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## Jong Ho "Philip" Won, Ph.D.

Associate

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### *Related Services*

Health Care ■ FDA/Food, Drug & Device

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As an expert in medical device technology and the FDA-regulated product life cycle, Philip Won deeply understands the challenges faced by all stakeholders in the highly regulated and competitive medical device industry. During his tenure at the FDA's Center for Devices and Radiological Health (CDRH), Division of Dental and ENT Devices, Office of Product Evaluation and Quality, Philip led a multidisciplinary team of engineers, scientists, and clinicians in reviewing complex submissions with significant industry impact. He worked with medical device companies with applying for a 510(k), Premarket Approval (PMA), breakthrough device designation, de novo, Emergency Use Authorization (EUA), Investigational Device Exemption (IDE), pre-submission, 513(g), and filing recall and complaint submission.

Before joining the FDA, Philip served as an assistant professor at the University of Tennessee, where he focused on designing, funding, and executing research projects related to hearing device development.

Philip graduated with the William P. Cunningham Award and a health law certificate from the University of Maryland Francis King Carey School of Law. During law school, he interned with the FDA's Office of Legislation for the Device-Biologics-Tobacco team, where he addressed inquiries from congressional committees and individual members regarding FDA regulatory policies and programs. Philip has published more than 50 peer-reviewed articles in top scientific journals. [Click here to view his work.](#)

### *Representative Experience*

- Advised manufacturers of FDA-regulated products on regulatory, quality and compliance matters, resulting in successful clearances, approvals, and breakthrough device designations.
- Evaluated and developed efficient regulatory strategies and clinical studies to advance innovative medical devices, AI/ML software products, combination products, and pharmaceutical products.
- Drafted and reviewed successful 510(k)s, de novos, PMAs (both original and supplements), pre-submissions, 513(g)s, IDEs, EUAs, and breakthrough device designation requests.
- Reviewed and provided feedback on promotional materials and product labeling.
- Assisted with determining regulatory requirements for product modifications, including design, supplier, and manufacturing changes.
- Performed FDA due diligence on complex life sciences mergers and acquisitions.

- Guided medical device companies through the Early Feasibility Studies (EFS) Program, including the development of pre-clinical and clinical testing protocols to support clearance or approval.
- Worked with a leading trade association and major hearing aid manufacturers to provide comments on the proposed over-the-counter hearing aids rule.
- Served as the FDA's Technical Expert for the Association for the Advancement of Medical Instrumentation (AAMI) cochlear implants standard and ISO cochlear implants standard.
- FDA point of contact for hearing device manufacturers and academia on inquiries and issues related to the FDA regulatory and administrative process.

## **Publications & Presentations**

### **Publications**

- "Effect of Spectral Degradation on Speech Intelligibility and Cortical Representation," *Frontiers in Neuroscience*, April 5, 2024.
- "A Computational Study to Model the Effect of Electrode-to-Auditory Nerve Fiber Distance on Spectral Resolution in Cochlear Implant," *PLoS One*, August 3, 2020
- "Influence of Visual Deprivation on Auditory Spectral Resolution, Temporal Resolution, and Speech Perception," *Frontiers in Neuroscience*, November 6, 2019.
- "Influence of Tinnitus on Auditory Spectral and Temporal Resolution and Speech Perception in Tinnitus Patients," *Journal of Neuroscience*, October 21, 2015.

### **Education**

- University of Maryland (J.D., 2020)
- University of Washington (Ph.D., 2010)
- Hanyang University (M.S., 2005)
- Hanyang University (B.S., 2003)

### **Languages**

- Korean

### **Admitted to Practice**

- Maryland
- District of Columbia