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Millennium : the Takeda
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How did I ... How did I get here?

- English major, grad-school dropout
- Started at the bottom at GSK, QCing PDF documents
- Learned to publish regulatory submissions (NDA, IND, 510(k), eCTD)
- Moved on to Baxter Healthcare, as a publisher, then to Millennium

The role of the Regulatory Publisher

- This didn't work out too Compile and format documents from various functional areas (e.g., Clinical, CMC) into paper or electronic material to be submitted to a regulatory authority
- Format-intensive, not content
- Old days: hundreds of volumes of paper, hand-stamping, loading onto trucks
- Now: eCTD, ESG, metadata, SPL
- If extreme attention to detail and the predictability of doing roughly the same thing every day is appealing, that's a good position, and there is a career path, provided you keep up with the tech
- well for me, however ... I didn't see a career as "the caboose"

What is it you do, anyway?

- Official title: Sr. Associate, Regulatory Affairs
- More appropriately: Business Analyst in the Regulatory Operations and Technology group; Technology Assessor, Planner, and Liaison to Medical Informatics. SOP-Writer and Editor, Web Master, Desk-Side Support, Trainer, All-Around Nice Guy
- Or, simply, "The Tech Guy"

Business Analysis

- The International Institute of Business Analysis defines the job as: "a liaison among stakeholders in order to understand the structure, policies, and operations of an organization, and to recommend solutions that enable the organization to achieve its goals"
- Elicit and gather requirements for systems, examine and document processes/workflows, write spec documents, and much more ...

Business Analysis

- Key skills:
 - Communication: negotiation, interviewing, managing disparate POVs, and translation between users and developers
 - Creativity: coming up with solutions for problems that exist, and plenty that don't exist; user experience
 - Detail: Functional specs are highly-detailed documents; inconsistency and vagueness lead to development problems; organizing information

Can you use it in a sentence?

- Global Oncology Planning and Tracking System (GOPATS)
- An integrated, innovative set of tools that streamline submission planning and tracking of all regulatory interactions
 - Microsoft Project (w/ MOPS) coupled with SharePoint
- Stakeholders from Reg Affairs, including International and CMC; Reg Operations including Submission Management and Publishing; Clinical and Nonclinical Medical Writing
- Components include mpp files integrated with a tracking form, publishing qc checklist workflow, and a question-and-response tracking and research system
- Requirements, process flows, mockups

Two paths diverged in a wood ... Or three. Four?

- There is no clear-cut path to Regulatory Operations
- Colleagues from the fields of Anthropology, History, Finance, English, and some with no degree at all
- Roles in Operations do not have to focus on the sciences, though that is where the vast majority of the roles in Affairs exist. Still, you can't have the department without the operations and technology that run it

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