

Hutch Humphreys

Keck Graduate Institute of Technology – Bioinformatics

Nominated by
Merlene Singleton

Current Employer:
Amylin Pharmaceuticals

Job Title:
Regulatory Affairs
Manager

Hutch studied chemical engineering at the University of Kansas. He served onboard the USS Helena for 5 years as a nuclear-trained submarine officer in the US Navy. He then earned a PSM at the Keck Graduate Institute (KGI) in 2003 when he accepted a position at Amylin Pharmaceuticals. Hutch fulfills various functions within the Regulatory Affairs Department at the crossroads between Amylin's scientists and marketers and the regulators at FDA. Hutch's multidisciplinary training at KGI was an excellent launching point for his role at Amylin. Soon after arriving at Amylin, he was involved in preparing the New Drug Application (NDA) for Byetta®, Amylin's first in class glucagon-like peptide-1 receptor agonist to treat type 2 diabetes. He has also played a significant role in filing of the Exenatide once weekly NDA, currently under review at FDA, and led the team responsible for completion of a supplemental NDA meant to expand Byetta's indication and increase the breadth of patients eligible to receive Byetta. He has also been heavily involved in the planning, construction, and submission of Amylin's early-stage drug development efforts for three Investigational New Drug applications to FDA, creating the pathway for Amylin to perform first-in-human studies with alternative delivery methods of existing diabetes products, as well as a new chemical entity for the treatment of obesity. He directed the development of several scientific briefing books meant to facilitate meetings and negotiations with the FDA on Amylin's clinical development plans in an effort to arrive at creative solutions for meeting regulatory requirements while also employing company resources most efficiently. Hutch is the company's primary representative for ensuring compliance related to clinical trial registry and data disclosure on ClinicalTrials.gov. Additionally, he currently serves on the Regulatory Affairs Professional Society Annual Conference planning committee, as well as the educational committee for his local RAPS chapter in San Diego, and has served as a mentor for various student projects at KGI. He received the RAPS's New Professional Award in 2006.