

PERSONAL INFORMATION

Eva Agurell

WORK EXPERIENCE

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- March 2016–Present **PDCO Alternate**
Eva Agurell (Sweden)
- February 2015–Present **Therapeutics Team Leader, Senior Expert, Clinical Assessor, Medical Products Agency**
Eva Agurell (Sweden)
Assessment of market authorisation applications, Scientific advice (national, CHMP), Clinical trial applications.
Anti-infectives, Antibiotics
- August 2008–January 2015 **Clinical Assessor, Senior Expert, Medical Products Agency (Sweden)**
Eva Agurell (Sweden)
Assessment of market authorisation applications, Scientific advice (national, CHMP), Clinical trial applications.
Anti-infectives, Respiratory system.
Antibiotics.
- June 2012–September 2012 **Deputy head of Department of Efficacy and Safety 4, Medical Products Agency (Sweden)**
Eva Agurell (Sweden)
- August 2002–August 2008 **Preclinical Assessor, Medical Products Agency (Sweden)**
Eva Agurell (Sweden)
Assessment of non-clinical part of market authorisation applications, Scientific advice (national, CHMP), Clinical trial applications.
- October 1992–July 2002 **Research scientist, Associate Director, Toxicology Project Leader, Principle Scientist, Astra AB/AstraZeneca, Safety Assessment (Sweden)**
Eva Agurell (Sweden)
Genotoxic assessments, toxicology assessments, reactive metabolites investigations.

EDUCATION AND TRAINING

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- October 1988–October 1992 **Ph.D. Toxicology Genetics**
Genetic and Cellular Toxicology, Stockholm University (Sweden)

ADDITIONAL INFORMATION

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- Expertise**
- Clinical assessment
 - Scientific advice/protocol assistance (national and CHMP)
 - Bioequivalence of orally inhaled products (asthma and COPD)
 - Non-clinical assessment
 - Genotoxicity

Drug development

- Publications** Nilsson L, Agurell E
1-Aminopyrene is a Salmonella mutagen requiring excess air in the absence of mammalian metabolic activation.
Environ Mutagen 1982;4:334-335.
- Agurell E
Variations of the mutagenic impurities in a carbon black.
Mutation Res 1983;113:222-223.
- Agurell E, Löfroth G
Presence of various types of mutagenic impurities in a carbon black detected by the Salmonella assay.
In: Waters M, Sandhu S, Lewtas J, Claxton L, Chernoff N & Nesnow S, eds. Short-Term Bioassays in the Analysis of Complex Environmental Mixtures III.
Plenum Press, New York, 1983;297-306.
- Moller M, Alfheim I, Löfroth G, Agurell E
Mutagenicity of extracts from typewriter ribbons and related items.
Mutation Res 1983;119:239-249.
- Löfroth G, Nilsson L, Agurell E, Yasuhara A
Salmonella/microsome mutagenicity of 1-nitropyrene-2-ol, a nitropyrene phenol formed in the photolysis of 1-nitropyrene.
Z Naturforsch 1984;39:193-195.
- Löfroth G, Toftgård, Nilsson R, Agurell E, Gustafsson J-Å
Short-term bioassays of nitroderivatives of benzo(a)pyrene and perylene.
Carcinogenesis 1984;5:925-930.
- Löfroth G, Lazaridis G, Agurell E
The use of the Salmonella/microsome mutagenicity test for the characterization of organic extracts from ambient particulate matter.
Environ Interact 1985;11;161-167.
- Löfroth G, Nilsson L, Agurell E, Sugiyama T
Salmonella/microsome mutagenicity of monochloro derivatives of some di-, tri-, and tetracyclic aromatic hydrocarbons.
Mutation Res 1985;155:91-94.
- Löfroth G, Agurell E and Romert L
Short-term bioassays of extracts of airborne particulate matter collected at street and rooftop levels.
Environ Mutagen 1986;8:46-47.
- Rannug A, Rannug U, Rosenkranz H, Winqvist L, Westerholm R, Agurell E, Grafström A-K.
Certain photooxidized derivatives of tryptophan bind with very high affinity to the Ah-receptor and are likely to be endogenous signal substances.
J Biol chem 1987;262:15422-15427.
- Löfroth G, Agurell E, Stensman C
Modulation of "direct"-acting mutagens by S9-cofactors in a Salmonella assay method.
Environ Mol Mutagen 1988;11:62.
- Löfroth G, Ling PI, Agurell E
Public exposure to environmental tobacco smoke.
Mutation Res 1988;202:103-110.
- Löfroth G, Agurell E
Korttidstester upptäcker mutagena effekter:
In: L. Möller, ed. Stadsluften - en bok om luften i våra tätorter.

Swedish National Environmental Protection Agency (SNV).
Gummessons Tryckeri AB, Falköping 1990;74-81.

Agurell E, Alsberg T, Assafaz-Redda Y, Brorström-Linden E, Gustafsson JÅ, Löfroth G, Romert L, Steen B, Toftgård R, Zakrisson S
Chemical and biological characterization of urban particulate matter.
Swedish National Environmental Protection Agency (SNV) Report 3841, 1991;1-68.

Agurell E, Cederberg H, Ehrenberg L, Lindahl-Kiessling K, Rannug U, Tömqvist M
Genotoxic effects of ethylene oxide and propylene oxide: a comparative study.
Mutation Res 1991;250:229-237.

Agurell E, Stensman C
Salmonella mutagenicity of three complex mixtures assayed with the microsuspension technique. A WHO/IPCS/CSCM study.
Mutation Res 1992;276:87-91.

Claxton L, Creason J, Leroux B, Agurell E, Bagley S, Bryant D, Courtois Y, Douglas G, Clare C, Goto S, Quillardet P, Jagannath D, Kataoka K, Mohn G, Nielsen P, Ong T, Pederson T, Shimizu H, Nylund L, Tokiwa H, Vink G, Wang Y, Warshawsky D.
Results of the IPCS collaborative study on complex mixtures.
Mutation Res 1992;276:23-32.

Agurell E, Li R, Rannug U, Norming U, Tribukait B, Ramel C
Detection of DNA alterations in human bladder tumors by DNA-fingerprint analyses.
Cancer Genet Cytogenet 1992;60:55-60.

Rannug U, Agurell E, Rannug A, Cederberg H
Certain tryptophan photoproducts are inhibitors of cytochrome P450-dependent mutagenicity.
Environ Mol Mutagen 1992;20:289-296.

Rannug U, Cederberg H, Agurell E, Hedenskog M, Westman MA, Wihlborg M
Spontaneous and chemically induced new length alleles at the human minisatellite locus MS1 integrated in a haploid yeast strain.
Pharm Toxicol 1992;70(5):part 2:14.

Agurell E
Comparative studies of alkylating and N-heterocyclic compounds on different genetic endpoints with special emphasis on amplification of minisatellite sequences.
Doctoral dissertation, University of Stockholm, 1992.

Agurell E, Löfroth G
Impurity variations in a carbon black: Characterization by the Ames Salmonella mutagenicity assay and polycyclic aromatic hydrocarbon analysis.
Environ Toxicol Chem 1993;12:219-223.

Cederberg H, Agurell E, Hedenskog M, Rannug U
Amplification and loss of repeat units of the human minisatellite MS1 integrated in chromosome III of a haploid yeast strain.
Mol Gen Genet 1993;238(1-2):38-42.

Agurell E, Cederberg H, Hedenskog M, Rannug U
Chemical induced changes of the spectrum of amplifications in the human minisatellite MS1 integrated in chromosome III of a haploid yeast strain.
Mol Gen Genet 1994;242(2):137-144.

Agurell E, Hamreby A-M, Lind J, Palm M, Rylander G, Westman A
Comparison of effects induced in vivo by carbon tetrachloride,
1-ethyl-1-nitrosourea and methyl methanesulfonate using the alkaline comet assay.
Mutation Res 1997;379(1):133.

Tice RR, Agurell E, Anderson D, Burlinson B, Hartmann A, Kobayashi H, Miyamae Y, Rojas E, Ryu J-C, Sasaki YF

Single Cell Gel/Comet assay: Guidelines for in vitro and in vivo genetic toxicology testing.

Environ Mol Mutagen 2000;35:206-221.

Hartmann A, Agurell E, Beevers C, Brendler-Schwaab S, Burlinson B, Clay P, Smith A, Speit G, Smith A, Thybault V, Tice RR.

Proposed guideline for conducting the in vivo alkaline Comet assay.

Mutagenesis. vol.18, no.1 pp.45–51, 2003.

Wiklund SJ, Agurell E

Aspects of design and statistical analysis in the Comet assay.

Mutagenesis, 2003 vol, 18 No 2:167-75.

Andersson M, Agurell E, Vaghef H, Bolcsfoldi G, Hellman B.

Extended-term cultures of human T-lymphocytes and the Comet Assay: A useful combination when testing for genotoxicity in vitro?

Mutation Research, 2003 Sep 9;540(1):43-55.

Burlinson B, Tice RR, Speit G, Agurell E, Brendler-Schwaab SY, Collins AR, Escobar P, Honma M, Kumaravel TS, Nakajima M, Sasaki YF, Thybaud V, Uno Y, Vasquez M, Hartmann A; In Vivo Comet Assay Workgroup, part of the Fourth International Workgroup on Genotoxicity Testing.

Fourth International Workgroup on Genotoxicity testing: results of the in vivo Comet assay workgroup

Mutation Research, 2007 Feb 3;627(1):31-5

Evans C, Cipolla D, Chesworth T, Agurell E, Ahrens R, Connor D, Dissanayake S, Dolovich M, Doub W, Fugelsang A, García Arieta A, Golden M, Hermann R, Hochhaus G, Holmes S, Lafferty P, Lyapustina S, Nair P, O'Connor D, Parkins D, Peterson I, Reisner C, Sandell, D, Jai Pal Singh G, Weda M, Watson P; Equivalence Considerations for Orally Inhaled Products for Local Action—ISAM/IPAC-RS European Workshop Report. Journal of Aerosol Medicine and Pulmonary Drug Delivery, 2012, vol 25, number 3, page 117-139.

Projects

Memberships

ISAM/IPAC-RS European Workshop on equivalence considerations for inhaled products (OIPs) for local action, invited speaker, "MPA/Swedish Experience with OIP Equivalence Determinations". Frankfurt, Germany, 12-13 October 2010.

Informa's Inhalation Drug Development conference. Invited speaker, "EU regulatory perspective: Current interpretations and expectations for bioequivalence", London October 2011

Informa's Inhalation Drug Development conference. Invited speaker, "Establishing bioequivalence for inhalable drugs: The regulatory perspective", Munich, September 2012

Management Forum Ltd. Bioequivalence for Inhaled Products. Invited speaker, "Bioequivalence – Use of OIP Guidelines, Application of the EMEA BE OIP guideline to generic products", London, November 2012.

Management Forum Ltd. Portable inhalers. Invited speaker, "Establishing bioequivalence for inhalable fixed dose combinations: The regulatory perspective", London, November 2012.

Informa's Inhalation Drug Development conference. Invited speaker, "Interpretation of the CPMP guideline on requirements for clinical documentation for orally inhaled products (OIP) CPMP/EWP/4151/00 Rev. 1", Berlin, September 2013.

Other Relevant Information

Summary of selected additional courses:

Assessors training on revised guideline for orally inhaled products, EMEA, London, November 10, 2008.

Assessors training on revised guideline for orally inhaled products, paediatric part of the guideline, EMEA, London, November 24, 2009.