

PERSONAL INFORMATION **Agnes Gyurasics**WORK EXPERIENCE

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- 2008- Present **EMA PDCO member**  
National Institute of Pharmacy and Nutrition (Hungary)  
CHMP - PDCO joint membership, connecting the activities of the two committees;  
NCWG member
- 2004- Present **EMA CHMP member (2010-2019) and alternate**  
National Institute of Pharmacy and Nutrition (Hungary)  
CHMP - PDCO joint membership, connecting the activities of the two committees  
SWP member
- 2008- Present **Chef Advisor /Counselor**  
National Institute of Pharmacy and Nutrition (Hungary)  
National Institute of Pharmacy and Nutrition Hungary (Hungary)  
EMA CHMP and PDCO joint member, connecting the two Committees; CHMP-SWP member; Centralised procedures, CHMP activities, PIP evaluations, PDCO activities; Lecturer in Basic and Clinical Pharmacology / Toxicology at Dept Pharmacology, Semmelweis University, Faculties of Medicine and Pharmacy, Budapest;  
Lecturer, Postgraduate Courses on Clinical Pharmacology, Semmelweis University, Faculty of Medicine, Budapest; Postgraduate Courses on Drug developmental toxicology, Veterinary University and Hungarian Society of Toxicology, Budapest
- 2002- 2008 **Head, Medical-Biological Division**  
National Institute of Pharmacy (Hungary)  
Marketing Authorization Applications: national - MRP - DCP procedures: scientific and regulatory support and supervision of clinical and non-clinical assessments; clinical trial applications: scientific and regulatory support and supervision of clinical and non-clinical assessments; coordination and leadership of work of Division within the whole NIP organization; dossier-upgrading and EU-harmonization process; EMA EWP member, SWP member, CHMP alternate, Lecturer in Pharmacology / Toxicology at Dept Pharmacology, Semmelweis University, Faculty of Medicine, Budapest; Lecturer, Postgraduate Courses on Clinical Pharmacology
- 1999- 2002 **Clinical and non-clinical assessor**  
National Institute of Pharmacy (Hungary)  
Clinical and non-clinical assessment of MAA dossiers and clinical trial applications Observer, EMA EWP, SWP
- 1980- 1999 **Assistant to Associate professor of pharmacology and toxicology**  
Medical University Pécs (Hungary)  
research in pharmacology and toxicology: hepatobiliary transport of xenobiotics, drug metabolism; lecturer in pharmacology and toxicology Board Certification in Clinical Laboratory Sciences 1984 Certification in Experimental Toxicology 1985 Board certification in Clinical Pharmacology 1999 PhD in toxicology 1999 Clinical work at the University Perinatal Intensive Center

EDUCATION AND TRAINING

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- 1974- 1980 **Medical Doctor**  
Medical University Pécs (Hungary)
- 1981- 1984 **Board Certification in Clinical Laboratory Sciences**  
Postgraduate Medical School (Hungary)

- 1983- 1985 **Certificate in Experimental Toxicology**  
Postgraduate Medical School, Hungarian Society of Toxicologists (Hungary)  
Basic safety studies in drug development; non-clinical
- 2001- 2001 **Toxicological Risk Assessment, Postgraduate Education in Toxicology, Wageningen University, European Commission, Wageningen, NL**  
Eurotox / Wageningen University (Netherlands)
- 1997- 1999 **Board Certification in Clinical Pharmacology**  
Semmelweis University, Budapest (Hungary) ()  
Design, conduct and evaluation of clinical trials; including GCP aspects
- 1999- **PhD in Toxicology**  
Medical University Pécs (Hungary)  
Basic research in hepatic metabolism of xenobiotics; invitro and in vivo experiments

## ADDITIONAL INFORMATION

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- Expertise** Basic and clinical Pharmacology, basic research;  
drug evaluation; diabetes, rheumatology, ophthalmology, metabolic diseases, neonatology, paediatrics:  
Drug (incl paediatric) regulation; Guidelines; Centralized and PIP procedures  
Lecturer: in pharmacology, toxicology non-clinical, clinical (incl paediatric) drug development and regulation; GCP courses, imi-Pharmatrain courses; Clinical Pharmacology courses
- Publications**
1. Jahn F, Gregus Z, Gyurasics A, Varga F and Klinger W: The influence of cadmium on the biliary excretion of eosine and bromsulphthalein and on microsomal monooxygenase activities in the rat. *Acta biol med germ* 41:255-261, 1982.
  2. Gyurasics A and Gregus Z: Effect of arsenicals on biliary excretion of endogenous non-protein thiols, mercurials and sulfobromophthalein. *Arch Toxicol Suppl* 13: 340-342, 1989.
  3. Gyurasics A, Varga F and Gregus Z: Effect of arsenicals on biliary excretion of endogenous glutathione and xenobiotics with glutathione-dependent hepatobiliary transport. *Biochem Pharmacol* 41: 937-944, 1991.
  4. Gyurasics A, Varga F and Gregus Z: Glutathione-dependent biliary excretion of arsenic. *Biochem Pharmacol* 42: 465-468, 1991.
  5. Gyurasics A, Koszorus L, Varga F and Gregus Z: Increased biliary excretion of glutathione is generated by glutathione-dependent hepatobiliary transport of antimony and bismuth. *Biochem Pharmacol* 44: 1275-1281, 1992.
  6. Gyurasics A, Varga F and Gregus Z: Biliary excretion of arsenic, antimony and bismuth: the role of glutathione. *Pharmacol Res* 25(S2): 339-340, 1992.
  7. Gyurasics A, Kelley DK, Rogers LK, Welty SE, Hansen TN and Smith CV: Mitochondrial compartmentalization of hyperoxic stresses investigated by measurement of Coenzyme A (CoASH) and CoASSG in rat lungs. *Pediatric Research* 35(4): 2337, 1994.
  8. Wafelman LS, Rogers LK, Gyurasics A, Gupta S and Smith CV: Evidence for a critical role of iron chelates in oxidative hepatic injury in rats. *Pediatric Research* 36(1): 246, 1994.
  9. Gregus Z, Gyurasics A and Koszorus L: Interactions between selenium and group Va metalloids (arsenic, antimony and bismuth) in the biliary excretion. *Environ Pharmacol Toxicol* 5: 89-99, 1998.
  10. Gyurasics A, Perjesi P and Gregus Z: Role of glutathione and methylation in the biliary excretion of selenium. The paradoxical effect of sulfobromophthalein. *Biochem Pharmacol*, 56: 1381-1389, 1998.
  11. Gregus Z, Gyurasics A and Perjesi P: Enhancement of selenium excretion in bile by sulfobromophthalein: elucidation of the mechanism. *Biochem Pharmacol*, 56: 1391-1402, 1998.
  12. Awasthi S, Gyurasics A, Knight SA, Welty SE and Smith CV: Protein oxidation biomarkers in hyperoxic lung injury in rats: Effects of U74389. *Toxicol Lett*, 95: 47-61, 1998.
  13. Gregus Z, Fekete T, Halaszi E, Gyurasics A and Klaassen CD: Effects of fibrates on glycine conjugation of benzoic acid in rats. *Drug Metab Dispos*, 26: 1082-1088, 1998.
  14. Gregus Z and Gyurasics A: Role of glutathione in the biliary excretion of the arsenical drugs trimelarsan and melarsoprol. *Biochem Pharmacol*, 59: 1375-1385, 2000.
  15. Gregus Z, Gyurasics A and Csanaki I: Effects of arsenic-, platinum-, and gold containing drugs

on the disposition of exogenous selenium in rats. *Toxicological Sciences* 57: 22-31, 2000.

16. Gregus Z, Gyurasics A and Csanaki I: Biliary and urinary excretion of inorganic arsenic: monomethylarsonous acid as a major metabolite in rats. *Toxicological Sciences* 56: 18-25, 2000.

17. Gregus Z, Gyurasics A, Csanaki I and Pinter Z: Effects of methylmercury and organic acid mercurials on the disposition of exogenous selenium in rats. *Toxicol Appl Pharmacol* 174: 177-187, 2001

**Projects** Hungarian national research funds OTKA on basic research on Xenobiotics' metabolism / Medical University Pecs, Hungary

**Memberships** Hungarian Society of Experimental and Clinical Pharmacology, EPHAR, EACPT, IUPHAR, European Society for Developmental, Perinatal and Paediatric Pharmacology (ESDPPP)

#### Other Relevant Information