Dear AAPS Fellows Selection Committee Members,

I would like to nominate <nominee's name> (<pharmaceutical company>, PHARMA) as a 20xx AAPS Fellow based on his/her key contributions to the fields of cytochrome P450 enzymes and drug metabolism. Over the past xx years, <nominee's name> has become an internationally recognized expert in drug metabolism within industry and academia. He/She has made substantial contributions through publications (n = xx), external oral/poster presentations (n=xx), drug research and development at PHARMA, and active participation within the AAPS, the International Society for the Study of Xenobiotics (ISSX), the <company location> Discussion Group and numerous Universities activities (seminars, PhD committees).

Summary of Nominee

<nominee's name> is currently the <company location>Site Head, Worldwide Drug Metabolism at <pharmaceutical company> Inc, where he/she is responsible for managing the overall DMPK support of over xx development and marketed compounds. He/She has xx years experience in the Pharmaceutical Industry supporting discovery and development, and another xx years in basic drug metabolism research at NIH. Prior to being appointed as the Site Head of Preclinical DMPK, he/she created and led a multidisciplinary team of senior scientists who evaluated and implemented new technologies pertinent for drug metabolism in a global organization for xx years, focusing on the productivity and predictability of in vitro ADME studies. As site Head, he/she manages a group of >xx scientists, whose primary activity is to support the in vitro, preclinical and clinical DMPK portion of the development package for all compounds at <company location>(n >xx compounds). He/She is skilled in organizational, managerial and technical areas with a proven track record of cross-departmental leadership, teamwork, productivity, interpersonal and staff development skills

Key Contributions and Impact of the Nominee

<nominee's name> has demonstrated both a depth and breadth of achievement relevant to drug metabolism and transport, and a commitment to scientific excellence and innovation.

1. Impact of Scientific Contributions to the Pharmaceutical Sciences

<nominee's name> is a pharmaceutical industrial scientist who manages to contribute new basic knowledge in the context of the demands of an industrial position. The result has been his/her substantial contributions to the fields of drug metabolism and transport, acknowledgment as a leader in the field, and clear impact on the drug development process across the pharmaceutical industry.

- Publications- <nominee's name> has a strong publication record with xx original research articles. Of the six selected publications in his Portfolio of Accomplishments, all six have xx or greater citations. This clearly demonstrates the broad impact that his/her publications have had in the pharmaceutical sciences. In particular, <nominee's name>'s research has provided insight into basic characterization of cytochrome P450s (lung and liver CYPs), development of recombinant systems to express these enzymes (first use of xxxxxxxxx for CYPs) and importance of their modulation by drugs (e.g., PXR regulation and xxxxxxxxxx). His/Her work has been widely read and cited in both academia and industry.
- Presentations- <nominee's name> has >xx invited speaking presentations and xx poster abstracts. He/She has been an invited speaker at AAPS and ISSX Annual Meetings, ISSX Short Courses, Gordon Research Conferences, the Pharmaceutical Education and Research Institute (PERI) Conference and at a number of universities.

2. Impact of Scientific Contributions to <pharmaceutical company>

<nominee's name> is recognized internationally within PHARMA as an expert in the area of drug metabolism, and as an outstanding scientist, project leader, manager, mentor, and team player who brings considerable value to the company. Some key contributions to PHARMA include:

- Providing technical, scientific and project leadership in the scientific area of drug metabolism and transport for Discovery Research, Preclinical Development and Regulatory. These include supporting key products such as xxxxxx (xxxxxxxxxx), xxxxxxxxx (xxxxxxxxxx), xxxxxxx (xxxxxxxxxxx), and xxxxxxx (xxxxxxxxxxx), and work on hundreds of other compounds addressing questions around disposition and drug interaction issues involving DMPK issues.
- <nominee's name> has authored/co-authored more than xxx internal reports and guidances. These guidances are used widely throughout the company as a resource for project teams to address ADME issues.
- Significant impact on the development of new technologies for lead optimization and candidate selection to address business needs. <nominee's name>'s group has developed and employed in vitro and in vivo assays used throughout PHARMA for screening or mechanistic studies of CYP inhibition / induction and drug transporters.

3. Service to Professional Societies, Journals, and Universities

<nominee's name> is an active member and leader in the Pharmaceutical Sciences community. He/She contributes regularly to a number of professional societies (e.g., ISSX, and Discussion Group), journals and universities. His/Her efforts have lead to a wide interest in the field of drug metabolism, and recognition of the importance of drug metabolism in industrial drug development. Selected key professional service includes:

- International Society for the Study of Xenobiotics, 20xx-20xx
  - President, responsible for overseeing annual meeting, reviewing budget

- Discussion Group 19xx-current
  - Founding chair and Executive committee member
  - Responsible for annual meeting and workshop programming
  - *Discussion Group Positions*
  - x dinner meetings (xx-xxx attendees) and x symposium (xxx-xxx attendees) annually.

- Gordon Research Conference on Drug Metabolism- 20xx
  - Chair, responsible for annual meeting programming and fundraising

In closing, <nominee's name> is most deserving of recognition as an AAPS Fellow based on his/her outstanding contributions to the field of drug metabolism, AAPS, ISSX, and the pharmaceutical industry. <nominee's name> is an excellent scientist, creative, dedicated, persistent in solving difficult problems, and effective in motivating others to develop professionally and scientifically. <nominee's name> is one of a few industrial scientists who have developed a successful external scientific track record with high impact scientific publications that are highly relevant to preclinical drug development. I urge you to favorably support the nomination of Dr. <nominee's name> as a 20xx AAPS Fellow.

Sincerely,

<nominator's name>, Ph.D.
Professor and Chair
Division of xxxxxxxxxxxx

Portfolio of Accomplishments for <nominee's name>

1. Publications and Book Chapters: Total: xx
(6 selected publications; see CV for complete list)

Recent publications and impact

In the early 19xx's there was no commercial source of recombinant CYP3A4 co-expressed with the CYP reductase at levels sufficient to reflect the human microsomal level of activity, and so allow screening of drug candidates for clearance by this important enzyme. Dr. <nominee> initiated this work that was pivotal in creating a reagent suitable for drug discovery and was the foundation for current commercial efforts. The baculovirus reductase construct has been provided to several external researchers to advance their cloning efforts.

1. **(citations 66)** Qqq, Q.Q., Qqqqqqq, Q.Q., Qqqq, Q.Q., and **<nominee's name>*.** (19xx) CYP3A4 Expressed by both CYP3A4 and Human NADPH-Cytochrome P450 Reductase is Catalytically Similar to Human Liver Microsomal CYP3A4. Archives of Biochemistry and Biophysics xxx(x):xxx-xxx.

Dr. <nominee>'s awareness of the drug interactions observed with this herbal drug prompted a discussion and subsequent collaboration with colleagues in the nuclear receptor group at PHRMA that resulted in this highly cited publication. Dr. <nominee>'s sustained contribution in this area was reflected by being the last minute replacement speaker at the 20xx ISSX plenary session in Qqqqq, Qqqqqq, reporting a new reagent for investigating the human QQQ. In 20xx she presented this work at an ASPET/FDA workshop (see below). Screening drug candidates against human nuclear receptors like PXR is now common for anticipating CYP induction in the clinic.

2. **(citations 281)** Qqqqq, Q.Q., Qqqqqqq, Q., Qqqqq, Q.Q., Qqqqqq, Q.Q., **<nominee's name>**, Qqqqqqq Q.Q., Qqqqqqq, Q.Q., Qqqqqqq, Q.Q*. (20xx) Qqqqqqqqq induces hepatic drug metabolism through activation of the pregnane X receptor. PNAS xx(xx) xxxx-xxxx.

This manuscript illustrates one of many efforts that Dr. <nominee> has led to select and validate approaches for evaluating early drug candidates for disposition properties. This work evaluated three common assays for Qqqqqqq interactions and provided the basis for selecting the efflux assay by illustrating that the bias of this assay generally was failure when passive permeability was high which compensates for this limitation.

3. **(citations- 96)** Qqqqq, Q.Q., Qqqqq, Q.Q., Qqqqqqqqq, Q.Q., Qqqqq, Q., Qqqqqq, Q.Q., Qqqqqqq, Q.Q., **<nominee's name> *.** (20xx) Rational Use of In Vitro Qqqqqqqqq Assays. Drug Discovery. J Pharmacol Exper Ther xxx:x-x

Early research and impact

The three highly cited manuscripts below represent some of Dr. <nominee>'s work to purify pulmonary CYPs, develop immunochemical methods to characterize individual enzymes and to visualize their cellular distribution in the lung. These specific and well characterized antibodies were later essential in identifying cDNA clones as CYP investigations moved from biochemistry to molecular biology approaches. The impact of the work also has been in the area of relating the presence of CYP to the cellular vulnerability of the lung to toxins (e.g. 4-xxxxxxxxx, a naturally occurring compound found in xxxxx xxxxxxx xxxxxxxx) that are activated by CYPs.

4. **(citations 184) <nominee's name>*.**, Qqqq, Q. Q., Qqqqqqq, Q. Q. and Qqqqqqq, Q. Q.: (19xx) Cytochrome P-450: Localization in the xxxxxx xxxx. Science xxx: xxxx-xxxx.

5. (citations 157) **<nominee's name>****, Qqqq, Q. Q. and Qqqqqqq, Q. Q.: (19xx) The xxxxxx pulmonary monooxygenase system: Immunochemical and biochemical characterization of the enzyme components. J. Biol. Chem. xxx: xxxx-xxxx.

6. (citations 87) **<nominee's name>***, Qqqqqq, Q.Q., Qqqqqqq, Q.Q. and Qqqqqqq, Q. (19xx) The distribution of cytochrome P-450 monoxygenase in cells of the xxxxxxxxxxx: An ultrastructural xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxx. Molec. Pharmacol. xx: xxx-xxx, 19xx.

* Principal or Corresponding Author

2. Presentations: Total: Oral (external to PHARM onnly*) = xx; Poster (external to PHARMA only) = xx

(xx selected oral presentations; see CV for complete list)

1. The Business Case for Investing in Drug Metabolism Science and Technology. Symposium on "Changing Paradigms for Drug Metabolism Support of Drug Discovery and Development – Impact of Novel Drug Metabolism Technology". North Jersey ACS Drug Metabolism Discussion Group. Somerset NJ. Invited Presentation. October 7th 1997.

2. Strategies in Drug Metabolism Support of Discovery. Phoenix International Life Sciences 9th Annual Symposium, Montreal Canada. Invited Presentation. June 19th 1998.

3. Gordon Research Conference on Drug Metabolism (1999): New technology and Approaches for Drug Metabolism and Drug Discovery (session organizer, speaker and chair).

4. Drug Metabolism and Toxicity: High-throughput Assay of P450 Induction Potential via PXR Nuclear Receptors: Cambridge Healthtech Institute's 2nd Annual Smarter Lead Optimization, Baltimore MD, March 16-17, 2000, Session Chair and speaker.

5. Gordon Research Conference on Drug Metabolism (2000): Hepatocytes; Drug Metabolism and Induction (session organizer and chair). Vice-chair of conference and organizer and chair of poster session.

6. Gordon Research Conference on Medicinal Chemistry (2000): Session organizer and Chair for "Can we really predict pharmacokinetics?"

7. Gordon Research Conference on Drug Metabolism (2001), Organizer and Chair.

8. Drug Metabolism in Drug Development (2001). Pharmaceutical Education and Research Institute, Inc. (PERI) Georgetown University Conference Center, Washington, DC. April 11-12. Course co-director and lecturer.

9. University of Washington Pharmacological Sciences Training Grant Symposium "Emerging Technologies in Drug Discovery and Development". Seattle, WA, May 16, 2002. Invited speaker "The pregnane X receptor: value to Drug Discovery."

10. Drug Interactions with Herbal Products and Food. FDA /ASCPT Educational Symposium, Bethesda MD July 22,23, 2002. Invited speaker "Industry Perspectives on Dietary Supplement-Drug Interactions: St. John's wort and PXR".

11. "Functional Comparison of PXR and CAR". Symposium presenter at the 8th European ISSX meeting, Dijon France, 2003.

12. "ADME in Drug Discovery and Development". Invited Lecturer for the Academy on Drug Development and Pharmacogenomics, presented by the Winship Cancer Institute and Emory University Dept. of Pharmacology, Atlanta GA, 2005

*The nominee gives 2-4 internal GSK talks per year in her area of expertise to drug research, development, commercial and marketing groups. These presentations are not counted in the numbers reported above.

3. Service as Editor, Associate Editor, Editorial Advisory Board member and Referee for Learned Journals in Pharmaceutical or Related Sciences

Currently provides occasional (<xx manuscripts per year) peer review.

- Editorial board of Drug Metabolism Reviews 20xx-20xx
- Reviewer for drug metabolism journals
- NIH contract proposals.

4. Organization of Symposia

International Society for the Study of Xenobiotics 19xx-20xx

- Multiple roles in the organization of short courses, meeting organizing committees and in identifying and approving site location and scientific programs for annual meetings, guidance to the Scientific Advisory Board, review and recommendation of awards (attendance 800 – 1,300)

Drug Metabolism Discussion Group 19xx-current

- Responsible for annual meeting and workshop programming

  Discussion Group Positions

  Founding chair and Executive committee member

  - 3 dinner meetings (50-130 attendees) and 1 symposium (125-180 attendees) annually.

Gordon Research Conference on Drug Metabolism- 20xx

- Chair, Responsible for annual meeting programming and fundraising

Pharmaceutical Education and Research Institute, Inc. (PERI) 20xx

- Drug Metabolism in Drug Development. Course co-director and lecturer.

Gordon Research Conference on Drug Metabolism 20xx

- Hepatocytes; Drug Metabolism and Induction (session organizer and chair).
- Vice-chair of conference and organizer and chair of poster session.

Gordon Research Conference on Medicinal Chemistry 20xx

- Session organizer and Chair for "Can we really predict pharmacokinetics?"

Gordon Research Conference on Drug Metabolism 19xx

- New technology and Approaches for Drug Metabolism and Drug Discovery (session organizer, speaker and chair).

Cambridge Healthtech Institute's 2nd Annual Smarter Lead Optimization, Baltimore MD 20xx

- Drug Metabolism and Toxicity : High-throughput Assay of P450 Induction Potential via PXR Nuclear Receptors:, Session Chair and speaker.

IBC preconference Workshop, Washington DC, Chair 19xx

- Advanced Genotyping: Methodology and Technology for Accelerated Pharmacogenetic Analysis.

6th North American ISSX meeting Short course 19xx

- Expression systems for enzymes of drug metabolism: An introduction to methods and applications. Organizer and Chair.

5. Mentoring of Graduate Students, Subordinates and Colleagues

Dr. <nominee> currently is the Site Head of Preclinical DMPK Department at the <pharmaceutical company> <company location> Facility with over xx full-time permanent staff. Over the years, he/she has directly or indirectly had x postdoctoral fellows, x visiting scientist, x contract employees and xx summer interns/co-ops over the past xx years. Dr. <nominee> is currently active or has participated in the PHARMA in Science Program, In-Roads program, and the Traveling Science Program. He/She conducted various workshops at elementary schools and participated in science fairs. He/She participated in an AAPS sponsored graduate student career discussion at UNIVERSITY in April 20xx.

6. Service to AAPS or Other Professional/Scientific Organizations

International Society for the Study of Xenobiotics 19xx-20xx

- President 20xx-20xx
- Secretary elect 19xx-19xx
- Councilor 19xx-19xx

American Chemical Society
American Society for Biochemistry and Molecular Biology
American Association of Pharmaceutical Scientists
PhRMA

7. Adjunct Faculty Positions in Universities

- University of Qqqqqqqqqq School of Pharmacy, 19xx-current
  Graduate Faculty and lecturer
  Doctoral Dissertation Committee Member for Qqqq Qqqqqq
- University of Qqqqqqqqqq, Corporate Advisory Board 20xx - current

8. IND's, NDA's and Related Contributions

Dr. <nominee> has authored or co-authored >xxx company reports supporting the development of compounds, that include Zzzzzz, Zzzzzzzzz, Zzzzzzz, Zzzzzzz, and Zzzzzzzzz. The majority of his/her direct contributions came in supporting in vitro studies required for INDs (an average of xx reports per year). These include drug metabolism studies (induction, inhibition of P450s), membrane permeability and drug transport assays, and toxicokinetic evaluations. As Site Head of Preclinical DMPK, Dr. <nominee> provides final management approval for the DMPK portions of regulatory documents (IND, CIB, CTA, NDA).

9. Level and Scope of Technical and/or Managerial Responsibility

Dr. <nominee> is a recognized expert in the field of drug metabolism within and outside of <pharmaceutical company>, especially in the area of lung and liver cytochrome P450 enzymology. He/She has xx years experience in the Pharmaceutical Industry supporting discovery and development, and another xx years in basic drug metabolism research at NIH. For xx years at <pharmaceutical company>, he/she created and led a multidisciplinary team of senior scientists who evaluate and implement new technologies pertinent for drug metabolism in a global organization; focusing on the productivity and predictivity of in vitro ADME studies. Currently, as Site Head of Preclinical DMPK, Dr. <nominee> directs a group of >xx scientists, whose primary activity is to support the in vitro, preclinical and clinical DMPK portion of the development package for all compounds (n >xx compounds). He/She is skilled in organizational, managerial and technical areas with a proven track record of cross-departmental leadership, teamwork, productivity, interpersonal and staff development skills.

10. Special Internal Awards, Recognition, etc. for Research and Development Related Achievements

Dr. <nominee> has been promoted xx times since joining <pharmaceutical company> in 19xx. In 20xx, he/she was recognized for her many contributions to the International Society for the Study of Xenobiotics.

CURRICULUM VITAE

<Nominee's Name>

Professional Profile:

-
  - …
- ..

Positions held

20xx- present	Site head, xxxx
20xx-20xx	Director of
19xx-20xx	Director of
19xx-19xx	Sr. Research Investigator,
19xx-19xx	Research Chemist,
19xx-19xx	Chemist, Laboratory of Pharmacology
19xx-19xx	Physical Science Technician,
19xx-19xx	Senior Laboratory Technician,

Selected Publications

1. .
2.
3.
4.
5.
6.
7.

Research Interests and Experience:

The development of tools and approaches to enhance the predictivity of preclinical ADME studies in the selection of lead drug candidates, evaluation and registration of medicines.

- Enzymology of drug metabolizing enzymes
- In vitro screening for metabolism and cell permeation of new molecular entities
- Computational approaches to predicting ADME parameters
- Pharmacogenetics
- Application of recombinant technology and transgenic technologies to develop robust models relevant to humans, especially with regard to drug-drug interactions.

Education:

19xx Ph.D., University, Location
THESIS:
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Awards, Scholarships and Societies:

Honor Scholarship, College of XXXXX
Honor Scholarship, University of XXXXXX
National Science Foundation Undergraduate Research Fellowship
NIH Equal Employment Opportunity Award
NIH Work Performance Award
American Chemical Society
American Society for Biochemistry and Molecular Biology
American Association of Pharmaceutical Scientists
International Society for the Study of Xenobiotics
Gordon Research Conference on Drug Metabolism.

Short Courses/Symposia

Short Course, 19xx, Lecturer on xxxxxxxxxxxxx.

Title. xth North American ISSX meeting Short course 19xx; Organizer and Chair.

Title. Washington DC, Invited Presentation, May 19xx.

Title. xx Annual Meeting of the American Association of Pharmaceutical Scientists, Location., Invited Symposium Presentation, November 19xx.

Title International Symposium on Drug-Drug Interactions: Scientific and Regulatory Perspectives, Location. Invited Symposium Presentation, November 19xx.

Title. X annual conference on Pharmacogenetics: Title. Washington DC, Invited Presentation, April 19xx

Title. Symposium on xxxx. University, Invited Presentation April 19xx.

Title. Symposium on xxxx. Location ACS Drug Metabolism Discussion Group. Location. Invited Presentation. 19xx.

Title. Life Sciences Annual Symposium, Location. Invited Presentation. 19xx.

Title. Workshop, Location, Chair 19xx

Title:. Pharmaceutical Education & Research Institute, Inc. (PERI), Location, 19xx

Conference on xxxxxxxxxxx (19xx): Title (session organizer, speaker and chair).

Title: Annual Seminar, Location, 20xx, Session Chair and speaker.

Conference on xxxxxxxx (20xx): Title (session organizer and chair). Vice-chair of conference and organizer and chair of poster session.

Conference on xxxxx (20xx): Session organizer and Chair for “Topic”

Conference on xxxxxxxxxxxxxx (20xx), Organizer and Chair.

Title (20xx) University, Location Course co-director and lecturer.

Title Location, (20xx).

Title FDA/ASCPT Symposium, Location, 20xx. Invited speaker “Topic”.

Title. Symposium European ISSX meeting, Location, 20xx.

<Pharmaceutical Company> INTERNAL RESEARCH REPORTS

1. {listing and impact}

BIBLIOGRAPHY

1. listing
2. listing
3. listing
4. listing
5. listing

……..

50. listing

BOOK CHAPTERS

1. chapter
2. chapter
3. chapter

…

9. chapter

PAPERS PRESENTED* AND PUBLISHED ABSTRACTS

1. listing
2. listing
3. listing

….

52. listing