approval under the Australian TGA framework.

- Classified as a Class IIb device, it required a conformity assessment followed by inclusion in the Australian Register of Therapeutic Goods (ARTG).

- The client required support to develop a regulator-ready evidence package, address complex device safety and performance requirements, and navigate end-to-end interactions with the TGA.

KEY CHALLENGES

- **Device performance consistency –** Demonstrating reliable and repeatable aerosol delivery across variable patient use conditions.
- **Biocompatibility of patient-contact materials –** Ensuring mouthpieces, tubing, and reservoirs complied with ISO 10993.
- **Toxicology and emissions testing –** Interpreting extractables, leachables, and aerosol emissions results to confirm patient safety.
- **Electrical & EMC safety –** Meeting IEC 60601-1 and related inhalation-device standards.
- **Human factors and usability –** Mitigating misuse risks, especially for home-based therapy patients.
- **Clinical evidence strategy –** Defining whether a literature-based justification was sufficient, or whether supplemental validation was needed.
- **Regulatory engagement –** Anticipating Additional Information (AI) requests, ensuring balanced disclosure, and minimizing approval delays.

OUR APPROACH

Elexes provided comprehensive device-side regulatory support:

- **Regulatory pathway mapping:** Confirmed Class IIb status (due to administering medicine by inhalation) and defined the TGA conformity assessment requirements, focusing on achieving a TGA Conformity Assessment Certificate by demonstrating compliance with the Essential Principles.

- **Technical documentation:** Prepared structured files (Dossier) to meet the Summary of Technical Documentation (STED) format, covering Design and Manufacturing Information, Verification and Validation (V&V) results, and the Usability Engineering File (IEC 62366-1).

- **Risk management (ISO 14971):** Developed a comprehensive Risk Management File, integrating risk-benefit analyses derived from toxicological data (E&L, emissions), biocompatibility, electrical safety (IEC 60601-1), and aerosol performance consistency to demonstrate risks are reduced to As Low As Possible (ALAP).

- **Performance and safety testing:** Defined and reviewed specialized testing protocols, including Aerosol Performance Characterization using Cascade Impaction; flow rate consistency; Emissions testing (VOCs, particulates) per ISO 18562; and reliability and shelf-life studies.

OUR APPROACH

- **Biocompatibility strategy:** Reviewed and executed ISO 10993-series compliance plans (e.g., Cytotoxicity Part 5, Sensitization Part 10, and Irritation Part 23) for all patient-contact materials (mouthpiece, tubing, reservoirs), classifying contact duration and type as Limited/Prolonged Contact with the respiratory tract.

- **Clinical evidence planning:** Developed a Clinical Evaluation Plan (CEP) and executed a rigorous Clinical Evaluation Report (CER) based on a systematic literature review (SLR), mapping device performance outcomes to equivalent, legally marketed nebulizer data to establish a strong equivalency justification and scoping minimal supplemental clinical/human factors validation.

- **End-to-end TGA interaction:** Compiled the complete Conformity Assessment Submission Dossier, proactively addressed potential Additional Information (AI) requests related to aerosol variability and E&L threshold justification, and managed all subsequent TGA queries to maintain assessment momentum

RESULT AND IMPACT

- TGA conformity assessment completed successfully, without major deficiencies.
- ARTG inclusion achieved within projected timelines, enabling timely commercialization.
- A robust technical and clinical documentation package was created, which also strengthened post-market surveillance readiness.
- The client gained a regulator-ready compliance framework, reusable for future device iterations.
- Market entry was accelerated by aligning evidence with TGA expectations from the outset.

BROADER RELEVANCE

The approach taken here is directly transferable to other therapeutic delivery devices requiring TGA approval, including:

- Inhalers (Dry Powder / Metered Dose Inhalers)
- Wearable infusion pumps (e.g., insulin, pain management)
- Autoinjectors for biologics and vaccines
- Nasal drug-delivery devices

These device types all share similar regulatory hurdles around technical documentation, biocompatibility, safety testing, human factors, and evidence justification.

WHY IT MATTERS

- **Accelerated approval:** Avoided unnecessary trial requirements through strong upfront evidence planning.
- **Smart compliance:** Balanced the level of detail shared with regulators to avoid over-disclosure or under-preparedness.
- **Transferable expertise:** Elexes' proven methodology can be applied across therapeutic delivery devices, helping clients achieve faster, smoother, and more confident market entry.