Boehringer Ingelheim

Licensing Assistance Team
US Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard
Suite 100
King Of Prussia, PA 19406-2713

Dr. 2

April 24, 2019

To Whom It May Concern:

This letter is to request two changes to License No. 06-19183-01./03017101

1. Replacement of the interim Radiation Safety Committee chair, Mitch Taub PhD (Director of Drug Metabolism and Pharmacokinetics) with Eleanore Seibert PhD, Vice President of Drug Metabolism and Pharmacokinetics. Enclosed is Dr. Seibert's resume for your review.

2. I would also like to request that Drané O'Brien replace William L. Galdenzi as the Radiation Safety Officer for Boehringer Ingelheim Pharmaceuticals, Inc. Per Boehringer Ingelheim's license requirements, the Radiation Safety Committee has reviewed Drané O'Brien qualifications and has approved her as the Radiation Safety Officer. Ms. O'Brien has managed the Radiation Safety Program at Boehringer Ingelheim Pharmaceuticals, Inc. for the past 5 years, working very closely with the RSO and managing all aspects of the Radiation Safety Program. During her tenure as Radiation Safety Manager, she instituted a number of program improvements and led two successful NRC inspections. In addition, Ms. O'Brien completed a 40-hour Radiation Safety Officer Training on September 2014 provided by Dade Moeller Radiation Safety Academy. Enclosed is her resume for your review and a copy of the certificate of completion from the RSO training class.

The delegation of authority letter will be mailed following Ms. O'Brien approval as RSO.

Best Regards,

Ulrich Roth PhD
Site Head Development US & Head of Development NCE

900 Ridgebury Rd. P.O Box 368
Ridgefield, CT06877
Telephone (203) 778-7350

E-mail: ulrich.roth@boehringer-ingelheim.com

Ulrich Roth PhD
Site Head Development US & Head of Development NCE

612057

Drané O'Brien

[redacted], Work (203) 798-4398
drane.obrien@boehringer-inglelheim.com

PROFESSIONAL EXPERIENCE

2013-Present **Boehringer Ingelheim Pharmaceuticals Inc. Ridgefield, CT.**
Department of Health Safety and Security
Environmental Health and Safety Manager

- Manage the BIPI Radiation Safety Program for both ionizing and non-ionizing radiation in compliance with all regulatory requirements.
- Represent BIPI to the Nuclear Regulatory Commission and State Agencies such as the Connecticut Department of Health, during on-site inspections
- Manage Biological Safety Programs in compliance with all regulatory requirements.
- Coordinate and facilitate the Radiation Safety Committee and Biological Safety Committee meetings.
- Prepare, manage and deliver associated training programs in order to fulfill regulatory requirements.
- Update current Environmental Health and Safety (EHS) e-learnings in accordance with regulatory requirements.
- Provide EHS instructor led training to employees to BIPI employees and contract workers.
- Establish and maintain permits and licenses in compliance with Federal, State and local regulations.
- Maintain all documentation for the Biological and the Radiation Safety Programs in accordance with regulatory requirements.
- Manage and archive all documents within EHS&S respect to current document policies
- Work with assigned Business Partners to act as focal point for resolution of their EHS concerns and issues.
- Work with respective Business Partners to modify processes or identify processes in order to address compliance risks.
- Develop EHS metrics and calculate KPIs in order to keep upper management and respective business partners informed.
- Evaluate and resolve compliance issues and or concerns.
- Monitor and audit business activities in order to improve operations and business processes.
- Present EHS initiatives to upper management, at Business Partner Meetings and at Site Safety Committee meetings.
- Work closely with client staff to bring about a high level match of EHS culture and worker safety activities to written policies, procedures, instructions and manuals
- Respond to incidents by gathering data, identifying root causes and implementing corrective actions.
- Lead and participate in inspections and audits, assign CAPAs for compliance incidents. Follow up and assist in closing CAPAs for compliance incidents.
- Conduct risk assessments for associated EHS programs, analyze hazards associated with work activities and tailor controls for hazards identified.
- Remain current in industry standards and best practices for Biological Safety, Radiation Safety, General Laboratory Safety.
- Created a harmonized document storage landscape for EHS in IDEA for GEN in order to facilitate : the on boarding process of new employees, the location and retrieval of documents and electronic records retention
- Participate on emergency response teams such as Fire Brigade, Evacuation and Hazmat teams.
- Proficient in the use of the Microsoft Office Suite

Continuous Process Improvement: Certified Green Belt

- Able to lead projects and make positive changes by improving processes
- Empower employees to deliver improved efficiencies by executing process improvements
- Enable employees to be more effective by providing training and coaching on business tools and concepts rooted into lean six sigma
- Facilitate and provide the foundation for collaborative problem solving
- **Green Belt Projects**
  1. Deliver and maintain a complete database of human infectious and biological material. Compliance initiative.
  2. Find opportunities for energy savings and enhancements by assessing older fume hoods in R&D Ensure that users are using proper containment devices for their tasks. Energy Savings and Risk Assessment Project.

Toastmasters-Member since 2016

Member of the club; joined in order to improve communicating, public speaking and leadership skills.

1997-2013 **Boehringer Ingelheim Pharmaceuticals Inc. Ridgefield, CT. Department of Drug**
Scientist IV **Metabolism and Pharmacokinetics**

Training, Mentoring and Quality Control

- Participated in a 3 month internship in Quality and Records Management.
- Provide training in Laboratory Notebook Documentation for new employees.
- Created a new Laboratory Notebook Documentation training class for summer interns. This course is currently being used every summer at BI.
- Collaborated with the Associate Director of Compliance Training to strengthen documentation and compliance skills within the Drug Metabolism Group through a variety of informative and interactive seminars.
- Presented training, educational and technical seminars to diverse audiences. Mentored and trained colleagues in the audit process (QC process) in order to ensure quality control within the Drug Metabolism Group.
- Designed, developed and implemented training classes for scientific equipment. Created documentation for all training platforms, which provided detailed operating instructions for colleagues.
- QC expert within the Drug Metabolism Group. Audited and reviewed a large number of reports which were incorporated in IND and NDA submissions.
- Lead coordinator for the generation of test procedures within the Drug Metabolism group. Responsibilities were to write, review, collate and archive test procedures. Provided, organized and centralized location in IDEA for GEN as a repository for all test procedures used within the Drug Metabolism Group.
- Verified notebooks and provided guidance to colleagues with regards to good documentation practices in accordance with the current Laboratory Notebook SOP.

Committees and BIPI Teams

- Responsible for organizing and managing current group meetings.
- DMPK representative on the Biological Safety Committee.
- Continuous Process Improvement (CPI) DMPK representative.
- VTI DMPK sub team member.
- Chaired and managed the Gap Analysis Committee, the Process Improvement Committee and the Records Retention Committee. Committees were formed in order to identify and evaluate areas for improvement with regards to documentation and increased efficiency. Results and solutions were gathered and presented to upper management.

Analytical and Automation Experience

- Increased data analysis and documentation throughput within the Drug Metabolism group by designing and establishing a variety of templates using Microsoft Word and Excel.

- Designed and implemented templates for data collection, calculations and report generation which streamlined data analysis.
- Provided project support through a variety of work packages, interpreted and documented data generated. Collated relevant findings into reports using IDEA for SUB.
- Evaluated various processes within the Drug Metabolism group in terms of operating efficiency. Recommendations and justifications were presented to upper management. Assessed, selected and purchased new instrumentation that would increase throughput, decrease variability, increase accuracy and precision. Instrumentation was implemented within the group, throughput increased by one hundred percent with an improvement in process variability, accuracy and precision.
- Proficient in Mass Spectrometry (methods development, analyte quantitation, and metabolite identification).
- Created and implemented two Microsoft Access databases. A tissue bank database which served as tracking system for the in house liver tissue and microsome bank. A chemical relational database utilizing Accord for Microsoft Access, relational tables containing chemical structures and biological data were created to facilitate substructure searches linked to biological data.
- Automation expert within the Drug metabolism group. Responsible for designing, programming and implementing a variety of *in vitro* assays. Automated assays resulted in improved efficiency and in improved data quality.

1994-1997 **Alteon Incorporated, Ramsey NJ. Department of Biopharmaceutics**
Senior Scientist

- Responsible for writing reports, generating and implementing protocols *(preclinical studies).*
- Assisted the Radiation Safety Officer and the General Safety Officer in implementing safety procedures within Biopharmaceutics.
- Trained and mentored colleagues in HPLC methods development, data analysis and report writing.
- Data and reports generated from pre-clinical studies utilized in IND submissions.
- Determined the disposition of non-radiolabeled test materials in rats (cold ADME).
- Played an integral part in the design of small animal pharmacokinetics and absorption studies *(adhered to GLP guidelines).*
- Developed analytical methodology *(according to GLP guidelines)* for the quantitation of non-radiolabeled compounds in biological matrices.
- Developed analytical methodology for testing stability and purity of new chemical entities.
- Utilized a Hewlett Packard Laboratory Automation System for data acquisition.
- Lotus 123 for data analysis, Harvard Graphics for the generation of graphs and Microsoft Word for report writing.

1990-1994 **Ciba Geigy, Pharmaceutical Division, Ardsley NY. Clinical Pharmacokinetics and**
Scientist II **Disposition**

- Conducted animal and human (ADME) studies to evaluate the metabolism and disposition of radiolabeled compounds in biological samples.
- Small animal surgical experience (cannulation of jugular vein and bile duct).
- Extensive background in *in-vitro (*microsomal and liver slice incubations).
- Developed analytical methodology for the quantitation of radiolabeled drugs and their metabolites in biological matrices.
- Isolated and purified metabolites from biological matrices for structure elucidation.
- Experience in trace analysis of compounds using HPLC and TLC.
- Conducted protein binding studies for new chemical entities.
- Utilized Lotus 123 for data analysis, Sigma Plot for the generation of graphs and Word Perfect for report writing.

1988-1990 **Ciba Geigy Pharmaceutical Division, Ardsley NY. Clinical Pharmacokinetics and**
Scientist I **Disposition**

- Trained and mentored new employees in the operation of scientific instruments.
- Evaluated and purchased equipment for a new radioimmunoassay lab.

- Validated assay transfer to other analysts.
- Developed and validated radioimmunoassays for use in Phase I clinical studies *(according to GLP guidelines.)*
- Assayed plasma samples for Phase I clinical studies *(according to GLP guidelines).*

PROFESSIONAL DEVELOPMENT (COURSES ATTENDED)

Quality Assurance

- Basic Good Laboratory Practices. Hosted by Monica Cahilly from Green Mountain Quality Assurance at Boehringer Ingelheim Pharmaceuticals, Inc. 2011.
- Bioanalytical Lab Compliance. Hosted by Monica Cahilly from Green Mountain Quality Assurance at Boehringer Ingelheim Pharmaceuticals, Inc. 2011.
- Documentation Skills. Hosted by Deb Garvin at Boehringer Ingelheim Pharmaceuticals, Inc. 2010
- Improving Quality by Focusing on Human Error. Hosted by Jim Vesper at Boehringer Ingelheim Pharmaceuticals, Inc. 2010.
- Train the Trainer Workshop 200. Boehringer Ingelheim Pharmaceuticals, Inc. June 2007.
- Quality Control Procedures. Boehringer Ingelheim Pharmaceuticals, Inc. Mar. 2007.
- Quality Assurance Procedures. Boehringer Ingelheim Pharmaceuticals, Inc. Mar. 2007.
- Good Laboratory Practices Workshop. GLPs and Bioanalysis; Personnel Responsibilities; Study Director Qualifications and Responsibilities. Boehringer-Ingelheim Pharmaceuticals Inc., June 2007.
- Train the Trainer Workshop 101. Boehringer Ingelheim Pharmaceuticals, Inc. June 2007.
- Good Documentation Skills Workshop. Boehringer Ingelheim Pharmaceuticals, Inc. Sept. 2007.
- GLPs for Study Directors. Hosted by West Coast Quality Training Institute. Boehringer Ingelheim Pharmaceuticals, Inc. Jan. 2005.

Management Training

- Influencing without Authority. Boehringer Ingelheim Pharmaceuticals, Inc. 2017
- Emotional Intelligence. Boehringer Ingelheim Pharmaceuticals, Inc. 2018
- Change Skills Management. Boehringer Ingelheim Pharmaceuticals, Inc. 2011
- Self Guided Mentoring. Boehringer Ingelheim Pharmaceuticals, Inc. 2011
- Communicating and Influencing Skills. Boehringer Ingelheim Pharmaceuticals, Inc. 2010
- Effectively Track my Performance. Boehringer Ingelheim Pharmaceuticals, Inc. 2009
- Dealing with Difficult People. Hosted by Career Track, 2008.
- Presentation Skills. Boehringer Ingelheim Pharmaceuticals, Inc. 2008
- Time Management. Hosted by American Management Association, 2007.
- Influence. Hosted by Opportunities Management Inc. Boehringer Ingelheim Pharmaceuticals, Inc. 2001.
- Building Accountable Organizations. Hosted by Opportunities Management Inc. Boehringer Ingelheim Inc. 2000.
- Developing Responsible Communication. Hosted by Opportunities Management Inc. 1999.
- Choice and Decision Making. Hosted by Opportunities Management Inc., 1999.

Scientific Training

- Metabolite Profiling and Screening. Applied Biosystems. Jan. 29th -Feb. 2nd, 2007.
- Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist. Boehringer Ingelheim Pharmaceuticals, Inc. April, 2006.
- LC/MS/MS workshop Hosted by Applied Biosystems. Boehringer Ingelheim Pharmaceuticals, Inc. 2006.
- 4000 Q TRAP operator training class (small molecule applications). Applied Biosystems. 2005
- Enzyme Kinetics short course: International Study of Xenotbiotic Meeting. Nov. 12th-15th , 2002
- Drug Metabolism Innovation in Discovery and Development. 2000.
- LC/MS/MS Workshop. Boehringer-Ingelheim Inc. 1999.

- Miniaturization & Increased Throughput Screening in Support of Drug Discovery. International Study of Xenobiotics, 1999.
- Novel Strategies for Accelerated ADME/ Toxicity Screening for Lead Optimization. 1997

Computer Education

- Excel Functions. Boehringer-Ingelheim Inc. 2011
- Documentum Training. Boehringer-Ingelheim Inc. 1999.
- MS Excel Intermediate. Boehringer-Ingelheim. Inc. 1999.
- MS Access Intermediate. Boehringer-Ingelheim. Inc. 1999.

SEMINARS

Automation in Drug Development: Challenges and Rewards: Caliper Life Sciences Open House and User's Meeting, 2009

EDUCATION

Saint John's University, Jamaica, NY
M.S. in Biology [redacted]

Thesis : Isotonic and Hypertonic Saline Act as Stressful Stimuli for the Oxytocinergic System of the Pituitary, Hypothalamus and Spinal Cord

Saint John's University, Jamaica, NY
B.S. in Biology [redacted]

PUBLICATIONS

1. **Lukic D.** Haldar J. Isotonic and Hypertonic Saline Act as Stressful Stimuli for the Oxytocinergic System of the Pituitary, Hypothalamus and Spinal Cord. Life Sciences 1993; 53 (7): 579-84 .

2. Miaskowski C. Ong GL. **Lukic D.** Haldar J. Immobilization Stress Affects Oxytocin and Vasopressin Levels in Hypothalamic and Extrahypothalamic Sites. Brain Research 1988; 458 (1): 137-41.

3. Vrba J. **Lukic D.** Haldar J. Effects of Cysteamine on Blood Pressure: Possible Mediation through Vasopressin Release. Proceedings of the Society for Experimental Biology and Medicine 1988; 188
(4): 485-8.

POSTERS

1. **D. O'Brien**, E. Seibert, D.Tweedie. Contribution of Enzymes other than CYP2E1 to Chlorzoxazone 6-Hydroxylation in Human Liver Microsomes. Sixteenth North American ISSX Meeting. October, 2009.

2. **D. O'Brien**, H. Sulkowski, K. Mosure, R. Mountfield, D. Tweedie : Streamlining Drug Development using Automation. Twelfth North American ISSX Meeting. October, 2003.

3. H. Sulkowki , R. Mountfield, D. Tweedie, **D. O'Brien** :Application of the Zymark Staccato for *In Vitro* Drug Metabolism Screens. International Symposium on Laboratory Automation and Robotics (ISLAR) October, 2001.

4. B. Walter, **D. Lukic** : Metabolism of [14C]CGS 19755 in Healthy Male Subjects After a Single 60 MG Intravenous Infusion: Fourth North American ISSX Meeting . Bal Harbour, Florida. November, 1992.

5. B. Walter, **D. Lukic** , Kevin Kunnen: The In-Vitro Metabolism of CGS 18102A and its Enantiomers by Human, Dog, and Rat Microsomes : Fourth North American ISSX Meeting . Bal Harbour, Florida. November, 1992.

6. B. Walter, **D. Lukic.** : Stereoselective Glucuronidation of CGS 15873A: A Dopamine Agonist. American Association of Pharmaceutical Scientists Meeting. Washington D.C. November 1991.

[redacted]

REFERENCES

Available upon request

ELEANORE SEIBERT, Ph.D.

[redacted] • Eleanore.Seibert@boehringer-ingelheim.com

EDUCATION

Ph.D., Biochemistry and Biophysics, [redacted]
Mount Sinai School of Medicine of New York University (NYU), New York, NY
Dissertation Title: *Contribution of DNA bending and opening dynamics to the specific recognition of damaged DNA by repair enzymes*
[redacted]

B.S., Forensic Science, *summa cum laude,* [redacted]
John Jay College of Criminal Justice of the City University of New York (CUNY), New York, NY
[redacted]

PROFESSIONAL EXPERIENCE

Vice President *4/2019 - Present*
Drug Metabolism and Pharmacokinetics, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Executive Director *1/2018 – 4/2019*
Study Management & Conduct, US Clinical Operations, Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

Executive Director *9/2015 – 12/2017*
Project Management & Process Improvement, US Medicine and Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Director, *2/2015 – 8/2015*
Project Management & Process Improvement, US Medicine and Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

R&D Project Leader (Sr. Associate Director), 4/2011 – 2/2015
R&D Project Management, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Principal Scientist, 11/2008 – 4/2011
Drug Metabolism and Pharmacokinetics, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Senior Scientist, 05/2005 – 11/2008
Drug Metabolism and Pharmacokinetics, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Printed on Tuesday, April 16, 2019

16 Apr 19

Postdoctoral Associate, 07/2004 – 05/2005
Drug Metabolism and Pharmacokinetics, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

Research Fellow, 01/2003 – 07/2004
Institute for Cancer Prevention, Valhalla, NY

CONTINUING EDUCATION

- Women Unlimited LEAD 2011-2012
- Lean Six Sigma Black Belt training/certification 2010-2012
- AAPS workshop on strategies to address therapeutic protein drug interactions during clinical development 2010
- Boehringer Ingelheim Management Development Program (MDP) 2010
- ADME properties of protein therapeutics – ISSX Short Course 2008
- Pharmacokinetics for pharmaceutical scientists – University of California, San Francisco 2008
- Shaping the future: The legacy of leadership – OMI Associates 2007
- Automated *in vitro in vivo* extrapolation – SimCyp Limited 2007
- Application of PK/PD mechanistic models in drug development – ISSX Short Course 2006
- Advanced PK/PD modeling methodology – Pharsight Corporation 2006
- Basic pharmacokinetic concepts for the pharmaceutical scientist 2006
- Pharmacology for chemists – American Chemical Society Short Course 2005

PROFESSIONAL SOCIETIES

- American Chemical Society (ACS)
- Mentor for Women Unlimited LEAD 2014-2015

SCHOLARSHIPS AND AWARDS

- NIH Training Grant in Cancer Biology 2002-2003
- NIH Training Grant in Molecular, Cellular, Biochemical and Developmental Sciences 1999-2001
- Salutatorian of Undergraduate Graduating Class 1997
- Jerome Metzner Award for Excellence in Forensic Science 1997
- Northeast Association of Forensic Scientists Scholarship 1996
- Dean's List 1993-1997

BOOK CHAPTERS

- Seibert E, Tracy TS (2014) Fundamentals of Enzyme Kinetics. Methods Mol Biol. 1113: 9-22

- Seibert E, Tracy TS (2014) Different Enzyme Kinetic Models. Methods Mol Biol. 1113: 23-35

- Seibert, E, Osman, R, Ross, JBA (2006) Dynamics of DNA damage recognition. In: Siede, W., ed. *DNA Damage Recognition*. Marcel Dekker, *New York, NY;* 3-19

PEER-REVIEWED PUBLICATIONS

- Sabo JP, Kort J, Ballow C, Kashuba AD, Haschke M, Battegay M, Girlich B, Ting N, Lang B, Zhang W, Cooper C, O'Brien D, Seibert E, Chan TS, Tweedie D, Li Y (2014) Interactions of the hepatitis C virus protease inhibitor faldaprevir with cytochrome P450 enzymes: *in vitro* and *in vivo* correlation. J Clin Pharm. 55(4): 467-77

- Vieira ML, Kirby B, Ragueneau-Majlessi I, Galetin A, Chien JY, Einolf HJ, Fahmi OA, Fischer V, Fretland A, Grime K, Hall SD, Higgs R, Plowchalk D, Riley R, Seibert E, Skordos K, Snoeys J, Venkatakrishnan K, Waterhouse T, Obach RS, Berglund EG, Zhang L, Zhao P, Reynolds KS, Huang SM (2014) Evaluation of various static *in vitro-in vivo* extrapolation models for risk assessment of the CYP3A inhibition potential of an investigational drug. Clin Pharmacol Ther. 2014 Feb;95(2):189-98

- Grimm SW, Einolf HJ, Hall SD, He K, Lim HK, Ling KH, Lu C, Nomeir AA, Seibert E, Skordos KW, Tonn GR, Van Horn R, Wang RW, Wong YN, Yang TJ, Obach RS (2009) The conduct of *in vitro* studies to address time-dependent inhibition of drug-metabolizing enzymes: a perspective of the pharmaceutical research and manufacturers of America. Drug Metab. Dispos. 37(7): 1355-1370

- Fiala ES, Sohn OS, Wang CX, Seibert E, Tsurutani J, Dennis PA, El-Bayoumy K, Sodum RS, Desai D, Reinhardt J, Aliaga C (2005) Induction of preneoplastic lung lesions in guinea pigs by cigarette smoke inhalation and their exacerbation by high dietary levels of vitamins C and E. Carcinogenesis 26(3): 605-612

- Beveridge DL, Barreiro G, Byun KS, Case DA, Cheatham TE 3rd, Dixit SB, Giudice E, Lankas F, Lavery R, Maddocks JH, Osman R, Seibert E, Sklenar H, Stoll G, Thayer KM, Varnai P, Young MA (2004) Molecular dynamics simulations of the 136 unique tetranucleotide sequences of DNA oligonucleotides. I. Research design and results on d(CpG) steps. Biophys. J. 87(6): 3799-3813

- Seibert E, Ross JBA, Osman R, (2003) Contribution of opening and bending dynamics to the specific recognition of DNA damage. J. Mol. Biol. 330(4): 687-703

- Seibert E, Chin AS, Pfleiderer W, Hawkins ME, Laws WR, Osman R, Ross JBA (2003) pH-dependent spectroscopy and electronic structure of the guanine analogue 6,8-dimethylisoxanthopterin. J. Phys. Chem. A 107:178-185

- Seibert E, Ross JBA, Osman R (2002) Role of DNA flexibility in the sequence-dependent activity of uracil DNA glycosylase. Biochemistry 41(36): 10976-10984

- Seibert E, Ross JBA, Osman R (2002) Quantum mechanical investigation of the electronic structure and spectral properties of 6,8-dimethylisoxanthopterin. International Journal of Quantum Chemistry 88(1): 28-33

- Rachofsky EL, Seibert E, Stivers JT, Osman R, Ross JBA (2001) Conformation and dynamics of abasic sites in DNA investigated by time-resolved fluorescence of 2-aminopurine. Biochemistry 40(4): 957-967

PRESENTATIONS AT SCIENTIFIC MEETINGS

- Seibert E (2011) Drug-drug interaction predictions: Case study involving CYP3A4 inactivation (Invited speaker at Drug-drug interaction prediction workshop sponsored by the FDA and the Drug Metabolism Leadership Group of the IQ Consortium; Silver Spring, MD)

- Seibert E (2010) Pre-clinical evaluation of compounds displaying complex DDI properties: Case studies involving enzyme inhibition, induction, and inactivation. (Invited speaker at DDI-2010; Seattle, WA)

- O'Brien D, Tweedie D, Seibert E (2009) Contributions of enzyme(s) other than CYP2E1 to chlorzoxazone 6-hydroxylation in human liver microsomes. (Presented at the 16th North American Regional Meeting of ISSX; Baltimore, MD)

- Seibert E, Tweedie D (2009) Prediction of genotoxic metabolite body burden from *in vitro* data: strategies and limitations. (Presented at the 16th North American Regional Meeting of ISSX; Baltimore, MD)

- Seibert E, McCabe M, Tweedie D (2008) Experiment design limitations in metabolic stability assays: impact on half-life determination and clearance prediction. (Presented at the 15th North American Regional Meeting of ISSX; San Diego, CA)

- Seibert E, Chin AS, Pfleiderer W, Hawkins ME, Laws WR, Osman R, Ross JBA (2002) Spectroscopy and theory of 6-methylisoxanthopterin, a fluorescent guanine analogue. Biophys. J. 82 (1): 2109 Pos, Part 2 (Presented at the 46th Annual Meeting of the Biophysical Society, San Francisco, CA)

- Seibert E, Ross JBA, Osman R (2001) Sequence-dependent DNA flexibility at the base-pair step level. (Presented at the Workshop on Atomistic to Continuum Models for Long Molecules and Thin Films, Ascona, Switzerland)

- Seibert E, Ross JBA, Osman R (2001) Sequence dependence of damage recognition and catalysis by UDG, Biophys. J. 80 (1) 2032 Pos, Part 2 (Presented at the 45th Annual Meeting of the Biophysical Society, Boston, MA)

- Seibert E, Rachofsky, EL, Luo N, Osman R, Ross, JBA (2000) Role of DNA bending in DNA damage recognition by UDG. Biophys. J. 78 (1): 1000 Pos, Part 2 (Presented at the 44th Annual Meeting of the Biophysical Society, New Orleans, LA)

Certificate of Training

Awarded To

Drané O'Brien

Recognizing completion of 5 days of specialized instruction in

Radiation Safety Officer with DOT Certification

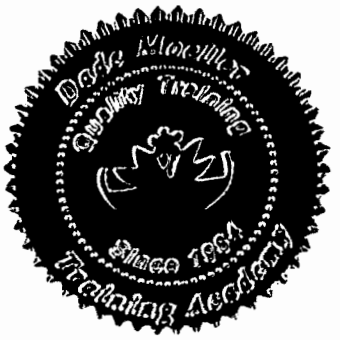
September 12, 2014

Presented By

Dade Moeller Training Academy

438 N. Frederick Avenue, Suite 220, Gaithersburg, MD 20877
www.moellerinc.com/academy -- 301-990-6006
AAHP has awarded this course 7.35 CM Points, CM Approval # 09-4747
ABIH Diplomates can claim this course for 40 hours in the IH CM Area

Alan L. Fellman, PhD, CHP



NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Boehringer Ingelheim Pharmaceuticals, Inc.
ATTN: Ulrich Roth, Ph.D., Head of Development
NCE & Sr. VP, Development US
900 Ridgebury Rd., P.O. Box 368
Ridgefield, CT 06877-0368

Date
April 30, 2019

License Number(s)
06-19183-01

Mail Control Number(s)
612057

Licensing and/or Technical Reviewer or Branch
Commercial, Industrial, R&D, & Academic Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 04/24/2019

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239