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Thomas Laughren

Director at Laughren Psychopharm Consulting, LLC

Rockville, Maryland | Pharmaceuticals

Previous Division of Psychiatry Products, FDA, Psychiatric Drug Products, Division of Neuropharmacological Drug Products, FDA

Education University of Wisconsin-Madison

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connections

www.linkedin.com/pub/thomas-laughren/64/683/1b5

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A. Eden Evins

Director, Center for Addiction Medicine at Massachusetts General Hospital

Michael Detke

Background

Summary

I have 29 years of experience at the FDA in assisting pharmaceutical companies with psychiatric drug development programs, and I hope to continue in this effort as an independent consultant.

Experience

Director

Laughren Psychopharm Consulting, LLC



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programs that will meet current regulatory requirements and standards

- Help with the design and conduct of clinical trials, and also the interpretation of findings
- Planning and preparation for end-of-phase 2 and other critical meetings with FDA and other regulatory agencies
- Planning and preparation for meetings with the Psychopharmacological Drugs Advisory Committee (PDAC)
- Drafting drug product labeling

Director

Division of Psychiatry Products, FDA

July 2005 – December 2012 (7 years 6 months)

As Director for the Division of Psychiatry Products, Dr. **Laughren** oversaw the review of all psychiatric drug development activities conducted under INDs and the review of all NDAs and supplements for new psychiatric drug claims.

Team Leader

Psychiatric Drug Products, Division of Neuropharmacological Drug Products, FDA

February 1986 – July 2005 (19 years 6 months)

As Team Leader, Dr. **Laughren** directly supervised the medical officers involved in the review of all psychiatric drug development activities conducted under INDs and the review of all NDAs and supplements for new psychiatric drug claims.

Honors & Awards

Dr. **Laughren** has received numerous awards for his regulatory accomplishments.

Organizations



PAUL LEBER

Director at Neuro-Pharm Group, LLC



Jelena Kunovac

Founder and Medical Director, Altea Research



Jeffrey Kasher

VP and COO Global Medical R&D at Eli Lilly



Maurizio Fava

Director, MGH Depression Clinical and Research Program



William Kennedy, MD

Senior Medical Director, Genentech



Anke Post

Senior Medical Advisor Psychiatry bei Eli Lilly



Gheorghe Doros

Associate Professor of Biostatistics, Boston University



Luc Van Nueten

Vice president experimental medicine neuroscience



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Publications

Dr. Laughren has authored and co-authored many papers and book chapters on regulatory and methodological issues pertaining to the development of psychiatric drugs, and is a frequent speaker at professional meetings on these same topics.

Certifications

Dr. Laughren is board certified in general psychiatry by the American Board of Psychiatry and Neurology.

Skills & Expertise

Regulatory and...

Education



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University of Wisconsin-Madison

Bachelor of Science (BS), Mathematics

1963 – 1967

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