
25th Annual Meeting of Japanese Society of Toxicology

**June 17-19
Nagoya Congress Center**

Programs

1998 Nagoya

25th Annual Meeting of Japanese Society of Toxicology

June 17-19, 1998

Nagoya Congress Center, Nagoya

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June 17, Wednesday

	Shiratori Hall (A) (Bldg. 4)	Room 224 (Bldg. 2, 2F)	Room 234 (Bldg. 2, 3F)	Shiratori Hall (B) (Bldg. 4)
9:00	Seminar: How to improve the quality of animal studies Co-chairs: K. Doi (Tokyo Univ.) and T. Matsuzawa (Yamanouchi)	9:00-10:15 General papers by oral Session 1 Reproduction	9:00-10:45 General papers by oral Session 2 PK and TK	General papers by poster presentation
10:00	Introduction K. Doi (Tokyo Univ.) Auditory function test H. Kuse, (Tanabe) Visual function test N. Nakayama, (Taisho) Cardiac function test N. Shimizu (Fuji Biomedics)	10:30-12:15 General papers by oral Session 3 Mutagenicity	11:00-12:15 General papers by oral Session 4 Hepatotoxicity	
11:00	Test for prostatic function M. Murakoshi (Teikokuzohki) Ultrasonic Image analyzer for renal toxicity A. Hashimoto (Hokkaido Univ.) Safety pharmacology testing in general toxicity studies Levis B. Kinter, (Astra Merk)			
12:10-13:20 Lunch break				
13:20	International harmonization of clinical pathology testing R. L. Hall (Covance)	13:30-15:15 General papers by oral Session 5 Carcinogenicity	13:30-15:15 General papers by oral Session 6 Cardiovascular	General papers by poster presentation
14:00	International trend of guidelines for Immuno-toxicity Junichi Sawada, (NIHS)			
15:00	Statistical science and quantitative understanding D. J. Finney (Edinburgh Univ.) Species differences in hepatotoxic responses Felix A. de la Iglesia (Warner-Lambert)	15:30-16:45 General papers by oral Session 7 Endocrinology	15:30-16:45 General papers by oral Session 8 Renal toxicity	
16:00	Teratogenicity of retinoids in rodents, primates and humans A. G. Hendrickx (California Univ.) Closing remark T. Matsuzawa (Yamanouchi)			

June 18, Thursday

	Shiratori Hall (A) (Bldg. 4)	Room 224 (Bldg. 2, 2F)	Room 234 (Bldg. 2, 3F)	Shiratori Hall (B) (Bldg. 4)
8:30	8:30-10:15 General papers by oral presentation	8:30-10:15 General papers by oral presentation	8:30-10:00 General papers by oral presentation	General papers by poster presentation
9:00	Session 9 Hematopoietic toxicity	Session 10 CNS toxicity	Session 11 technology and methodology	Discussion hours 9:00-10:00 P1-1 - P1-9 P2-1 - P2-3 P5-1 - P5-6 P12-1 - P12-4 P13-1, P13-2
10:00		10:30-12:00 General papers by oral presentation	10:15-12:00 General papers by oral presentation	10:00-11:00 P1-10 - P1-18 P3-1 - P3-3 P6-1 - P6-8 P8-1 - P8-4
11:00		Session 12 Immunotoxicity	Session 13 Statistics for data analysis	11:00-12:00 P4-1 - P4-4 P9-1 - P9-5 P10-1, P10-2 P11-1 - P11-12
12:00	12:00-13:00 Senior member meeting at Shiratori Hall (A)		Lunch break	
13:00	General Assembly at Century Hall (Bldg. 1)			
14:00	<p>Presentation of Tanabe Award: The Best Paper(s) of the Year at Century Hall (Bldg. 1)</p> <p>Paper 1: Effect of hyperprolactinemia induced by neuroleptic agent, timiperone, on porphyrin content of mouse Harderian gland. by Tetsuyo Kajimura, Hiroshi Satoh and Mamoru Nomura (Daiichi Pharmaceutical) Journal of Toxicological Sciences 22, 219-229 (1997)</p> <p>Paper 2: A flow cytometric analysis of cytotoxic effects of nitrobenzene on rat sperm atogenesis. by Shigeru Iida, Hirofumi Onsaka and Seijinn Naya (Kyowa Hakkou) Journal of Toxicological Sciences 22, 397-407 (1997)</p>			
15:00	<p>Special lectures at Century Hall (Bldg. 1)</p> <p>"Pharmacokinetic studies for good extrapolation of animal data for the human safety assessment of drugs" by Yuichi Sugiyama (Tokyo University)</p> <p>"Mechanism of Tumor Promotion: Chemical Carcinogen-Induced Oxidative Stress, Signal Transduction and Modulated Cell-Cell Communication" by James E. Trosko (Michigan State University)</p>			
17:30	Social Party at Reception Hall (Bldg. 1, 4F)			

June 19, Friday

	Century Hall (Bldg. 1)
8:30	Symposium 1: Relevance of animal studies to clinical adverse reactions Introduction Hiroshi Mayahara (Takeda Chemical Industries) Assessment of drowsiness and headache in animal studies S. Manabe (Sankyo)
9:00	Repeated dose clinical trial on an anti-angina test drug with known toxicity of anemia. Toshiyuki Fujii (Fujisawa Pharmaceutical) Safety assessment and prediction of the starting dose for human application in cytostatic anti-cancer drugs Ikuo Horii (Nippon Roche)
10:00	(9:50-10:05 Break)
	Prolongation of QTc by astemizole and other drugs in humans and animal models. Keitaro Hashimoto (Yamanashi Medical University) Drug interaction disaster of sorivudine can be detected by animal models? Tadashi Watabe (Tokyo Univ. of Pharmacy and Life Science)
11:00	Dealing with false positive and negative preclinical data in predicting human risk David Brown (Covance Laboratories, USA) Discussion chaired by Ryuichi Kato (Keio University)
	Lunch break
13:00	Symposium 2: Animal studies based on human-type reactions Introduction Yukio Miyake (Shionogi & Co.) The use of human-derived tissues in drug discovery and development Andrew Parkinson (Xenox, University of Kansas Medical Center)
14:00	Japanese perspectives of use of human-derived materials for new drug development Tetsuo Satoh (Showa University) Genotoxicity tests with human origin cells Toshio Sofuni (NIHS)
	(14:35-14:50 Break)
15:00	A carcinogenicity testing method with transgenic mice Satoshi Yamamoto (Banyu Seiyaku) Application of bacteria incorporated with human P450 gene to toxicity studies Tetsuya Kamataki (Hokkaido University)
16:00	Perspectives of safety assessment based on human-type reactions Tohru Inoue (NIHS) Discussion chaired by Tohru Inoue (NIHS)

Special Programs

- A. Special lectures
- B. Presentations by winners of Tanabe Award
- C. Seminar: How to improve the quality of animal studies
- D. Symposium 1: Relevance of animal studies to clinical adverse reactions
- E. Symposium 2: Animal studies based on human-type reactions

A. Special lectures

Thursday, June 18 at Century Hall (Bldg. 1)

15:00-16:00

Chaired by Toshiji IGARASHI, Eisai Co., Ltd.

“Pharmacokinetic studies for good extrapolation of animal data for the human safety assessment of drugs”

Yuichi SUGIYAMA, Hiroshi SUZUKU and Kiyomi ITOH *
Department of Pharmaceutics, Tokyo University and * Department of Pharmaceutics, Kitazato University

16:00-17:00

Chaired by Yuji KUROKAWA, National Institute of Health Sciences

“Mechanism of tumor promotion: Chemical carcinogen-induced oxidative stress, signal transduction and modulated cell-cell communication”

James E. Trosko
Department of Pediatrics and Human Development,
Michigan State University, USA

B. Presentations by winners of Tanabe Award:

The best paper(s) of the Year 1997 appeared in the Journal of Toxicological Sciences.

Thursday, June 18 at Century Hall (Bldg. 1)

Chaired by Morio KANNO, Hokkaido University

14:00-14:20

Paper 1

Effect of hyperprolactinemia induced by neuroleptic agent, timiperone, on porphyrin content of mouse Harderian gland

Journal of Toxicological Sciences 22, 219-229 (1997)

Tetsuyo KAJIMURA, Hiroshi SATOH and Mamoru NOMURA
Daiichi Pharmaceutical Co., Ltd.

14:20-14:40

Paper 2

A flow cytometric analysis of cytotoxic effects of nitrobenzene on rat sperm atogenesis

Journal of Toxicological Sciences 22, 397-407 (1997)

Shigeru IIDA, Hirofumi ONSAKA and Masato NAYA
Kyowa Hakko Kogyo Co., Ltd.

C. Seminar:
How to improve the quality of animal studies
Wednesday, June 17 at Shiratori Hall (Bldg. 3)

9:00-9:10

Introduction:

Organizers:

Kunio DOI

Tokyo University, Graduate School of Agricultural and Life Sciences

Toshiaki MATSUZAWA

Yamanouchi Pharmaceutical Co., Ltd., Safety Research Laboratories

9:10-9:35 Chaired by Harushige OZAKI, Takeda Chemical Industries LTD.

Auditory brainstem response in beagles as an auditory functional test

Hiroshi KUSE.

Safety Research Laboratory, Tanabe Seiyaku Co., Ltd.

9:35-10:00 Chaired by Hiroshi KUNO, Banyu Pharmaceutical Co., Ltd.

An investigative electrophysiological examination of visual function in beagle dog toxicity studies

Naoki NAKAYAMA.

Toxicology Laboratory, Taisho Pharmaceutical Co., Ltd.

10:00-10:25 Chaired by Keiji SAMURA, Banyu Pharmaceutical Co., Ltd.

Cardiac toxicity study in monkeys using mainly an ambulatory electrocardiography

Noritsugu SHIMIZU

Kobuchisawa Laboratories, Fuji Biomedix Co., Ltd.

Break 10:25-10:40

10:40-11:05 Chaired by Keiichi WATAMABE, Tokai University

Prostatic function and drug safety assessment

Masanori MURAKOSHI

Safety Research Department, Teikoku Hormone Mfg. Co., Ltd.

11:05-11:30 Chaired by Kunio DOI, Tokyo University

Ultrasonographic evaluation of drug-induced renal injury in experimental animals

Akira HASHIMOTO.

Department of Veterinary Clinical Sciences, HOKKAIDO University

11:30-12:10 Chaired by Kazuhide INOUE, National Institute of Health Sciences

Safety pharmacology testing in general toxicity studies

Lewis B. Kinter and David K. Johnson *

Preclinical Skill Center, Astra Merck, Inc., Wayne, PA, U. and * Department of

Biological Sciences, Nycomed Amersham, Inc., USA

Lunch break 12:10-13:20

13:20-14:00 Chaired by Mamoru NOMURA, Daiichi Pharmaceutical Co., Ltd.
Joint scientific committee for international harmonization of clinical pathology testing in animal
toxicity and safety studies: Process and outcome

Robert L. Hall

Department of Pathology, Covance Laboratories Inc. USA

14:00-14:25 Chaired by Kazuichi NAKAMURA, Shionogi & Co., LTD.
Current topics in immunotoxicity testing guidelines

Jun-ichi SAWADA

Division of Biochemistry and Immunochemistry, National Institute of Health Sciences

14:25-15:05 Chaired by Chikuma HAMADA, Tokyo University
Statistical sciences and quantitative understanding

David J. Finney

Emeritus Professor of Statistics, University of Edinburgh, UK

Break 15:05-15:20

15:20-16:00 Chaired by Hiroshi MASUDA, Sankyo Co., Ltd.
Approaches to understanding species differences in hepatotoxic responses to therapeutic
agents

Felix A. de la Iglesia

Pathology and Experimental Toxicology, Parke-Davis Pharmaceutical Research
Division, Warner-Lambert Company, USA

16:00-16:40 Chaired by Takashi TANIMURA, Kinki University
Teratogenicity of retinoids in rodents, primates and humans

Andrew G. Hendrickx

California Regional Primate Research Center, University of California, USA

16:40-17:00

Overall discussion

D. Symposium 1: Relevance of animal studies to clinical adverse reactions

Friday, June 19 at Century Hall (Bldg. 1)

Co-chairs: Ryuichi KATO, Keio University, School of Medicine
Hiroshi MAYAHARA, Takeda Chemical Industries LTD

8:30-8:35

Introduction

Hiroshi MAYAHARA
Takeda Chemical Industries LTD.

8:35-8:50

Case report: Side effects (drowsiness and headache) in clinical studies and animal studies

Sunao MANABE and Hiroshi MASUDA*
Lab. Anim. Sci. & Toxicol. Labs. and * Research Institute, Sankyo Co., Ltd.

8:50-9:05

A case: Anemia in animal and human studies

Toshiyuki FUJII, Kaname OHARA
Toxicology Research Laboratories, Fujisawa pharmaceutical Co., LTD.

9:05-9:30

Case study: Determination of the safety dose and dose regimen of cytostatic anticancer drugs for clinical trials based on the pre-clinical safety studies

Ikuo HORII and Akira KAWASHIMA
Nippon Roche Research Center

Break 9:30-9:45

9:45-10:15

Drug induced QT prolongation and proarrhythmic effects in animal studies

Keitaro HASHIMOTO
Department of Pharmacology, Yamanashi Medical University

10:15-10:45

Toxicokinetic and enzymatic studies on the lethal interactions between the antiviral Sorivudine and the anticancer prodrugs of 5-Fluorouracil

Tadashi WATABE, Haruhiro OKUDA, and Kenichiro OGURA
Dept. Drug Metab. Mol. Toxicol., School of Pharm., Tokyo Univ. Pharm. & Life Sci.

10:45-11:15

Dealing with false positive and negative preclinical data in predicting human risk

David Brown
Pharmaceutical Services, Covance Laboratories, USA

11:45-12:00

Overall discussion

E. Symposium 2: Animal studies based on human-type reactions

Friday, June 19 at Century Hall (Bldg. 1)

Co-chairs: Tohru INOUE, National Institute of Health Sciences and
Yukio MIYAKE, Shionogi & Co., LTD.

13:00-13:05

Introduction

Yukio MIYAKE, Shionogi & Co., LTD.

13:00-13:05

The use of human-derived tissues in drug discovery and development

Andrew Parkinson

Xeno Tech L.L.C. and the Department of Pharmacology, Toxicology and Therapeutics,
University of Kansas Medical Center, USA.

13:35-14:00

Benefits and problems of the use of human materials in drug development in Japan

Tetsuo SATOH.

Faculty of Pharmaceutical Sciences, Showa University

14:00-14:25

Mutagenicity tests using cultured human cells: Application of gene mutation assay in thymidine
kinase (tk) gene of a human lymphoid cell line (TK6)

Masamitsu HONMA, Makoto HAYASHI and Toshio SOFUNI

Division of Genetics and Mutagenesis, National Institute of Health Sciences

Break 14:25-14:40

14:40-15:05

A rapid carcinogenicity testing system using transgenic mice harboring human prototype c-Ha-ras
gene

Satoshi YAMAMOTO and Koji URANO*

Banyu Pharmaceutical Co., Ltd. and Central Institute for Experimental Animals

15:05-15:30

Application of genetically engineered bacteria carrying human cytochrome P450 to toxicological
studies

Tetsuya KAMATAKI, Akihiro SUZUKI, Kenichi FUJITA, Katsuo NAKAYAMA and
Takahiko Nohmi*

Laboratory of Drug Metabolism, Hokkaido University Graduate School of Pharmacy
and *Division of Genetics and Mutagenesis, National Institute of Health Sciences,

15:30-15:55

Development of humanized animals to detect possible human reaction in the model animals:

Future Prospects

Tohru INOUE

Division of Cellular & Molecular Toxicology, National Institute of Health Sciences

15:55-16:40

Overall discussion

General Programs

A. Oral presentation

Note 1: Each paper is expected to be presented by 12 minute speech and 3 minute discussion.

Note 2: A 15 minute overall discussion is programmed at the end of each session consisting 4 to 6 papers. The discussion should cover papers by poster presentation in the respective category.

A. Oral presentation

1. Reproductive toxicity

Wednesday, June 17 at Bldg. 2, 2 F, Room 224

Chaired by Kunio KAWASHIMA and Masao HORIMOTO*

Osaka Branch, National Institute of Health Sciences and

* Fizer Pharmaceuticals Co., Ltd.

9:00-10:15

O1-1

Organ distribution and sex difference of dioxin-related genes in Long Evans rats exposed to 2,3,7,8-Tetrachlorodibenzo-p-dioxin

Junzo YONEMOTO, Nihar R. JANA, Shubhashish SARKAR, Chiharu TOHYAMA* and Hideko SONE

Regional Environment Division, *Environmental Health Division, National Institute for Environmental Studies

O1-2

Acute testicular toxicities of 4,6-dinitro-o-cresol and 2-sec-butyl-4,6-dinitrophenol in rats

Ken TAKAHASHI, Hitoshi HOJO, Hiroaki AOYAMA and Shoji TERAMOTO.

Toxicology Division, Institute of Environmental Toxicology

O1-3

A possible mechanism for development of Leydig cell tumors in aged Fisher 344 rats.

Yoshihiro FUTAMURA, Yoshimasa HAMADA, Chihaya KAKINUMA, Masaki NAKAMURA and Yasunori SHIBUTANI.

Toxicology Laboratory, Mochida Pharmaceutical Co., Ltd.

O1-4

Strain Difference in sperm examination in Crj:CD (SD) IGS, Jcl:Wistar and F344/DuCrj rats

Kiyoshi MATSUMOTO, Shiori MATSUMOTO, Kenji SAMEJIMA and Yojiro OOSHIMA.

Drug Safety research Laboratories, Takada Chemical Industries LTD.

Overall Discussion

2. PK/TK

Wednesday, June 17 at Bldg. 2, 3 F, Room 234
Chaired by Mitsuhiro TSUDA and Michio MOTOHASHI*
National Institute of Health Sciences and
*Takeda Chemical Industries LTD.

9:00-10:45

O2-1

Simultaneous analysis of blood drug concentrations and blood chemistry parameters using LC-MS/MS

Takeshi IGAWA, Masaya CHINO, Ritsuko HATA, Toshihide HAYASHI
Ina Research Inc.

O2-2

Analytical method for determination of DDT and its metabolite in rat plasma, liver and brain, and their concentrations through single oral administration

Naruto TOMIYAMA, Hiromi TSUJI, Momiko WATANABE, Makio TAKEDA, Takanori HARADA and Hiroko KOBAYASHI
Institute of Environmental Toxicology

O2-3

Prediction of plasma concentration-time profiles after a single oral administration by feeding : Application to toxicokinetic study of DDT in F344 male rats

Momiko WATANABE, Naruto TOMIYAMA, Hiroko KOBAYASHI, Makio TAKEDA, Takanori HARADA.
Institute of Environmental Toxicology

O2-4

Suicidal inactivation of dihydropyrimidine dehydrogenase (DPD) by 5-(2-bromovinyl) uracil (BVU) and determination of the amino acid residue modified by BVU

Kenichiro OGURA¹⁾, Haruhiro OKUDA¹⁾, Kazuhito ARAKAWA²⁾, Masakazu FUKUSHIMA²⁾, and Tadashi WATABE¹⁾.

¹⁾Dept. of Drug Metab. Mol. Toxicol., School of Pharm., Tokyo Univ. Pharm. Life Sci.,
²⁾Hanno Res. Center and Taiho Pharmaceu. Co. Ltd.

O2-5

Establishment of genetically engineered E. Coli co-expressing human CYP2B6 and NADPH-P450 reductase

Ken-ichi FUJITA, Makiko MORI, Akihiro SUZUKI, Takahiro KUSHIDA and Tetsuya KAMATAKI.
Faculty of Pharmaceutical Sciences, Hokkaido University

O2-6

Silencing of CYP1A1 expression in rabbits by a DNA methylation

Yoshiki TAKAHASHI, Chiharu SUZUKI and Tetsuya KAMATAKI
Faculty of Pharmaceutical Sciences, Hokkaido University

Overall Discussion

3. Mutagenicity

Wednesday, June 17 at Bldg. 2, 2 F, Room 224

Chaired by Tadashi WATANABE and Hiroyasu SHIMADA*

Dept. Drug School of Pharm., Tokyo Univ. Pharm. & Life Sci and

* Daiichi Pharmaceutical Co., Ltd.

10:30- 12:15

O3-1

Time-course variations and organ specificity of five carcinogens induced mutagenesis in muta TM mice: Results of the 2nd collaborative study on the transgenic mutation assay by JEMS/MMS

Satoru ITOH¹⁾, Takayoshi SUZUKI²⁾, Madoka NAKAJIMA³⁾, Noriyuki HACHIYA⁴⁾ and Takumi HARA⁵⁾.

¹⁾Daiichi Pharmaceutical, ²⁾NIHS, ³⁾Biosafety Research Center, ⁴⁾Akita University and

⁵⁾Food and Drug Safety Center

O3-2

Antimutagenic structural modification of quinoline assessed by an in vivo mutagenesis

Ken-ichi SAEKI¹, Yuko MIYATA¹, Yutaka KAWAZOE¹, Takayoshi SUZUKI², Makoto HAYASHI² and Toshio SOFUNI².

¹Fac. Pharm. Sci., Nagoya City Univ. and ²Div. Genet. Mutagen., Natl. Inst. Health Sci.

O3-3

Estimation of cancer risk from somatic mutation assay

Atsushi HAKURA, Jiro SONODA, Yoshie TSUTSUI, Takashi MIKAMI and Kazuo TSUKIDATE.

Drug Safety Research Laboratories, Eisai Co., Ltd.

O3-4

gpt delta Transgenic mouse mutagenesis test system

Ken-ichi MASUMURA and Takehiko NOHMI.

Division of Genetics and Mutagenesis, National Institute of Health Sciences

O3-5

Establishment of salmonella tester strain co-expressing cytochrome P450 and NADPH-cytochrome P450 reductase

Kazuo NAKAYAMA¹, Hirotaka KUSHIDA¹, Hiroshi IWATA¹, Akihiro SUZUKI¹, Satoshi YAMAORI¹, Ken-ichi FUJITA¹, Masami, YAMADA², Takehiko NOHMI² and Tetsuya KAMATAKI¹.

¹Fac. of Pharmaceut. Sci., Hokkaido Univ. and ²National Institute of Health Sciences

O3-6

Roles of rat and human epoxide hydrolase in hydrolysis of aflatoxin B1, 8,9-epoxide

Hiroshi YAMAZAKI, W.W. JOHNSON, Y.-F. UENG, F. Peter GUENGERICH, and Tsutomu SHIMADA

Osaka Pref. Inst. Public Health and Vanderbilt Univ., USA.

Overall Discussion

4. Hepatotoxicity

Wednesday, June 17 at Bldg. 2, 3 F, Room 234
Chaired by Katsumi IMAIDA and Toshiyuki FUJII*
1st Dept. Pathol., Nagoya City Univ. Med. Sch. and
* Fujisawa Pharmaceutical Co., LTD.

11:00- 12:15

O4-1

Investigational study for hepatotoxicity in rats induced by E2011 repeated administration.

1)Aspects from involvement of phase II conjugating enzymes

Gen SATO, Toyohiko AOKI, Satoru HOSOKAWA and Fumio SAGAMI.
Drug Safety Research Laboratories, Eisai Co., Ltd.

O4-2

Effects of monosodium glutamate pretreatment on the rat liver changes by clofibrate administration

Isao IGARASHI, Toshihiko MAKINO, Atsuko MURAMATSU, Sunao MANABE and
Takashi YAMOTO.
Laboratory Animal Science & Toxicology Laboratories, Sankyo Co., Ltd.

O4-3

The role of tumor necrosis factor alpha in hepatotoxicity induced by combined exposure of D-galactosamine and lipopolysaccharide to precision-cut rat liver slices

Naoya MASUTOMI, Jiro SUGIMOTO, Kumiko SHIMAMURA and Eiji TANAKA.
Toxicology Laboratory, Yokohama Research Center, Mitsubishi Chemical Corporation

O4-4

Effects of phenobarbital, a drug-metabolizing enzyme inducer, on hepatic DNA ploidy in hepatectomized rats

Mayumi WATANABE, Shinobu HAKAMATA, Takashi YAMOTO, Toshihiko MAKINO,
Shinya SEHATA, Koji TANAKA, Isao IGARASHI, Masaya TAKAOKA, Sunao MANABE.
Laboratory Animal Science & Toxicology Laboratories, Sankyo Co., Ltd.

Overall Discussion.

5. Carcinogenicity

Wednesday, June 17 at Bldg. 2, 2 F, Room 224

Chaired by Shoji FUKUSHIMA and Mamoru MUTAI*

1st Dept. Pathol., Osaka City Univ. Med. Sch. and

* Toxicology Laboratory, Mitsubishi Chemical Corporation

13:30- 15:15

O5-1

Comparison of the results of rat and mouse carcinogenicity studies for pharmaceuticals

Toyohiko AOKI¹⁾, Kenji IRIMURA, Teruji KOGA, Motonobu SATO, Satoshi NAGAYAMA, Toshiyuki FUJII, Toshiaki MATSUZAWA, Mamoru MUTAI, Masashi YASUBA, and Satoru YAMASHITA and Toshimi USUI

Carcinogenicity Working Group, Japan Pharmaceutical Manufacturers Association, Belonging to Eisai Co., Ltd.¹⁾ and other companies

O5-2

Susceptibility of human proto c-Ha-ras transgenic rats to carcinogens

Makoto ASAMOTO, Hiroyasu TORIYAMA-BABA, Akira ANDO, Hiroki SUZUKI, Fumitaka TAKESHITA and Hiroyuki TSUDA

National Cancer Center Research Institute, Chemotherapy Division

O5-3

Susceptibility to carcinogenesis by urethane in genetically engineered mice

Tomoyuki WATANABE, Masakazu OZAKI, Hajime KAWASAKI and Seiichi Ito*
EHSI, Sumitomo Chemical Co., Ltd. and *NEMRI

O5-4

Alternatives to carcinogenicity testing using ras H2 mice: dose range finding study for the 26-week assay by the intermittent dosing of cyclophosphamide in order to assess the inducibility of urothelial tumors

Shigeru HISADA, Masako NAGASHIMA, Hisato TANIFUJI, Seiji SHIBATA, Kazuhiro IZUKA Atsuko SATO, Mitsui ISOBE, Noriyuki KUWAYAMA, Hideki MORIMOTO, Noriko IIDA, Shuji MASUDA, Ryuji NAKAYAMA and Toshimi USUI*

Teikoku Hormone Mfg. Co., Ltd. and *Central Institute of Experimental Animals

O5-5

Analysis of 47 non-genotoxic carcinogens in the medium-term liver bioassay (Ito test)

A. HAGIWARA¹, H.GOSHIMA^{1,2}, M.SANO^{1,2}, H.TANAKA¹, S.TAMANO¹, T.SHIRAI²

¹Daiyu-kai Inst. Med. Sci. and ²1st Dept. Pathol. and Nagoya City Univ. Med. Sch.

O5-6

Validation of Medium-Term Multi-Organ Bioassay Protocols for Carcinogens

Seiko TAMANO¹, Masashi SANO^{1,2}, Hikaru TANAKA¹, Mayumi KAWABE¹, Akihiro HAGIWARA¹ and Tomoyuki SHIRAI²

¹Daiyu-kai Institute Medical Science and ²1st Dept. of Pathol., Nagoya City Univ. Med. Sch.

Overall Discussion

6. Cardiovascular System

Wednesday, June 17 at Bldg. 2, 3 F, Room 234

Chaired by Hiroshi ONO and Masaharu HASHIMOTO*

Food and Drug Safety Center, Hatano Research Institute and

* Fujisawa Pharmaceutical Co., LTD.

13:30- 15:15

O6-1

Tachycardia during anaphylactoid reaction induced by HCO-60 in dogs:

Assessment using a radio-telemetry technology

Hiroyasu MIYAZAKI, Yasunaga KAWASHIMA, Hiroshi KUNO, Hiroyoshi MATSUMOTO,
and Fumihiko IKEMOTO

Development Research Laboratories, Banyu Pharmaceutical Co., Ltd.

O6-2

Electrophysiological study of cardiovascular collapse by specific carbamate insecticide, 2-s-butylphenyl methylcarbamate: Inhibitory effects on the L-type Ca^{2+} current of guinea-pig ventricular myocytes

Haruko FUTAGAWA, Hiroaki TAKAHASHI, Satomi ADACHI-AKAHANE* and
Taku NAGAO*

Inst. Environ Toxicol and *Lab. of Pharmacol. & Toxicol. Grad. Sch. Pharmaceut. Sci.,
University of Tokyo

O6-3

Non-invasive measurement of cardiac output in cynomolgus monkeys

Atsushi AKUNE, Koichiro FUKUZAKI, Ryoichi NAGATA and Go KITO

Shin Nippon Biomedical Laboratories, Ltd.

O6-4

Doxorubicin-induced late cardiotoxicity: impairment of the Ca^{2+} releasing mechanism in the sarcoplasmic reticulum

Kyosuke TEMMA, Akihito CHUGUN, Toshifumi OYAMADA, Yukio HARA,
Takushi SASAKI, Hiroshi KONDO and Tai AKERA1

School of Veterinary Med. and Animal Sci., Kitasato Uni. and 1MSDRL-Japan

O6-5

Inhibitory effects of dexamethasone on a new mitomycin C derivative KW-2149 induced pulmonary toxicity in rats

¹Tomoko HARADA, ¹Katsumi TAKABA, ¹Takuji HARA, ²Noboru YAMAMOTO,

²Tomohide TAMURA, ²Nagahiro SAIJO and ¹Akio ISHII

¹Toxicological Reserch Laboratories, Kyowa Hakko Kogyo Co., Ltd. and

²National Cancer Center Hospital

O6-6

A usual change in acid/base balance: The alkalization of blood after feeding in conscious dogs, Postprandial Alkaline Tide

Junichiro OZAKI, Noriaki TANIMOTO and Hiroshi KUSE.

Safety Research Laboratory, Tanabe Seiyaku Co., Ltd.

7. Endocrinology

Wednesday, June 17 at Bldg. 2, 2 F, Room 224

Chaired by Kimio KARIYA and Tomoaki INOUE *
Fac.Pharm.Sci., Kobegakuin University and
* Nippon Roche Research Center.

15:30- 16:45

O7-1

A relation of serum thyroid hormone levels(T4 and T3) to serum TSH level in thyroid hormone-infused thyroidectomized rats:

A comparative study between Phenobarbital and Fluconazole

Setsuko TAKIZAWA and Ikuo HORII

Preclinical Science Department, Nippon Roche Research Center

O7-2

Effect of Kojic Acid on rat thyroid gland administered orally for 4 weeks

Atushi OHKUBO¹⁾, Yoshitaka HIGA¹⁾, Tsutomu ICHIKI²⁾, Shunichi KITAJIMA²⁾ and
Kimio KARIYA³⁾

¹⁾ R&D SANSHO SEIYAKU, ²⁾ Panapharm Lab. and ³⁾ Fac.Pharm.Sci.Kobegakuin Univ.

O7-3

Development of safety evaluation method by monitoring the endogenous nitric oxide formation.
Endogenous NO formation stimulated by LPS in hypothyroid rats treated with 2-mercapto-
benzimidazole

Mitsuhiro TSUDA, Kazue SAKEMI, Makoto USAMI and Yasuo OHNO

National Institute of Health Sciences

O7-4

Application of In Vitro Thyrocyte Spheroid Culture System for the Toxicity Evaluation System

Tomoaki INOUE, Akira INOMATA and Ikuo HORII

Nippon Roche Research Center

8. Renotoxicity

Wednesday, June 17 at Bldg. 2, 3 F, Room 234

Chaired by Hitoshi ENDOU and Takashi MIKAMI*
Department of Pharmacology and Toxicology, Kyorin University
School of Medicine and * Drug Safety Res. Labs., Eisai Co., Ltd.

15:30- 16:45

O8-1

Effects of low protein diet on the toxicity induced by potassium bromate in rats
Hideaki NAKAMURA, Koichi SUWA, Takahiro ISHII, Kazushi OKAZAKI, Masao
TAKASU, Toshiaki TAKAMATSU, Susumu NISHIMURA, Tomonori ENAMI, Nobuo
NISHIMURA, Kazuhisa HATAYAMA, Shuzo OKAZAKI
Gotemba Laboratory, BOZO Research Center Inc.

O8-2

Mechanism of Sevoflurane degradation product-induced nephrotoxicity in rats
Yuko MURASAKI, Takako OHKURA, Kouhei TOYOOKA, Osamu MITANI, Keiji INOUE,
Toshio CHOW, Yoichiro KAWAI and Takashi TAMURA
Central Research Laboratory / Maruishi Pharm Co., Ltd.

O8-3

Effect of Cephloridine (CER) in mouse terminal proximal straight tubule (S3) cell lines stably
expressing organic anion transporter1 (OAT1)
Michio TAKEDA, Mami KOBAYASHI, Takashi SEKINE, Makoto HOSOYAMADA,
Yoshikatsu KANAI and Hitoshi ENDOU
Department of Pharmacology and Toxicology, Kyorin University School of Medicine

O8-4

The plasma membrane transport of ochratoxin A by multispecific organic anion transporter (OAT1)
expressed in *Xenopus laevis* oocytes
Minoru TSUDA, Takashi SEKINE, Yoshio UENO* and Hitoshi ENDOU
Department of Pharmacology and Toxicology, Kyorin University School of Medicine,
and *Department of Toxicology and Microbial Chemistry, Faculty of Pharmaceutical
Science, Science University of Tokyo

9. Hematopoietic toxicity

Thursday, June 18 at Shiratori Hall A (Bldg. 3)

Chaired by Kiyoshi MATSUMOTO and Akihiro WAKATA*

Shinshu University, School of Medicine and

* Medicinal Safety Laboratories, Yamanouchi Pharmaceutical Co., Ltd.

8:30- 10:15

O9-1

Hematological toxicity of anticancer drugs(MMC, ACNU) in common marmosets

Mitsuo YAMAMOTO, Tetsuji IKENAGA, Yuriko ISHII, Naoki MATSUMOTO,

Tuyoshi TAKEDA, Yuzuru KATO and Akio ISHII

Toxicological Research Laboratories, Kyowa Hakko Kogyo Co., Ltd.

O9-2

An attempt to measure erythrocyte fragility with stirrer: Study in rats administered with acetylphenylhydrazine (APHZ)

Yoshie MANABE¹⁾, Norifumi MATSUSHITA¹⁾, Taiji HAYASHI¹⁾ and

Kiyoshi MATSUMOTO²⁾

¹⁾Drug Safety Research Lab, TAIHO Pharm. Co., Ltd. and ²⁾Institute of Experimental Animals, Shinshu Univ. Sch. of Med.

O9-3

Establishment and evaluation of Colony-Forming Units assay using rat hematopoietic progenitor cells as a toxicological test system

Kazuhiko TAKAMATSU, Akihiro WAKATA

Medicinal Safety Laboratories, Yamanouchi Pharmaceutical Co., Ltd.

O9-4

Potassium oxonate modulation of 5-fluorouracil-induced myelotoxicity in colony forming assay of hematopoietic precursor cells

Yasuhiro MAEDA, Yasuhide KOUCHI, Charles A. Tyson* and Akinobu OHUCHIDA

Drug Safety Research Laboratory, Taiho Pharmaceutical Co., Ltd. and

*SRI International, USA

O9-5

Hematopoietic stem-cell kinetics evaluated by bromodeoxyuridine incorporation followed by near-UV exposure to kill cycling stem cells (BUUV). 3) Differences between in vitro labeling and in vivo labeling and 4) Bone marrow cells from P53-KO mice

Yoko HIRABAYASHI, Takashi UMEMURA, Yukio KODAMA, Toyozo KANEKO,

Jun KANNO, Yuji KUROKAWA and Tohru INOUE

Biological Safety Research Center, NIHS

O9-6

Evaluation of efficacy and safety for gene transduction into hematopoietic progenitor cells by various virus vectors

Hitoshi HIBINO^{1,3)}, Kanzaburo TANI¹⁾, Hajime SUGIYAMA¹⁾, Yoshikuni TANIOKA²⁾ and Sigetaka ASANO¹⁾

¹⁾Dept. of Hematology/Oncology, The Institute of Medical Science, Univ. of Tokyo,

²⁾Central Institute of Experimental Animals, ³⁾Chugai Pharmaceutical Co.

10. CNS and nerve toxicity

Thursday, June 18 at Bldg. 2, 2 F, Room 224

Chaired by Toshitaka NABESHIMA and Toshihito KADOTA*
Nagoya University, School of Medicine and * Bristol Myers Squibb

8:30- 10:15

O10-1

Metabolism of MPTP, accumulation and disposition of MPP* in brain of suncus murinus:
Comparison between rats and suncus

Taisei MUSHIRODA, Noritaka ARIYOSHI, Tsuyoshi YOKOI, Eiji TAKAHARA, Osamu
NAGATA and Tetsuya KAMATAKI.

Div. of Drug Metab., Hokkaido Univ. and Hokuriku Seiyaku CO., LTD.

O10-2

Allylnitrile-induced apoptosis in neurocytes

Xiaoping ZHANG, Hideji TANII and Kiyofumi SAIJOH

Department of Hygiene, Kanazawa University School of Medicine

O10-3

An assessment for measurement of motor activity with an automated device in neurotoxicity
study

Shigehiro TACHIBANA, June SATO, Hiromasa TAKASHIMA, Makoto SEKI, Tomomi
MORIMURA, Tomoko HARADA and Kiyoshi IMAI

Food and Drug Safety Center, Hatano Research Institute

O10-4

Screening method for learning and memory in neurotoxicity study: automated measurement of
tone/context-conditioned freeze response

Hiroaki TAKAHASHI, Yasumasa KAMESAKA, Momoko HAYASHI, Tsutomu

MATSUMOTO, Haruko FUTAGAWA and *Yoshio HASEBE

Inst. Environ. Toxicol. and *Muromachi Kikai Co., Ltd.

O10-5

Schedule-controlled operant behavior as a memory measure and effects of Scopolamine,
Mecamylamine and Methamphetamine in rats

Muneyuki MIYAGAWA, Katsumi OHTANI, and Takeshi HONMA

National Institute of Industrial Health, Ministry of Labour

O10-6

Motor nerve conduction velocities during growth of SD rats fed ad libitum or restricted diets

Kotaro YAMASHITA¹, Yoshimasa OKAZAKI¹, Shingo HIDUME¹, Masato SUDO¹ and
Isao NARAMA²

¹Mitsubishi Chemical Safety Institute Ltd. and ²Setsunan University

11. Technology and methodology

Thursday, June 18 at Bldg. 2, 3 F, Room 234

Chaired by Tsuyoshi FURUYA and Masaki MIYAMOTO*

National Institute of Health Sciences and * Inan Research Center

8:30- 10:00

O11-1

Evaluation study of startle pinna reflex audiometry to detect chemically induced olfactory defects

Hiromasa TAKASHIMA, Azusa TAKANA, Shinsuke YOSHIMURA, Yoshiaki SAITOU and Kiyoshi IMAI

Hatano Research Institute, Food and Drug Safety Center

O11-2

Improvement of intravenous infusion technique in toxicity studies

Keisuke AKAGI, Dai WATANABE, Yasumoto MIZOGUCHI, Michiyo KUMAHARA, Toshiya ISHII, Kiyohisa FUKUSAWA, Tetsuya MATSUOKA, Ryoji SHIBATA, Kosuke HORIGUCHI, Yoshikazu NAGASHIMA, Azusa OKANIWA

Kannami Laboratories, BOZO RESEARCH CENTER, Inc.

O11-3

A case of continuous intravenous infusion -3-month study in cynomolgus monkeys

Hideshi TSUSAKI, Koichiro FUKUZAKI, Hidenobu SAMESHIMA, Hiroshi MAEDA and Hiroaki MIYAJIMA

Shin Nippon Biomedical Laboratories, Ltd.

O11-4

Osteoporosis model in cynomolgus monkeys: Effect of ovariectomy and low calcium diet on bone density, structure and metabolism

Soichi TAKASHIMA¹⁾, Masataka KAWAGOE²⁾, Hirokazu TAKAHASHI²⁾, N.L.J Miranda³⁾, D. Collins³⁾, Takashi HAYASHI¹⁾, Norio MUTO¹⁾, Toshitaka NAKAMURA⁴⁾

¹⁾Ina Research Inc., ²⁾Teijin BIO Laboratories, Inc., ³⁾Ina Research Philippines Inc.

⁴⁾University of Occupational and Environmental Health

O11-5

The changes in clinical examination's data after ovariectomy in cynomolgus monkeys

Naoto HORAI, Hiroyuki IZUMI, Koichiro FUKUZAKI and Hiroaki MIYAJIMA

Shin Nippon Biomedical Laboratories, Ltd.

12. Allergy and immunotoxicity

Thursday, June 18 at Bldg. 2, 2 F, Room 224

Chaired by Motoyasu OHSAWA and Eiji Maki*

Department of Environmental Toxicology, Teikyo University and

* Preclinical Development Dept. R&D, Janssen Kyowa Co., Ltd.

13:30- 15:15

O12-1

The results of surveys about antigenicity and immunotoxicity studies conducted in pharmaceutical companies in Japan

Naohisa TSUTSUI¹⁾, Kenkichi SHINKAI, Kazuichi NAKAMURA and Eiji Maki
Japan Pharmaceutical Manufacturers Association (Mitsubishi Chemical Corporation¹⁾ and other member companies)

O12-2

A suitable sensitizing method of mice in antigenicity studies of low molecular drugs

Takashi KUWAHARA, Shougo ASANAMI and Takumi TAMURA
Naruto Research Institute, Otsuka Pharmaceutical Factory, Inc.

O12-3

Evaluation of allergic potential of low molecular weight drugs by mouse popliteal lymph node assay

Kenkichi SHINKAI¹⁾, Yoshiki SUGIHARA, Yoshiharu KUNINISHI, Kazuichi NAKAMURA, Yoshinobu IWAKI, Hitoshi NISHIDA, Ritsuyoshi SUZUKI, H.W.VOHR, Miharū TAKAHASHI, Kenji TAKAHASHI, Naohisa TSUTSUI, Yasuhiro KAMIMURA and Eiji MAKI: Japan Pharmaceutical Manufacturers Association (Sankyo Co., Ltd.¹⁾ and other member companies)

O12-4

Investigation of in vitro anaphylaxis test

Tomoaki INOUE, Nobuyuki SHISHIDO, Kounosuke NAKANO and Ikuo HORII
Nippon Roche Research Center

O12-5

Evaluation of recombinant Cholera toxin B subunit as a nasal mucosal adjuvant

Norihisa GOTO¹, Jun-ichi MAEYAMA¹, Yoko YASUDA², Keiko MATANO², Masanori ISAKA², Satoshi KOZUKA², Tooru TANIGUCHI², Yutaka MIURA² and Kunio TOCHIKUBO²

¹Dept. of Safety Research on Biologics, National Institute of Infectious Diseases and

²Dept. of Microbiology, Nagoya City University Medical School

13. Statistical data analysis

Thursday, June 18 at Bldg. 2, 3 F, Room 234

Chaired by Chikuma HAMADA and Jun HANDA*

Department of Pharmacoepidemiology, University of Tokyo and

* Drug Safety Research, Nippon Kayaku Co., Ltd.

10:15-12:00

O13-1

The statistical consideration in animal toxicity studies:

1) General consideration in non-clinical studies

Osamu KOMIYAMA, Atsuyoshi HIRATA, Tatsuhiro MITUMORI, Jungo SAWA, Hidefumi KASAI, Akio KUMAGAYA, Hironobu TAMURA, Takeshi HIRAKAWA and Jun HANDA (Japan Pharmaceutical Manufacturers Association)

O13-2

The statistical consideration in animal toxicity studies :

2) In view of scientific data-management in toxicity studies

Atsuyoshi HIRATA, Osamu KOMIYAMA, Tatsuhiro MITUMORI, Jungo SAWA, Hidefumi KASAI, Akio KUMAGAYA, Hironobu TAMURA, Takeshi HIRAKAWA and Jun HANDA

Statistics Subcommittee, Japan Pharmaceutical Manufacturers Association

O13-3

Pitfalls of multiple comparisons in general toxicity studies

Chikuma HAMADA

Department of Pharmacoepidemiology, University of Tokyo

O13-4

Investigation on statistical methods for quantitative data in repeated dose toxicity studies in rats

Hideyuki SAKAKI, Hiroshi IMAMIZO, Toshiji IGARASHI, Katsuhiro OHMICHI, Hiroshi TERAJ, Hideo YOKOUCHI, Tsuyoshi TAKIZAWA, Shinihi HISAICHI, Takashi IKEDA, Kazuo TOTSUKA, Yoshiki MURAKAMI, Hideyuki MIZUMA, Masayuki YAMADA, Atsuyoshi HIRATA, Osamu TSUKAMOTO, Jun HANDA.

Statistics Working Group, Japan Pharmaceutical Manufacturers Association

O13-5

Analysis of quantitative data from the repeated dose toxicity studies in non-rodents

Nobuhiko KOWATA, Shigeaki HORIE, Kazunori SATO, Hideo UCHIDA, Kazuo WATANABE, Masayuki WACHI, Kazuhiro NINOMIYA, Haruki TSUBOUTI, Shinya KANEDA, Osamu SADANAGA, Osamu YAMAKITA, Jun HANDA, Masakazu ANDOH, Yukio TAKAHASHI, Toshiro HAGA

Statistics Working Group, Japan Pharmaceutical Manufacturers Association

O13-6

Examination of the predictability of Draize eye irritation score by alternative assays from statistical viewpoint

Isao YOSHIMURA and Takashi OMORI (Science Univ. of Tokyo), Yasuo OHNO, Toyozo KANEKO and Makoto HAYASHI (NIHS), Hiroshi ITAGAKI, Kenji OHKOSHI, Akihiro KURISHITA, Hajime KOJIMA and Katsuhiro TAKANO, Tasuku TAKAMATSU (Japan Cosm. Industry Assoc) and Takemi YOSHIDA (Showa Univ.)

Overall discussion

General Programs

B. Poster presentation

from 10:00 June 17 (Wednesday) to 13:00 June 18 (Thursday)
at Shiratori Hall B (BLDG.3)

Note 1: The panel size for a poster presentation is W150cm x H210cm.

Note 2: Posters are expected to be set in the morning (8:30 - 10:00) June 17 (Wednesday) and exhibited until 13:00 June 18 (Thursday). Please take posters away during 12:30 - 15:00 June 18 (Thursday).

Note 3: Discussion hours for poster presentation are as follows. The authors of respective poster are expected to be positioned in front of their posters during the designated time period.

Poster discussion hours

June 18, Thursday

9:00-10:00

Reproductive toxicity	P1-1 - P1-9
PK/TK	P2-1 - P2-3
Carcinogenicity	P5-1 - P5-6
Allergy and immunotoxicity	P12-1 - P12-4
Statistics and data analysis	P13-1 - P13-2

10:00-11:00

Reproductive toxicity	P1-10 - P1-18
Mutagenicity	P3-1 - P3-3
Cardiovascular systems	P6-1 - P6-8
Renotoxicity	P8-1 - P8-4

11:00-12:00

Hepatotoxicity	P4-1 - P4-4
Hematotoxicity	P9-1 - P9-5
CNS and nerve toxicity	P10-1 - P10-2
Techniques and methodology	P11-1 - P11-12

1. Reproductive toxicity

P1-1

Method for estimation of the rat sperm: in vitro study of α Chlorohydrin
Eishun TOMABECHI, Michio FUJIWARA and Toshiaki MATSUZAWA
Medicinal Safety Laboratories, Yamanouchi Pharmaceutical Co., Ltd.

P1-2

The effect of α Chlorohydrin on sperm motility and other characteristic parameters measured by CASA-system (IVOS)
Katsuhiro FUKUNISHI, Mie TERAOKA and Norio AWATA
New Drug R&D Laboratory, KANEBO LTD.

P1-3

Characteristics of several parameters to evaluate male fertility:
Comparison of sensitivity on reproductive parameters using a testicular toxicant, Adriamycin
Masashi KATO, Harumi HAYASHI, Aiko MABUCHI, Sachiko NOMURA, Kazuyoshi
NAITO, Keiko KATO, Takao OTA and Tadakazu FURUHASHI
Safety Study Department, Nihon Bioresearch Inc.

P1-4

Effects of boric acid on sperm morphology in rats
Hiroshi YOSHIZAKI, Yuko IZUMI, Chizuka HIRAYAMA, Takashi MINAGI,
Yuko YOSHIMOTO, Shuichi KANESAKI, Akihiro FUJIMOTO, Toshiyasu SUGITANI,
Takeshi NAKATSU
Drug Safety Research Laboratories, Hikari Branch, Pharmaceutical Development
Division, Takeda Chemical Industries, Ltd.

P1-5

Evaluation for fertility under optimized diet restriction in male rats
Yoshiki BAN, Satoru INAGAKI, Miki UCHIDA, Urumi ASANABE, Toshio NAKATSUKA,
Masayuki KEMI and Hiroyoshi MATSUMOTO
Development Research Laboratories, Banyu Pharmaceutical Co., Ltd.

P1-6

Estrogenic activity of phthalate esters in vitro and in vivo.
Keiko SUDO, Kenji NAGAI, Maki MAEDA, Hiromi IIZUKA and Masanobu KATO
Kashima Laboratory, Mitsubishi Chemical Safety Institute Ltd.

P1-7

Effect of DBP and DEHP administration on in vivo estrogenic activities in ovariectomized rats
Seiichi KATAYAMA, Hideaki HIRATSUKA, Kenji NAGAI, Yasuhiko YAMAGISHI,
Makoto MIYAGAWA, Minoru TSUTANI, Minoru MIURA and Masanobu KATO
Kashima Laboratory, Mitsubishi Chemical Safety Institute Ltd.

P1-8

Reproductive failure induced by plasticizer butyl benzyl phthalate in pregnant and pseudopregnant rats
Makoto EMA, Emiko MIYAWAKI and Kunio KAWASHIMA.
National Institute of Health Sciences, Osaka Branch

P1-9

Evaluation of implantation failure induced by tributyltin chloride administered during the preimplantation period: Effect on decidual cell response

Akira HARAZONO, Makoto EMA and Kunio KAWASHIMA

Biological Evaluation, National Institute of Health Sciences, Osaka Branch

P1-10

A short-term screen to detect estrogen-like compounds using female rats

Tomoya YAMADA, Kaori MIYATA, Hiroshi SAKO, Kaoru YOSHIOKA, Yusuke KAMITA, Takaki SEKI, Yasuyoshi OKUNO, Shunji HOSOKAWA, Setsuo YAMANE and Masatoshi MATSUO

Environmental Health Science Laboratory, Sumitomo Chem.Co. Ltd.

P1-11

The risk assessment of endocrine disrupting chemicals in the aquatic environment using in vivo exposures with fish

C.T.Bowmer & Gimeno

Dept. of Environmental Toxicology, TNO Nutrition & Food Research Institute
The Netherlands

P1-12

Additive estrogenic effect of Genistein and Bisphenol A, and anti-estrogenic effect of (-)-Epigallocatechin Gallate in MCF-7 cells

Kyung-Sun Kang, Jun Kanno and Tohru Inoue

Division of Cellular and Molecular Toxicology, National Institute of Health Sciences

P1-13

An in vitro developmental toxicity test using murine embryonic stem cell differentiation in culture

Atsuya TAKAGI, Satoshi KITAJIMA, Yoko HIRABAYASHI, Yumiko SAGA, Yuji KUROKAWA and Tohru INOUE

Div. of Toxicol., Biological Safety Research Center, NIHS

P1-14

Effects of aminopyrine on cultured rat embryos

Atsushi YOKOYAMA¹⁾, Masaharu AKITA¹⁾, and Yukiaki KURODA²⁾.

¹⁾Kamakura Women's College and ²⁾National Institute of Genetics

P1-15

Back ground data for reproductive and development toxicity studies of Crj: CD(SD)IGS rats

Masato NAYA, Chizuru TAKENAKA and Taeko SAKUMA

Toxicological Research Laboratories, Kyowa Hakko Kogyo Co., Ltd.

P1-16

Testicular toxicity could be detected in studies of shorter duration than 4 weeks

Toshiharu SAKAI¹⁾, Junji KURODA, Yukio FUJIMAKI, Norimitsu SHIRAI, Ken-ichi KOBAYASHI, Yukihiro WATANABE, Masakazu FURUKAWA, Takahiro NARITA, Shigeki HATAKEYAMA, Yoshinori SUGAWARA, Shin-ichi OGAWA and Shigeru SATOH

Japan Pharmaceutical Manufacturers Association: ¹⁾Yamanouchi Pharm. and others

P1-17

Reproductive toxicity database survey 1: Wavy rib

Sunao IKEGAWA (Teijin), Masao MATSUURA (Nippon Chemiphar), Tatsuo INOUE (Maruishi), Yasutaka OHKUBO (Fijirebio), Atsushi SANBUISSHO (Sankyo), Hidemi TANIGUCHI (Hisamitsu), Katsuhiko FUKUNISHI (Kanebo), Junichi YOSHIDA (Hoechst Marion Roussel), Masao HORIMOTO (Pfizer), Toshiyuki Fujii (Fujisawa)

P1-18

Reproductive toxicity database survey 2: Cervical rib and supernumerary rib

Satoshi HANADA (Toray), Shunpei DAIDOUJI (Kaken), Fumio ARIYUKI (Tanabe), Hiroyuki ISHII (Toa eiyo), Takayuki IWASE (Mitsubishi Chemical), Kiminori SEKIYA (Otsuka), Mizuno TANI (Novartis), Naoki NISHI (Zeria), Yasuki YOKOMOTO (Torii), Masao HORIMOTO (Pfizer), Toshiyuki FUJII (Fujisawa)

2. PK/TK

P2-1

Sex difference and effect of growth hormone on daily fluctuation of hepatic P450 monooxygenase activities in rats

Tadashi FURUKAWA, Toshiyuki WATANABE, Sunao MANABE, Yoshihiko OHASHI, Shinya SEHATA, Tadahiko OKADA and Yuji MORI¹⁾
Laboratory of Animal Science & Toxicology Laboratories, Sankyo Co., Ltd.
¹⁾Veterinary Medical Science, Univ. of Tokyo.

P2-2

Comparison of toxicities and toxicokinetics between 2-mercapto-4-methyl-benzimidazole (4MeMBI) and its 5-methyl isomer (5MeMBI) in rats treated by single and repeated oral-dose administrations

Kazue SAKEMI, Rieno ITO, Makoto USAMI, Yasuo OHNO and Mitsuhiro TSUDA.
National Institute of Health Sciences

P2-3

Phenotyping of flavin-containing monooxygenase using caffeine metabolism and genotyping of FMO3 gene in a Korean population

C.S.Park, W.G.Chung, J.H.Kang, H.K.Roh, K.H.Lee and Y.N.Cha
Department of Pharmacology and Toxicology, Inha University, Korea

3. Mutagenicity

P3-1

Photomutagenicity/phototoxicity in vitro assays

E.Wollny*, L.Ullmann, J.Klecak, G.Arcelin, T.R.Allen

RCC, Research & Consulting Company Ltd., Switzerland and *RCC, Cytotest Cell Research GmbH,, Germany

P3-2

Effect of food deprivation on micronucleus induction by mitomycin C in mice

Shougo ASANAMI and Kazuyuki SHIMONO

Naruto Research Institute, Otsuka Pharmaceutical Factory, Inc.

P3-3

Metabolic activation of aromatic amines bladder carcinogens by human N-acetyltransferase enzyme expressed in bacterial SOS/Umu test system

Yoshimitsu ODA and Pramod ARYAL

Osaka Prefectural Institute of Public Health

4. Hepatotoxicity

P4-1

Sucrose-mediated modulation of acetaminophen-induced hepatotoxicity

Kenichi HANIOKA^{1,2}, Mayumi HOJO² and Yasushi YAMAZOE²

¹Toxicol. Res. Lab., Fujisawa Pharmaceutical Co. Ltd, Osaka and

²Faculty of Pharmaceutical Sciences, Tohoku University

P4-2

Application of precision-cut liver slice incubation system for in vitro toxicity study:

Use of acetaminophen as a model hepatotoxicant

Yasuhiro TOKITO, Eriha DEKURA, Kazuyuki KITAMURA and Yoshiaki KAWAI

Lead Optimization Research Laboratory, Tanabe Seiyaku Co., Ltd.

P4-3

Stability and toxicity of microcystin LR conjugated with L-cysteine

Shigeyuki TAKENAKA*, Ryuichi OTSU* and Sanae FURUSHO**

*Fukuoka Institute of Health & Environmental Sciences, Dazaifu and

**JASCO International Co. Ltd.

P4-4

Species difference between rat and dog in LPS-induced Kupffer cell-mediated cytotoxicity

Takako HAMANO, Vicent TONG, Tadashi MURASE and Eiji TANAKA

Toxicology Laboratory, Yokohama Research Center, Mitsubishi Chemical Corporation

5. Carcinogenicity

P5-1

Survey of carcinogenicity studies of the pharmaceuticals in rodents

Mamoru MUTAI¹, Toyohiko AOKI, Kenji IRIMURA, Teruji KOGA, Motonobu SATO, Satoshi NAGAYAMA, Toshiyuki FUJII, Toshiaki MATSUZAWA, Masashi YASUBA, Satoru YAMASHITA, and Toshimi USUI

Japan Pharmaceuticals Manufactures Association (Toxicology Laboratory, Yokohama Research Center, Mitsubishi Chemical Corporation¹ and other member companies)

P5-2

Carcinogenesis study of monochlorobenzene in the F344 rat by inhalation

Mamoru OHSAWA, Tomoshi NISHIZAWA, Shigetoshi AISO, Seigo YAMAMOTO and Tajjiro MATSUSHIMA

Japan Bioassay Research Center and Japan Industrial Safety & Health Association

P5-3

Effects of methapyrilene and pyrilamine on hepatocellular replication in rats following 14 day treatment

Masanori OTSUKA, Hatsune EHARA, Shinya IMATANAKA, Keiji SHIRAIISHI, Satsuki HOSHUYAMA, Kazutoshi SHINODA and Kanji YAMASAKI

Hita Research Laboratories, Chemicals Inspection and Testing Institute

P5-4

Analysis of in vivo cisplatin cytotoxic reduction mechanism in rat hepatoma cells

Ken-ichi MIYAMOTO, Mitsuo TAMAI, Yoshie ITO, Masaaki NOMURA, Tomoyoshi MINAMINO and Tohru OHSHIMA.

Kanazawa University

P5-5

Analysis of cell death-inducing activity of cinobufagin, a novel bufadienolide in venom of giant toad

Hiroki OKUMURA¹, Kazumi NAKAMURA¹, Tomomi IHARA², Masao SUGAMATA², Ken TAKEDA¹ and Yoshio UENO¹

¹Faculty of Pharmaceutical Sciences, Science University of Tokyo and ²Institute of Tochigi Clinical Pathology

P5-6

Establishment of Micrometastasis Models Using Bacterial lacZ Gene-tagged Cells.

Kiyoshi KOBAYASHI^{1,2}, Hayao NAKANISHI¹, Jirou SUGIMOTO², Yoshimi INOUE², Mamoru MUTAI², and Masae TATEMATSU¹.

¹Laboratory of Pathology, Aichi Center Cancer Research Institute and ²Toxicology Laboratory, Mitsubishi Chemical Co. Yokohama Research Center

6. Cardiovascular System

P6-1

Evaluation of cardiovascular safety pharmacology study using new data acquisition and real time data analyzing system (HEM)

Mikio TAKEDA, Ayami TOMITA, Shigeko SATOH, Hiroshi MIZUNO, Mamoru SAITO,
Takeru KANEKO and Yoshiharu YAMANISHI
Department of Developmental Efficacy Research, Drug Evaluation Research
Laboratories, Eisai Co., Ltd.

P6-2

Comparison of QT interval in several experimental animals and effects of E4031, a Class III antiarrhythmic agent

Hiroshi KATOH, Ken-ichi NOMOTO, Takahashi YOSHINAGA, Kohei SAWADA
Tsukuba Research Laboratories, Eisai Co., Ltd.

P6-3

Using telemetry to identify drug induced changes in QT interval without estimating QTc in canine Electrocardiography

L.B. Kinter
Preclinical Skill Center, Astra Merck Inc., USA

P6-4

Measurement of blood pressure and heart rate using telemetry method in conscious cynomolgus monkeys, and effect of cardiovascular drugs on the circadian rhythms

Satoshi UNAKAMI, Atsushi FUJIWARA, Shingo HIZUME, Hiromi IIZUKA
Kashima Lab., Mitsubishi Chemical Safety Institute

P6-5

Application of radio-telemetry technology for safety assessment in dogs (Report 2):
A case of assessment of anaphylactoid reaction

Hiroyasu MIYAZAKI, Hiroshi KUNO, Kazuhiko SASAKI, Yukio FUJIMAKI, Hiroyoshi
MATSUMOTO, Fumihiko IKEMOTO
Development Research Laboratories, Banyu Pharmaceutical Co., Ltd.

P6-6

Present status and perspective of cardiac function testing in toxicity studies

Nritusugu SHIMIZU and Yoshinori ISHIYAMA
Kobuchisawa Laboratories, Fuji Biomedix Co., Ltd.

P6-7

Analysis of the cause of death by Compound A in rats

Kenji YAMAUCHI, Kuniko SUGIYAMA, Masahiro MATSUMOTO, Yuji OISHI and
Masaharu HASHIMOTO
Dept. General Toxicol., ¹⁾ Dept. Pathol., ²⁾ Toxicol. Res. Lab., Fujisawa Pharm. Co. Ltd.

P6-8

Effects of diet composition and restriction on spontaneous cardiomyopathy in male Sprague-Dawley rats

Masayuki KEMI, Kevin P. KEENAN* , Carol L. BOLDWIN* , Chao-Min M. HOE* ,
Keith A. SOPER* , G.C. BALLAM** , Matthew J. VAN ZWIETEN* , and Hiroyoshi
MATSUMOTO

Development Research Laboratories, Banyu Pharmaceutical Co., Ltd.

* Merch Research Laboratories, USA, and ** Purina Mills, USA.

8. Renotoxicity

P8-1

Basic study on the spontaneous nephropathy in the Milan normotensive strain rats

Naoki YOSHIOKA¹, Hisahide TAKAHASHI², Kosei INUI³, Keizo MAITA³, Hiromitsu
TANAKA¹ and Mitsuo IWATA¹

¹Kureha Chemical Industry Co., Ltd., ²Laboratory Animal Center, Fujita Health
University and ³The Institute of Environmental Toxicology

P8-2

Toxicological evaluation of systemic candidiasis mouse model treated with antifungal compound

Hiroko MORIMOTO, Akira INOMATA, Nobuyuki SHISHIDO, Kazuko KOBAYASHI,
Setsuko TAKIZAWA, Toshihiko SHIGA and Ikuo HORII

Preclinical Science Department, Nippon Roche Research Center

P8-3

Application of partially nephrectomized rats to the toxicity study:

Comparison of partially nephrectomized rats and normal rats

Yukie MIZUNO¹, Manabu OKUYAMA¹, Nobuyuki ASaeda¹, Hisakazu Iwai¹,
Tatemitsu MOCHIZUKI¹, Yoshiaki TAGAWA^{1,2} and Shoji FUKUSHIMA².

¹Safety Assessment Laboratory, Sanwa Kagaku Kenkyusho Co., Ltd. and

²First Department of Pathology, Osaka City University Medical School

P8-4

Investigation of nephrotoxicity induced by Cisplatin in common marmosets

Yuriko ISHII, Koji AIMOTO, Masakazu KAKUNI, Tsuyoshi TAKEDA, Mitsuo
YAMAMOTO, Takuji HARA and Akio ISHII

Toxicological Research Laboratories, Kyowa Hakko Kogyo Co., Ltd.

9. Hematopoietic toxicity

P9-1

Effects of Clofibrate on the erythrocyte membrane in rats

Kazushi OKAZAKI, Masahiro MOCHIZUKI, Hideaki NAKAMURA, Kazuhisa HATAYAMA, Toshiaki TAKAMATSU, Nobuo NISHIMURA, Tomonori ENAMI, Shuzo OKAZAKI

Gotemba Laboratory, BOZO Research Center Inc.

P9-2

Effect of anticancer drug (Mitomycin C) on peripheral blood and marrow:

Comparison of dogs and rats

Naoki MATSUMOTO, Mitsuo YAMAMOTO, Tomomi YONESHIGE, Yuzuru KATO and Takuji HARA

Toxicological Research Laboratories, Kyowa Hakko Kogyo Co., Ltd.

P9-3

Prolongation of PT and APTT under excessive anticoagulant in the plasma from rats and dogs

Masaaki KURATA, Noriko NOGUCHI, Yoshitomo KASUGA, Tetsuro SUGIMOTO, Kouichi TANAKA and Takashi HASEGAWA

Safety Assessment Laboratory, Chugai Pharmaceutical Co.Ltd.

P9-4

Case study in the anomaly of blood cell distribution determined using automated hematology analyzer on toxicity studies

Yoko TANABE, Fumitoshi MOCHIZUKI, Midori FUJIMURA and Yuji NAKANO

Toxicological Research Institute for Life Science Research, Asahi Industry Co., Ltd.

P9-5

Circadian rhythm of blood chemistry in cynomolgus monkeys

Hiroaki INAMOTO, Koichiro FUKUZAKI, Masatoshi KASHIMA, Hiroaki IKEDA, Hodenobu SAMESHIMA, Keiko OKASAKI and Hiroaki MIYAJIMA

Shin Nippon Biomedical Laboratories, Ltd.

10. CNS and nerve toxicity

P10-1

Studies on the neurotoxicity using functional observational battery and neuropathological examination: Behavioral abnormality induced by vincristine in rat

Tetsuo OGAWA, Yuuichi MIMURA, Hitomi KATO, Masanori MURAKOSHI, Takaharu NAKAYAMA

Safety Research Department, Teikoku Hormone Mfg. Co., Ltd.

P10-2

Studies on the neurotoxicity using functional observational battery and neuropathological examination: Peripheral neurotoxicity induced by adriamycin in rat

Tetsuo OGAWA, Yuuichi MIMURA, Hitomi KATO, Masanori MURAKOSHI, Takaharu NAKAYAMA

Safety Research Department, Teikoku hormone Mfg. Co., Ltd.

11. Technology and methodology

P11-1

Validation and utilization of delivery device for intratracheal administration of dry powders

Shin-ichi SATOH, Yasuji SEKITANI, Susumu SUYAMA, Yuzuru MIYAZAKI and

Toshiaki NISHIGAKI

Ina Research Inc.

P11-2

Pentachlorophenol-induced apoptosis in rat liver epithelial cells: Relation to inhibition of gap junctional intercellular communication and oxidative Stress

Kimie SAI, Kyung-Sun KANG, Yuji KUROKAWA* and Tohru INOUE.

Division of Cellular and Molecular Toxicology, NIHS and

*Biological Safety Research Center, NIHS

P11-3

The results of questionnaires about the electron microscopy in general toxicity studies.

Shin-ichi OGAWA ¹⁾, Jo MORI, Nobuaki HIGUCHI, Motohiro OGURA, Yoshiya AZE,

Kazuo SUZUKI, Hideakira IZUMI, Tomohide AKIBA, Yoshiaki TAGAWA, Takashi

TAKESHITA, Shigeru SATO, Toshiharu SAKAI

Japan Pharmaceutical Manufacturers Association (¹⁾Asahi Chemical Industry Co. and other member companies)

P11-4

Construction of a data base on correlation between clinical laboratory data and histopathological findings.

Shigeru SATO¹⁾, Hitoshi FUNABASHI, Hirofumi YUASA, Masanao KANITANI, Megumi

OHTAKI, Takahiro SANZEN, Toshiharu OIKAWA, Hiroyuki YOSHIMURA, Masayuki

MITSUMI, Mariko HAYASHI, Shin-ichi OGAWA, Toshiharu SAKAI

Japan Pharmaceutical Manufacturers Association (Tobishi Pharmaceutical Co. Ltd¹⁾)

P11-5

Body temperature of laboratory animals using an infrared tympanic thermometer

Hajime TABATA, Rika HIROTA, Hiroshi KURIHARA, Michie KUBO, Satoru SASAKI and

Kazuo KITAMURA

Medicinal Safety Laboratories, Yamanouchi Pharmaceutical Co., Ltd.

P11-6

Examination on blood sampling volume from jugular vein under non-anesthetic condition in rats

Yukari HOSHI, Yoshihiro YAMANAKA, Takeshi IJIMA, Mika ABE, Kimiko JONOUCHI,

Mitsuru KOBAYASHI, Hideshi KANEKO, Junko HATA, Yukiya KOIKE and Hiroshi

UNO

Safety Research Department, Pharmaceuticals Development Research Laboratories,

TEIJIN Co., Ltd.

P11-7

Effect of blood sampling for hematological and biochemical parameters in toxicokinetics study of rat

Shin-ichi MUTO*, Satoru TANAKA*, Shinichi INUKAI*, Takahiro IMAMURA*, Shinji SOMA*, Masaru TSUTSUI*, Yasunori MOMOSE*, Nobuo SHIBATA*, and Kiyoshi MATSUMOTO**.

*Toxicology Laboratories, Kissei Pharmaceutical Co., Ltd. and **Inst. of Exp. Anim., Shinshu Univ. Sch. of Med.

P11-8

Vascular access ports for repeat-daily intravenous dosing in rats

J.Harms, C.Crewell, G.Disalvo, K.Johnson, P.Losco, N.Fetrow, D.K.Johnson, and L.B.Kinter

Department of Biological Sciences, Nycomed Inc., USA

P11-9

A maximal rapid intravenous injection volume in dogs (Canis familiaris)

L.B.Kinter, H.Donkin and D.K.Johnson

Department of Biological Sciences, Nycomed Inc., Wayne, PA.

P11-10

Effect of osmolality on phlebotic potential of infusion solutions for peripheral parenteral nutrition

Takahashi KUWAHARA, Shougo ASANAMI and Takumi TAMURA

Naruto Research Institute, Otsuka Pharmaceutical Factory, Inc.

P11-11

Effect of discodermin A, an antimicrobial peptide, on the cytoplasm membrane

Hiroshi OZAKI, Koichi SATO, Kikuko HORIBE, Minoru SAITO-MITSUI, Masatoshi HORI, Shigeki MATSUNAGA, Nobuhiro FUSETANI and Hideaki KARAKI

Department of Veterinary Pharmacology, Radio Isotope Center, Department of Aquatic Bioscience, Graduate School of Agriculture and Life Sciences, The University of Tokyo

P11-12

Toxicity study in male rats infused intravenously L-cysteine

Miwa HARADA, Ken-ichi UMEOKA, Shinya KANEDA, Kohji KISHIMOTO, Sadakatsu KYO, Kunihiro YAMASHITA, Sanae KISHIMOTO, Osamu SAWAMOTO and Yoshifumi CHONE

Naruto Research Institute, Otsuka Pharmaceutical Factory, Inc.

12. Allergy and immunotoxicity

P12-1

17 Years experience with allergenicity/photoallergenicity tests in albino guinea pigs:

A critical review

G.Arcelin, L.Ullmann, Th.Pfister, J.Klecak, T.R.Allen
RCC, Research & Consulting Company Ltd., Switzerland

P12-2

The ELISA of SRBC-specific antibody (IgM) concentration as an alternative method for the PFC assay

Tomoko ADACHI, Yukiko KANAZAWA, Mami FURUYA, Kazumi TAGO and
Kohichi KOJIMA
Hatano Research Institute, Food and Drug Safety Center, Hadano

P12-3

Structure-activity relationships for skin sensitization potential of 2-mercapto-benzimidazole derivatives in guinea pigs

Kazuo Isama¹⁾, Junko MOMMA²⁾, Masa-aki KANIWA¹⁾ and Akitada NAKAMURA¹⁾
¹⁾National Institute of Health Sciences and ²⁾The Organization for Drug ADR Relief,
R&D Promotion and Product Review

P12-4

Suppressed response of Eisai hyperbilirubinuria rats to recombinant human IL-1 β in the expression of stress response protein and chemokine genes

Takiko OGURO, Masayoshi OHNO, Eida H.S. Hausmann* and Takemi YOSHIDA
Showa Univ. and , *Univ. Kansas Med. Ctr., USA

13. Statistical data analysis

P13-1

Results of the survey about toxicological assessments of quantitative data from the repeated dose toxicity studies in non-rodents

Jun HANDA¹⁾ Nobuhiko KOWATA, Shigeaki HORIE, Kazunori SATO, Hideo UCHIDA,
Kazuto WATANABE, Masayuki WACHI, Kazuhiro NINOMIYA, Haruki TSUBOUTI, Shina
KANEDA, Osamu SADANAGA, Osamu YAMAKITA
Statistics Working Group, Japan Pharmaceutical Manufactures Association
(Belonging to ¹⁾ Nippon Kayaku Co., Ltd. and other companies)

P13-2

Studies on the application of the historical control data obtained from the blood chemistry values of toxicity studies with dogs

Shogo KITAJIMA, Katumi KOBAYASHI, Norio OISHI and Hiroyuki INOUE
Biosafety Research Center, Foods, Drugs and Pesticides (An-Pyo Center)

Social program

- 1) Welcome party for distinguished guests and invited speakers
Tuesday, June 16, 1998, 18:00 - 20:00
At Cypress Garden Hotel (South front of JR Kanayama Station)
Tel: 052-679 1661, Fax: 052-679-1661

- 2) Buffet dinner party
Thursday, June 18, 1988, 17:30 - 19:30
At Reception Hall, Bldg. 1, Floor 4, Nagoya Congress Center
All invited speakers and Exhibition sponsors will be welcomed.