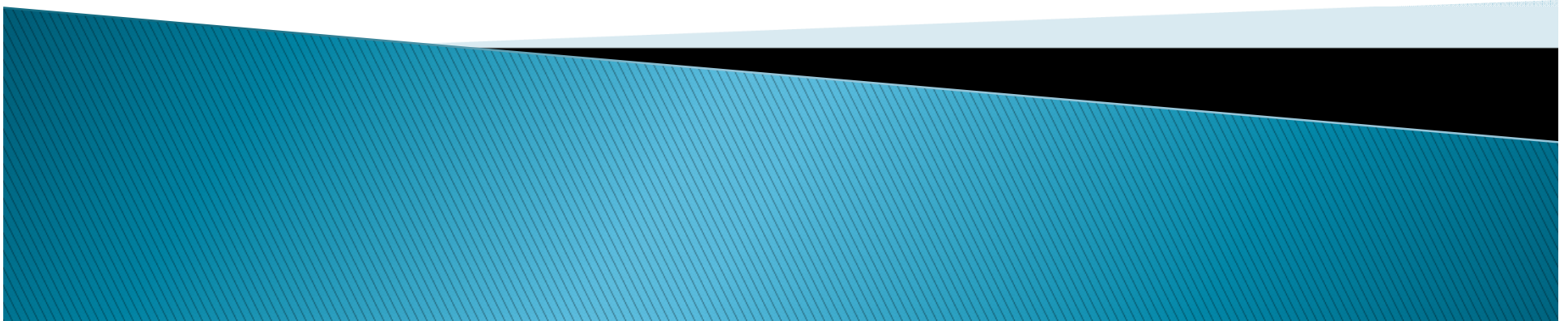


August 16, 2016

Academia: A Primer for a Career in Pharma

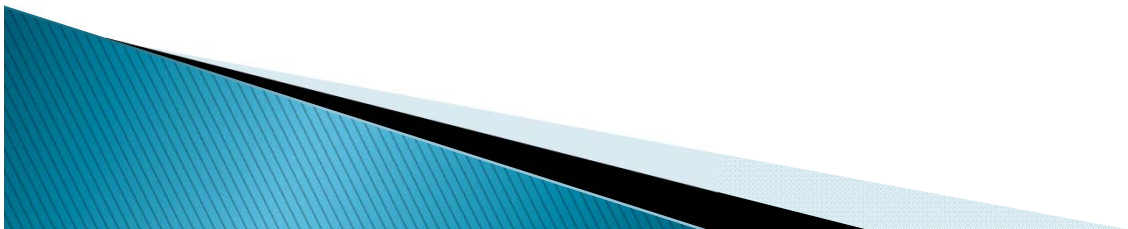
How research skills translate to industry

Rachael L. Gerlach, MSPH, PhD
Regulatory Specialist, US WorldMeds, LLC

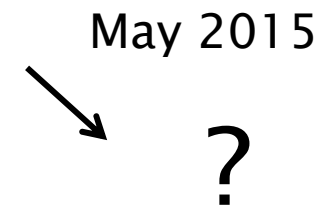


Outline

- ▶ My Path to Industry
- ▶ What I've Learned Along the Way
- ▶ Explore Opportunities for Life Scientists in Pharma



My Background– Path to Industry



May 2015

?



Decision to move into industry



Benefits

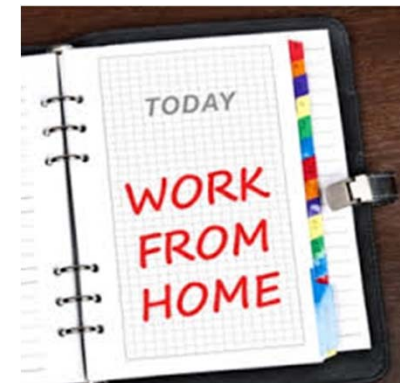
Public Health
Prevent. Promote. Protect.



40
Hours



Day to Day Challenges



I wish I knew then
what I know now

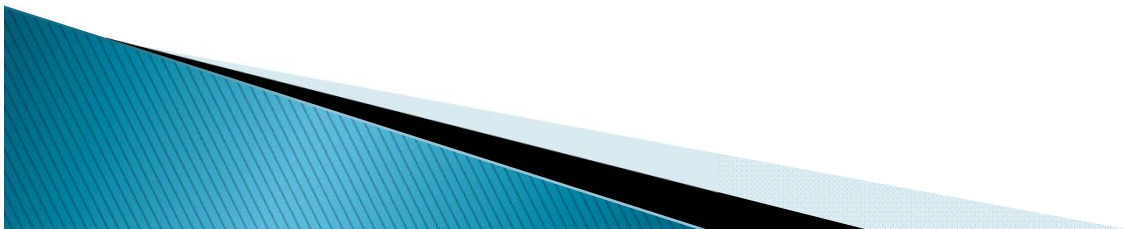


7 Transferrable Job Skills

How to articulate those skills in a “value proposition” to an employer



1. Analysis and Problem Solving
2. Interpersonal and Leadership
3. Project Management and Organization
4. Research and Information Management
5. Self Management and Work Habits
6. Written and Oral Communication
7. Subject Matter Expertise– this extends farther than you think?



#1 Analysis and Problem Solving

- ▶ Ability to define a problem and identify possible causes/solutions
- ▶ Comprehend large amounts of information
- ▶ Form and defend independent conclusions
- ▶ Design an experiment, plan, or model that defines a problem, tests potential resolutions and implements a solution



#2 Interpersonal and Leadership

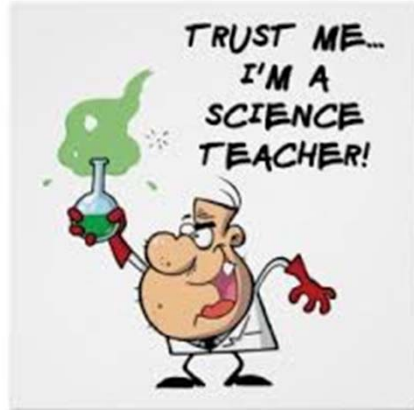


- ▶ Facilitate group discussions or conduct meetings
- ▶ Motivate others to complete projects (group or individual)
- ▶ Respond appropriately to positive or negative feedback
- ▶ Collaborate on projects and well on a team (your lab, your department or center) as well as cross-functionally (in collaboration within your group or with other groups)

Group Discussion



#2 Interpersonal and Leadership



- ▶ Effectively mentor and coach subordinates and/or peers
- ▶ Teach skills or concepts to others (classroom, one-on-one)
- ▶ Influencing and negotiating skills (from writing funding bids, securing resources from within your dept etc)



#3 Project Management and Organization



- ▶ Manage a project or projects from beginning to end (dissertation research, lab got new instrument)
- ▶ Identify goals and/or tasks to be accomplished and a realistic timeline for completion
- ▶ Prioritize tasks while anticipating potential problems
- ▶ Maintain flexibility in the face of changing circumstances
- ▶ Put together a budget (grant application)
- ▶ Line Management (hiring, developing, motivating and assessing performance)
- ▶ Financial and resource management

#4 Research and Information Management



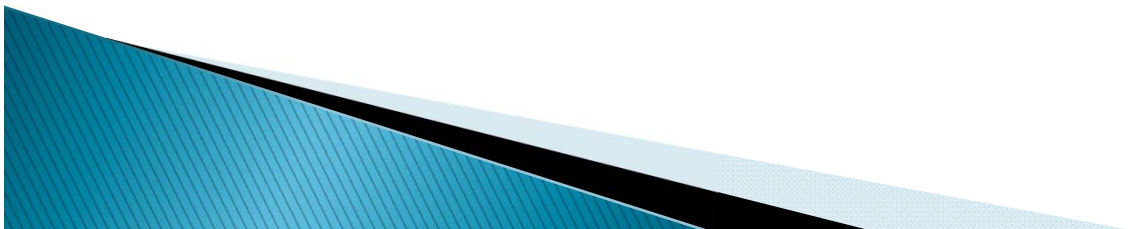
- ▶ Identify sources of information applicable to a given problem
- ▶ Understand and can prioritize large quantities of data
- ▶ Develop organizing principles to effectively sort and evaluate data



#5 Self-management and work habits



- ▶ Work effectively under pressure and to meet deadlines
- ▶ Comprehend new material and subject matter quickly
- ▶ Work effectively with limited supervision



#6 Written and Oral Communication

- ▶ Prepare concise and logically-written materials
- ▶ Designing, preparing and delivering ideas (in lectures)
- ▶ Organize and communicate ideas effectively in oral presentations to small and large groups (conferences, journal clubs, etc.)
- ▶ Write at all levels — brief abstract to book-length manuscript/dissertation
- ▶ Debate issues in a collegial manner and participate in group discussions
- ▶ Use logical argument to persuade others
- ▶ Explain complex or difficult concepts in basic terms and language

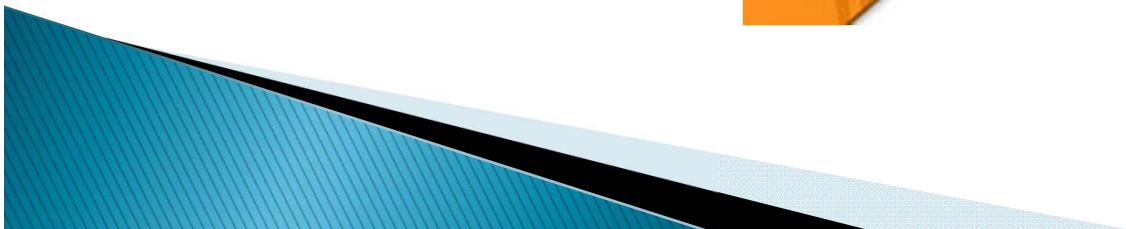


#7 Subject Matter Expert

- ▶ Flow cytometry, cell culture, western blotting, cloning, PCR, using various isolation kits, animal models, serology, etc.
- ▶ Research area: can be as broad as microbiology, biochemistry, cancer

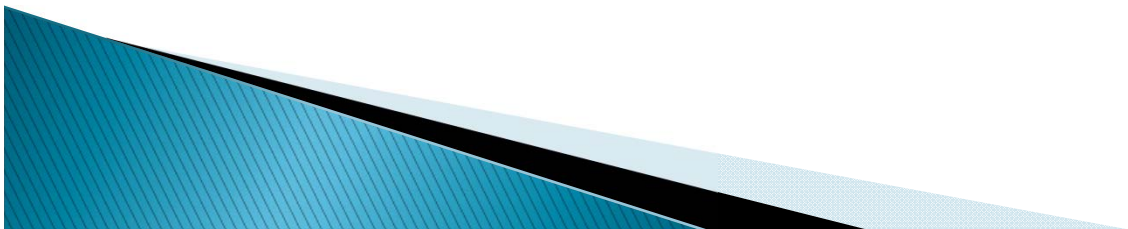


Don't Be Afraid to Intern



Internships

- ▶ Myth: Internships are only for undergrads
- ▶ However, there are number of major companies who offer short summer workshops and internships and many Universities that allow graduate researchers to do such internships
- ▶ These internships are offered by large biotechnology and biopharmaceutical companies, consulting firms, and intellectual property firms.
- ▶ If you do an internship in a non-research role that is aligned with the career you want to pursue, it will allow you to rapidly develop the transferable skills you need to get an industry job.



Benefits to Interning– Competitive Edge



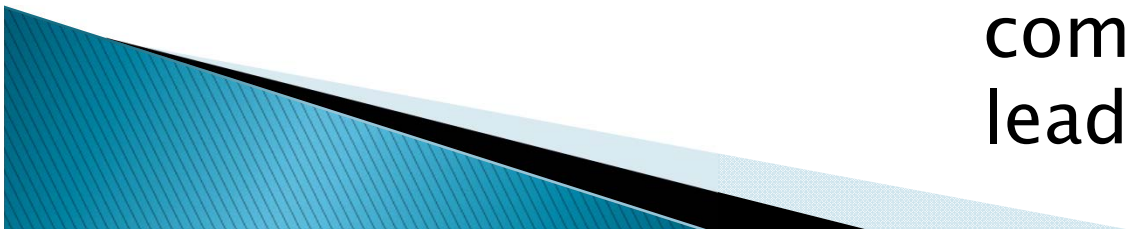
Building your CV

Academia

- ▶ Emphasis on what you have already achieved
- ▶ Focus on scientific credibility
- ▶ Focus on scientific accomplishments
- ▶ List publications, presentations, and conferences

Industry

- ▶ Emphasis on how your achievements can be applied
- ▶ Focus on skills necessary for job you are applying for
- ▶ Short, sharp and to the point
- ▶ List teamwork, communications, leadership (management)



How to interview



- ▶ In an interview situation, be eager, show a desire to learn and be flexible, and ask the questions you want answered
- ▶ Highlight your **transferrable skills**
- ▶ Think of examples of each
- ▶ Give thought to your values and what your career goals are– doesn't have to be a grand view



Where Can I Fit?



If you don't know– start small

- ▶ Look for small–medium size company
- ▶ Ability to join different cross–functional projects
- ▶ Ability to learn about the different areas of the company
- ▶ Ability to learn where you provide value most

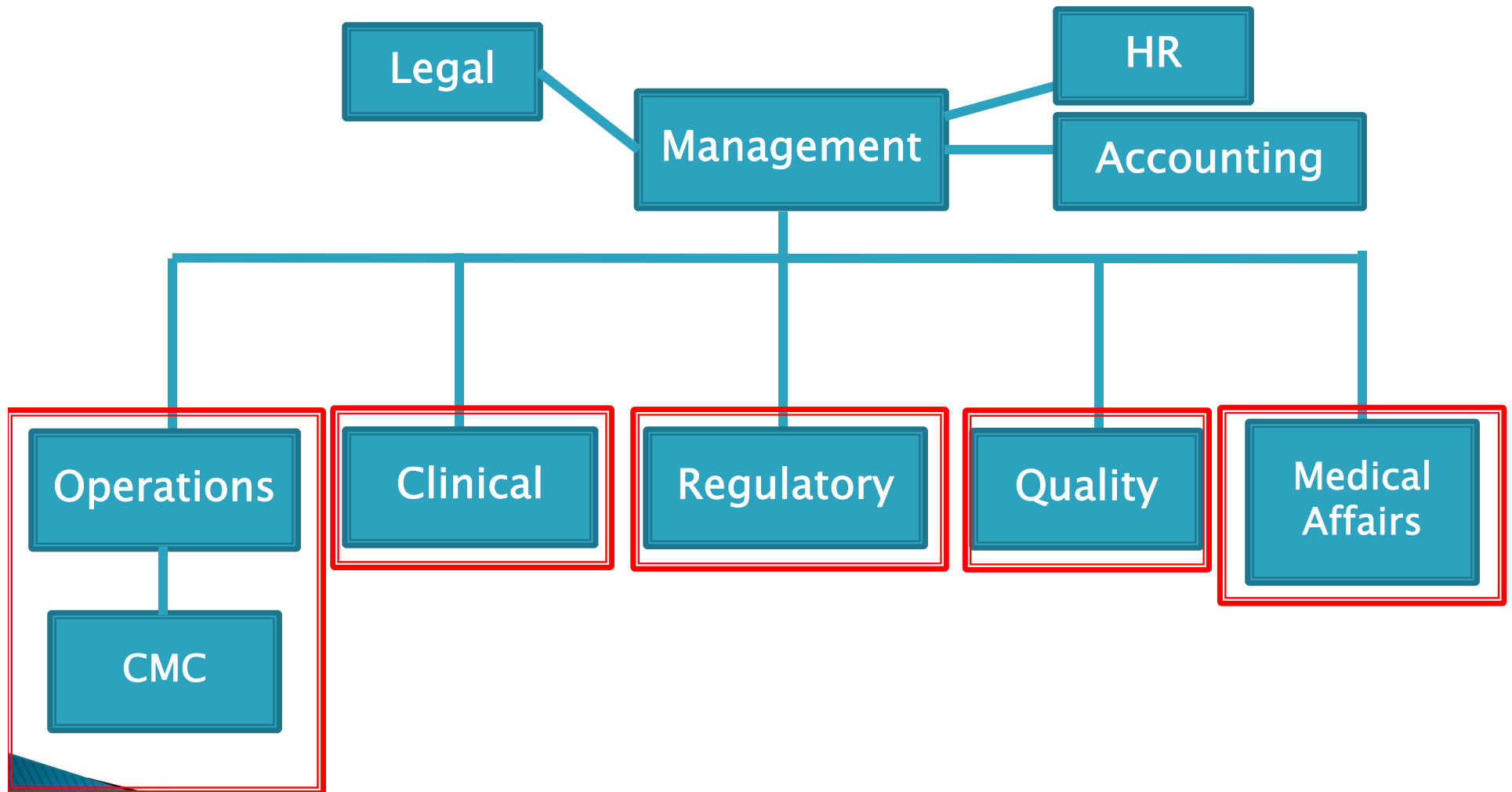


Role of Pharmaceutical Company

- ▶ Pharma companies are responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare



Pharmaceutical Company Structure



US WorldMeds

Revonto®
(dantrolene sodium for injection)

- Indicated for acute, intermittent treatment of hypomobility, "off" episodes associated with advanced Parkinson's disease (PD). When injected during an off episode, APOKYN may enable people with PD to walk, talk, and move around more easily

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

- Indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

APOKYN®
apomorphine hydrochloride injection

- Indicated, along with appropriate supportive measures, for the management of fulminant hypermetabolism of skeletal muscle characteristic of malignant hyperthermia crises in patients of all ages

Lofexidine Hydrochloride
for treatment of opiate withdrawal symptoms

- first non-narcotic and non-addictive medication approved in the United States for the mitigation or relief of symptoms associated with acute withdrawal from short-acting opioids

CMC– Chemistry, Manufacturing and Controls



- ▶ Roles: Defines and implements formulation and process development strategies across company pipeline initiatives.
- ▶ Responsibilities: Collaborates closely with multiple departments – scientific, regulatory, quality, and operations – within the company and drives external activities at contract manufacturing and contract laboratory organizations (CMOs and CROs, respectively)
 - Determine appropriate formulation and manufacturing conditions that result in a drug product with acceptable physicochemical properties. complete all necessary studies to satisfy current regulatory requirements, and utilize this knowledge to establish a shelf life and validate a process that ensures the drug product identity, quality, purity and potency
 - Ensure drug is manufactured according to cGMP requirements and manage lifecycle of drug product (i.e, new formulations)
 - Responsible for pre-clinical study and design
- ▶ Skills: strong chemistry and analytical background, familiarity with manufacturing process optimization and cGMP principles, knowledge of appropriate regulatory requirements, scientific rigor, troubleshooting, and analysis



Quality Management

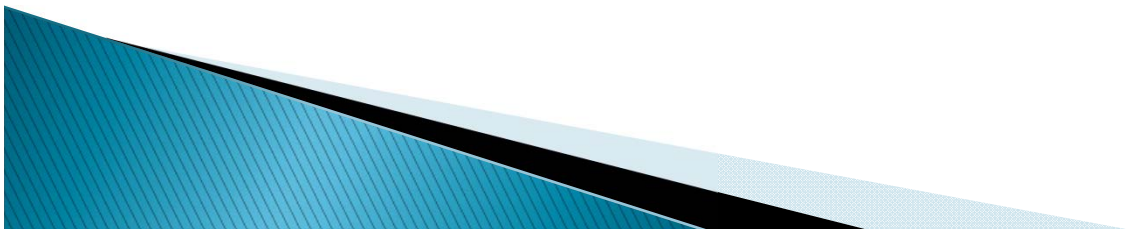


- ▶ Role: Ensure drug manufacturers are cGMP compliant:
 - their personnel have appropriate educational and experiential backgrounds
 - equipment is installed, operational and fully maintained
 - complete traceability and proper storage of ingredients, packaging components and products
 - production, process, packaging, labeling and laboratory controls are present
 - documentation (from formulation, through production and testing) is complete and has appropriately dated verification steps.
- ▶ Skills: Strong writing skills, detail-oriented

Medical Affairs



- ▶ Role:
 - managing key thought–leader relationships
 - publishing data from corporate–sponsored trials
 - presenting educational information about a product or therapeutic landscape
 - answering questions from healthcare providers regarding product safety or efficacy that is not addressed in a product’s label
 - supporting research initiatives outside labeled indications for marketed products.
- ▶ Skills: scientific rigor, ability to communicate effectively both in person and in writing



Clinical Operations



- ▶ Role: Plan, track and manage the conduct and evaluation of clinical research, develop clinical protocols, collect and process clinical data (statistical team), analyze and report clinical data
- ▶ Importance: Goal of trials to determine the products potential at benefiting the patients
- ▶ Skills: Project Management, organizations, detail oriented, strong written and oral communication



Regulatory



- ▶ **Role:**
 - Kind of a capture all
 - Manages and interactions with government agencies (FDA, EMA, etc.)
 - Collect, collate, and evaluate scientific data the CMC and Clinical Ops teams are generating and communicate to proper authorities
 - Give strategic and technical advice, from the beginning of product development– making an important contribution both commercially and scientifically
- ▶ **Skills:** Strong writing and communication skills, critical thinking and strong time/project management skills



Recommendations

- ▶ Work diligently no matter what the task
- ▶ Speak up
- ▶ Communicate respectfully and effectively
- ▶ Invested time is worthwhile





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