

Are Toxicologists Certified?

We often get asked the question, "Is toxicologist certified?". To answer this question, it is important to ascertain exactly what is the question that you are trying to answer.

First, there is no independent organization in the world that "certifies" on a company-wide basis as being qualified to prepare OEL/ADE/PDE monographs. Certifications such as ISO 9001, ISO 14001, OHSAS 18001, etc are management system certifications - not toxicology certifications; therefore, ISO or OHSAS certifications are meaningless in regards to the preparation of health-based exposure limit monographs (ADE, PDE, HBEL). These three certifications have little to no applicability to the field of toxicology.

Second, there are two organizations in the world that "certify" individuals as toxicologists. These organizations are as follows:

- American Board of Toxicology (ABT)
- European Registry of Toxicology (ERT)

Individuals that are certified by the American Board of Toxicology are considered Diplomate American Board of Toxicology (DABT) or those listed in the European Registry of Toxicology are considered European Registry of Toxicology (ERT). These certifications are not company-specific and follow the specific individual when they change employers.

While both organizations are globally recognized, it does appear, that based on the certification criteria, that a DABT is more rigorous to obtain (see below chart) than an ERT.

Finally, there is no requirement in the European Medicines Agency's "Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities" that toxicologist are certified. What it does say in Section 6 of the guidance document is as follows:

	American Board of Toxicology (DABT)	European Registered Toxicologist (ERT)
Education and Work Experience	<p>Doctorate Degree in Appropriate Field with 3+ Years Full-Time Professional Post Degree Experience</p> <p>OR</p> <p>Masters Degree in Appropriate Field with 7+ Years Full-Time Professional Post Baccalaureate Experience</p> <p>OR</p> <p>Bachelor's Degree in Appropriate Field with 10+ Years Full-Time Professional Post Baccalaureate Experience</p>	<p>Academic Degree (MD, PhD, MSc, BSc) in Appropriate Field</p> <p>WITH</p> <p>Basic Knowledge of the Major Areas of Toxicology</p> <p>AND</p> <p>5+ Years of Relevant Toxicological Experience</p>
Passed Exam	<p>YES</p> <p>6 Hour Exam 200 Questions</p>	<p>NO</p>
Recertification	<p>YES</p> <p>Every 5 Years</p>	<p>YES</p> <p>Every 5 Years</p>

However, in the recently released ASTM standard on "Standard Guide for Derivation of Health-Based Exposure Limits (HBELs)" it does say the following:

IMPORTANT NOTE

6. Reporting of the PDE determination strategy

The identification of a "critical effects" in the establishment of a PDE as outlined in section 4 should be based on a comprehensive literature search including handbook and monographs as well as searches in electronic scientific databases. The search strategy and the results of the search must be clearly documented. **Following an expert review**, the company should provide a discussion with respect to the critical endpoints of concern and their rationale for the choice of endpoints and dose that is to be used in the derivation of the PDE. The pivotal animal and human studies used for the derivation of the PDE should be sourced to the original reference and reviewed regarding their quality (study design, description of finding, accuracy of the report etc.). The PDE determination strategy should provide a clear rationale regarding the adjustment factors that were applied in deriving the PDE. Moreover, in order to provide an overview to the GMP inspectors, the initial page of any prepared PDE determination strategy document should be a summary of the assessment process (please see Annex for template example).

As is common practice in all toxicology consulting companies, not everyone that is involved in the preparation of a monograph needs to be "certified." Typically, consulting organizations will have junior-level staff perform many of the tasks that required less experience. These tasks could include data and information gathering literature searches, preparing citations lists, preparing the draft document, and QC activities. The final report is then reviewed and approved by the certified toxicologists.

5.2 The establishment of an HBEL is a process that requires expertise and needs to be done by a qualified expert and, if possible, should be peer reviewed by relevant subject matter experts. A curriculum vitae (CV) should be available on request that demonstrates the educational background (for example, toxicology, pharmacology, medicine, or other health-related disciplines), certifications such as the Diplomate of the American Board of Toxicology (DABT) or European Registered Toxicologist (ERT), years of experience in the field, and publications related to the field. While all are not required for a "qualified expert," the appropriate documentation in these areas demonstrates the expertise to work in this area. Typically, certification registries require an academic degree in a relevant subject, basic knowledge of the major areas of toxicology, at least five years of relevant toxicological experience, suitability for registration (for example, by published works, reports, or assessments), and current professional engagement in the practice of toxicology (30, 31).

Reference: [Are Affygility Solutions' toxicologists certified? - OEL Fastrac Help](#)

Can I obtain a copy of the CVs for the authors of the OEL monographs?

Yes. CVs (PDF) may be found here:

[Curriculum Vitae for Affygility people \(affygility.com/cv\)](https://affygility.com/cv)