

KECK GRADUATE INSTITUTE
 of Applied Life Sciences

Keck Graduate Institute, the MBS, and Pharmaceutical Drug Development

PSM Biennial Meeting - Alumni Panel
 Hutch Humphreys
 Manager, Regulatory Affairs, Amylin Pharmaceuticals
 San Diego, CA

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My Background

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What is Keck Graduate Institute (KGI)?

- Founded in 1997 with a grant from the W.M. Keck Foundation
- 7th and newest member of the Claremont Colleges in Claremont, CA
- Dedicated to education and research aimed at translating into practice the power and potential of the life sciences
- First class of 28 students graduated in 2002
- Current enrollment of ~ 95 students across two classes

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Master of Bioscience (MBS) Degree at KGI

First Year

- Initial Project
- Applications-Oriented Technical Courses
 - Molecular biology, bioengineering, computational biology
- Business and Bioethics Courses
 - Finance, organizational behavior, entrepreneurship, patents

Summer Internship

Broad exposure to many aspects of pharmaceutical, medical device, and biotech industries

Second Year

- Career Focus Tracks
 - e.g., Bioprocessing, Business of Bioscience, Clinical & Regulatory Affairs
- Team Master's Project

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After KGI: Drug Development at Amylin

Amylin Pharmaceuticals

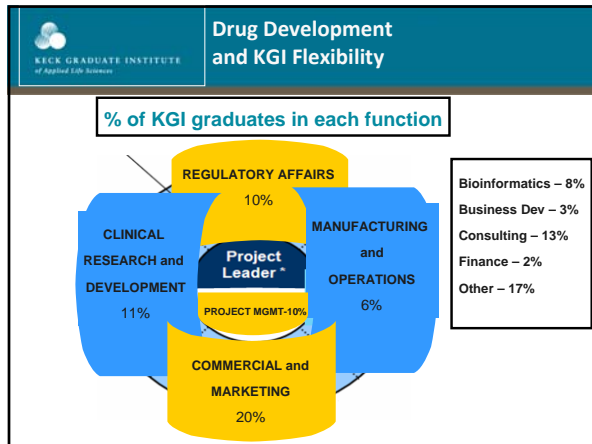
- Founded in 1987 in Oxford, England (HQ now San Diego, CA)
- Develop peptide hormone therapies for diabetes and obesity
- ~1200 employees today; ~500 when I started 6 years ago
- Two marketed products for type 1 and 2 diabetes

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After KGI: Drug Development at Amylin

Regulatory Strategy

- Integral to development strategy: creativity within confines of regulations
- Interface between Amylin scientists / commercial and FDA
- Most in regulatory come from other functions
- Previously lead IND and NDA teams
- Current focus is on early phase non-invasive options



- Advantages of PSM / MBS**
- Smooth transition from nuclear submariner to regulatory strategist
 - MBS versus Master's in Regulatory Affairs
 - Broad understanding of various functions in pharma company
 - Flexibility of program

- A few final thoughts...**
- For Students**
- Generalist or specialist
 - Not a traditional graduate school experience
- For Program Directors**
- Stand-alone program as much as possible
 - Professors from industry
 - Saturate students with industry interactions