



Developing the Regulatory Scientist for Product Medical Development: Successful Examples from Pfizer Worldwide R&D

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Outline

- Discuss several measures my group and PFE taken to develop new regulatory science talent (all 'learn by doing')
 - Secondments (formal and informal)
 - Internships
 - Mentoring

Will relate each to similar/potential mechanism(s) in USG (disclaimer: USG experience 20 yrs ago), provide 'practicality' comments

Bridge to ideas for the future (hope provocative and practical)

- Formal post-doctoral programs in regulatory science
- Regional industry, industry/FDA collaboration in internship programs



Importance of Topic

- The most important element of reg science infrastructure are analog computers between ears of regulatory scientists
 - Innovations often come from industry as well as govt and academia
- However, regulatory science is an “alternative career” for basic and medical scientists
 - Substantial knowledge gaps outside narrow community
 - Too often move to reg science accidental
 - Need to develop ‘high scientific/medical talent pipeline’ mentality



My Personal Experience

- Illustrates randomness of path to regulatory science
 1. Near end of graduate education, was considering “alternative career” (away from bench)
 2. Had no idea where to start – walked by FDA table at conference job fair, made it through inexplicable hiring process; blind luck.
- Graduate advisor “not supportive” (understatement)
 - Advisor later had change of heart, invited me to author paper on topic:

“Perspectives on an alternative career path in regulatory science”

Molecular Biology of the Cell

Volume 24, July 15, 2013, Pages 2157-2159
 - Analyzed paths of 6 Pfizer colleagues – all included a ‘blind luck’ element.



1) Secondments

- Description: Temporary or part-time work by scientists in regulatory science function
- USG Cognate: Analogous to USG “details”
- Examples:
 - One day/week to enrich “day job” role (8 examples)
 - One year full time (only one example)
 - 3 staff hired into function.
 - Typically assign to assist, lead ‘bite sized’ efforts, do regulatory research
- Practicality: One day/week more practical to ‘donor’ unit. Salary/stability in regulatory science in industry is competitive with internal functions. FDA pay comparable with NIH.



2) Mentoring

- Description: Hiring highly qualified scientists into role for which not qualified by direct experience, 'train by doing'
- USG Cognate: This is the norm in USG.
 - Examples:
 - Person 1 - Ph.D. MoBio, ran discovery lab
 - Person 2 - Ph.D. MoBio, top-ten program, post-doctoral role
 - Person 3 – Ph.D. Immuno, top-ten program, post-doctoral role
 - Person 4 – Ph.D. MoBio, top-ten program, ran discovery lab
 - Person 5 – Ph.D. MolGen, top-ten program, consulting role
- Practicality: Industry salaries for PhD scientists competitive; entry level industry regulatory salaries not competitive for MDs.



3) Internships

- Description: Temporary role as a “contractor” following graduation with advanced degree
 - USG Cognate: Commissioner’s Fellowship Program, others:
<http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm#fellowships>
 - PFE program year 1: Northeastern, Masters biotech, regulatory science concentration
 - PFE program year 2: Northeastern, Masters biotech, regulatory science
 - Interviewed 5 candidates; selected subsequently hired
 - PFE program year 3: Johns Hopkins, 25 applicants – 3 engaged
 - 1 hired FT thus far
- Practicality: industry salaries competitive; good “bang for buck”;
FDA pay grades competitive
- We under-rated value of “resume building”



The Future – Continue Above Plus (?)

Long-term Goal: Devise ways to make path to this ‘alternative career’ less random:

- Regulatory science post-doctoral programs?
 - USG Cognate: NIH post-doctoral programs, FDA Fellowships

Practicality: both USG and industry pay rates competitive

- ‘Intern’ rotations across different employers/units?
 - Areas with multiple employers/units

- Philadelphia
- Cambridge, MA
- Bay Area
- FDA Centers, FDA/industry rotations feasible?

Practicality issues: COI (esp. USG/Industry), confidentiality, cooperation between competitive entities

