

Revisiting Certifications in General Toxicology— ABT / ERT / ATS

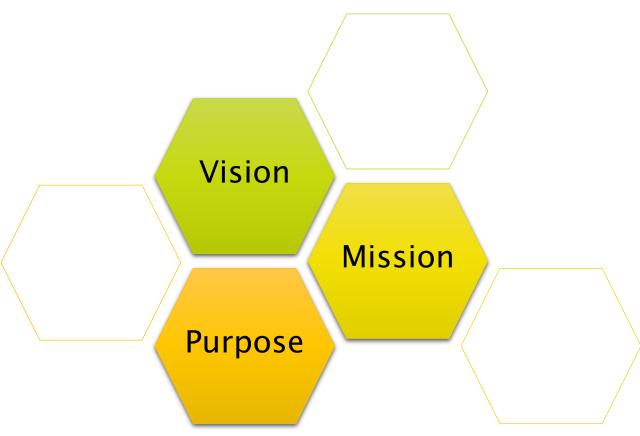


History and Overview of the American Board of Toxicology (ABT)

Alex Eapen, PhD, DABT ABT Board of Directors











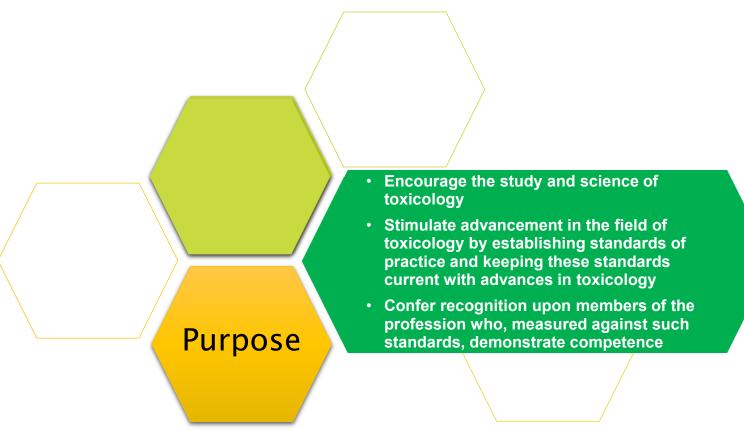














- Incorporated in Washington, DC in 1979
- First exam was given on August 4, 1980
- 217 Diplomates from this first examination
- First Board members were elected 1980 class, starting the transition to Board members being Diplomates
- ▶ 4068 candidates have passed the exam

 American College of Toxicology Signature Webinar























Certification Components





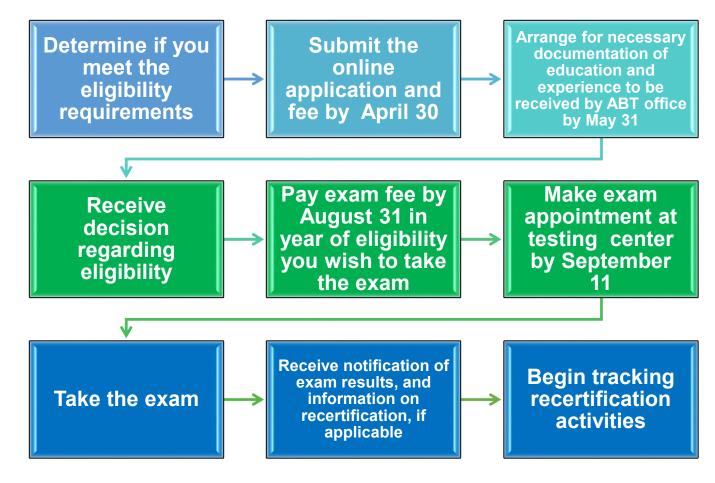


Application Process

- Applications accepted online only
- Deadline to apply for each year's exam is April 30
- All supporting documentation (transcripts, supervisor letters) due May 31
- Eligibility decisions typically sent out in late June
- Eligibility is for a period of 3 years
- All information available at <u>www.abtox.org</u> in the Candidate Handbook



Certification Process







 Doctoral degree in an appropriate scientific field and at least three years of full-time experience in toxicology

OR

 Master's degree in an appropriate field and at least seven years of full-time post-baccalaureate experience in toxicology

OR

- Bachelor's degree in an appropriate field and at least ten years of full-time experience in toxicology
 - In each case, the applicant must have active involvement in the practice of toxicology within the year immediately prior to application





Certification Examination

- A separate exam fee is due by August 31 in any year of eligibility in which the exam will be taken.
- It is administered once per year in October.
- The examination is given at testing centers; there are locations worldwide.
- After fee is paid, candidates must register on the Pearson VUE website for exam appointment by September 11.
- Availability of exam appointments at test centers in specific locations cannot be guaranteed.





Certification Examination

Then

- 300 questions
- Multiple answer multiple choice questions
- 1.5 days & travel/hotel costs for an in-person written test

Results

Now

- 160 questions (140 scored and 20 beta questions)
- Multiple choice with 4 possible responses
- Electronic format exam offered globally at local testing centers in 4 hours
- Significant increase in applicants (US and international)
- Percent of applicants passing exam has remained consistent
- Passing score has remained consistent





Exam consists of 140 scored questions and 20 pre-test items.

- ▶ The examination is given in a four-hour time block.
- Examination based on the most recent practice analysis study of the knowledge required for general toxicology





- First survey conducted in collaboration with SOT in 2015
- Study of the knowledge required for general toxicology
- A follow-up Practice Analysis was conducted in 2021
- Exam content outline updated in 2022 to reflect results from the updated Practice Analysis
- Results of both were published and are open access.
- Links to both are on ABT website.





Examination Domains

Domain/Sub-domain	% of Exam
I. Conduct of Toxicological Studies	<u>36</u>
A. Design	11
B. Execute	9
C. Interpret	16
II. Mechanistic Toxicology	<u>13</u>
III. Risk Assessment	<u>38</u>
A. Hazard Identification	12
B. Exposure Assessment	8
C. Dose Response Assessment	9
D. Risk Characterization and Management	9
IV. Applied Toxicology	<u>13</u>
TOTAL	100%





All questions are multiple choice with a single correct answer.

Example:

What is a major life-threatening effect following poisoning with phenol?

- A) optic neuritis with permanent blindness
- B) severe gastrointestinal irritation
- C) esophageal stricture
- D) fatty degeneration of the liver





After the Examination...

- ▶ Exams are graded and the statistics are thoroughly analyzed and discussed by the ABT Board.
- ▶ The passing score is based on a Standard Setting exercise. Details can be found on the ABT website about this process.
- ▶ Results are sent out in late November.
- ▶ Unsuccessful candidates are given feedback on how they performed in each Domain.
- ▶ Candidates whose eligibility has expired must reapply and pay the application fee again.

ABT Recertification Basics

- Certification as a Diplomate of the American Board of Toxicology® (DABT) is for a period of five years
- Process is the same for all diplomates
- ▶ Applications are due by March 31 in the fourth year of a recertification cycle.



























Current Stats and Fun Facts



Total Active DABTs

2631

137

Total Board members since 1979

Total number of candidates that have passed the exam

4068

32

Countries with active Diplomates





Facebook: facebook.com/DABTExam

Twitter: @ToxicologyExam

LinkedIn: https://www.linkedin.com/company/abtox/



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Questions?





Academy of Toxicology Science (ATS): Advanced Certification in Toxicology

Lorrene A. Buckley, PhD, DABT, ATS Past President, ATS

ATS: Vision and Mission



Vision

To be recognized as the leading international organization that certifies toxicologists by peer review of

- education
- professional experience
- leadership
- demonstrated achievement
- scientific expertise

Mission

To establish a process by which practicing toxicologists are certified based on peer review of the following three focus areas

- education, both formal and continuing
- professional practice of toxicology
- professional recognition



Founding of the Academy



- In 1980, ACT formed the Task Force on Professional Standards,
 - "The rapid development of the science of Toxicology has prompted the need to assure uniformly high standards in the understanding and interpretation of toxicity data developed for the protection of public health. The identification of qualified individuals meeting these high standards is of prime importance." (Borzelleca, ACT Pres-Elect)
- ATS was founded in 1981 based on ACT's recognition of the importance of regulatory toxicology in industry and government

Purpose of the Academy



- ATS certifies as Fellow toxicologists who are recognized by their peers for their expertise and sound scientific judgment
- Such recognition and certification is to ensure, through peer review of credentials, the competence and experience of professionals whose work affects public welfare.
 - Candidates for certification must have demonstrated evidence of knowledge of toxicology and active involvement in toxicological activities.
 - Fellows of the Academy must have an exemplary record of professional accomplishment as well as extensive evidence of recognition by peers of competency and sound scientific judgment in toxicology as reflected by appointment or election to councils, committees, etc.



Who are the Fellows?



- Currently 195 full Fellows and 75 Emeritus Fellows
- Mid-late career with proven track record of:
 - Publications (peer-reviewed; technical/confidential reports)
 - Professional Engagement (committees, work groups, teaching)
 - Leadership (professional societies, governmental advisory committees, depositions for congressional committees)
 - Recognition (awards, honors, peer-recognition)
- Academia, Research Institutes, Government, Industry, Consulting
- International
- Spanning all areas of toxicology



Application for Fellowship (1/3)



- Carefully review the Application Instructions and Guidance document (acadtoxsci.org)
- Contact a member of the ATS Board to discuss proposed content and eligibility to meet expected criteria
- Complete the Application Form (as detailed as possible)
- Prior to full peer evaluation by the ATS Board, all applications will be prereviewed for completeness by a Board member
 - Form may be revised based on feedback prior to formal submission
- Submit application form with fee
 - Application deadlines: June 30, October 30, and January 15



Application for Fellowship (2/3)



- Section 1: Education and Experience
 - Degree in relevant field
 - Year of professional experience in the active practice of toxicology
 - Continuing Education (beyond terminal degree)
 - University, professional society-sponsored (SIT, ACT, DIA) and/or other courses such as webinars or training specifically related to toxicology
- Section 2: Professional Practice of Toxicology
 - Publications and technical reports
 - Peer-reviewed papers, technical reports, major reviews, and/or book chapters
 - Editorial and peer-review responsibilities
 - Participation in toxicology activities both external and internal to your professional responsibilities



Application for Fellowship (3/3)



- Section 3: Professional Recognition identify those activities demonstrating a high level of recognition for both expertise and impact in the practice of toxicology
 - Professional career advancement
 - Demonstrating how each position reflects increasing responsibility and leadership during your employment history
 - Recognition of prominence in the toxicologic sciences
 - Outside (non-employer) activities associated with decision-making and/or advisory activities that demonstrate regional, national, and international leadership & recognized expertise
 - Elections and/or appointments to scientific and professional committees of tox-related organizations
 - Recognition through invited lectures & presentations



Why should I apply for ATS Fellowship?



- Certification as a Fellow of ATS
 - enhances your creditability and professional standing as a toxicologist
 - provides advantages in opportunities for professional service and employment
 - facilitates professional and social networking
 - confers a strong sense of personal accomplishment
 - offers opportunity for eligibility of recognition through the Mildred Christian Women's Leadership in Toxicology Award
- Certification of ATS Fellows is an important part of ensuring the highest scientific expertise and competent experience and integrity of professionals whose work and advice informs and affects public welfare.



ATS Fellows Adhere to High Ethical & Professional Standards



- Conduct their work and themselves with objectivity and integrity
- Hold as inviolate that credible science is fundamental to all toxicologic research and forms the basis for communicating results
- Recognize a duty to communicate information concerning health, safety, and toxicity in a timely and responsible manner, with due regard for the significance and credibility of the available data
- Give due consideration to the ethical, legal, social and policy implications of their research & communications
- Be thoughtful advocates for human and environmental health
- Abstain from professional judgments influenced by undisclosed conflicts of interest (CoI), make reasonable efforts to disclose any material conflicts of interest and, insofar as possible, avoid situations that imply Cols
- Observe the spirit, as well as the letter, of law, regulations, and ethical standards with regard to the welfare of humans and animals involved in their experimental procedures
- Practice high standards of occupational health and safety for the benefit of themselves, their co-workers, trainees, and other personnel



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Academy of Toxicological Sciences (ATS): Advanced Certification in Toxicology

Thank You for Your Interest and Attention!

Academy of Toxicological Sciences

Knowledge + Experience + Leadership + Involvement = Fellowship

acadtoxsci.org





Why become an ERT?

Advantages to the Individual and to the Community

Professor Ruth A. Roberts, PhD, ATS, FBTS, ERT, FRSB, FRCPath

Director and Co-founder ApconiX Ltd, UK

Chair and Director of Drug Discovery University of Birmingham, UK

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Conflict of Interest Statement

RR is an employee of ApconiX, an integrated toxicology and ion channel company that provides expert advice on nonclinical aspects of drug discovery and drug development to academia, industry, and not-for-profit organizations.

Challenges in Toxicology: The Pivotal Role of Experience

You too can be a toxicologist in two easy lessons, each of ten years.

— Arnold Lehman

Arnold J. Lehman (1900-1979)

Profiled in *Toxicological Sciences*, Volume 70, Issue 2, December 2002, Pages 159–160, https://doi.org/10.1093/toxsci/70.2.159

'Half a century later, this statement is truer than ever as our discipline grows in complexity'

Nancy Claude
Dr. Pharm., Ph.D. Toxicology, ERT
Former President of Furotox



Not Just a Problem for Toxicology: Scientific Credibility Is under Scrutiny

In "Six red flags for suspect work," C. Glenn Begley explains how to recognize the preclinical papers in which the data won't stand up.

Begley, C.G. Nature. 497, 433 – 434 (2013)

"...the majority of preclinical cancer papers in top-tier journals could not be reproduced, even by the investigators themselves."

cgbegley@tetralogicpharma.com

See also:

Prinz, F., Schlange, T. & Asadullah, K. Nature Rev. Drug Dis. 10, 712 (2011) Begley, C. G. & Ellis, L. M. Nature 483, 531–533 (2012).



Collaboration and competition: ethics in toxicology

Walker, E.S. and Roberts, R.A. *Toxicol. Res.*, 2018,**7**, 576-585 (2018)



Table 1. Six red flags for suspect work. Six key common findings are highlighted with suggestions for remediation (concepts taken from Begley 2013 with some modification)

6 Red Flags

Were experiments performed blinded?

Were experiments repeated?

Were all results presented?

Were positive and negative controls included?

Were reagents validated?

Were statistical tests appropriate?

Assertion

Animal studies, *in vitro* work and reading of gels can and should all be done, blinded to the experimental *versus* control groups.

Implementation

Check the methods and figure legends



Toxicology as an academic discipline in European Universities.

Wallace, H., Roberts, R., Corsini, E., Bonefeld-Jorgensen, E., Orhan, H., Mach, M., Weiser, T., Carvalho, F., Iscan, M., Tsatsakis, A.

Toxicology Letters, 30 Apr 2016, 234: 63

DOI: 10.1016/j.toxlet.2016.04.024 PMID: 27143510

'In the absence of appropriately experienced toxicologists, governments will be forced to seek toxicological input from non-experts who may inadvertently offer the wrong advice. This means we need to train toxicologists which means we need academic toxicology.'

'EUROTOX believes that research and teaching in toxicology must be maintained and strengthened across Europe and is convinced of the need to protect existing and found new institutions devoted to basic research in toxicology.'



Reasons to Become ERT!

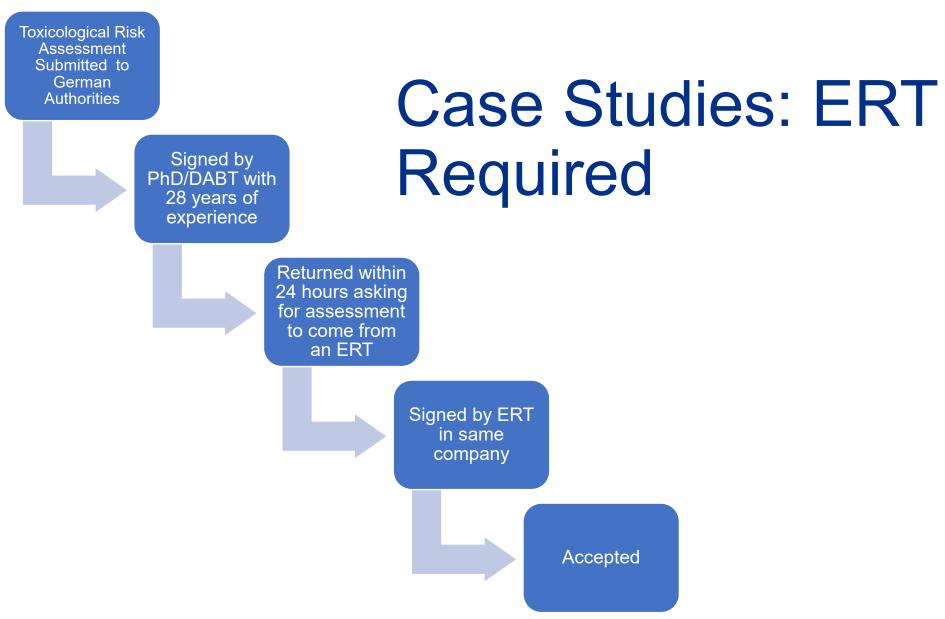
- An ERT is a member of the European Register of Toxicologists, an accreditation system initiated within Europe but now recognized worldwide
- ERT ensures that practicing toxicologists first achieve and then retain an appropriate level of professional competence to practice toxicology via:
 - Education
 - Training
 - CPD
- ERT advances our community by ensuring that the discipline of toxicology is respected and trusted within the scientific community.
- In addition, ERT certification offers the public an authoritative source of information with proven toxicological competence



A Comparison of the Different Schemes

ABT	ERT	ATS	
DIPLOMATE OF THE AMERICAN BOARD OF TOXICOLOGY (DABT®)	EUROPEAN REGISTERED TOXICOLOGIST (ERT)	FELLOW OF THE ACADEMY OF TOXICOLOGICAL SCIENCES (FELLOW, ATS)	
Requirements	Requirements	Requirements	
One of the following combinations of education in toxicology or a related field and full-time professional experience in the active practice of toxicology in one of the following combination: Ph.D /3 years of experience Master's/7 years of experience Bachelor's/10 years of experience	 Minimum of 5 years of practical training and expertise in toxicology Current active professional participation in the field of toxicology AND	 Relevant Education, both formal and continuing Evidence of professional practice of toxicology Professional recognition AND Admission to the Academy after peer review of and approval of credentials by the Board of the	
AND Successful performance on the ABT certification examination	 Be admitted to a National Register Request certification by EUROTOX 	Δcademy	
Recertification Requirement	Re-Registration Requirement	Recertification Requirement	
Every five years with evidence of continuing active practice, continuing education, and maintaining expert knowledge of general toxicology.	Every five years measured by documentation of continued professional awareness, education and practice as well as work in the field of toxicology.	Every five years with evidence of continuing active practice and recognition in the profession of toxicology.	







Chair of the Turkish Society of Toxicology called by a large international company specializing in safety and quality assurance

Case Studies: ERT Required

Company had 5 ERT toxicologists but insufficient to respond to huge increase in demand

Could Turkish ERT toxicologists serve as external consultants for toxicological risk assessments for cosmetics and consumer products?



Qualifications

Case Studies: ERT Preferred

Requirements

- An advanced degree in toxicology or related area (Ph.D. preferred; candidates with M.Sc. and relevant experience will be considered)
- ERT preferred
- Two or more years of proven experience as a toxicologist within a multi-disciplinary team
- A background in risk assessment and practical experience in the areas of neurotoxicology and reproductive toxicology is highly desirable.

Senior Regulatory Toxicologist

•Company:

Location: N

•Contract: Full Time

Job Description

Employee Status: Regular

Experience: Ten Years or More Preferred

Education: PhD or equivalent, European Register of Toxicologists Preferred

Do you have?

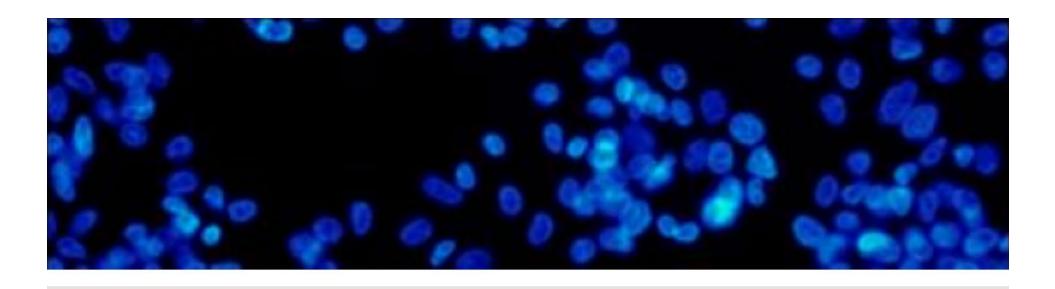
- Post-graduate degree in a scientific discipline or relative industry experience required
- ERT is encouraged
- Health & Safety, CoSHH and Risk Assessment experience is beneficial
- Regulatory submission experience would also be preferred



How Do I Become an ERT – A Perspective from the UK

- Application is via National Registers that are in turn accredited by EUROTOX
- National Registration Committees decide on the basis of evidence provided by the candidate
- Some registers emphasize course and certificates while others accept evidence via Structured on the Job Training (e.g., UK)

"Registered Toxicologist" status has to be maintained by a 5 yearly review of continuing education and practice in toxicology. Members of the UK Register of Toxicologists gain automatic membership of the **EUROTOX** Register of Toxicologists and are entitled to use ERT as a post nominal.



UK Register of Toxicologists

The UK Register of Toxicologists (UKRT), sponsored by the Royal Society of Biology and the British Toxicology Society, was established in 1993 and is now a Special Interest Group of the Royal Society of Biology. The attainment of registration is seen as a significant milestone in a career in toxicology and will become increasingly desirable for career progression.

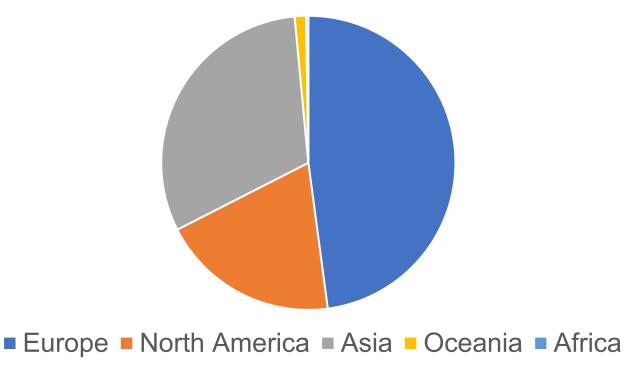


Distribution of Members of the UK Register

The UK Register:

>522 members Many non-UK

Data from Cara Froggatt, AMRSB
Senior Professional Development Officer
RSB



www.rsb.org.uk

Royal Society of Biology | 1 Naoroji Street | London | WC1X 0GB



Recertification

- Yearly documentation of ongoing continuing professional development (CPD) is required (50 credits/yr).
- Many aspects of your job qualify for CPD under the UKRT

Examples (not all Inclusive)		Work Based Learning (max/year = 20)	Discussions with colleagues, supervising colleagues or students, participation in appraisal and goal setting, lesson learnt activities, course development
	.	Professional Activity (max/year = 20)	Professional body involvement, referee for a journal, expert witness, presentation giving or discussant, networking with other professionals, coaching/mentoring
	œ p	Formal Education (max/year = 20)	Attendance at training course, conference attendance, distance learning, writing papers, presentation prep (for scientific meetings)
	6	Self-Directed Learning (max/year = 20)	Reading, reviewing/summarizing, upgrading knowledge
	+	Other (max/year = 20) *may be obtained outside of scientific activities	Finance skills, strategic thinking, leadership skills, organization and planning skills



Recertification – Tips for Recording CPD

- Keep all documentation of your activities (e.g., registration, certificates of attendance, etc.) in the event of audit and request for provision to support CPD record for any given year.
- Be detailed and specific in reflective statements (avoid generic statements)
- Recent Feedback for a senior level ERT (recertified, but cautioned):
 - "...presented a range of activities, generally with an appropriate number of credits claimed, and in the most recent years described and reflected upon in an appropriate level of detail. Entries for the earlier years mostly contain inadequate description and information about learning and development.
 - Learning and development will be more obvious for particular types of activities compared to others.
 For the latter, it is especially important that specific learnings are recognized and documented, and generic statements about learning are avoided. For example:
 - Entries for 'Being a referee for a journal [what manuscript topic was reviewed and what learning or development resulted?]
 - Grouping together 'Discussions with colleagues.
 - Likewise for activities that are primarily a routine part of the 'day job'
 - To claim as CPD there should have been clear learning/development that can be documented.



Examples from Senior ERT Reflective Statements

Insufficient

- <u>Discussions with Colleagues.</u> Over the course of the year, this amounts to a significant part of my job. I have regular discussions with direct reports regarding the strategic aspects of projects and also hold skip-level strategic meetings with their direct reports quarterly.
 - *Review*: This is a useful activity that forces me to stay close to the science.
- <u>Distance Learning.</u> Listed webinar title, sponsor, and speaker(s).
 Review: Attending webinars such as this allows one to stay current on the latest technologies and regulatory thinking
- Being a Referee for a Journal. Provided a manuscript review for [journal].
 Review: It is important to stay current with the science in order to be an effective reviewer for any journal. Being a reviewer also is beneficial to keep current in various areas of your own discipline.
- These reflective statements are bland and do not show a clear learning or how the individual developed as a result.

Examples from Senior ERT Reflective Statements

Appropriate

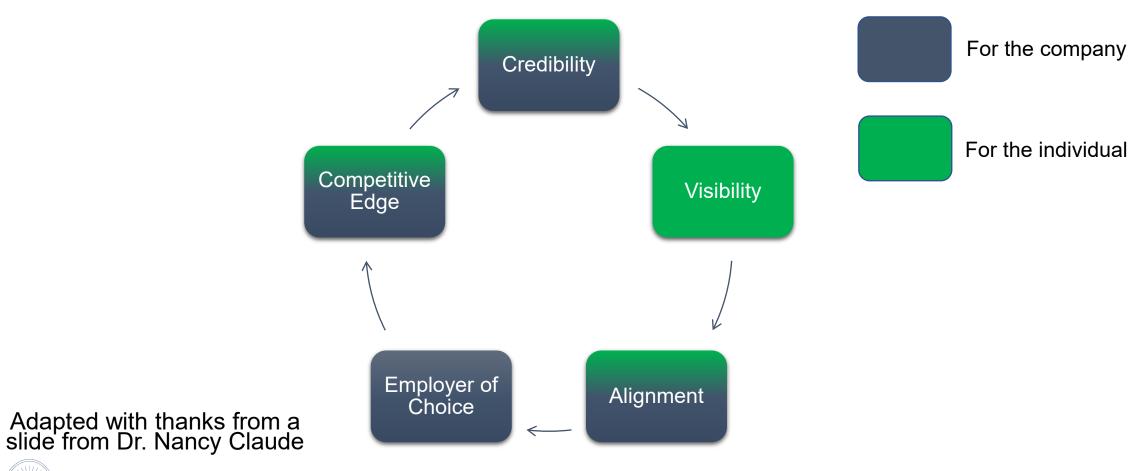
<u>Distance Learning.</u> Listed webinar title, sponsor, and speaker(s).

Review: This seminar series (this was Module 2 of 4) will be useful to be sure I am as up to date on the state of the science and testing expectations as possible. This session was mostly novel to me. I'm aware of cell therapies, but the explosion of types of cells, new regulations (especially in the US) are key to understanding this area. It also highlighted that I am correct in my assessment that...

- Being a Referee for a Journal. Provided peer review of a manuscript being developed by XYZ Working Group, as required by the organizations internal processes.
 - Review: ... I was required to brush up on my understanding of state of the science regarding functionality as well as methods to assess [topic].
- Attendance at Conferences or Scientific Meetings. Listed conference and date.
 - Review: The focus of the workshop was on the state of the science of [topic] and how that might impact ways we assess it in toxicology studies. This was one of the most eye-opening workshops I've attended as the field (and our understanding) has clearly advanced significantly and well-beyond what which I was aware prior to my attendance.
- These reflective statements are more specific to each event and show a clear learning or how the individual developed as a result.



Summary: A Positive Cycle!



References

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 https://doi.org/10.1177/10915818231171834
- Certification (UK Register)
- Recertification (UK Register)
 - http://www.rsb.org.uk/images/RSB_learning_for_life.pdf
 - https://www.rsb.org.uk/images/CPD_Guidance_for_UKRT_May_2021.pdf

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- UK Register
- RSB

Magnolia Toxicology Consulting

University of Aberdeen

Retired, ex-Servier

Retired, ex-Utrecht University

GSK



Why become an ERT? Advantages to the Individual and to the Community

Questions?



