

Course Title:

IVD Australia: Fees for Including an IVD Device on the TGA or ARTG

Product ID: N154

Duration: 43 mins

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First Released On: 05/17/2017

Course Description:

This course examines the fees and charges related to making applications to either the Australian Therapeutic Goods Administration (TGA) for conformity assessment certificates or the Australian Register of Therapeutic Goods (ARTG) for the inclusion of IVDs. It also describes the provisions available for reduced fees and the circumstances in which they may be granted.

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, trainees will be able to:

- Understand the nature and structure of fees and charges for TGA and ARTG applications
- Determine whether an application is eligible for reduced fees

Who Should Enroll:

Regulatory affairs professionals driving market access for IVDs in Australia are encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following courses are required:

- IVD Australia: Basics for Including an IVD on the ARTG (ID N150)
- IVD Australia: The Use of GMDN Codes for IVDs in Australia (ID N151)
- IVD Australia: Making Applications for Inclusion on the ARTG (ID N152)
- IVD Australia: Obtaining a TGA Conformity Assessment Certificate for IVD Devices (ID N153)

Price:

Premium: €129.00.- **Basic:** €172.00.-

Course Format:

All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: <http://www.adobe.com/products/flashplayer>).

Premium Account Holders:

Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.