



TGA Regulations for IVDs: Introductory Course

Course Overview:

Understanding and complying with Therapeutic Goods Administration (TGA) regulations is vital for the success of any business operating in the In Vitro Diagnostics (IVD) market in Australia. This introductory course offers a clear and comprehensive overview of the TGA regulatory framework, including key definitions, roles, and processes related to IVDs.

Designed for those new to the field or seeking to strengthen their regulatory knowledge, this course ensures participants are equipped to navigate TGA requirements and maintain compliance throughout the product lifecycle.

What You Will Learn:

- **TGA Regulatory Framework:** Learn the essential elements of TGA regulations and what they mean for IVDs.
- **Key Terminology:** Understand crucial definitions and terminology used in the TGA regulatory framework, helping you stay compliant.
- **Australian Register of Therapeutic Goods (ARTG):** Gain a clear understanding of the ARTG, including how to register your products and navigate conformity assessments.
- **Sponsor and Manufacturer Responsibilities:** Learn about the roles and responsibilities of sponsors and manufacturers in managing compliance with TGA regulations.
- **Introduction to TGA Structure:** Familiarise yourself with the organisational structure of the TGA and its core functions.

Learning Outcomes:

- Develop a solid understanding of the TGA regulatory landscape for IVDs in Australia.
- Gain clarity on the roles of sponsors, manufacturers, and other stakeholders in regulatory compliance.
- Learn the key steps for registering products on the ARTG, including market authorisation and conformity assessment requirements.
- Understand the core definitions and terms that underpin the regulatory framework, ensuring you stay compliant throughout the product lifecycle.

Who Should Attend?

This course is ideal for professionals in regulatory affairs, quality assurance, product development, or anyone involved in the manufacturing and distribution of IVDs. It's also well-suited to individuals seeking to deepen their understanding of Australia's regulatory requirements as they apply to IVDs, including new entrants to the industry.