

**PERSONAL INFORMATION** **Harald Enzmann****WORK EXPERIENCE**

October 2018–Present

**CHMP Chair**

European Medicines Agency (United Kingdom)

Chair of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)

November 2016–September  
2018**CHMP Vice-Chair**

European Medicines Agency (United Kingdom)

Vice Chair of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)

April 2016–Present

**Section Head**

Federal Institute for Drugs and Medical Devices - Bundesinstitut für Arzneimittel u. Medizinprodukte (Germany)

Head of Section "European and International Affairs" at the German federal Institute for Drugs and Medical devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)

2005–Present

**CHMP Member**

European Medicines Agency (United Kingdom)

Member of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) since 2005

September 2005–March 2016

**Division Head**

Federal Institute for Drugs and Medical Devices - Bundesinstitut für Arzneimittel u. Medizinprodukte (Germany)

Head of licensing division 2 at the German Federal Institute for Drugs and Medical device (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). The licensing division 2 has currently 98 staff members and is responsible for medicinal products with an indication cancer, immunology, hematology, endocrinology, metabolism, diabetes, gastrointestinal disorders, cardiovascular system and medicinal products for diagnostic use (e.g. contrast media).

December 2002–September  
2005**Division Head**

Federal Institute for Drugs and Medical Devices - Bundesinstitut für Arzneimittel u. Medizinprodukte (Germany)

Preclinical Pharmacology and Toxicology: medicines, regulatory, experimental research on carcinogenesis

January 2000–December 2002

**Division Head**

Bayer HealthCare (Germany)

Head of the Department of Rodent Studies and Genotoxicity: responsible for genotoxicity, carcinogenicity, rodent studies for pharmaceuticals, agrochemicals and chemicals

November 1996–December 1999

**Laboratory Head**

Bayer HealthCare (Germany)

Research and Development, Toxicology; in vivo and in vitro cancer models

- March 1995–November 1996 **Visiting Scientist**  
American Health Foundation, Valhalla, New York (United States)  
Research on various of short term carcinogenicity models, development of the in ovo carcinogenicity assessment
- January 1989–February 1995 **Laboratory Head**  
Bayer HealthCare (Germany)  
Toxicology, short term carcinogenicity testing in vivo (rodents)
- December 1988–December 1989 **Postdoctoral Researcher**  
Friedrich-Alexander Universität Erlangen-Nürnberg (Germany)  
Research on pathomechanisms of autoimmunity in arthritis
- January 1985–December 1988 **Postdoctoral Researcher**  
dkfz - German Cancer Research Center (Germany)  
Research on carcinogenesis, chemically induced, and realted changes in carbohydrate metabolism, rodents, liver, pancreas; research on animal model of osteoporosis
- January 1983–January 1985 **Graduate Student Researcher**  
dkfz - German Cancer Research Center (Germany)  
Doctoral thesis; hepatocarcinogenesis, histochemistry, morphometry

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**EDUCATION AND TRAINING**

- 1979–1985 **Doctor of Medicine (MD), Medizin**  
Karl Ruprechts University, Heidelberg (Germany)
- 1995–1996 **Master of Science Degree, Experimental Pathology**  
New York Medical College, NY, USA (United States)

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**ADDITIONAL INFORMATION**

- Expertise** Regulatory Affairs  
Research  
Drug Development  
Pharmaceutical...  
Pharmacology  
Toxicology  
Oncology  
Cancer Research  
Cancer Biology  
Diabetology  
Histology  
Healthcare  
Lifesciences
- Publications** 2018

Blake K., Bonelli M., Ponzano S., Enzmann H.:

Response to: "The Role of Quantitative Systems Pharmacology in the Design of First-in-Human Trials".

Clinical Pharmacology & Therapeutics 10 (2018).1002/cpt.1148.

Schnorr J., Fütterer S., Spicher K., Catarinolo M., Schlösser C., Enzmann H, Langguth P.:

Bioequivalence decision for nanoparticulate iron complex drugs for parenteral administration based on their disposition.

Regulatory Toxicology and Pharmacology 94 (2018), 293-298.

Ponzano S., Blake K., Bonelli M., Enzmann H.:

Promoting Safe Early Clinical Research of Novel Drug Candidates: A European Union Regulatory Perspective.

Clin Pharmacol Ther. Apr;103(4) (2018):564-566. doi: 10.1002/cpt.899. Epub 2017 Nov 6.

2017

Kaestner, B., Spicher, K., Jaehde, U., Enzmann, H.:

Effects of sorafenib and cisplatin on preneoplastic foci of altered hepatocytes in fetal turkey liver.

Toxicol. Res. 6 (2017) 54-62.

de Bekker-Grob, E.W., Berlin, C., Levitan, B. et al.:

Giving Patients' Preferences a Voice in Medical Treatment Life Cycle: The PREFER Public-Private Project.

Patient 10 (2017), 263. doi:10.1007/s40271-017-0222-3

2016

Enzmann, H., Meyer, R., Broich, K.

The new EU regulation on in vitro diagnostics: potential issues at the interface of medicines and companion diagnostics"

Biomarkers in Medicine (in press)

Enzmann., H., Norta, M.

Development of Innovative Medicines for European Patients and Impact of Brexit

Pharmaceut Reg Affairs 5: 171. doi:10.4172/2167-7689.1000171

August 12, 2016

Enzmann, H.:

New trends and challenges in the European regulation of innovative medicines, Regul Toxicol Pharmacol. 2016 May 27. pii: S0273-2300(16)30147-7. doi: 10.1016/j.yrtph.2016.05.033. [Epub ahead of print]

Bergmann, L., Enzmann, H., Thirstrup, S., Schweim, JK., Widera, I., Zwierzina, H.:

Access to innovative oncology medicines in Europe

Ann Oncol 27 (2016) 353-356

2015

Spicher, K., Brendler-Schwaab, S., Schlösser, C., Catarinolo, M., Fütterer, S., Langguth, P., Enzmann H.:

Differences in tissue distribution of iron from various clinically used intravenous iron complexes in fetal avian heart and liver.

Regulatory Toxicology and Pharmacology 73 (2015) 65-72.

Pfeifer, V., Metzger, A., Norta, M., Enzmann, H., Eckstein, N.:

Hilfe bei seltenen Krankheiten.

Deutsche Apotheker Zeitung 38 (2015) |58-64.

Pfeifer, V., Metzger, A., Norta, M., Enzmann, H., Eckstein, N.:

Ähnlich, gleich oder klinisch überlegen?

Deutsche Apotheker Zeitung 38 (2015) 66-72.

2014

Cortes-Blanco, A., Prieto-Yerro, C., Martinez-Lazaro, R., Zamora, J., Jiménez-Huete, A., Haberkamp, M., Pohly, J., Enzmann, H., Zinserling, J., Strassmann, V., Broich, K.:

Florbetapir ((18)F) for brain amyloid positron emission tomography: Highlights on the European marketing approval.

Alzheimers Dement. (2014) S395-S399.

Eckstein N., Röper L., Haas B., Potthast H., Hermes U., Unkrig C., Naumann-Winter F., Enzmann H.:

Clinical pharmacology of tyrosine kinase inhibitors becoming generic drugs: the regulatory perspective.

J Exp Clin Cancer Res. 33 (2014) 15.

Williams, G., Iatropoulos, M., Enzmann, H., Deschl, U.:

Principles of Clinical Pathology for Toxicology Studies.

Hayes' Principles and Methods of Toxicology, Sixth Edition, Edited by A. Wallace Hayes and Claire L. Kruger, CRC Press (2014) 1251-1304.

Hanaizi Z., Unkrig C., Enzmann H., Camarero J., Sancho-Lopez A., Salmonson T., Gisselbrecht C., Laane E., Pignatti F.:

The European Medicines Agency Review of Bosutinib for the Treatment of Adult Patients With Chronic Myelogenous Leukemia: Summary of the Scientific Assessment of the Committee for Medicinal Products for Human Use.

Oncologist. 19 (2014) 421-425. doi: 10.1634/theoncologist.2013-0294. Epub 2014 Mar 25.

Bartsch, R., Frings, S., Marty, M., Awada, A., Berghoff, AS., Conte, P., Dickin, S., Enzmann, H., Gnant, M., Hasmann, M; Hendriks, HR., Llombart, A., Massacesi, C., von Minckwitz, G., Penault-Llorca, F., Scaltriti, M., Yarden, Y., Zwierzina, H., Zielinski, CC.:

Present and future breast cancer management - bench to bedside and back: a positioning paper of academia, regulatory authorities and pharmaceutical industry. Ann Oncol 25 (2014) 773-780.

Bergmann, L., Enzmann, H., Broich, K., Hebborn, A., Marsoni, S., Goh, L., Smyth J. F., Zwierzina, H.:

Actual developments in European regulatory and health technology assessment of new cancer drugs: what does this mean for oncology in Europe?

Ann Oncol 25 (2014) 303-306.

Enzmann HG., Brunnemann KD., Kästner B., Iatropoulos MJ., Williams GM.:

Dose-dependent induction of preneoplastic lesions by the tobacco-specific nitrosamine carcinogen NNK in the in ovo carcinogenicity assessment (IOCA) assay.

Exp Toxicol Pathol 66 (2014) 35-40.

Tzogani K., Straube M., Hoppe U., Kiely P., O'Dea G., Enzmann H., Salmon P., Salmonson T., Pignatti F.:

The European Medicines Agency approval of 5-aminolaevulinic acid (Ameluz) for the treatment of actinic keratosis of mild to moderate intensity on the face and scalp: Summary of the scientific assessment of the Committee for Medicinal Products for Human Use.

J Dermatolog Treat 25 (2014) 371-374.

2013

Enzmann H, Broich K.:

Cancer: Is it really so different? Particularities of oncologic drugs from the perspective of the pharmaceutical regulatory agency.

Z Evid Fortbild Qual Gesundheitswes. 107 (2013) 120-128.

Berntgen, M., Enzmann, H., Schabel, E., Prieto Yerro, C., Gómez-Outes, A., Salmonson, T., Musaus, J.:

Linaclotide for treatment of irritable bowel syndrome—The view of European regulators.

Digestive and Liver Disease, Volume 45 (2013) 724-726.

Enzmann H., Brunnemann K., Iatropoulos M., Shpyleva S., Lukyanova N., Todor I., Moore M., Spicher K., Chekhun V., Tsuda H., Williams G.:

Inter-laboratory comparison of turkey in ovo carcinogenicity assessment (IOCA) of hepatocarcinogens.

Experimental and Toxicologic Pathology 65 (2013) 729-735.

Enzmann H, Broich K.:

Therapie der Folgekrankheiten kindlicher Adipositas.

Treatment of sequelae of childhood obesity.

Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 56 (2013) 485-486.

2012

Mayer, P., Reitzenstein, U., Warnken, M., Enzmann, H., Racké, K.

Insulin action on H292 bronchial carcinoma cells as compared to normal bronchial epithelial cells.

Pulm Pharmacol Ther 25 (2012) 104-114.

Enzmann, H., Kaestner, B., Todorova, L., Kamusheva, M., Vlaskovska, M., Petrova, G.:

Current Issues in Orphan Drug Regulation in the EU.

Hayka Farmakologia / Наука Фармакология 2 (2012) 8-16.

2011

Enzmann, H., Broich, K.:

Die Therapie von Adipositas bei Kindern und Jugendlichen: Ein ungenügend bestelltes Feld?

The therapy of obesity in children and adolescents : An insufficiently researched area?

Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 54 (2011) 525–526.

Williams, GM., Brunnemann, KD., Iatropoulos, MJ., Smart, DJ., Enzmann, HG.:

Production of liver preneoplasia and gallbladder agenesis in turkey fetuses administered diethylnitrosamine.

Archives of Toxicology 85 (2011) 681-687.

Enzmann, H., Weise, M.:

Current european regulatory perspectives on insulin analogues.

Diabetology & Metabolic Syndrome 3 (2011) 14.

Kästner, B., Wagner, C, Spicher, K., Jaehde, U., Enzmann, H.:

Study on the Modulation of Cancer Prestages and Host Tissue in Embryonic Avian Liver by Sorafenib; internationale Konferenz "Cell Cycle Regulators: Inhibitors and Cancer", Februar 2011, Wien, Poster

Mayer P., Haas B., Celner J., Enzmann H., Pfeifer A.:

Glitazone-like action of glimepiride and glibenclamide in primary human adipocytes.

Diabetes Obes Metab. 13 (2011) 791-799.

Enzmann, H., Weise, M.:

Regulatory perspectives on innovative insulin analogues.

Hayka Farmakologia / Наука Фармакология 2 (2011) 11-15.

2010

Warnken M., Reitzenstein U., Sommer A., Fuhrmann M., Mayer P., Enzmann H., Juergens UR., Racké K.:

Characterization of proliferative effects of insulin, insulin analogues and insulin-like growth factor-1 (IGF-1) in human lung fibroblasts.

Naunyn-Schmied Arch Pharmacol 382 (2010) 511–524.

Wagner C., Kästner B., Spicher K., Mayer P., Jaehde U., Enzmann, H.:

Potential Targets for Anticancer-Therapy show different Gene Expression Patterns in HepG2 Cells grown in Culture compared to the same Tumor Cell Line grown as Nodular Tumor.

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Experimental Oncology 32 (2010) 1-108. S3.25.

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Chemical Induction of Tumors and Tumor Prestages in Embryonic Avian Liver.

S4.27 Experimental Oncology 32 (2010) 1-108.

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Effect of Anti-Tumor Drugs on Foci of Altered Hepatocytes and Surrounding Host Tissue in Embryonic Turkey Liver;  
international conference "Tumor and Host: Novel Aspects of old Problem", 2010, Kiew, Vortrag;  
Abstract published in:  
Experimental Oncology 32 (2010) 1-108: S5.6.
- 2009
- McCabe, C., Bergmann, L., Bosanquet, N., Ellis, K., M., Enzmann, H., von Euler, M., Jönsson, B., Kallen, K.-J., Newling, D., Nüssler, V., Paschen, B., de Wilde, R., Wilking, N., Teale, C., Zwierzina, H.:  
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Annals of Oncology 20 (2009) 403-412.
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Analysis of Signaling Pathways Related to Cell Proliferation Stimulated by Insulin Analogs in Human Mammary Epithelial Cell Lines.  
Endocrine-Related Cancer 16 (2009) 429-441.
- Shuklan A., Enzmann, H., Mayer, D.:  
Proliferative effect of Apidra® (insulin glulisine), a rapid-acting insulin analogue on mammary epithelial cells.  
Archives of Physiology and Biochemistry, 115 (2009) 119-126.
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Klinische Forschung Auswirkungen der europäischen Gesetzgebung und aktuelle Entwicklungen.  
Bundesgesundheitsbl 52 (2009) 375-376.
- 2008
- Mayer, D., Shukla, A., Enzmann, H.:  
Proliferative effects of insulin analogues on mammary epithelial cells.  
Archives of Physiology and Biochemistry, 114 (2008): 38-44.
- Roth, S., Langguth, P., Spicher, K., Enzmann, H.:  
Comparative toxicity and cell-tissue distribution study on nanoparticulate iron complexes using avian embryos and HepG2-cells.  
Translational Research 151 (2008) 36-44.
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European Incentives for Orphan Medicinal Products.  
Bundesgesundheitsbl Gesundheitsforsch Gesundheitsschutz, 51 (2008) 500-508.
- Schneider C., Enzmann, H.:  
The role of the Committee for Medicinal Products for Human Use (CHMP) in the European centralised procedure.  
Bundesgesundheitsbl - Gesundheitsforsch -Gesundheitsschutz, 51 (2008) 731-739.
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Bundesgesundheitsbl - Gesundheitsforsch -Gesundheitsschutz, 51 (2008) 703.
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Principles and Methods of Toxicology, Fifth Edition, Edited by A. Wallace Hayes  
CRC Press/Taylor and Francis Group, FL (2007) 1265-1316.
- 2005
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Dehydroepiandrosterone causes hyperplasia and impairs regeneration in rat liver.

International Journal of Oncology 27 (2005) 1551-1558.

2004

Perrone, C., Ahr, H., Duan, J., Jeffrey, A., Schmidt, U., Williams, G., Enzmann, H.:

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Archives of Toxicology 78 (2004) 589-598.

2003

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Prevalidation of a Rat Liver Foci Bioassay (RLFB) Based on Results from 1600 Rats: A Study Report, Toxicologic Pathology 31 (2003), 60–79.

2002

Brunnemann, K.D., Enzmann, H.G., Perrone, C.E., Iatropoulos, M.J., Williams, G.M.:

In ovo carcinogenicity assay (IOCA): evaluation of mannitol, caprolactam and nitrosoproline.

Archives of Toxicology 76 (2002) 606-612.

2001

Iatropoulos M.J., Jeffrey A.M., Schlüter G., Enzmann H.G., Williams G.M.:

Bioassay of mannitol and caprolactam and assessment of response to diethylnitrosamine in heterozygous p53-deficient (+/-) and wild type (+/+) mice.

Arch Toxicol 75, (2001) 52-58.

Korr H., Botzem B., Schmitz C., Enzmann H.:

N-Nitrosomorpholine induced alterations of unscheduled DNA synthesis, mitochondrial DNA synthesis and cell proliferation in different cell types of liver, kidney, and urogenital organs in the rat. Chemico-Biological Interactions 134, (2001) 217-233.

Iatropoulos M.J., Jeffrey A.M., Enzmann, H.G., Von Keutz, E., Schlüter, G. Williams, G.M.:

Assessment of chronic toxicity and carcinogenicity in an accelerated cancer bioassay in rats of moxifloxacin, a quinolone antibiotic.

Experimental and Toxicologic Pathology 53 (2001) 345-347.

1999

Williams, G.M., Enzmann, H.:

The rat liver hepatocellular altered focus limited bioassay for chemicals with carcinogenic activity.

Carcinogenicity: Testing, Predicting and Interpreting Chemical Effects. K. T. Kitchin (Ed.), Marcel Dekker, Inc., New York, Basel, 1999, pp 361-394.

Enzmann, H., Wiemann, C., Ahr, H.J., Schlueter, G.:

Damage to mitochondrial DNA induced by the quinolone Bay y 3118 in embryonic turkey liver.

Mutation Research 425, (1999) 213-224.

Wiemann, C., Enzmann, H., Löser, E., Schlüter, G.:

Nonlinearity of Nuclear Enlargement in Hepatocytes Induced by the Carcinogen N'-Nitrosomorpholine in Ovo.

Cancer Detection and Prevention 23, (1999) 485-495.

1998

Ahr, H.J., Bomhard, E., Enzmann, H., Karbe, E., Sander, E., Schlüter, G.:

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Cardiovascular Drugs and Therapy 12 (1998) 157-169.

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The Prototypes Mouse Skin Tumor Assay and Rat Liver Focus Assay.  
Food and Chemical Toxicology 36, (1998) 979-995.
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Short- and Intermediate-term Carcinogenicity Testing - A Review.  
Part 2: Available Experimental Models.  
Food and Chemical Toxicology 36, (1998) 997-1013.  
1997
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J. Toxicol. Environm. Health 105 (1997) 1196-1203.
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The in ovo carcinogenicity assay (IOCA): a review of an experimental approach for research on carcinogenesis and carcinogenicity testing.  
Frontiers in Bioscience 2, (1997) 30-39.  
1996
- Witt, A., Kühlem, C., Enzmann H.:  
Das in ovo Modell der Karzinogenese.  
Der Tierschutzbeauftragte 5 (1996) 139-142.  
1995
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Rapid induction of preneoplastic liver foci in embryonal turkey liver by diethylnitrosamine.  
Toxicologic Pathology 23 (1995) 560-569.
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Damage to mitochondrial DNA induced by the hepatocarcinogen diethylnitrosamin in ovo.  
Mutation Res. 329 (1995) 113-120.
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Dose dependence of diethylnitrosamin-induced nuclear enlargement in embryonal turkey liver.  
Carcinogenesis 16 (1995) 1351-1355.
- Enzmann, H., Zerban, H., Kopp-Schneider, A., Löser, E., Bannasch, P.:  
Effects of low doses of N-nitrosomorpholine on the development of early stages of hepatocarcinogenesis.  
Carcinogenesis 16 (1995) 1513-1518.
- Wimitzer, U., Enzmann, H., Rosenbruch, M., Bomhard, E.:  
Accumulation of p53 protein in chemically induced oval cells during early stages of rodent hepatocarcinogenesis.  
Carcinogenesis 16 (1995) 697-701.  
1992
- Enzmann, H., Kaliner, G., Watta-Gebert, B. and Löser, E.:  
Foci of altered hepatocytes induced in embryonal turkey liver.  
Carcinogenesis 13 (1992) 943-946.
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Glycogen phosphorylase hyperactive foci of altered hepatocytes in aged rats.

Virchows Arch. B 62 (1992) 3-8.

1990

Enzmann, H., Dettler, T., Ohlhauser, D., Stumpf, P. and Bannasch, P.:

Dietary fructose enhances the development of atypical acinar cell nodules in the pancreas of rats pretreated with N-nitrosomorpholine.

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1989

Bannasch, P., Enzmann, H., Hacker, H.J., Weber, E., Zerban, H.:

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1988

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Cellular differentiation during neoplastic development in the liver.

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Non-persisting early foci of altered hepatocytes induced in rats by N-nitrosomorpholine.

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Elevation of glucose-6-phosphate in early stages of hepatocarcinogenesis induced in rats by N-nitrosomorpholine.

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1987

Bannasch, P., Enzmann, H., Zerban, H.:

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Enzmann, H., Bannasch, P.:

Morphometric study of alterations of extrafocal hepatocytes of rat liver treated with N-

nitrosomorpholine.

Virchows Archiv B 53 (1987) 218-226.

Enzmann, H., Bannasch, P.:

Potential significance of phenotypic heterogeneity of focal lesions at different stages in hepatocarcinogenesis.

Carcinogenesis 8 (1987) 1607-1612.

Enzmann, H., Edler, L., Bannasch, P.:

Simple elementary method for the quantification of focal liver lesions induced by carcinogens.

Carcinogenesis 8 (1987) 231-235.

1985

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Tigroid cell foci and neoplastic nodules in the liver of rats treated with a single dose of aflatoxin B1.

Carcinogenesis 6 (1985) 1641-1648.

Bannasch, P., Moore, M.A., Hacker, H.J., Klimek, F., Mayer, D., Enzmann, H., Zerban, H.:

Potential significance of phenotypic instability in focal and nodular liver lesions induced by hepatocarcinogens.

In: Hepatology: A Festschrift for Hans Popper. Hrsg.: H. Brunner u.a., New York, Raven Press 1985, pp. 191-209.

#### Projects

#### Memberships

EACR European Association for Cancer Research

IATP International Academy of Toxicologic Pathology

SOT Society of Toxicology

ESTP European Society of Toxicologic Pathology

Science Pharmacology (editorial board)

#### Other Relevant Information