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The Diplomate in Safety Pharmacology (DSP) certification scheme

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ABSTRACT

As with other professional disciplines there is a growing need from within industry as well as global regulatory authorities for implementation of a certification process in order to assure that appropriate expertise is developed and quality standards are identified for professionals involved in the practice of Safety Pharmacology (SP). In order to meet this need, the Safety Pharmacology Society (SPS) has developed the Diplomate in Safety Pharmacology (DSP) certification process. There are many benefits to certification including authentication of the discipline within the overall pharmaceutical community and with regulatory authorities. It also encourages participation in SPS activities by other professionals (toxicologists, clinicians, academics) who wish to broaden their professional expertise. It provides an opportunity for candidates to strengthen their fundamental scientific knowledge, and stimulates the sharing of data, methods and model development in the form of publications and presentations on relevant topics in SP. Accreditation in SP occurs after candidates successfully complete a written certification examination conducted at the annual SPS meeting. The DSP exam consists primarily of material pertinent to the conduct of SP vital function core battery studies (i.e., cardiovascular, respiratory and central nervous systems), supplemental SP studies (i.e., renal/urinary, gastrointestinal, immunology, and hematology), Regulatory Guidelines (ICH Guidelines) as well as relevant cross-functional knowledge (e.g., physiology, pharmacology, toxicology, biochemistry, pathology, pharmacokinetics, dosing formulation, analytical methods, and statistics). Maintenance of the DSP certification results from the accrual of credits which are gained from a range of educational and scientific contributions. Eligibility requirements include a combination of at least a bachelor degree in science and two years of relevant professional SP experience and one poster presentation on a SP topic as first author at a recognized major scientific meeting.

1. The Safety Pharmacology Society (SPS) certification program

The Safety Pharmacology Society (http://www.safetypharmacology.org) is a not-for-profit international organization, incorporated in 2000, composed of scientists from all facets of the pharmaceutical industry (large and small pharma; biotechnology companies), academics, students, clinicians, contract research organizations, technology providers and global regulatory authorities. The SPS mission is to promote knowledge, development, application, and training in SP — a distinct scientific discipline that integrates the best practices of pharmacology, physiology

Abbreviations: DSP, Diplomate in Safety Pharmacology; SP, safety pharmacology; SPS, Safety Pharmacology Society; JSPS, Japanese Safety Pharmacology Society; ICH, International Conference on Harmonization; SOT, Society of Toxicology; ACT, American College of Toxicology.

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and toxicology (Bass, Vargas, & Kinter, 2004a, 2004b, in press; Pugsley, Authier, & Curtis, 2008; Redfern & Valentin, 2011). Moreover, there is willing and effective outreach of the Society including active engagement with universities and other scientific societies including the British Pharmacological Society and the Society of Toxicology, as well as global consortia including Health and Environmental Sciences Institute (HESI; http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=1) and the Cardiac Safety Research Consortium (CSRC; http://cardiac-safety.org/). The SPS is recognized as a well-established and active organization. The SPS has evolved over the last 10–15 years to become an important resource for the pharmaceutical and biotechnology industries (Bass et al., 2004a, Bass, Kinter, & Williamsn, 2004b, in press).

The objective of the conduct of SP studies is to further the discovery, development, and safe use of new chemical and biological entities by the identification, monitoring, and characterization of potentially undesirable pharmacodynamic activities in nonclinical studies. The SPS also supports the human safety of drugs and biologicals by fostering scientific research, education, and dissemination of scientific information through meetings and other scientific interactions.

The SPS has established a process for discipline certification which would evaluate and document competency within the field of SP. There has long been a need arising from within the industry as well as from global regulatory authorities for the implementation of a certification process to confirm expertise and identify quality standards for professionals involved in the practice of SP. In response to such needs, SPS has provided recommendations on best practices in a form of peer-reviewed publications, as well as discussions during annual meetings (Authier, Vargas, Curtis, Holbrook, & Pugsley, 2013; Cavero, 2013, 2014; Curtis & Pugsley, 2012; Holbrook, Malik, Shah, & Valentin, 2009; Leishman et al., 2012; Pugsley & Curtis, 2012; Vargas et al., 2008).

The benefits of establishing certification for Safety Pharmacologists are that certification provides authentication of the discipline and stimulates recognition of the discipline in the overall global drug development and regulatory communities. Further it encourages participation in SPS activities by other professionals (i.e., toxicologists, clinicians, academics, regulators) who wish to broaden their professional expertise. It also provides an opportunity for candidates to strengthen their fundamental scientific knowledge and stimulates the sharing of data, methods and model development in the form of publications and presentations on relevant topics in SP. DSP certification entrusts professional recognition in the discipline of safety pharmacology. Awardees receive a recognition by the Society by receipt of a certificate and SPS pin at the Annual Meeting.

A number of other professional organizations have a certification program (Hulla, Kinter, & Kelman, 2015), including The American Board of Toxicology who developed the 'Diplomate of the American Board of Toxicology' (DABT) in 1979 (Brock, Woolley, & Sugimoto, 2009). Similarly, The Association of European Toxicologists and European Societies of Toxicology (EUROTOX) developed the 'European Registered Toxicologist' (ERT; Savolainen, 1998; Fowler & Galli, 2007) certification program in 1994. Also, in Japan, similar membership certification as a Diplomate of the Japanese Society of Toxicology (DJST) started in 1998 (Brock et al., 2009). For pathologists, it is The American College of Veterinary Pathologists (ACVP) that is the organization of board-certified scientists that established the standard for veterinary pathology in the US since 1949 by the DipACVP accreditation (Christopher, Schultze, & Bird, 2003; Weiser & Cohen, 2009). The UK established the 'Fellow of the Royal College of Pathologists' (FRCPath) which sets the standards for training in pathology (GMC, 2012) in the UK while the European College of Veterinary Pathologists (ECVP) ensures standards of training, experience and examination for qualification as a specialist in veterinary pathology by DipECVP accreditation (ECVP, 2015; Kipar, Aleksandersen, Benazzi, & Suter, 2007). In 2012, the SPS Board of Directors initiated the DSP certification process to provide an educational opportunity for SP practitioners to demonstrate a basic mastery of the discipline in a formal manner. It is hoped that by establishing the DSP, recipients will be encouraged to contribute substantially to the discipline of SP through conduct of their professional work, publications/presentations and attendance at scientific meetings.

2. The certification process

Becoming a DSP is achieved by mastering the certification examination. The written examination is typically scheduled the day immediately prior to the start of the annual SPS meeting each year.

Eligibility requirements for taking the exam include a combination of at least (1) a bachelor degree in science, (2) two years of relevant professional SP experience and (3) one scientific presentation on SP as first author at a recognized major scientific meeting. The DSP certification committee invites potential candidates to contact the SPS office (http://www.safetypharmacology.org/) to assess any particular situation to confirm eligibility.

An annual review of the examination material will ensure that the contents of each certifying examination are relevant to the changing dynamics of the SP discipline and that critical skills and knowledge required for successful practice of the profession are maintained. As well, an annual review of examination material will assure DSP candidates that examinations are of equivalent annual difficulty.

3. The certification examination

Each examination consists of four one and a half hour parts with 75 questions each. The examination contains 300 multiple-choice questions that cover the following areas of SP (approximate distribution):

Areas covered on exam	% questions*	Areas covered on exam	% questions*
SP core battery		Cross-discipline knowledge	10
Cardiovascular system	30	Analytical methods	
Cardiac electrophysiology	20	Biochemistry	
Hemodynamics & contractility	10	Dosing formulation	
Central nervous system	20	Good laboratory practice (GLP)	
General neurological evaluation	15	Immunology	
Drug abuse potential	2	Pathology	
Seizure liability	3	Pharmacokinetics	
Respiratory system	15	Pharmacology	
Supplemental SP	15	Physiology	
Renal/urinary	5	Toxicology	
Gastrointestinal	5	Statistics	
Other (immunology, hematology)	5	Regulatory guidelines	10

*Indicates an approximate distribution of material.

The central nervous, cardiovascular and respiratory systems have been designated as vital, and the tests that address these systems are designated the "Safety Pharmacology Core Battery" of studies (Anon, 2001). The core battery study paradigms are set out in the ICH S7A guidance (Anon, 2001). These may be supplemented with ancillary studies that evaluate drug safety on other organ systems such as the gastrointestinal, genitourinary, renal, immune and hematological systems (Pugsley et al., 2008). Thus, because such a broad basis upon which a drug needs to be tested is required, the safety pharmacologist must be proficient in many physiological systems and skilled in many non-clinical methods; the DSP examination format and detail of material reflects this requirement. SPS believes that the strength of the discipline is in its ability to evaluate the whole body (animal or human) response to certain challenges, and as such, integrative cross-discipline knowledge is essential.

4. Training and preparation for the examination

Examination questions are prepared by safety pharmacologists based on the areas that were detailed above using scientific literature and experience in drug development. In this context, answers to the questions that are included in the DSP examination are typically not from a single scientific reference. Most peer reviewed scientific articles relating to the scope of the examination presented above are published in the following list of journals:

- Journal of Pharmacological & Toxicological Methods
- Regulatory Toxicology and Pharmacology
- British Journal of Pharmacology
- Journal of Cardiovascular Pharmacology
- Journal of Applied Toxicology
- Cardiovascular Toxicology
- Expert Opinion on Drug Safety
- Toxicology and Applied Pharmacology
- Fundamental and Clinical Pharmacology

Similarly, the following list of books is recommended as reference material in preparation for the examination:

- Guyton and Hall Textbook of Medical Physiology (Saunders)
- Textbook of Veterinary Internal Medicine, Stephen Ettinger and Edward C. Feldman Eds., 7th Ed. (note that earlier editions may not have the same chapters outlined below)
  - Electrocardiographic Techniques
  - Echocardiography
  - Syncope
  - Pathophysiology of Heart Failure
  - Electrocardiography and Cardiac Arrhythmias
  - Neurologic Examination and Neuroanatomic Diagnosis
  - Vestibular Disease
  - Clinical Approach and Laboratory Evaluation of Renal Disease
- Principles of Safety Pharmacology, Michael K. Pugsley and Michael J. Curtis, Eds., (Springer, 2015)

Examination participants can view the full list of suggested references to assist in preparation for the exam under the Diplomate section of the SPS website. Refer to the site via this link: http://www.safetypharmacology.org/diplomate.asp. Note that recordings are also available for DSP candidates from previously conducted SPS webinars that provides focused reviews in safety pharmacology. Other webinars from Continuing Education courses that have been conducted at previous SPS Annual Meetings are also posted and are available for review.

5. Results of the examination

Candidates are required to complete all parts of the exam. Successful candidates are certified and accepted as a DSP. To date there are 43 members of SPS that are certified DSP. According to best practices for professional certification programs, the minimum score required to pass the certifying examination is objectively determined by the DSP Certification Committee each year based upon specific knowledge criteria from participants for the year and not on a "grading on the curve" or comparative performance of candidates. A participant failing to achieve the minimal score to pass the examination will be invited to take the certification examination at his/her convenience at either of the next two SPS Annual meetings without charge. The next DSP exam will occur at the SPS Annual Meeting in Prague, Czech Republic on September 27, 2015 and in 2016 the exam will take place in Vancouver, B.C., Canada.

6. Maintenance of Diplomate status

Maintenance of the DSP certification results from continued membership in the SPS, and the accrual of credits that confirm active involvement in SP which may include:

- Maintain valid membership of the SPS
- Pay annual Diplomate fees (currently $75)
- Obtain a total of at least 15 SP "credits" over a three year cycle. Diplomates are required to submit their SP credits every three years to the DSP Certification Committee, and retain all receipts and acceptance/invitation letters for the following items:
  - Attendance at the Annual SPS meeting (5 credits)
  - Invited oral presentation on a topic related SP at recognized academic institution or recognized scientific meeting (e.g. SOT, ACT, JSPS, EUROTOX) (5 credits)
  - Attendance at a scientific meeting related to SP (e.g. SOT, ACT, EUROTOX) (3 credits)
  - Each first author poster presented at a recognized scientific meeting (2 credits)
  - Each non-first author poster presented at a recognized scientific meeting (1 credit)
  - Peer-reviewed publication in the field of safety pharmacology (10 credits)
  - Attendance at a Continuing Education Course (2 credits in addition to the 5 credits for attending the annual SPS meeting)
  - SPS Webinar Attendance (1 credit per webinar attended for a maximum of 3 credits in 3 years)
  - Annual question submission for the DSP exam (1 credit)

The DSP Certification Committee believes that SP is a young, constantly developing discipline (Redfern & Valentin, 2011). Because of this, the DSP Certification Committee is always open for suggestions and constructive feedback, and is always willing to re-evaluate criteria for DSP accreditation and/or maintenance.

7. The DSP certification committee

Each year the DSP Certification Committee receives suggestions for exam questions from current DSPs. Nomination of members to the certification committee is voted on by the Board of Directors of SPS at least every 2 years. The committee is composed of at least three current DSPs. The committee should include at least one member, each with expertise in one section of the core battery studies of cardiovascular, CNS, and respiratory safety pharmacology. Each year the committee prepares, as a minimum, 100 new questions to be added to the exam question database. New questions that are received are submitted to current DSPs, with expertise in the particular area, for review. DSPs then evaluate questions based on three criteria: (1) relevance, (2) clarity and (3) difficulty of the new questions by scoring the attributes of each new question. The new questions that are considered appropriate are added to the certification exam database for possible use in development of the exam the following year. Questions vary from 'relatively easy' to 'relatively difficult' in equal proportions. Exam questions that have been previously used will be reviewed and modified by the committee before inclusion in the examination for the following year. Note that the committee will update the list of scientific references (i.e., both journals and textbooks) that are relevant for the preparation of the certification examination for prospective DSPs and this list of references will be maintained in the SPS website. Upon successful completion of the exam, certified DSPs are entitled to use the title DSP after their names in recognition of this achievement in the field of SP.

8. Summary and conclusion

Certification as a Diplomate in Safety Pharmacology (DSP) by the Safety Pharmacology Society (SPS) provides the individual with a globally recognized credential by members of the discipline. The DSP represents the commitment of the individual and provides a measure of competency for that individual within the overall pharmaceutical community and with regulatory authorities. Certification encourages participation in global SPS activities and provides an opportunity for candidates to strengthen their fundamental scientific knowledge regarding cutting edge non-clinical methods and model development relevant to vital function core battery (cardiovascular, respiratory and central nervous systems) and supplemental SP studies (renal/urinary, gastrointestinal, immunology, hematology, pathology, etc.). DSP certification is a dynamic, ongoing process; thus, achievement requires maintenance by the individual from the accrual of credits which are gained from a range of educational and scientific contributions to this exciting field of study.

Disclaimer

This publication reflects the views of the authors and should not be construed to represent FDA's, or other authors' parent organizations' views or policies.

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