

Curriculum Vitae

Personal information **Hiroshi Takeda**

Work experience

Jul 2023 – present: He is a deputy review director, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA), Japan. His major role is management of review team for anti-infectious drugs. He is also a reviewer of quality section of small molecules and Topic Leader of ICH-Q3E EWG.

Feb 2020 – Jun 2023: He was a principal reviewer, Office of Generic Drugs, PMDA. His role was review of post-approval partial change applications. He experienced review of various modalities such as synthetic peptides, medicinal gas, herbal medicines, small molecules from fermentation process or continuous manufacturing etc.

Apr 2018 – Jan 2020: He was a technical officer, Division of Pharmacopoeia and Standards for Drugs, Office of Standards and Guidelines Development, PMDA as well as an Exchange Visitor at the United States Pharmacopeia Convention, MD, USA. His role was a secretariat of Japanese Pharmacopoeia and contact point of both pharmacopoeias for harmonization projects.

Apr 2009 – Mar 2018: He was a principal reviewer, Office of New Drug III, PMDA. He started working at PMDA from this office as a reviewer, which reviews drugs for neurology and psychiatry.

Education and training

Apr 2013 – Sep 2018: Doctor degree (Pharmaceutical Science) at Graduate School of Life Science, Hokkaido University, Japan. He received his Doctor degree for his research on manufacturing liposomal drugs and regulations for nanomedicines.

Apr 2007 – Mar 2009: Master degree (Pharmaceutical Science) at Graduate School of Pharmaceutical Science, Kyoto University, Japan. He received his Master degree for his research on organic chemistry.

Apr 2003 – Mar 2007: Bachelor of Pharmaceutical Science, Faculty of Pharmaceutical Science, Kyoto University, Japan. He obtained national license of pharmacist.

Additional information

Publications

Sakushima K, Takeda H, Aoi Y. Orphan drug designation and development in Japan: 25 years of experience and assessment. *Nat Rev Drug Discov* 2021; 20: 893-4.

Takeda H, Ishida T, Takemoto Y. Synthesis of indolo[2,3-b]quinolines by palladium-catalyzed annulation of unsaturated isothioureas. *Chem Lett* 2009; 38(8): 772-3.

Yasui Y, Kakinokihara I, Takeda H, Takemoto Y. Preparation of α,β -Unsaturated Lactams through Intramolecular Electrophilic Carbamoylation of Alkenes. *Synthesis* 2009; 23: 3989-93.

Yasui Y, Takeda H, Takemoto Y. Toward general access to the aspidosperma-type terpenoid indole alkaloids: synthesis of the key 3,3-disubstituted piperidones through enantioselective intramolecular heck-type reaction of chloroformamides. *Chem Pharm Bull* 2008; 56(11): 1567-74.

Kobayashi Y, Kamisaki H, Takeda H, Yasui Y, Yanada R, Takemoto Y. Intramolecular Cyanoamidation of Unsaturated Cyanoformamides Catalyzed by Palladium: An Efficient Synthesis of Multi-Functionalized Lactams. *Tetrahedron* 2007; 63(14): 2978-89.

Projects

Memberships

Other Relevant Information