David J. Mason, Jr., Ph.D.

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Certifications

DABT, *Diplomate of the American Board of Toxicology*, American Board of Toxicology (2012 - 2015)
Business Strategy, McKinsey & Company (issued 2021)
Problem Solving, McKinsey & Company (issued 2021)

Education

Ph.D. *Pharmacology & Toxicology*, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA

B.S. *Biology*, Virginia State University, Petersburg, VA

Professional History

Sasol (USA) 10/2022 – present
Senior Toxicologist
Houston, Texas
(Remote)

Responsibilities: Management of non-clinical strategies and regulatory testing (in vivo, in vitro) to support registrations in the United States and global applications. Actively contribute to cross functional teams including regulatory affairs, business operations, research and development and project stewardship through direct participation and formal communications with functioning global regulatory entities.

- Coordinate the utilization of contract research organizations and outside consulting services for global product safety projects.
- Assess the risk to humans and the environment (focus on human) over the entire life cycle of products and develop strategies to mitigate risk potential risks.
- Represent the organization in registration and consortia ensuring that the organization's interests are considered via study monitoring and strategic contributions to strategy development (e.g., REACH, TSCA)
- Management of GHS categorization, supporting data, references in SAP
- Identification of New Approaches and Methods (NAMs) to reduce in vivo studies when ethically feasible.

Kimberly Clark, Neenah, WI 12/2019 – 10/2022
Principal Toxicologist

Responsibilities: Management and coordination of non-clinical strategies and regulatory testing to support Class II medical device registrations in the United States and global personal care products. Actively contribute to cross functional teams including regulatory affairs, business operations, research and development and project stewardship through direct participation and formal communications with functioning global regulatory entities.

- Provide toxicological expertise to support research and development, regulatory affairs, manufacturing, commercialization, and marketing teams.

- Author regulatory dossiers to support registration and commercialization of new products and procure continued support of commercial products.
- Develop non-clinical strategies incorporating ISO 10993-part 1 biocompatibility and regional regulatory guidance for biocompatibility and product safety.
- Interpret in vivo, in vitro data and perform literature reviews to support all phases of human exposure assessment, new product development and stewardship of commercial products.
- Identify qualified external laboratories and internal resources for the execution of GLP and exploratory studies. Also responsible for the management and fiduciary aspects of contracted research
- Prepare human exposure and health risk assessments in support of regulatory submissions worldwide including human validation studies.

Ethicon Inc., a Johnson & Johnson Company, Somerville, NJ 2/2019 – 12/2019
Contract Toxicologist

Responsibilities: Prepare, submit, and manage regulatory submissions for medical device compliance with MDR requirements and technical documents for the EU.

- Provide toxicological expertise and regulatory compliance strategies**.**
- General knowledge of FDA Regulatory Requirements for Medical Devices
- General knowledge of ISO 10993 standards for Medical Devices
- Prepare, design, review, evaluate and interpret toxicology studies (mammalian and in vitro).
- Prepare human health risk assessments in support of regulatory submissions worldwide.

Altria Client Services. Richmond, VA 6/2016 – 2/2019
Head of Regulatory Toxicology, Principal Toxicologist

Responsibilities: Direct a team of toxicologists and scientists to coordinate global tobacco and nicotine delivery product registrations. Design and execute strategic regulatory paradigms for securing compliance and legal sales of tobacco and nicotine delivery products (PMTA, PMA). Actively contribute to safety and regulatory teams, business operations, research and development of new tobacco derived products and technologies through coordination of projects across regions.

- Provide toxicological expertise and regulatory compliance strategies to R&D project teams and Altria business units**.**
- General knowledge of FDA Regulatory Requirements for various industries (e.g., Tobacco, Chemical, etc.).
- Lead and participate on internal product and regulatory teams to address product and regulatory challenges in collaboration with colleagues in Research & Development, Legal, Marketing, Sales, etc.
- Develop and promote use of alternative toxicological methods to advance science, drive innovation and influence current regulatory framework.
- Prepare, design, review, evaluate and interpret toxicology studies (mammalian and in vitro).
- Prepare human health risk assessments in support of regulatory submissions worldwide.
- Support the Regulatory Sciences team for all product safety and regulatory compliance matters (FDA, etc.).

Novozymes, Inc., Franklinton, NC 11/2012 – 6/2016
Regulatory Affairs Project Manager
Biofuels IPG (Global Product Management Team)
Senior Regulatory Specialist

Responsibilities: Participated in a cross functional team of regulatory specialists to coordinate global biofuel enzyme and yeast registrations and project tracking. Design and execute strategic regulatory paradigms for

securing compliance and legal sales. Establish strong relationships with regulators and customers to ensure Novozymes achieves global biofuel business, market and growth objectives. Actively contribute to safety and regulatory teams, business operations, research and development through coordination of projects across regions.

- Developed regulatory applications, communicated driectly with regulators to garner regulatory approvals, provide scientifically sound briefings and responses to customer inquires and regulatory challenges in all regions
- Secure regulatory aprovals for yeasts and enzymes derived from fungi and microbes (Genetically Modified (GMO) and non GMO) for use in the production of fuel ethanol and/or beverage alcohol and starch processing
- Where applicable, ensure compliance for the inclusion of co-products of ethanol production, yeast, and enzymes in animal feed
- Advise and/or provide strategic regulatory stewardship via core group and Industry Product Group (IPG) representation to support Novozymes' biofuel business objectives and market platforms
- Contribute to industry trade organizations to help steward the use of yeast and microbes in biofuel production and use of co-products in animal feed
- Establish strong communications with international, federal and state regulators

Accomplishments:

- Global registration of Novozymes' novel products for fuel ethanol production with concomitant use of economically significant side streams for use in animal feed
- Over twenty-four registrations of GMO production organisms for use in fuel ethanol production
- Co-Chair of the Enzyme Technical Association's Biotech committee

Syngenta Biotechnology, Inc. 11/2009 – 11/2012
Regulatory Affairs Manager

Responsibilities: Obtain and defend regulatory approvals for Syngenta traits. Contribute to the development of strategies for obtaining global regulatory approvals of new biotechnology traits. Provide input on the design and reporting of studies for use in regulatory dossiers. Contribute to the preparation, including substantial independent writing, of US regulatory applications for submission to EPA, USDA, and FDA. Monitor the progress of applications through regulatory review, draft responses to questions from regulatory agencies, and provide technical support for regulatory dossiers developed outside of the US. Interact with regulatory agencies on defined matters. Provide technical support to Syngenta regulatory colleagues seeking similar approvals. Participate in the management of post-approval regulatory activities.

- Obtained regulatory approvals (USEPA) of 6 trait products
- Succesfully obtained re-registrations of 4 trait products
- Managed successful global submissions and registrations

Pharmaceutical Product Development, Inc. 4/2007 – 11/2009
Associate Director, Preclinical Development

Responsibilities: Responsible for the overall development and implementation of preclinical/nonclinical programs to supported the development of new chemical entities, biologics, and/or devices. Developed pharmacology and toxicology components of regulatory dossiers (INDs, NDAs, BLAs, IMPDs, CTXs).

- Prepared toxicologic assessments of extractables and leachables
- Provided toxicology consultation in support of drug development programs from pre-IND to market
- Advised and/or provided sponsor representation to regulatory agencies (ex. FDA) as nonclinical/toxicology expert
- Negotiated and managed preclinical services and consulting contracts

- Ensured that preclinical programs supported the intended clinical indication, dosing regimen and manufacturing requirements
- Managed subcontracted preclinical/nonclinical regulatory studies:
- (GLP/non-GLP Exploratory) rodent, non-rodent, acute, repeat-dosing

Ethicon Inc., a Johnson & Johnson Company, Somerville, NJ 10/2005 – 4/2007
Senior Scientist, Toxicologist

Responsibilities: *Senior Scientist*: Managed a safety group consisting of Study Directors for in-house projects and Study Monitors for contracted biocompatibility and safety studies.

Responsibilities: *Toxicologist*: Responsible for safety assessment, biocompatibility, and investigative toxicology research to support the development of medical devices. Responsibilities included, but not limited to developing study protocols and/or reviewing study reports for the evaluation and implementation of toxicological research and biocompatibility testing of prototypes at initial stages of the medical device development process. These decision-making responsibilities included analyzing and interpreting data, drawing conclusions, arriving at timely technical decisions, modifying methodologies to improve the quality, accuracy, and usefulness of data, as well as contributing to the valuation/modification of research objectives. Additional requirements included an understanding of existing regulations and standards and functioning as a Study Monitor for outsourced studies, as well as functioning as a Lead Scientist when participating in project teams.

Merck Research Laboratories, Merck & Co. Inc., West Point, PA 6/2003 – 10/2005
Sr. Research Toxicologist

Responsibilities: *Compound Manager*: Responsible for the overall development and implementation of a preclinical safety program to support compound development from preclincal safety studies through NDA filing.

Responsibilities: *Study Director*: Overall Planning, technical conduct and reporting of toxicity studies in compliance with GLP regulations. Development, preparation, approval and distribution of study protocols. Preparation and/or, approval of all amendments to and deviations from study protocols as well as informational notes to the study file. To monitor ongoing in house and contracted (off-campus) studies for GLP compliance as well as compliance to the study protocol and appropriate SOP's.

Responsibilities: *Toxicologist*: To monitor ongoing preclinical safety studies for GLP compliance and compliance to the study protocol and appropriate SOP's. Ensure that the data are accurately recorded and complete. Conduct regular evaluations of study findings and regularly report findings to the Study Director/Compound Manager. Ensure that all raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study.

Regulatory Research Experience (GLP/non GLP):
Acute and repeated dosing paradigms
Species:
Rodents: Rats, Mice
Non Rodents: Dogs, Primates, Rabbits, Mini Pigs

Hoffmann-La Roche, Nutley, New Jersey 6/2001 – 6/2003
Principal Scientist/Study Director

Responsibilities: Overall planning, technical conduct and reporting of toxicity studies in compliance with GLP regulations. Development, preparation, approval and distribution of study protocols. Preparation and/or, approval of all amendments to and deviations from study protocols as well as informational notes to the study file. To monitor in house and contracted (off-campus) studies for GLP compliance, compliance to the study protocol and appropriate SOP's. Ensure that data are accurately recorded and complete. Conduct regular evaluations of study findings and regularly report findings to management. Ensure compliance with applicable Animal Research

Proposals and appropriate Sop's such that the welfare of study animals is not compromised. Ensure that all raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study. Interpretation, analysis, documentation and reporting of data for submission to or other health authorities.

Regulatory Research Experience (GLP/non GLP):
Acute and repeated dosing paradigms, diet
Species:
Rats, Mice

United States Environmental Protection Agency, Research Triangle Park North Carolina 9/1998 – 6/2001
Post-Doctoral Researcher

Responsibilities: To design an independent neurotoxicology research project pursuant to the mission of the United States Environmental Protection Agency. Additional responsibilities include developing collaborative efforts with other scientists, maintaining accurate data files, and publishing in peer-reviewed literature, presenting findings at national and international meetings.

Research Objective: To further understanding of neurotoxic interactions resulting from co-exposure to multiple environmental contaminants via coordinated *in vivo* and *in vitro* exposure paradigms. These studies utilized *in vitro* cell culture, cellular imaging, ELISA, and other techniques of molecular biology to investigate the activities underlying the neurotoxic responses of these compounds.