

毒理學家是否經驗證？

常被問到這樣的問題：“毒理學家是否經驗證？”重要的是，回答此問題前，需(準確)確定問題。

首先，世界上沒有一個(獨立的)組織在公司領域(a company-wide basis)“經驗證”具資格編寫 OEL/ADE/PDE 個論(monograph)。ISO 9001、ISO 14001、OHSAS 18001 等屬管理體系認證，非毒理學認證；故，ISO 或 OHSAS 認證在編製 HBEL 個論(ADE、PDE、HBEL)方面“不具意義”。這 3 項認證對毒理學領域(幾乎)無適用性。

其次，世界上有 2 個組織“經驗證”個人為毒理學家。(這些)如下：

- 美國毒理學委員會(ABT)
- 歐洲毒理學登記處(ERT)

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

個人經 ABT 經驗證可視為 ABT 文憑(DABT)，或登記於 ERT 可視為 ERT。(這些)認證非指公司，屬(特定的)個人(與僱主/公司無關)。

雖此 2 組織皆得到全球認可(recognized)，然依認證標準(certification criteria)，DABT (似乎)比 ERT 更嚴(見表)。

最後，EMA 的「關於設置 HBEL 應用於共用設施(備)中製造不同藥品的風險辨識指南」中沒有要求毒理學家獲得認證。指南 Ch 6 內容如下：

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).

然，最近發佈的 ASTM 標準「HBEL 推導標準指南」中，
(確實)說明，內容如下(紅框)：

重要提示

同(所有)毒理學諮詢公司，並非每個參與編寫個論的人皆
需“認證”。通常，諮詢組織由初級員工執行(許多)需較少
經驗的任務。(這些)任務(可能)含收集數據/資訊及檢索文
獻、準備引文清單、準備文件草案和 QC 活動。然，最終
報告由(認證的)毒理學家審查和批准。

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](#)

是否可取得(OEL 個論)作者的 CV?

是。簡歷(PDF)可於此處找到：

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