

USP Update: Beal Award and New Expert Committee

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At the April 2010 meeting of the U.S. Pharmacopeial Convention (USP), the prestigious Beal Award for Distinguished Volunteer Service was given to Thomas S. Foster, Ph.D. The award is given only once every five years in conjunction with the USP Convention, in recognition of outstanding individual contribution by a USP volunteer. Dr. Foster has made significant contributions to the science of quality standards in a variety of capacities; he is well-known among industry professionals with an interest in dissolution. Since 1990, Dr. Foster served on the Bioavailability, Bioequivalence, and Dissolution Subcommittee, first as member from 1990 to 1995 and then as chair from 1995 to 2000. He was chair of the Biopharmaceutics Expert Committee during both the 2000–2005 and 2005–2010 cycles. Dr. Foster also was vice-chair of the Nominating Committee for the USP Council of Experts for the 2000–2005, 2005–2010, and 2010–2015 cycles, helping to recruit nominees for USP service. Over his decades of service, Dr. Foster has been a member of the Nomenclature and Labeling Expert Committee (1995–2010), the Reference Standards Expert Committee (1995–2005), and the Medicare Model Guidelines Expert Committee (2000–2005).



Thomas Foster- Beal Award Recipient

During his service with the Bioavailability, Bioequivalence, and Dissolution Subcommittee and its successor, the Biopharmaceutics Expert Committee, a number of revisions to general chapters relating to drug product performance were made official or revised. The harmonization of <701> Disintegration and <711> Dissolution was a product of the Committees under Dr. Foster's leadership. Additionally, <724> Drug Release, <1087> Intrinsic Dissolution, <1088> In Vitro and In Vivo Evaluation of Dosage Forms, <1090> In Vivo Bioequivalence Guidances, and <1092> The Dissolution Procedure: Development and Validation were all introduced and revised during his tenure. He is an author of the PF Stimuli article, "Development of a *Compendial Taxonomy and Glossary for Pharmaceutical Dosage Forms*" (*Pharmacopeial Forum* 29(5)), that describes the five routes of administration forming the organizing principle for the work plan of the new General Chapters Dosage Forms Expert Committee (GCDF EC).

Dr. Foster will continue as a USP volunteer during the 2010–2015 cycle as a member of the new GCDF EC. That EC is responsible for pharmaceutical dosage forms and is chaired by Jim DeMuth, Ph.D., who previously chaired the USP Statistics Expert Committee from 2000–2005 and the General Chapters Expert Committee from 2005–2010. Dr. DeMuth will be assisted by 21 members elected by the Council of Experts at their meeting on June 15, 2010. Full Committee membership is listed at <http://test.usp.org/aboutUSP/governance/expCommitteeMembers/dosageForms.html>. The members of the new GCDF committee are as follows: James E. De Muth, Ph.D., Chair; Dale S. Aldrich; Paul D. Curry, Jr., Ph.D.; Russell P. Elliott, Ph.D.; Gordon L. Flynn, Ph.D.; Thomas S. Foster, Pharm. D.; Mario A. Gonzalez, Ph.D.; Vivian A. Gray; Ralph A. Heasley, Ph.D.; Anthony J. Hickey, Ph.D., D.Sc.; Michael E. Houghton; Munir A. Hussain, Ph.D.; Johannes Kraemer, Ph.D.; David F. Long, Ph.D.; Jolyon P. Mitchell, Ph.D., FRSC; Alan F. Parr, Pharm.D., Ph.D.; Guirag Poochikian, Ph.D.; John G. Shabushnig, Ph.D.; Raymond D. Skwierczynski, Ph.D.; Jason A. Suggett, Ph.D., M.B.A.; Thomas R. Tice, Ph.D.; and Terrence P. Tougas, Ph.D.

The GCDF EC will take on the standards-setting tasks formerly held by the Parenteral Products, Industrial, Aerosols, Pharmaceutical Dosage Forms, and Biopharmaceutics Expert Committees, which have been dissolved. A focus of the GCDF EC will be quality and performance testing for dosage forms by route of administration. This effort was begun during the 2005–2010 cycle by Advisory Panels reporting to the Biopharmaceutics Expert Committee. The most notable

results of the work of the Advisory panels were the proposed new general chapters, <3> Topical and Transdermal Drug Products—Product Quality Tests and <725> Topical and Transdermal Drug Products—Product Performance Tests, which were presented in the *Pharmacopeial Forum* 35 (3), May–June 2010.

The Biopharmaceutics Expert Committee 2005–2010 was responsible not only for general chapters relating to product performance but also for the specific dissolution, disintegration, and drug release tests found in individual USP product monographs. During the 2010–2015 cycle,

the GCDF EC will attend to the establishment and maintenance of general chapters relating to dosage forms with the approval of revisions to dissolution and other performance tests in USP product monographs moving under four newly formed Small Molecules Expert Committees.

The Performance Verification Test (PVT) is part of the general chapter description of the USP dissolution test. The GCDF EC will serve as the advisory body charged with the review of collaborative studies of new reference standard materials and procedures relating to the PVT.

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