Curriculum Vitae

Gerald J. Kolaja, DVM, Ph.D., DACVP

Personal:

Residence: 2500 6th Avenue #107
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Education:

Undergraduate: Michigan State University
East Lansing, MI
BS- Biology
1961-1965

Veterinary Medicine: Michigan State University
East Lansing Michigan
D.V.M
1963-1967

Graduate: University of Maryland
School of Medicine
Baltimore, MD
Ph.D. Pathology
1973-1977

Preceptorship: US Army, Veterinary Corps
Edgewood Arsenal, MD
ACVP Diplomate
1972-1978

Society Memberships:

American College of Veterinary Pathologists

Society of Toxicologic Pathology, Editorial Board, Committee On Toxicologic Pathology Registry and Chairman of the Annual Meeting Poster Session 1990-1993

Employment History:

Balboa BioConsulting-Pathology and Safety Assessment Consultant

I established Balboa BioConsulting in 2008 to provide expertise to pharmaceutical and biotechnology companies in toxicologic pathology and safety assessment strategies. Histopathology of toxicology studies is provided in support of pre-clinical development programs. The emphasis of Balboa BioConsulting is in evaluating safety issues and establishing strategies for resolution. Coordination of preclinical programs to enable Phase I clinical studies is also provided.

Amgen

Distinguished Fellow/Scientific Director/Scientific Executive Director – July 2002 – November 2007

Responsibilities for this position included representing the Vice President of Metabolic Disorders and Pathology on development teams as an Early Development Leader (EDL). The focus of this responsibility was to expedite the development process, integrate pre-clinical data and provide risk assessment expertise. Additionally, to assist the development teams in identifying appropriate animal models to evaluate pre-clinical safety and efficacy. I have served on Project Strategy Teams as an Early Development Leader (AMG 303, AMG 386, peg B1, and AMG 753). This role included presentation to the Research Review Board and Development Review Board on a regular basis to update on progress of development programs. An additional responsibility included providing expertise to business development activities in evaluating external laboratories. These laboratories provided immunohistochemistry services and developed diagnostic kits for Amgen products. Another responsibility was the assignment to corporate committees responsible for the re-design of Amgen administrative processes and improvement of work processes. These committees include Six Sigma and Corporate Leadership. Report writing for all of Amgen research programs has been the focus of the latest Six Sigma project. I also participated in the redesign of the early Project Strategy Team process. The position was also responsible for coordinating pre-clinical toxicology and pathology data into development programs as required. I also coordinated and assisted in writing and editing the pharmacology section of the BLA for palifermin. This resulted in an early submission to the FDA for this product.

I was also responsible for providing pathology support to several discovery programs in phenotyping knock out mice, characterizing orphan receptors using ISH and IHC. Teams

were located in both Thousand Oaks as well as the San Francisco site. I also served on the Corporate Compliance and Quality Committee to ensure pharmacology studies are in compliance with world-wide regulations. I have served as a consultant for the restructuring of the commercialization process at Amgen. I served on the committee to select a system for electronically capturing data from pharmacology studies.

Immunex

Director of Pathology - November 2000 – July 2002

Responsible for managing and providing leadership to the Pathology Department for Immunex that supported the Discovery and Clinical Development programs. The pathology program was developed from a single pathologist supporting a limited number of discovery programs to 5 pathologists and 11 technical staff supporting the entire discovery and clinical development programs over a period of 14 months. Responsibilities in Discovery Research included providing morphologic support for animal model development, phenotyping knock out and transgenic mouse models, collaborating with individual investigators evaluating the therapeutic potential of antibodies and proteins, coordinating immunohistochemistry support for all research and clinical development programs and participating on discovery staff planning and strategy meetings. Clinical Development was supported by providing input to toxicology development programs, providing immunohistochemistry and diagnostic support to clinical development programs and conducting peer reviews for GLP toxicology studies. Pathology department staff members monitored animal studies that had primary pathology endpoints.

Senior Investigator, Clinical Development - January - November 2000

I provided pathology support to clinical development programs by monitoring toxicology studies, conducting immunohistochemistry on human tumors and participation on project development teams. I served as the acting Director of the Bioanalytical Laboratory and provided leadership and management to this group. I actively participated in clinical development staff meetings related to clinical trial implementation. I also provided collaborative support to discovery programs and served on the Pharmacology sub team for the CD40L program. I presented an overview of the use of CD40L in the treatment of cancer at the 2001 Pharma meeting.

Pharmacia and Upjohn

Vice President, Toxicology Operations - North America 1996-1999

Responsibilities included providing leadership and management to a staff of over 125 scientists, associates, technicians and secretaries in pre-clinical discovery support and

pharmaceutical development. Review and approval for all regulatory documents, such as INDs, NDAs, expert reports and toxicology summaries produced by Pharmacia and Upjohn for the U.S. Research and Development site was a major component of this position. Another major responsibility was the oversight of external toxicology studies conducted through contract research organizations.

This position required close collaboration with discovery research, clinical development, drug metabolism research and pharmaceutical sciences. In addition, this position included serving as a member of the Preclinical Development staff. This responsibility required being intimately involved and collaborating with senior management in formulating strategy for worldwide pharmaceutical development and registration. Close interactions were also maintained with the Pharmacia and Upjohn discovery and toxicology programs in Italy, Sweden and Japan. Interactions with regulatory agencies regarding pre-clinical development issues were an integral responsibility of this position. Close interactions with CEDR were maintained and included participation on FDA sponsored collaborations with industry to streamline the IND process.

This position required the frequent briefing of senior research and development staff on progress of development programs. Also, frequent discussions with the FDA regarding pre-clinical safety issues were part of the responsibilities of this position.

Director, Pathology & Toxicology Research 1988-1996

This position was responsible for the management and scientific leadership for 5-6 scientists in drug discovery support and development. Review of study design, study reports and regulatory documents were a key part of this position. This position was responsible for formulating toxicology development plans for pharmaceutical products under development at the Upjohn Company.

Drug Safety Program Director, European Operations, Crawley, England 1986-1988

This position was responsible for establishing a toxicology laboratory in the UK for the Upjohn Company. This involved establishing and monitoring toxicology programs through contract laboratories in Europe. Interactions with regulatory agencies in Europe regarding pre-clinical development issues were a responsibility of this position. In addition, this position was responsible for day-to-day interactions with the Upjohn Company marketing, regulatory, clinical and pre-clinical programs

Associate Director, Pathology Toxicology Research 1984-1986

This was an entry-level management position responsible for the management of a group of 3-4 scientists conducting toxicology studies in support of pharmaceutical development.

Research Veterinary Pathologist/Toxicologist 1979-1984

This position was responsible for conducting toxicology studies and providing pathology

expertise in the development of pharmaceutical products.

U.S. Army

Aberdeen Proving Ground, MD: 1976-1979 - Major, Chief of Pathology and Director of the pathology preceptorship training program.

Aberdeen Proving Ground, MD: 1972-1976 - Trainee in Pathology Training Program in US Army Preceptorship Program.

Ft. Bragg, NC - Post Veterinarian: 1970-1972 - Responsible for Post veterinary duties and disease surveillance program.

Vietnam - 9th Medical Laboratory: 1969 - Responsible for rabies diagnosis and acting as the project officer for a tropical canine disease program. Acted as second in command for the Veterinary program at the 9th Medical Laboratory and supervised the activities of several enlisted personnel. Awarded Bronze Star Medal for Service.

Aberdeen, MD - Post Veterinarian: 1968-1968 - Responsible for Post veterinary program that included animal disease surveillance and food inspection.

Other Employment:

Consultant Pathologist with University of Maryland in the conduct of pathology review of the potential carcinogenicity of Aspartame: 1978-1979

Consultant Pathologist, Litton Bionetics, Rockville, MD - National Toxicology Program: 1978-1979

Veterinary Practice, Birmingham, MI - Small animal practice: 1969-1970

Self-employed, Montague, MI - Veterinarian in a small animal and dairy practice: 1967-1968

Publications:

1. Kolaja, G.J and Fairchild, D.G. (1973): Leiomyoma in the duodenum of a dog. Amer. Vet. Med. Assoc. J. 163, 275-276.

2. Kolaja, G.J. and Hinton, D.E. (1976): Histopathologic alterations in shell gland accompanying DDT-induced thinning of eggshells. Env. Poll. 10, 225-231.

3. Kolaja, G.J. and Hinton, D.E. (1977): In vitro inhibition of microsomal Ca ATPase

from eggshell gland of mallard duck. Bull. Env. Contam. Tox. 1(5), 591-594.

4. Kolaja, G.J. (1977): The effects of DDT, DDE and their sulfonated derivatives of eggshell formation in the mallard duck. Bull. Env. Contam. Tox. 17(6), 697-701.

5. Kolaja, G.J. (1977): The effects of DDT on eggshell formation in the mallard duck. Ph.D. Thesis, University of Maryland.

6. Kolaja, G.J. and Hinton, D.E. (1977): Effects of DDT on eggshell quality and Ca ATPase. J. Tox. Env. Hlth. 3, 699-704.

7. Kolaja, G.J. and Hinton, D.E. (1978): Ultrastructural alterations in the eggshell gland after chronic exposure to DDT. Env. Pollut. 17,237-244.

8. Werner, R., Balady, M.A. and Kolaja, G.J. (March 1978): Phycomyocotic dermatitis in an eastern indigo snake. Vet. Med. Small Ani. Clin., pp. 362-363.

9. Kolaja, G.J. and Lund, J.E. (1981): Monocytic origin of Fischer Rat Leukemia. Micron, 12, 99-100.

10. Ruwart, M.J., Rush, B.D., Friedle, N.M., Piper, R.C. and Kolaja, G.J. (1981): Protective effects of 16, 6-dimethyl PGE2 on the liver and kidney. Prostaglandins, Sup. Vol. 12, 97-102.

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11. Lincoln, K.L., Kolaja, G.J. and Mathews, J. (1981): A scanning electron microscopic comparison of normal and postmenopausal osteoporotic trabecular bone. Micron, 12, 1295-296

12. Bonnema, K.J., Kolaja, G.J., Piper, R.C., Ruwart, M.J., Lancaster, C. and Nezamis, J.E. (1981): Morphologic evaluation of gastric cytoprotection by 16,16-dimethyl PGE2. Micron, 12, 309-310.

13. Block, E.M., Jones, C.L., Stevens, D.R., Kolaja, G.J. and VonVoigtlander, P.F. (1981): Comparison of endothelial corneal lesions in Fischer 344 rats after treatment with an antidepressant drug U-48753E or imipramine. Micron, 12, 307-308.

14. Kolaja, G.J. and Fast, P.E. (1981): Lupus-like kidney lesions in MRL mice. Micron, 12, 305-306.

15. Kolaja, G.J. and Fast, P.E. (1982): Renal lesions in MRL mice. Vet. Path., 19, 663-668.

16. VonVoigtlander, P.F., Kolaja, G.J. and Block, E.M. (1982): Corneal lesions induced by antidepressants: A selective effect upon young Fischer 344 rats. J. Pharm. Exp. Therapeutics, 222, No. 1, 282-286.

17. Wiser, S.K. and Kolaja, G.J. (1982): PAS staining of paraffin embedded tissue for ultrastructural evaluation. Micron, 13, No. 4, 451-452.

18. Ruwart, M.J., Sammons, D.W., Kolaja, G.J., Rush, B.D., Friedle, N.M. and Adams, L.D. (1982): Alloxan-induced hyperglycemia in rats is reduced by 16,16-dimethyl-PGE2. Research Commun. in Chem. Path. and Pharm., 40, No. 2, 233-243.

19. Smith, R.J., Bowman, G.J., Iden, S.S., Kolaja, G.J. and Wiser, S.K. (1983): Biochemical, metabolic and morphological characteristics of human neutrophil activation with pepstatin A. Immunology, 49, 367-377.

20. Ochoa, R., Kolaja, G.J. and Klei, T.R. (1983): Hemosiderin deposits in the equine small intestine. Vet. Path., 20, 641-643.

21. Elliget, K.A. and Kolaja, G.J. (1983): Preparation of primary cultures of rat hepatocytes suitable for in vitro toxicity testing. J. Tissue Culture Methods, 8, 1-6.

22. Kolaja, G.J., VanderMeer, D.A., Packwood, W.H. and Satoh, P.S. (1993): The use of SDS PAGE to detect renal damage in Sprague Dawley rats treated with gentamicin sulfate. Toxicol. Pathol. 20:603-607.

23. Kolaja, G.J., Packwood, W.H., Bell, R.R., Ratke, C.C. and Stout, C.L. (1994): Renal Papillary Necrosis and Urinary Protein Alterations Induced in Fischer- 344 Rats by D-Ormaplatin. Toxicol. Pathol. 22:29-38.

24. Bell, R.R., Bombardt, P.A., DuCharme, D.W., Kolaja, G.J., Packwood, W.H., Bothwell, B.E. and Satoh, P.S. (1994): A Non-Radioactive Iothalamate and p-Aminohippuric Acid High-Performance Liquid Chromatographic Method for Simultaneously Measuring Glomerular Filtration Rate and Renal Blood Flow in the Rat. (1994) 8, 224-229.

25. Packwood, W.H., Satoh, P.S., Bell, R.R., Kolaja, G.J., and VanderMeer, D.A. Improved Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis of Urinary Proteins for Assessing Renal Function: Method Development and Preliminary Assessment. (1994) Toxicology Methods 4, 92-101.

26. Olson, H., Betton G., Robinson D., Thomas K., Monro A., Kolaja G., Lilly P., Sanders, J., Sipes G., Bracken W., Dorato M., Van Deum K., Smith P., Berger., and Heller A. (2000) Concordance of the Toxicity of Pharmaceuticals in Humans and Animals. Regulatory Toxicology and Pharmacology 32, 56-67.

Abstracts:

Packwood, W.H., Satoh, P.S. Frailey, D., VanderMeer, D.A., and Kolaja, G.J. (1992): Evaluation of drug-induced nephrotoxicity by SDS PAGE. Society of Toxicologic Pathologists: Eleventh International Symposium.

Packwood, W.H., Satoh, P.S., Frailey, D., VanderMeer, D.A., Kolaja, G.J. (1992): Evaluation by SDS-PAGE of drug-induced nephrotoxicity. Thirteenth Annual Biology/Biochemistry Associates Symposium. (96).

Frailey, D.M., VanderMeer, D.A., Satoh, P.S., Kolaja, G.J., Packwood, W.H. (1992): SDS-Polyacrylamide electrophoresis of urinary proteins for assessing renal damage by various compounds: Method development and preliminary assessment. Upjohn Technicians Symposium.

Kolaja, G.J., Packwood, W.H., Bell, R.R., Ratke, C.C., Stout, C.L., VanderMeer, D.A., Frailey, D.M. and Satoh, P.S. (1993): The evaluation of urinary proteins as a means of assessing renal toxicity. Society of Toxicology, Midwest Discussion Group.

Boysen, B., Harris, R., Black H., Kircher C., Kolaja, G., Pletcher, J., Riley G., Street, S., King, D. The registry of toxicologic pathology for animals.

Kolaja, G., Packwood, W., Bell, R. (1993): The evaluation of urinary proteins by SDS Page in the assessment of renal toxicity. American College of Veterinary Pathologists: Forty-fourth Annual Meeting.

Books:

Kolaja, G.J. and Hinton, D.E. (1979): DDT-induced reduction in eggshell thickness, weight and calcium is accompanied by inhibition of calcium ATPase. In: Animals as Monitors of Environmental Pollutants. National Academy of Sciences, Washington, DC.

Hinton, D., Lipsky, M., Klaunig, J. and Kolaja, G.J. (1982): Hepatic morphology of the Lesser Bushbaby (Galago): A light and electron microscopic study. In: Lesser Galago as an Animal Model: Selected Topics Haines, D.E. (Vol. Ed.). Volume 12, In: Primates in Medicine, Goldsmith, E.I. and Moor-Jankowski, J. (Series Ed.), S. Krager, BASEL.

Kolaja, G.J., Kirton, K.T. (1994): Toxicology Studies with Prostaglandin E1. Excerpta Medica, The Role of Alprostadil in the Diagnosis and Treatment of Erectile Dysfunction. ed. Irwin Golostein and Tom Flue MD.