Deborah Rice, CMAR

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SUMMARY

Certified Manager of Animal Resources, and a registered technologist with extensive experience in coordinating biocompatibility testing of medical devices and drug product components. Broad experience in the technical conduct of general toxicology studies.

PROFESSIONAL EXPERIENCE

BAXTER HEALTHCARE, Round Lake, IL 1979- 2013

Senior Manager Toxicology, Technology Resources, Life Sciences (2005 to 2013)
Responsible for managing the Materials Testing and Registry group at the Round lake facility this includes working with engineers to determine suitable materials to be used for Baxter devices and identifying the Biological testing requirements. Managed a group of 4 employees responsible for maintaining the Material Data Management System. This database tracked and stored information for all Baxter medical devices and device components.

Manager Toxicology, Technology Resources, Life Sciences (2002 to 2005)
Managed the pyrogen and biological safety testing performed at the Round lake facility. Responsibilities include training new employees, interns and contractors to perform the various tests involved. Acquired the SQL*LIMS Computer system that allowed data generated from pyrogen and safety testing to be entered and approved.

Senior Research Associate, Supervisor Acute Toxicology (1998 to 2002)
Supervised the Cell Culture and Acute Toxicology laboratory. Responsible for reviewing all data generated, revising standard procedures related to this activity, participating in feasibility studies and ensuring data is completed and reported in a timely manner.

Research Associate III, Supervisor Acute Toxicology (1994 to 1998)
Coordinate the scheduling of all Toxicology laboratory studies to include scheduling of toxicology personnel on various projects within other Baxter departments. Assisted in the preparation of study cost estimates that include estimates from our support groups and monitoring actual costs for comparison with projected costs. Responsible for supervising 5 employees that includes technical training, reviewing data generated (laboratory notebooks, data sheets, protocols and reports). Review, revise and approve all Toxicology standard procedures and some procedures that affect Toxicology work (Biomaterial Evaluation, General Safety Test, Hemolysis and Pyrogen) and devise new standard procedures for the department when required. Responsible for protocol development, study design and directing protocols and feasibility

studies, generate and compile scientific data, and issue subsequent reports in compliance with GLP guidelines in support of Baxter's Division and Business Units objectives. Study Director for non-clinical mammalian safety and R&D studies for *in vivo* toxicology. Provide technical and administrative support to other Toxicology study directors and provide technical training or assistance to other departments within Baxter.

Senior Laboratory Supervisor, Comparative Medicine (1989 to 1994)
Responsibilities include: study management, data review and interpretation, hands-on study activities in mammalian toxicology testing such as subcutaneous, intravenous and intramuscular injections; surgical implantation of indwelling catheters; "quik catheterization" of caudal veins; clinical observations; necropsies; blood collection via cardiac puncture and retro-orbital withdrawal; word processing for protocol and reports preparation; budget estimates for toxicology studies, which include cost estimates for all support groups; scheduling and coordinating all projects and feasibility studies in the Toxicology Department; supervision of technical staff work activities to insure quality and efficacy as well as compliance with Good Laboratory Practices/FDA requirements. Responsible for monitoring and coordinating training of new personnel and providing direction and assistance to technical staff in the development of new procedures to be utilized in the performance of preclinical safety studies. Ensure that all Toxicology personnel maintain the highest technical competence level in the laboratory and maintain documentation in compliance with GLP. Technical assistance and/or training also extend to other departments within the organization.

Laboratory Supervisor, Toxicology Department (1988 to 1989)
Responsibilities included scheduling and coordinating all projects and feasibility studies in the Toxicology Department; supervision of technical staff work activities to insure quality and efficacy as well as compliance with Good Laboratory Practices/FDA requirements. Responsible for coordinating and monitoring Biomaterial testing according to US Pharmacopeia. This involved study preparation, scheduling tests, ordering animals and selection of animals for tests, test article preparation, monitoring dosing and observation of animals and reporting results to study sponsors. Also responsible for monitoring and coordinating training of new personnel and providing direction and assistance to technical staff in the development of new procedures to be utilized in the performance of Biomaterial testing and preclinical safety studies.

Research Associate I, Toxicology Department (1986 to 1988)
Responsibilities included protocol development in conjunction with senior scientific personnel, direct protocol studies, generate and compile data, and issue subsequent reports in compliance with GLP guidelines.

- Writing and revising Standard Operating Procedures
- Supervised and trained technical personnel
- Responsible for timely and efficient completion of biomaterial screening evaluations.

Research Assistant I Toxicology Department (1984 to 1986)
Performed acute toxicology studies to include review of data and report preparation.

- Provided assistance to senior scientific personnel in the development of new animal models.

- Performed technical and surgical procedures as required for acute, subchronic, and feasibility studies.
- Trained technical staff in administration of substances to various species (rats, mice, ferrets, dogs, guinea pigs, rabbits) and blood collection techniques.
- Scheduled work activities for projects and feasibility studies.

Senior Technician, Toxicology Department (1982 to 1984)
Responsibilities included performing technical procedures as required.

- Performed tests to assess immunocompetence of mice and effects of immunopharmacologic agents.
- Performed as study director in guinea pig maximization assays to assess the immunogenicity of medical extracts.

Technician, Toxicology Department (1981 to 1982)
Responsibilities included preparation of test solutions, handling laboratory animals, recording original data collection of blood, plasma and urine, monitoring food consumption and body temperature, sterile filtration of plasma, assisting with preparation of animals for surgery, administration of test substances to rats, mice, dogs and guinea pigs using oral, intravenous, intradermal, intramuscular, intraperitoneal and subcutaneous techniques.

Quality Control Technician, Pilot Plant (1979 to 1981)
Responsibilities included inventory control, material handling and good manufacturing practices, raw material inspection and release to include in-process inspections, production monitoring and auditing.

- Review and revised existing Standard Operating Procedures
- Organized and maintained the calibration system for the Quality Control Department
- Instituted a program for internal auditing of the calibration system.

PATENTS
U.S. Application of White et. al. Serial No. 08/164, 069.
Filed: December 9, 1993
For: Method of Reducing Cyclophosphamide Induced Hemorrhagic Cystitis

EDUCATION
G. Westinghouse AVHS
Majored in Cooperative Health Occupations Assistance Program

CERTIFICATIONS
Laboratory Animal Technician, American Association for Laboratory Animal Science, Certification 1983
Laboratory Animal Technologist, American Association for Laboratory Animal Science Certification 2000
Certified Manager of Animal Resources, American Association for Laboratory Animal Science, Certification 2005

SCIENTIFIC ORGANIZATIONS

American College of Toxicology
Midwest Regional Chapter of the Society of Toxicology
American Association for Laboratory Animal Science

PROFESSIONAL DEVELOPMENT

- Supervisor's Course, Baxter Management Institute
- Career Development Planning
- Technical Writing
- Team Building
- Coaching and Feedback
- Selection Interviewing
- Export Compliance
- Supervisor Safety Training
- Times System Planner Workshop

PUBLICATIONS AND PRESENTATIONS

Publication. Histologic lesions associated with intravenous infusions of large volumes of isotonic saline solution in rats for 30 days. D. Morton, J. A. Safron, J. Glosson, D. W. Rice, D. M. Wilson, and R. D. White: Toxicol Pathol, Vol. 25: 390 - 394, 1997.

Publication. Effects of infusion rates in rats receiving repeated large volumes of saline solution intravenously. D. Morton, J.A. Safron, D.W. Rice, D. M. Wilson, R.D. White. Lab Animal Sci 47: 656-659, 1997.

Publication. Protective effect of L-2-oxothiazolidine-4-carboxylate treatment on cyclophosphamide-induced cystitis in rats. J. Safron, D. Rice, D. Gordon, C. Leaf, R. White. J Urology 157: 1946 –1950, 1997.

Poster Presentation. Evaluation of the Sprague Dawley® rat as an alternative model for the subcutaneous implantation assay. J.D. Baker, D.W. Rice, C.A. Hilbert, R.D. White, D.E. Gordon, D.M. Wilson. Presented at ACT annual meeting 1995.

Poster Presentation. Evaluation of the potential protective effect of Procysteine® or Procysteine congener treatment on cyclophosphamide-induced alopecia in neonatal rats. D.W. Rice, D.M. Wilson, I.B. Henriksen, and R.W. White. Society of Toxicology, Thirty-fourth Annual Meeting, The Toxicologist 15:303 (abstract#1624), March 1995.

Poster Presentation. Evaluation of Potential Protective Effect of Procysteine® or Procysteine Congener Treatment on Cyclophosphamide-Induced Alopecia in Neonatal Rats. D.W. Rice, D.M. Wilson, I.B. Henriksen, and R.D. White. Presented at SOT annual meeting 1994.

Poster Presentation. Maximal repeated intravenous infusion rates in rats. D.W. Rice, D.G. Morton, D.M. Wilson, and R.D. White. American College of Toxicology, Fifteenth Annual Meeting, October 23-26, 1994.

Oral Presentation. Intravenous Administration Techniques Used for Preclinical Safety Testing. D.W. Rice, D.M. Wilson, R.D. White. Presented at the Pharmacia Deltec Symposia, "Use of Portable Infusion Technology and Implantable Access Systems in Preclinical Research, 1993."

Poster Presentation. Evaluation of the potential protective effect of Procysteine® treatment on cyclophosphamide-induced hemorrhagic cystitis in Rats. J.A. Safron, D. W. Rice, D.E. Gordon and R. D. White. American College of Toxicology, Fourteenth Annual Meeting, October 3-6, 1993.

Publication. Acute Toxicity in neonatal rats and young adult dogs, rats and mice intravenously administered L-2-oxothiazolidine-4-carboxylate. R.D. White, D.W. Rice, D.W. Wilson, and D.I. Goldberg. J. Amer. Coll. Toxicol. Part B 1(3): 164-165, 1992.

Poster Presentation. Subcutaneous Exposure as an Alternative Method to Intramuscular Implantation during the Assessment of Biological Reactivity of Biomaterials. D.W. Rice, C.A. Hilbert, L.S. Coleman, S.J. Northup, R.D. White. Presented at ACT annual meeting 1991.

Poster Presentation. Preclinical Toxicity Assessment of L-2-Oxothiazolidine-4-Carboxylate. R.D. White, D.W. Rice, D.M. Wilson, D.I. Goldberg: Presented at ACT annual meeting 1991.

Poster Presentation. Intravenous Administration Techniques Used for Preclinical Safety Testing. D.W. Rice, J.A. Glosson, D.M. Wilson, R.D. White. Presented at ACT annual meeting 1991.

Publication. Acute Toxicity in Neonatal Rats and Young Adult Dogs, Rats and Mice Intravenously Administered L-2-Oxothiazolidine-4-Carboxylate. R.D. White, D.W. Rice, D.M. Wilson, and D.I. Goldberg: J. Amer. Coll. Toxicol. Part B 1(3): 164-165, 1991.

Poster Presentation. Intravenous administration techniques used in preclinical safety testing. D. W. Rice, J.A. Glosson, D.M. Wilson and R.D. White. American College of Toxicology, Twelfth Annual Meeting, October 21-23, 1991.

Poster Presentation. Multiple Immunoassay in a Single Mouse Model: Evaluation in Normal and Cyclophosphamide Immunosuppressed Mice and Correlation with Bacterial Host Resistance. J. Chapman, G. Bruszer, D. Rice, E. Youkilis, and E. Woods: Toxicol Appl. Pharmacol. (1985). Presented in part at the Third International Immunopharmacology Conference, May 2-5, 1985, Florence Italy.

AWARDS

1. Baxter Healthcare Corporation, Applied Sciences Outstanding Service Award– *Dedicated Service. 1989*

2. Baxter Healthcare Corporation, Applied Sciences Outstanding Technical Award – *Develop Animal Model to Assess Vein Irritation Potential, 1991*
3. Baxter Healthcare Corporation, Applied Sciences Firefighters Award –*FLOGARD 8000 Cassettes, 1992*
4. Baxter Healthcare Corporation, Applied Sciences Outstanding Technical Contribution Award – *Intrepid Safety Evaluation, 1992*
5. Corporate Research and Technical Services - Leader of Today Award - *Outstanding Leadership Skills, 1993*
6. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Mission Impossible – *DCLHb Pharamacokinetic Study, 1995*
7. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Team Spirit – *Outstanding Team Work in Toxicology, 1995*
8. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Quality Working Team (QWT) – *Commitment to the Continuous Improvement Process, 1996*
9. Baxter Healthcare Corporation, Corporate Research and Technical Services Team Spirit Award – *Large Animal Adhesion Model, 1997*
10. Baxter Healthcare Corporation, Renal Division Technical Award - *FDA Reuse/Relabeling Initiative, 1997*
11. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Excellence in Customer Service – *Successful Completion of Testing for Pre-Clinical Evaluation, 1997*
12. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Team Spirit – *Outstanding Teamwork, 1998*
13. Baxter Healthcare Corporation, Corporate Research and Technical Services Award The 3 R's – *Exemplary Modeling and balancing of Baxter's Shared Values, 1999*
14. Baxter Healthcare Corporation, Hemoglobin Therapeutics Technical Award – *Solving the Pyrogen Problem for rHb 2.0 Production, 2000*
15. Baxter Healthcare Corporation, Corporate Research and Technical Services Award Stellar Award – *Successful Completion of Testing to Support Development of the Syntra+Dialyzer, 2002/2003*
16. Baxter Healthcare Corporation, Technology Resources Award – The Alliance Award *Partnering Initiatives to Support Global Product Registration, 2006*
17. Baxter Healthcare Corporation, Technology Resources Award – Enterprise Award *Cardiovascular Disease Model Development Supporting Regenerative Medicine, 2006*
18. Baxter Healthcare Corporation, Technology Resources Award – The Alliance Award *Outstanding Efforts in Support of Manufacturing Objectives, 2010*