Gregg D. Cappon, Ph.D.

DIRECTOR, PHARMACEUTICALS PRACTICE

SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Gregg Cappon is a pharmacological toxicologist with more than 25 years of experience in the pharmaceutical industry. His expertise focuses on nonclinical safety assessment and drug development, with an emphasis on reproductive toxicology and pediatric drug development. He has managed organizations of up to 34 scientists in designing and conducting studies to support drug development candidates, internal and external study conduct, preparation of regulatory submission, and responding to regulatory queries. In addition to management responsibilities, he has experience as a drug development project team representative, affording him broad knowledge of drug development and regulatory strategies, including vaccines, nonalcoholic steatohepatitis (NASH), dermatology, pain, osteoporosis, and various metabolic and central nervous system (CNS) conditions. Provided project team support at all stages of the drug development process, from discovery research, to investigational new drug (IND) submission, through early and late clinical development, to marketing authorization.

EDUCATION AND DEGREES

1997 Ph.D. in Neuroscience
University of Cincinnati College of Medicine, Cincinnati, Ohio

1988 B.S. in Biology
Albany State University, Albany, New York

PROFESSIONAL ASSOCIATIONS

1997–Present	Society of Toxicology
1997–Present	Society of Birth Defects Research and Prevention (former Teratology Society)
2005–Present	European Teratology Society

PEER REVIEWER

Birth Defects Research

Reproductive Toxicology

Food and Chemical Toxicology

PROFESSIONAL EXPERIENCE

Global Pharmaceutical Company

Global Head of DART and Nonclinical Lead for Partner of Choice initiative

Global leadership role in a pharmaceutical environment, heading efforts in developmental and reproductive toxicology (DART) and company initiative to improved integration with biopharmaceutical partners to advance innovative therapies.

Responsibilities for initiative to improved integration with biopharmaceutical partners included:

- Consulting with interested biopharmaceutical partners to understand how the company's drug development capabilities could facilitate their development efforts
- Using scientific and business knowledge to develop appropriate strategies to meet partner needs
- Identifying and evaluating internal and external capabilities to manage the needs of various collaborations
- Developing proposals, including cost and timelines, and integrating with other contributing lines (e.g., pharmaceutical sciences, clinical) to provide partners with seamless drug development strategies.

Global Head of DART and Toxicology Laboratories

Responsible for developing the strategic vision for a newly formed group consisting of DART, genetic toxicology, and secondary pharmacology. Efforts focused on implementing new approaches and establishing best practices across *in vitro* screening, *in vivo* study conduct, and outsourcing.

Global Head of DART

Globally recognized developmental and reproductive toxicology (DART) subject-matter expert (SME).

- Developed fit-for-purpose strategies for assessment of potential developmental and reproductive toxicity and pediatric drug development

- Executed regulatory studies, both internally and at CROs
- Prepared regulatory documents (e.g., Pediatric Investigative Plans, WoE arguments, product labels, query responses).

Drug Development Project Team Toxicologist

- Supported compound development from Discovery through approval, including designing nonclinical safety assessment strategy, overseeing study conduct, and resolving issues.
- Preparation of regulatory submission documents (e.g., IND, NDA, BLA, briefing packages)
- Experienced with a broad range of therapeutic indications and drug modalities.

Contract Research Organization

Lead of Neurotoxicology Laboratory and DART Toxicologist

SELECTED PEER-REVIEWED PUBLICATIONS

Campion SN, Bowman CJ, Fuchs A, Karanian D, Rana P, **Cappon GD**. 2022. Juvenile toxicity study of PF-07256472/Recifercept, a recombinant human soluble FGFR3, in 2–3-month-old cynomolgus monkeys. Birth Defects Res 115(3):348–356; https://doi.org/10.1002/bdr2.2124.

Catlin NR, Bowman CJ, Campion SN, Lewis EM, Nowland WS, Stethem CM, **Cappon GD**. 2022. The postnatal resolution of developmental toxicity induced by pharmacological DGAT2 inhibition during gestation in rats. J Toxicol Sci 189:225–236.

Campion SN, Nowland WS, Gropp K, Liu C-H, Ritenour HN, Syed J, Catlin NR, Stethem CM, Coskran TM, **Cappon GD**. 2022. Assessment of postnatal femur development in Wistar Han rats. Bone Rev 80:319–325.

Campion SN, Potter DM, Bowman CJ, Catlin NR, Davis S, Millard C, Nowland WS, Stethem CM, Hollingshead BD, Radi ZA, Coder PS, **Cappon GD**. 2022. Lack of effects on bone growth and development following administration of tofacitinib, a JAK inhibitor, to juvenile rats and evaluation of the association between offspring growth and femur length. Reprod Toxicol 113:35–41.

Buetow BS, **Cappon GD**, Aschenbrenner L/M, Updyke L, Torti VR, Evans M, et al. 2022. Regulatory experience assessing the carcinogenic potential of a monoclonal antibody inhibiting PCSK9, Bococizumab, including a 2-year carcinogenicity study in rats. Int J Toxicol 5:389–401.

Catlin NR, Bowman CJ, Campion SN, Cheung JR, Nowland WS, Sathish JG, Stethem CM, Updyke L, **Cappon GD**. 2022. Reproductive and developmental safety of nirmatrelvir (PF-07321332), an oral SARS-CoV-2 Mpro inhibitor in animal models. Reprod Toxicol 108:56–61.

Catlin NR, **Cappon GD**, Engel S, Rohde CM, Nowland WS, Buitrago S, et al. 2021. Maternal Immunization with Group B streptococcus 6-valent polysaccharide conjugate vaccine supported by lack of toxicity in rat and rabbit fertility and developmental toxicity studies. Birth Defects Res 113(19):1343–1356.

Bowman CJ, Bouressam M, Campion SN, **Cappon GD**, Catlin NR, Cutler MW, et al. 2021 Lack of effects on female rat fertility and pre/postnatal development with BNT162b2, a mRNA-based COVID-19 vaccine. Reprod Toxicol 103:28–35.

Catlin NR, Bowman CJ, Campion SN, Davenport SD, Esler WP, Kumpf SW, … **Cappon GD**. 2020. Inhibition of ACC causes malformations in rats and rabbits: Comparison of mammalian findings and alternative assays. J Toxicol Sci 179:183–164.

Huard K, Smith A, **Cappon G**, Dow R, Edmonds D, El-Kattan A, et al. 2020. Optimizing the benefit/risk of acetyl-CoA carboxylase (ACC) inhibitors through liver targeting. J Medicinal Chem 63(19):10879–10896.

Kelly KL, Reagan WJ, Sonnenberg GE, Clasquin M, Amor PA, Carvajal-Gonzalez S, … **Cappon GD**, et al. 2020. De novo lipogenesis is essential for platelet production in humans. Nature Metab 2:1163–1178.

Catlin NR, Stethem CM, Bowman CJ, Campion SN, Nowland WS, **Cappon GD**. 2020. Knockout mouse models are predictive of malformation and embryo-fetal death in drug safety evaluations. Reprod Toxicol 96:11–16.

Catlin NR, Bowman CJ, Engel SM, Sacaan A, Thibault S, Lewis EM, **Cappon GD**. 2019. Reproductive and developmental toxicity assessment of palbociclib, a CDK4/6 inhibitor, in Sprague-Dawley rats and New Zealand White rabbits. Reprod Toxicol 88:76–84.

Antonia S, Claffey M, Balan G, Barreiro G, Barricklow J, Bohanon, M, Boscoe B, **Cappon G**, et al. 2017. Discovery and characterization of PF-06462894 (8), an alkyne-lacking metabotropic glutamate receptor 5 negative allosteric modulator profiled in both rat and non-human primates. J Medicinal Chem 60:7764–7780.

Theunissen PT, Beken S, Beyer BK, Breslin WJ, **Cappon GD**, Chen C, et al. 2016. Comparing rat and rabbit embryo-fetal developmental toxicity studies for 379 pharmaceuticals: On systemic dose and developmental effects. Crit Rev Toxicol 47:402–414.

Theunissen PT, Beken S, Beyer BK, Breslin WJ, **Cappon GD**, Chen C, et al. 2016. Comparison of rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects. Crit Rev Toxicol 46:900–910.

Schmitt G, Ridings J, De Schaepdrijver L, van Doesum-Wolters C, **Cappon GD**, Hartmann A. 2016. Nonclinical safety considerations for the development of pediatric-first drugs: An industry view. Therapeut Innov Regul Sci 50(5):632–638.

Campion SN, Han B, **Cappon GD**, Lewis EM, Kraynov E, Liang H, Bowman CJ. 2015. Decreased maternal and fetal cholesterol following maternal bococizumab (anti-PCSK9 monoclonal antibody) administration does not affect rat embryo-fetal development. Regul Toxicol Pharmacol 73:562–570.

Palanisamy GS, Marcek JM, **Cappon GD**, Whritenour J, Brady JT, Houle C. 2015. Drug-induced skin lesions in cynomolgus macaques treated with metabotropic glutamate receptor 5 (mGluR5) negative allosteric modulators. Toxicol Pathol 43:995–1003.

Campion SN, Marcek JM, Kumpf SW, Chapin RE, Houle C, **Cappon GD**. 2015. Age-related testicular toxicity of mGluR5 negative allosteric modulators appears to be unrelated to testis drug transporter maturity. Reprod Toxicol 52:7–17.

Theunissen P, Beken S, **Cappon GD**, Chen C, Hoberman A, van der Laan J-W, Stewart J, Piersma A. 2014. Towards a comparative retrospective analysis of rat and rabbit developmental toxicity studies for pharmaceutical compounds. Reprod Toxicol 47:27–32.

Cappon GD, Potter D, Hurtt ME, Weinbauer GF, Luetjens CM, Bowman CJ. 2013. Sensitivity of male reproductive endpoints in nonhuman primate toxicity studies: A statistical power analysis. Reprod Toxicol 41:67–72.

Campion SN **Cappon GD**, Carvallo F, NowlandWS, Chapin RE. 2013. Comparative assessment of the timing of sexual maturation in male Wistar Han and Sprague-Dawley rats. Reprod Toxicol 38:16–24.

Cappon GD, Bowman CB, Hurtt ME, Grantam L. 2012. Object discrimination reversal as a method to assess cognitive impairment in non-human primate ePPND studies: Statistical power analysis. Birth Defects Res (Part B) 95:354–362.

Coburn AM, **Cappon GD**, Bowman CJ, Stedman DB, Patyne S. 2012. Reproductive toxicity assessment of Sunitinib, a multi-targeted receptor tyrosine kinase inhibitor, in male and female rats. Birth Defects Res (Part B) 95:267–275.

Cappon GD, Bowman CJ, Campion SN, Finch GL, Hurtt ME, Lewis EM. 2012. Developmental toxicity study of Lersivirine in mice. Birth Defects Res (Part B) 95:225–230.

Campion SN, Bowman CJ, **Cappon GD**, Finch GL, Harrison A, Hurtt ME. 2012. Developmental toxicity of Lersivirine in rabbits when administered throughout organogenesis and when limited to sensitive windows of axial skeletal development. Birth Defects Res (Part B) 95:250–261.

Campion SN, Davenport SE, Nowland WS, Bowman CJ, **Cappon GD**, Hurtt ME. 2012. Sensitive windows of axial skeletal development in rabbits determined by hydroxyurea exposure at different times throughout gestation. Birth Defects Res (Part B) 95:238–249.

Campion SN, **Cappon GD**, Chapin RE, Nowland W. 2012. Isoflurane reduces motile sperm counts in the Sprague-Dawley rat. Drug Chem Toxicol 35:20–24.

Mirsky ML, Sivaraman L, Houle C, Potter DM, Chapin RE, **Cappon GD**. 2011. Histologic and cytologic detection of endocrine and reproductive tract effects of exemestane in female rats treated for up to 28 days. Toxicol Pathol 39:589–605.

Mansell P, Robinson K, Minck DR, Hurtt ME, **Cappon GD**. 2011. Toxicology and toxicokinetics of oral pantoprazole in neonatal and juvenile dogs. Birth Defects Res (Part B) 92:345–352.

Cappon GD. 2011. Nonclinical support of pediatric drug development in a global context. Birth Defects Res (Part B) 92:269–272.

Cappon GD, Chapin RE, Hurtt ME, Wajnrajch MP, Burns-Naas LA. 2011. Impaired reproduction in adult male, but not female, rats following juvenile treatment with the aromatase inhibitor, exemestane. Birth Defects Res (Part B) 92:304–313.

Campion SN, Hurtt ME, Chatman LA, **Cappon GD**. 2011. Toxicity study in juvenile rats with the $\alpha_4\beta_2$ nicotinic acetylcholine receptor partial agonist CP-601,927. Birth Defects Res (Part B) 92(4):323–332.

Cappon GD, Bailey GP, Buschmann J, Feuston MH, Fisher JE, Hew KW, et al. 2009. Juvenile animal toxicity study designs to support pediatric drug development. Birth Defects Res (Part B) 86:463–469.

Cappon GD, Bush B, Newgreen D, Finch GL, Alper RH. 2008. Tolterodine does not affect memory assessed by passive-avoidance response test in mice. Europ J Pharmacol 579:225–228.

Sivaraman L, Tassinari MS, Horimoto M, Hurtt ME, **Cappon GD.** 2008. Timing of implantation and closure of the palatal shelf in New Zealand white & Japanese white rabbits. Drug Chem Toxicol 31(2):104–111.

Watson RE, DeSesso JM, Hurtt ME, **Cappon GD**. 2006. Postnatal growth and morphological development of the brain: A species comparison. Birth Defects Res (Part B) 77:471–484.

Cappon GD, Fleeman TL, Chapin RE, Hurtt ME. 2005. The effects of feed restriction during organogenesis on embryo-fetal development in the rabbit. Birth Defects Res (Part B) 74:424–430.

Fleeman TL, **Cappon GD**, Chapin RE, Hurtt ME. 2005. The effects of feed restriction during organogenesis on embryo-fetal development in the rat. Birth Defects Res (Part B) 74:442–449.

Cappon GD, Fleeman TL, Cook JC, Hurtt ME. 2005. Combined treatment potentiates the developmental toxicity of ibuprofen and acetazolamide in rats. Drug Chem Toxicol 28(4):409–421.

Walthall K, **Cappon GD**, Hurtt ME, Zoetis T. 2005. Postnatal development of the gastrointestinal system: A species comparison. Birth Defects Res (Part B) 74:132–156.

Hurtt ME, Daston G, Davis-Bruno K, Feuston M, Silva Lima B, … **Cappon GD**. 2004. Juvenile animal studies: Testing strategies and design. Birth Defects Res (Part B) 71:281–288.

Fleeman TL, **Cappon GD**, Hurtt ME. 2004. Postnatal closure of treatment-induced membranous interventricular septal defects. Birth Defects Res (Part B) 71:185–190.

Cappon GD, Horimoto M, Hurtt ME. 2004. Reproductive toxicity assessment of lasofoxifene, a selective estrogen receptor modulator (SERM), in male rats. Birth Defects Res (Part B) 71:142–149.

Terry KK, **Cappon GD**, Hurtt ME, Gupta U. 2004. Reproductive toxicity assessment of lasofoxifene, a selective estrogen receptor modulator (SERM), in female rats. Birth Defects Res (Part B) 71:150–160.

Wood SL, Beyer B, **Cappon GD**. 2003. Species comparison of postnatal CNS development: Functional measures. Birth Defects Res (Part B) 68:391–407.

Cappon GD, Fleeman TL, Rocca MS, Cook JC, Hurtt ME. 2003. Embryo/fetal development studies with hydroxypropyl methylcellulose acetate succinate (HPMCAS) in rats and rabbits. Birth Defects Res (Part B) 68:421–427.

Hurtt ME, **Cappon GD**, Browning A. 2003. Proposal for a tiered approach to developmental toxicity testing for veterinary pharmaceutical compounds. Food Chem Toxicol 41:611–619.

Cappon GD, Gupta U, Cook JC, Tassinari MS, Hurtt ME. 2003. Comparison of the developmental toxicity of aspirin in rabbits when administered throughout organogenesis or during sensitive windows of development. Birth Defects Res (Part B) 68:38–46.

Cappon GD, Cook JC, Hurtt ME. 2003. The relationship between cyclooxygenase (COX) 1 and 2 selective inhibitors and fetal development when administered to rats and rabbits during the sensitive periods for heart development and midline closure. Birth Defects Res (Part B) 68:47–56.

BOOK CHAPTERS

Catlin NR, Cook JC, **Cappon GD**. 2022 (in press). Assessment of male reproductive toxicology. In: Cheairs T, Hayes W (eds), Hayes' Principles and Methods of Toxicology. CRC Press, Boca Raton, FL.

Cappon GD, Hurtt M.E. 2010, Developmental toxicity of the renal system. Chapter 11 in: Kapp R, Tyl S (eds), Reproductive Toxicology, 3rd Edition. CRC Press, Boca Raton, FL.

Hurtt ME, **Cappon GD**. 2009. Integration of whole animal developmental toxicity data into risk assessment. In: Hansen D, Abbott B (eds), Developmental Toxicology (Target Organ Toxicology), 3rd Edition. CRC Press, Taylor & Francis Group, Boca Raton, FL, pp 275–292.

Cappon GD, Stump DG. 2001. Developmental neurotoxicity: What have we learned. In: Massaro EJ, Schardien J (eds), Neurotoxicology Handbook, Volume 2. The Humana Press Inc., Totowa, NJ, pp 81–110.