Global Recognition of Qualified Toxicologic Pathologists: Where We Are Now and Where We Need to Go*

Robert A. Ettlin, Brad Bolon, Ian Pyrah, Yoichi Konishi, and Hugh E. Black

Introduction

Pathology examinations to characterize unwanted effects of chemicals, drugs, particles and biological components on living organisms and the ecosystem are a cornerstone of modern toxicologic investigations. Toxicologic pathology uses a holistic approach to study the relationships in various test systems between pharmacologic and toxicologic effects of compounds at various doses, given by various routes and for various durations. This broad scope renders the practitioner of toxicologic pathology an essential member of public health teams that protect the environment and the communal wellbeing of people and animals throughout the world.

To function, toxicologic pathologists (TP) require a comprehensive understanding of morphologic and clinical pathologic features of tissue injury, and mechanisms of disease founded on a thorough understanding of anatomy, biology, physiology, pharmacology and toxicology. Armed with such knowledge, TP contribute significantly not only to hazard identification and risk assessment, but also to risk evaluation and to making proposals for risk avoidance and therapeutic intervention to counter toxic effects (e.g. Morton et al, 2006; Boorman et al, 2002; Pilling, 1999; Tryphonas and Germann, 2002; Tryphonas et al, 1994).

Institutions that employ TP as well as regulators and health authorities who must rely on the judgment of TP are naturally interested in methods by which the competence of TP may be evaluated. Such assessments are quite complex due to the absence of universally recognized standards by which to judge TP. In all countries, TP have come from different disciplines such as veterinary medicine, human medicine, comparative pathology, toxicology, pharmacology, biology, and others. Furthermore, significant differences exist between the world’s regions regarding the requirements for education, specialization and ongoing training needs of TP (e.g., Wester, 2003).

The toxicologic pathology profession faces two challenges:

• to define those characteristics which would be likely to result in a consensus judgment that a given individual is a qualified TP.
• to develop and implement a globally acceptable set of criteria based on these characteristics to recognize competency in toxicologic pathology.

The objective of this paper is to initiate discussions among the worldwide TP community which will advance these two tasks.

* The view of toxicologic pathologists from the three regions Asia, Europe and North America.

Address correspondence to: Dr. Robert Ettlin, Novartis Pharma AG, WSJ-386.14.35, CH-4056 Basel, Switzerland.
telephone: 41 61 324 4490  Fax: 41 61 324 3874
E-mail: robert.ettlin@novartis.com

Abbreviations

ACVP American College of Veterinary Pathologists
BSTP British Society of Toxicological Pathologists
CRPTP Committee for the Registration of Laboratory Animal / Toxicological Pathologists in the Netherlands
DESV Diplômes d’Etudes Supérieures Vétérinaires
ESTP European Society of Toxicologic Pathology
IATP International Academy of Toxicologic Pathologists
IFSTP International Federation of Societies of Toxicologic Pathologists
JSTP Japanese Society of Toxicologic Pathology
KSTP South Korean Society of Toxicologic Pathology
LA STP Latin American Society of Toxicologic Pathology
MRCPath Member of the Royal College of Pathologists (United Kingdom)
NA STP North American Society of Toxicologic Pathology
NVT Nederlandse Vereniging voor Toxicologie (Netherlands Society of Toxicology)
RENI Registry Nomenclature Information System
SFPT Société Française de Pathologie Toxicologique (French Society of Toxicologic Pathology)
TP toxicologic pathologist(s)
Means of Acquiring Proficiency in Toxicologic Pathology

Attributes which can be employed to endorse the capability of TP generally fall into three categories: education, examination, and experience. The weight given to these three measures—alone or in combination—varies among regions and institutions around the globe. Regardless of the weighting, these traits are the only means by which competence can be certified in toxicologic pathology. This section provides an update on some of the mechanisms used in various localities (see also Wester, 2003).

Education

Many educational institutions around the world have university-level programs in which some exposure to toxicologic pathology is obtained. The most comprehensive training in this discipline is obtained in those venues in which the core curriculum includes exposure to multiple courses in both comparative pathology and toxicology which emphasize broad (systemic) rather than limited (single-organ) knowledge of normal and morbid anatomy and physiology. Such concentrations may be achieved in graduate schools (typically in comparative pathology, toxicology, or pharmacology programs), or in medical schools (human or veterinary core curricula). In some instances, considerable effort is spent coordinating the energies of multiple institutions in a given region to provide more wide-ranging contact (e.g., governmental research agencies, chemical and pharmaceutical industries, and universities with broad programs related to toxicology and pathology in locales such as Research Triangle Park, North Carolina, USA [e.g. NIH/NIEHS website], and Surrey, UK [University of Surrey website]).

It is essential that this theoretical foundation be followed by extensive hands-on instruction in pathology. The most thorough practical training in this field is best attained in the context of a medical school (human or veterinary) pathology residency and/or through a mentored on-the-job apprenticeship, both of which employ a case-oriented approach to impart problem-solving skills.

Once the fundamentals and nuances of toxicologic pathology have been acquired in this manner, TP must still continue to develop and maintain their proficiency. One common mechanism for continued education is attending courses at professional meetings for pathology, toxicology, or toxicologic pathology (e.g., BSTP training modules; C.L. Davis, D.V.M. Foundation seminars [CL Davis Foundation]; DESV anatomic pathology symposia). Individuals can also undertake targeted self-study of classic texts in toxicologic pathology (e.g., Boorman et al, 1990, 2002; Greaves, 2007; Haschek et al, 2002; Haschek and Rousseaux, 1998; Jones et al, 1997, 1998; Maronpot et al, 1999; Mohr, 1992-1997. 2001; Mohr et al, 1992-1994, 2001; and further text books), perusing articles in pertinent technical journals (e.g., Experimental and Toxicologic Pathology, Toxicologic Pathology, Journal of Toxicologic Pathology, etc.), or by accessing relevant reference materials over the Internet (e.g., websites for RENI and TOXNET).

Examination

Various national and regional organizations offer certifying tests to accredit physicians and veterinarians as pathologists. Prominent examples include the single-tier veterinary anatomic pathology boards (ACVP [ACVP website] and ECVP [ECVP website]). These vehicles typically include some questions designed to assess familiarity with toxicologic pathology; they are not targeted to test one’s expertise in this field. Rather, they seek to determine overall competency in the core information required for the successful conduct of pathology investigations. Most geographic regions and nations offer separate certification by examination in toxicology (for an overview, see e.g. TOXLINKS website); such credentials are often also obtained by TP (see e.g. Eurotox website, Ettlin, 1992; Ettlin et al., 2001; Ettlin and Hodel, 2000; Fowler and Galli, 2007).

At present only the Japanese Society of Toxicologic Pathology (JSTP) and the Royal College of Pathology (UK) administer a board certification examination specifically focused toward testing one’s specific knowledge of toxicologic pathology (Wester, 2003; JSTP website; RCPath website).

Therefore, the current certifying examinations do not provide a globally accepted standard for demonstrating that a given individual has attained a suitable degree of proficiency as a TP.

Experience

Employers, regulatory agencies, and health authorities recognize that the quality of interpretations varies among TP. These constituencies recognize that neither education (whether formal graduate work or occasional courses) nor a general examination in pathology or toxicology is a suitable substitute for actual experience in toxicologic pathology. Many skills of the TP must be learned “on the job.” At this stage of training, close mentorship by experienced TP is critical for future development. Except the specific examinations listed above (RCPath, JSTP), the only current means for assessing whether a person’s endeavors in toxicologic pathology have been sufficient to create proficiency in the field is a formal review of his or her documented experiences by a credentialing committee whose members have been previously identified as qualified TP. The Society of Toxicology in the Netherlands (CRPTP website) uses a system whereby a candidate is recognized (usually termed “accredited” or “registered”) as a qualified TP based upon his/her length of time in the field of TP (generally 5 years or longer) and types of professional experiences which imply the likelihood that a satisfactory degree of expertise in toxicologic pathology has been achieved.

A similar format of credentialing by document review is the basis for the “Fellow” designation accorded by the
International Academy of Toxicologic Pathologists (IATP). The IATP, founded in 1999, is an offshoot of the International Federation of Societies of Toxicologic Pathologists (IFSTP), which was itself launched in 1989 to – among other activities – create worldwide standards for recognizing the competence of qualified TP (IFSTP website). The IATP was established especially to craft criteria for accrediting qualified TP. Recognition as an IATP Fellow is reserved for long-established scientists who have gained global acknowledgement as experts in the practice of toxicologic pathology through scientific leadership and innovation to benefit society and their profession (IATP website). Accreditation as an IATP Fellow is based on formal training in pathology, but even more so on demonstrated experience in toxicologic pathology: proven expertise and continuing practice as evidenced by significant external recognition through peer-reviewed publications, presentations, membership in prestigious organizations (including expert panels and review bodies comprised of TP), and university assignments. At present, acknowledgement as an IATP Fellow is the only method that attempts to provide global recognition of proficiency in toxicologic pathology.

Characteristics of a Qualified Toxicologic Pathologist

Obviously, a qualified TP will have some combination of the education, examination, and experience credentials listed above. Competence as a TP can be assumed in individuals who have attained education and professional experience in toxicologic pathology, and have affirmed that competence either by completion of a relevant examination (e.g., board certification in toxicologic pathology) or by review and approval by a credentialing committee comprised of previously recognized peers in TP. Persons who meet all these criteria – education, examination, experience – should have little difficulty in being acclaimed as competent either by their peers in TP, by those institutions which hire TP, or by regulatory agencies and health authorities around the world.

But what about TP who have not completed a certifying examination or who have not had their credentials reviewed by a committee like the IATP? For many TP working in either industry or regulatory bodies (i.e., where publications and presentations are often thwarted) or for younger members of university-based toxicology institutes (who have had little time to achieve widespread recognition), it is often difficult to gain recognition as a skilled TP regardless of the length and types of toxicologic pathology experience they may have. The needs of these individuals, and of the institutions that need the skills of a qualified TP, are addressed in the second and more critical task in accreditation.

As a community, TP throughout the world must debate and agree on a universal set of criteria by which individuals can be affirmed as competent TP. But how should we proceed from here?

Means of Recognizing Qualified Toxicologic Pathologists

Several avenues are available for defining a universal set of criteria by which TP can be recognized globally as having attained proficiency in toxicologic pathology.

The two basic options are:

- to explicitly examine individuals for a common store of core knowledge in the field, or
- to define an algorithm by which relevant education and experiences can be weighed independently by a group of peers.

These two alternatives essentially serve as extensions of the practices described above. However, if implemented either alternative will engender a new system providing international recognition based on global standards of expertise, and as such would go beyond the sanctioning supplied by the national and regional recognitions that are presently in place.

The only logical choice to examine core knowledge would be to devise an international certifying examination in toxicologic pathology. This test could be designed to cover basic understanding of major concepts in toxicology and toxicologic pathology such as would be presented in central textbooks from these disciplines. The worldwide reach of the Internet would allow it to be given globally with minimal effort and expense as a multiple-choice exercise. This format would even test candidates on their ability to recognize classic lesions in toxicologic pathology at the gross, microscopic, and ultrastructural level via the use of high-quality digital images. The major drawbacks to this option would be

1. the need to maintain an international examination committee to regularly revise the content
2. the possibility of inappropriate support of a candidate by an experienced colleague
3. the unwillingness of individuals who have already passed a national (e.g., JSTP or MRCPath boards) or regional (e.g., ACVP or ECVP boards) certifying examination to take another one
4. the difficulty of demonstrating the relevance of the exam content and the appropriateness of the passing score based on objective information

If the examination path is excluded, two rational options still exist for evaluating the suitability of an individual’s experience in toxicologic pathology. Both would provide the global TP community with a continued infusion of creativity as people with divergent backgrounds are recognized as qualified TP and can bring their own unique educations, experiences, and thought processes to bear on various toxicology problems.

- The first alternative would be to develop a global system for tracking any given TP continuing education activities. Such a database would be simple to administer, especially if maintained using an Internet format, because each individual would be responsible for entering his or her own training exercises. The principal problems with this
choice would be (1) preventing fraudulent entries and (2) devising a means by which interested parties (e.g., potential employers, regulators) could readily ascertain the qualifications of TP. Furthermore, a mere record of continuing education credits should not be considered an adequate mechanism on which an initial recognition of competence may be based.

- The second alternative would be to conduct a formal review system by which a committee of previously qualified TP could measure and approve the training and experiences undertaken by more recent entrants to the field. This mechanism would be particularly attractive to anatomic pathologists working at “the bench” (i.e., engaged in traditional activities such as macroscopic and microscopic evaluation of tissues from toxicity studies) in contract laboratories and industry, pathologists engaged in non-traditional functions (such as discovery pathology and investigative toxicology), and mid-career scientists doing toxicologic pathology research in academic institutions. Advantages of employing this second option are that the new system could be modeled after the existing IATP Fellow credential (which represents the first global attempt to provide international recognition of proficiency in the field) and may even be administered by the IATP or a separate agency on behalf of the Member Societies coordinated by IFSTP. This choice would also avoid the disadvantages of a self-reported continuing education database. However, a potential drawback of the review system is that a single certification likely would be insufficient to affirm competence with respect to both performing regulated study work and investigative activities.

In our experience, TP engaged in any aspect of the discipline for an extended period (5 or more years under the supervision of an experienced TP) will have learned toxicologic pathology fundamentals sufficient to maintain their employment. In addition to this common core knowledge, a major strength for the profession of toxicologic pathology is its diversity in education and experience. For this reason any future effort to devise a universal standard for qualifying TP proficiency should be geared more to ensuring that the types of experience an individual has received have been of sufficient quality and quantity to recommend him or her as a proficient TP. We believe that this outcome can be best achieved by an internationally accepted review system similar to that currently used for IATP Fellows rather than by a self-reported log of continuing education activities or another examination. Such a peer-review structure will specifically assess experience in toxicologic pathology or toxicology using a recognized gauge, a panel of qualified TP well versed in the attributes needed for competency in TP.

**Where We Need to Go Now**

The rapid pace of globalization is already encompassing the discipline of toxicologic pathology. It will behoove the global TP community to address sooner rather than later the need for global acknowledgement of common standards by which to recognize a qualified TP competence, so that our communal experience can effectively mold the final product.

Therefore, the IFSTP and its accreditation body IATP – two organizations seeking to promote international standards for the global community of TP – are proposing to create a new echelon of credentialing for the universal recognition of qualified TP. The accreditation will be designed to benefit the individual members of national and regional societies of toxicologic pathology and the institutions (e.g., industry, regulatory and health agencies) who rely on the scientific interpretations produced by these members. In particular, the new credential will be formulated to serve the professional development needs of those experienced TP (e.g., bench pathologists in industry and contract laboratories) who typically have difficulty certifying expertise in toxicologic pathology using accreditation mechanisms available today.

Such an internationally accepted form of recognition will add value to global research in public health in several respects:

1. It will provide a method by which the individual TP can reliably and rapidly convey proficiency in the field.
2. A global recognition will give managers, colleagues, regulators and health agencies who are dependent upon TP data to make decisions, the confidence that their decisions have a firm underpinning.
3. An international set of standards will spare STPs in developing nations from the difficulties associated with creating and validating their own certifying processes from scratch.
4. Becoming internationally accredited has the potential to lead to an increase in the perceived value of the work performed by the individual; greater respect by superiors, peers and subordinates; and very likely enhanced career opportunities.
5. Finally, the universal acceptance of such a credential will streamline global harmonization efforts and eventually provide a relatively uniform quality of toxicologic pathology data sets submitted from any region of the world.

The effort to devise this new means of recognizing proficiency in toxicologic pathology is now in the early stages but is steadily gathering momentum. The initial proposal (under the heading “IFSTP Publication” – “Accreditation as IFSTP/IATP Accredited Toxicologic Pathologist”) may be found on the IFSTP website, and will be updated regularly to maintain its accuracy as the process moves forward. Please participate in this discussion by relaying your comments, concerns, and suggestions to the elected representatives of your society of toxicologic pathology or to the editor of a toxicologic pathology journal so your comments may receive due consideration. The debate is about your future, and that future is now.
Recognition of Qualified Toxicologic Pathologists

Notes

1 Current membership in this global professional and scientific coalition of TP includes the regional societies of toxicologic pathology representing Europe (ESTP) and North America (STP) as well as the national societies of toxicologic pathology from France (SFPT), Japan (JSTP), the Netherlands (NVT), South Korea (KSTP), and the United Kingdom (BSTP). Dedicated societies have also been founded recently in Latin America and India, although these societies are not yet IFSTP members.

2 The original IATP criteria were established and accepted by the following, then existing societies of toxicologic pathology under the coordination of the IFSTP: the Austrian-German-Swiss GTP (now ESTP), the Dutch NVT, the French SFPT, the Italian STP, the Japanese JSTP, the North European STP, the North American STP, and the United Kingdom BSTP.

References

ACVP - American College of Veterinary Pathologists
http://www.acvp.org/

CRPTP - Committee for the Registration of Laboratory Animal / Toxicological Pathologists in the Netherlands
http://www.toxicologie.nl/uk/doc/toxpath%20crptp.PDF


BSTP training modules
http://www.bstp.org.uk/html/about_the_modules.html

CL Davis, DVM Foundation
http://www.cldavis.org/

DESV - Diplômes d’Études Supérieures Vétérinaires (veterinary pathology postgraduate courses)

ECVP - European College of Veterinary Pathologists
http://www.ecvp.org/


Eurotox
http://eurotox.umh.es/

Experimental and Toxicologic Pathology. Journal of the European Society of Toxicologic Pathology
http://www.elsevier.de/etp


IATP - International Academy of Toxicologic Pathology:
http://www.iatpfellows.org/

IFSTP - International Federation of Societies of Toxicologic Pathologists
http://ifstp.org/


Journal of Toxicologic Pathology. Journal of the Japanese Society of Toxicologic Pathology
http://www.jstage.jst.go.jp/browse/tox-char/en

JSTP - Japanese Society of Toxicologic Pathology


Royal College of Pathology
http://www.rcpath.org/

NIH/NIEHS: Post-doctoral fellowship in toxicologic pathology


REN1: The standard reference for nomenclature and diagnostic criteria in toxicologic pathology
http://www.goreni.org/

Toxicologic Pathology: Journal of the (North American) Society of Toxicologic Pathology and British Society of Toxicologic Pathology
http://www.toxpath.org/toxpath.asp

TOXLINKS

TOXNET

Recognition of Qualified Toxicologic Pathologists

Toxicologic pathology: Modern challenges and the need for a new educational strategy. Toxicol Pathol 22: 330
University of Surrey: MSc/postgraduate diploma in applied toxicology.
http://www.surrey.ac.uk/SBMS/pg_taught_courses/Applied-Toxicology.html