

Report of the IFSTP Professional Standards Subcommittee (PSSC)

BACKGROUND

The Professional Standards Subcommittee was established by the IFSTP in 1996. Its mandate was to summarize the academic requirements for a toxicologic pathologist in the various sister societies. The intent of this exercise was to create a standard that would be generally acceptable as a minimum standard for a practicing toxicologic pathologist and to serve as a blueprint for those wishing to enter or develop an education program.

From the outset it was realized that a uniform accreditation standard was far from realistic, while a formal accreditation system was already under development, though at a more senior level, by the International Academy of Toxicologic Pathology (IATP).

The PSSC has met annually during STP and IFSTP meetings. Due to changes in representation of the societies during the course of the process, more representatives have contributed than those currently mentioned.¹ In the course of the discussions it became clear that the situation with regard to education and accreditation is a dynamic one. The reader is cautioned that the present report summarizes the standards given by the sister societies at the time of writing.

CURRENT STATUS

Europe

In Europe toxicological pathologists may be certified as veterinary pathologists through the European College of Veterinary Pathology (ECVP) and American College of Veterinary Pathology (ACVP) accreditation. Both colleges hold an annual examination, which includes a significant section on Toxicological Pathology. Toxicological pathologists may also be registered through National mechanisms as described below.

UK: The general educational background for toxicological pathologists is a veterinary or medical degree. A bachelor of science or doctor of philosophy in one of the biological

sciences may also serve for the basis upon which pathology training commences. There is no formal certification process in the UK for toxicological pathology.

In-house training and experience varies between employers, and competence to practice of an employee is determined by corporate management. It is common practice, however, for most newcomers to undergo a prolonged period of training and supervision from a senior pathologist with extensive expertise in the field of toxicological pathology.

Formal training is available as a 13-week modular program from the British Society of Toxicological Pathology (BSTP), spread over 4 years. It should be noted that there is no certification by examination. The European Centre for Toxicological Pathology at the Royal Veterinary College (ECTP-RCVS) runs a residency program for veterinary graduates culminating in a PhD. Both BSTP and ECTP-RCVS training programs are intended to prepare candidates for the examinations offered by the Royal College of Pathologists or European College of Veterinary Pathology.

Membership of the Royal College of Pathologists (MRCPATH) is by examination and candidates can choose to take the examination in Toxicology (specializing in Pathology), Veterinary Pathology (specializing in Laboratory Animals) or Veterinary Clinical Pathology. The examination is in 2 parts, usually taken after at least 3 (Part I) and 5 (Part II) years training under the supervision of a senior toxicological pathologist. These examinations consist of written papers, practical and oral examinations. After a further 8 years, membership is converted to fellowship. This examination is open to overseas candidates, although few have taken it in veterinary pathology or toxicology.

MRCPATH in a relevant specialty is generally regarded as a definitive professional qualification for toxicological pathologists. The MRCPATH is supported by a formal Continuing Professional Development (CPD) scheme for members and non-members alike. As yet, continued membership and fellowship with the Royal College of Pathologists is not dependent on CPD; however, this situation may change at any time.

Italy: The Italian Society of Toxicological and Experimental Pathology (SIPTS) was formed in 1993 under the Italian civil code. The SIPTS does not provide a formal certification in toxicological pathology. Practicing toxicological pathologists in Italy have a background of veterinary, medical, or postgraduate training (MSc/PhD) in medical biology.

Usually, bench training in Toxicological Pathology is given on site at the sponsor's facility under the supervision and

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responsibility of an experienced pathologist. The period of active training depends on the preexisting background of the trainee. Two (2) to four (4) years is required and comprises external courses in the Academy and in institutions with professional development programs in toxicological pathology. As no formal accreditation is in place, training programs taken and supervision received are documented. Most corporate institutions suggest that an in-company peer review process using other toxicological pathologists in other countries be used.

Switzerland and Germany: Most practicing toxicologic pathologists in Switzerland and Germany have a background degree in veterinary medicine or medicine. Training in pathology is performed in a five-year training program. Basic veterinary or human pathology and post academic training in histopathology is normally undertaken at the various university faculties.

In Switzerland a commission approves the candidate if all educational requirements are met, whereas in Germany the five-year training period is followed by an oral examination by the board of various veterinary and medical institutions in Germany, only if the prerequisites for this examination are fulfilled. After successful examination (Germany) or approval (Switzerland) the applicant is entitled to the title "Fachtierarzt" or "Facharzt für Pathologie." In Switzerland the titles are FVH for the Swiss Society for Veterinary Pathology (SSVP) and FMH for the Swiss Society for Medicine (SSM).

Bench training in Toxicologic Pathology is commonly done on site at the sponsor's facility, under the supervision of a registered pathologist experienced in toxicology pathology. The period of active training depends on the preexisting academic background.

In Germany there is an additional certification procedure for "Toxicological Pathologist" open to veterinary pathologists in most veterinary schools. This training requires at least 2 years of certified on-the-job training especially in Toxicology Pathology and a final oral examination in front of a specialized Board of Toxicological Pathologists. The successful candidates are entitled to call themselves "Fachtierarzt für Pathologie, Zusatzbezeichnung "Toxikopathologist." As in most societies, professional education is available through regular seminars.

The Netherlands: Most practicing toxicologic pathologists in the Netherlands have a degree in veterinary medicine, human medicine or postgraduate training (MSc/PhD) in medical biology. Accreditation of a Toxicological Pathologist is given by the Committee for Registration of Laboratory Animal/Toxicologic Pathologist (CRPTP), a joint committee of the Royal Dutch Veterinary Association (KNMvD) and the Netherlands Society for Pathology (NVVP). This committee is responsible for the design of the training program, monitoring and accreditation of candidates following satisfactory progress through the program. One of the members of the committee acts as the supervisor for the trainee.

Training in pathology follows a modular form: basic veterinary science with emphasis on pathology (for non-veterinarians) and postacademic training in histopathology (module from veterinary pathology specialization program at

the Veterinary Faculty, Utrecht University). Bench training in toxicologic pathology is done mainly on-site at the sponsor's facility, under the supervision of a local registered pathologist (tutor) and supervisor (representative of the CRPTP). The period of active training depends on the candidate's background and is determined by the CRPTP. Due to the limited number of candidates and close supervision, training programs are individually designed and no formal exam is held. Renewal is required every 5 years on the basis of an updated CV and continuing education record.

Requirements for a training program and accreditation are documented and can be downloaded from the societies website. Membership of the Dutch STP is open to members of the Dutch Society for Toxicology without specific requirements with respect to experience in pathology.

The Nordic Countries: Most practicing toxicologic pathologists in Denmark, Sweden, Finland, and Norway have a veterinary or medical degree. A few have a background in biology such as BSc or PhD.

Training in toxicological pathology is the responsibility of the employer (sponsor). Typically, the training program is designed with respect to the pathologist's background and experience. Usually the training takes 1–5 years, and is supervised by an experienced toxicological pathologist. The in-house training is often supported by relevant external education including courses such as the BSTP modules mentioned above.

In the Nordic countries, there is no formal body which supervises training, registers toxicological pathologists or performs exams.

France: Most practicing toxicologic pathologists in France have a veterinary or medical degree, with a minority having post graduate training (MSc/PhD) in biological sciences. With sufficient experience, no further qualification is required as there is no formal accreditation process.

In-house training is very important and it is common practice for new toxicologic pathologists to follow a prolonged period (3–5 years) of training and supervision from a pathologist with recognized qualifications and expertise.

The training under supervision is highlighted by the requirements for membership of the French Society of Toxicological Pathology (FSTP). The requirements include a MD, DVM, MSc, or PhD degree and demonstration of at least 3 years of acceptable experience in toxicologic pathology of laboratory animals. Candidates are nominated by 2 members and adopted by an Admission Committee and Executive Committee.

Until a few years ago there were 2 academic courses for toxicologic pathology at the veterinary schools of Toulouse and Paris/Maisons-Alfort. These courses are currently inactive due to the lack of available positions and the decreased number of students applying for training. However, it is anticipated that these courses will recommence in the not too distant future.

The French STP offers a 2-day conference on a special topic during the annual meeting for continuing education of members. An important part of the training followed by the French toxicologic pathologists is attendance at international scientific symposia or training programs relevant to the field.

Japan

Most practicing toxicologic pathologists in Japan hold a veterinary, medical or post graduate training (BSc/PhD) in medical biology. Training in pathology is followed in a modular form; basic human pathology for doctors, veterinary pathology for veterinarians, and postgraduate medical biologists.

The Japanese Society of Toxicological Pathologists (JSTP) organizes 2 seminars in histopathology, and recent topics in toxicologic pathology, for certified or noncertified members of the society.

Specific university courses in toxicological pathology do not exist. After a 5-year training period, members can take a certification examination administered by JSTP certified toxicologic pathologists. The examination is held once a year, and a renewal of the certification is required every 5 years.

USA and Canada

The definition of a toxicologic pathologist by the Society of Toxicologic Pathology (STP) is "Any person who is a toxicologic pathologist by virtue of training, experience and/or scientific contributions to the field, and is actively involved in safety assessment, teaching or research in toxicologic pathology or the administration of these activities."

The United States and Canada both follow similar training requirements. A toxicologic pathologist must hold a veteri-

nary, medical, or international equivalent degree, and have achieved advanced training in pathology. This training consists of at least 2–3 years of residency training in diagnostic pathology or research training combined with university courses. Many toxicologic pathologists obtain certification by the American College of Veterinary Pathology (ACVP).

Alternatively, a toxicologic pathologist must hold a degree in dentistry, osteopathy, or postgraduate research degrees (PhD, ScD) or international equivalent. Individuals must have attended at least three years of formal advanced training in pathology, including evidence of training in anatomy, physiology, and pharmacology, or documented full-time training with an STP recognized toxicologic pathologist for at least four (4) years.

GLOBAL ASSESSMENT

The training requirements and recognition procedures for becoming a recognized toxicological pathologist vary depending on the country concerned (Table 1). This variability is of concern to some wishing for common standards in global research and development of products.

Since our committee began its work, the International Academy of Toxicologic Pathologists has been formed under the auspices of the International Federation of Toxicologic Pathologists (IFSTP). This body gives accreditation through review of certified degrees and *curriculum vitae* of

TABLE 1.—Overview of training and accreditation in Toxicologic Pathology within the IFSTP, June 2002.

Society	Prior education	Training
USA/Canada	DVM/MD (+ PhD preferred), or equivalent ratio 83/7/10 DO, DDS, PhD, or equivalent	2–3 y residency training diagnostic pathology and/or research training combined with university postgraduate courses. Either advanced training in pathology, including anatomy, physiology, and pharmacology, or documented full-time training with a recognized toxicologic pathologist for at least four years.
Japan	DVM/MD/Others; ratio 53/27/12	JSTP membership, annual slide seminars and ILSI symposia for minimum of 5 y. Record and point system; no university courses
United Kingdom	DVM/MD/Others; ratio 75/10/15	In approved institutions. Min. 3 y and 5–8 y training for PI and II exam, resp.
Netherlands	DVM (preferred). MSc/PhD/MD after appropriate compensation; ratio 60/40/	4-y residency training and modular courses
Swiss	DVM/MD plus "Fach(tier)arzt." Others not eligible for accreditation.	5 years for (vet)pathologist, min. 2 y in university, 1 y in related field possible
German	DVM/MD plus "Fach(tier)arzt." Others not eligible for accreditation; ratio 75/25	5 y (Fach(tier)arzt) min. 3 y in university, 2 y in certified industrial laboratory + 2 y Tox. Path.
French	DVM, MD, others (MSc, PhD equivalent) "with proper background" ratio: about 80/10/10	3 y program in universities and labs. In-house training in approved institutions
Italian	DVM/MD/MSc; ratio 52/17/30	In-house training, in- and external courses (2–4 y)
Nordic	DVM/MD/BSc and PhD; ratio 90/7/3	In-house training, in- and external courses (2–5 y)
Assessment	Authority	Remarks
ACVP board exam. (min. 3 y training). Only for DVMS; Anat. and clin. path., Tox. Path. module available	ACVP	Specific ACVP Tox. Path. exam
Record and point system, then exam. Recertification after 5 y (point system)	JSTP	Proportion certified: 67/12/20 (DVM/MD/Others) (total 263)
Modular exam program (including Tox. Path.). Two parts. Written/oral and practical	Royal Coll. Pathologists	8 y after exam: Fellowship
Close and continuous assessment, documented supervision, final interview.	Joint Cie. (CRPTP) from Royal Vet. Med. Ass. and Hum. Pathol. Ass.	Not accessible for non-residents (due to continuing assessment)
Exam for MDs; no exam for DVMS	Swiss Society for Veterinary Pathology (FVH), Swiss Society for Medicine (FMH)	Scientists, who are working in Tox. Path. for 5 y can be registered within EUROTOX as toxicologist
Examination, both for Fach(t)arzt and Tox. Path. (some regions). Tox. Path. only after DVM PhD (oral exam)	"Kammer" certifies Fach(t)arzt	
Exam after 1 and 2 y, graduation after 3 y (including practical experience = Certificate (CES) in Toxicol. Pathology.	CES by Ecole Nat. Vet.Toulouse. Authority is Ministry of Agriculture	Previously: "Experts Agrs in Histopathology" (Min. of Health).
Close and regular documented supervision, no formal examination. Peer review.	NA	
Close and regular documented supervision, no formal training and examination. Peer review.	NA	Comprises 4 countries (Denmark, Sweden, Norway, and Finland)

TABLE 2.—Proposed general profile for education and training acceptable for the IFSTP, based on some commonly prevailing profiles.¹

Basic education	(Postdoc) specialization ²	Training ³
DVM	Veterinary pathology	1–2 years, depending on experience in L-A pathology
MD	Human pathology	3 years
BSc/PhD	Comparative anatomy/physiology, biochemistry, pharmacology, general/special pathology, pathophysiology ⁴	4 years

¹This table is descriptive rather than prescriptive, and generated on the basis of the existing profiles in Annex I. From these profiles, the first is the most common.

²Preferably in authorized institutions and as modular courses. Documentation required.

³Suggested length of training period, and comprising toxicologic pathology, comparative pathology and laboratory animal pathology.

⁴Depending on the profile of the basic education.

the candidate against a grading system. Successful candidates are recognized as Fellows of the Academy.

CONCLUSION

From this overview it can be seen that there is a general consensus that practicing toxicologic pathologists require university education in the biomedical field and postgraduate training in toxicologic pathology. All countries require a number of years of practical training under the supervision of a recognized toxicological pathologist.

It is important to note that even basic qualifications such as MD, DVM, MSc, BSc, and PhD are not always equivalent among the various countries. For toxicologic pathology, formal qualifications also depend on regional/national conditions such as access to training facilities, academic history and structure, and status of professional organization. In some countries the need for certification is still a matter of debate (1). Most Societies of Toxicologic Pathology (Pathologists), have some form of regular seminars and courses, which are also open to members from abroad. At present Continuing Professional Development is not formally required by most countries; however, reregistration is often required at specific time intervals. A summary of background, specialization and training can be seen in Table 2.

Because of significant heterogeneity, it is not (yet) feasible to establish a formal basic recognition of a toxicologic pathologist at the—global—IFSTP level without interfering with the various established systems. Instead, this summary may serve as a guide for those wishing to establish or optimize a structure for a professional society or career path for those wishing to work as a toxicologic pathology at a global level—principally for a “license to practice.” Alternatively, the IFSTP offers through The International Academy of Toxicologic Pathologists the possibility of a global recognition for those with adequate training and experience in the field, though the requirements are generally higher than those currently applied by the various sister societies described above.

Points of Concern

An important aspect that emerges from the various discussions held among the PSSC is that—despite existing and increasing training opportunities—the number of trainees

seems to be decreasing (2). This trend is occurring even though the need for toxicologic pathologists remains strong. In fact, the positions available for trained toxicologic pathologists in many countries remain unfilled. This is a worrying development, since the impression is that in the future we may face a skewed demographic situation with loss of experienced, qualified trainees and senior members of the profession as they retire. This threatened decline in qualified toxicologic pathologists in the future will not only diminish our professional and scientific standing, but may also reduce the quality of the risk assessment process.

Toxicologic pathology plays a pivotal role in the design, conduct, and evaluation of nonclinical safety assessment studies both for industry, academia and regulatory bodies. In addition, good laboratory practices (GLP) requirements for these studies are unlikely to diminish. Indeed, recent developments in the field of molecular biology and genomics are attracting more attention and resources stretching the toxicologic pathologist pool even further.

Although these new developments provide significant and valuable information in the nonclinical portion of product development, the data these technologies reveal still require an integrated interpretation with respect to biological relevance and interspecies extrapolation. These skills are core to the field of toxicologic pathology, where the training of the toxicologic pathologist gives him, or her, the ability to address histopathological changes, integrate and interpret mechanistic data for risk assessment. In a world of increasing specialization and complexity, the toxicologic pathologist remains at the center of nonclinical development of products.

The lack of new recruits into the field is not the only pressure faced by toxicologic pathologists. Another feature of the increasing workload of pathologists is the tendency in industry to commit pathologists to drug discovery teams, where the combination of both new technologies and the skills of pathologists prove to be effective and profitable in early detection of toxicity and efficacy (3–4).

For these reasons we encourage academic authorities to foster the future generation through recruitment and provision of educational opportunities. Veterinary and medical students and trainee pathologists need to be informed about the career possibilities and how toxicologic pathologists play a critical role in development and safety assessment of chemicals, pharmaceuticals, food components.

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