

TRAVELING DOWN YOUR CAREER PATH

LESSONS LEARNED ALONG THE WAY

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The Road Not Taken-Robert Frost

Two roads diverged in a wood,

And I, I took the one

LESS TRAVELED BY.

And that has made

all the difference.



STARTING THE JOURNEY:

TECHNOLOGY CHANGES.....WHAT CARRIES
YOU THROUGH YOUR CAREER?



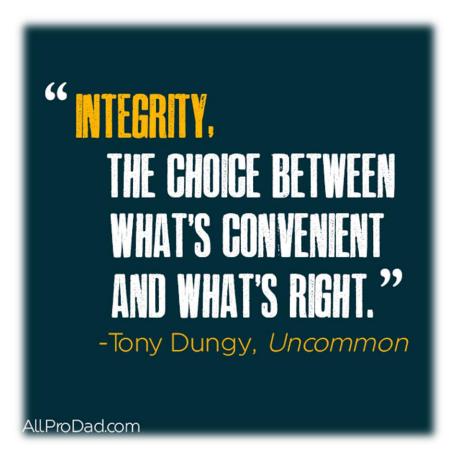
Since Technology Changes: what skills carry you down the path....

- Maintain your Personal Integrity
- Ability to Communicate
- Ability to Learn
- Ability to Change



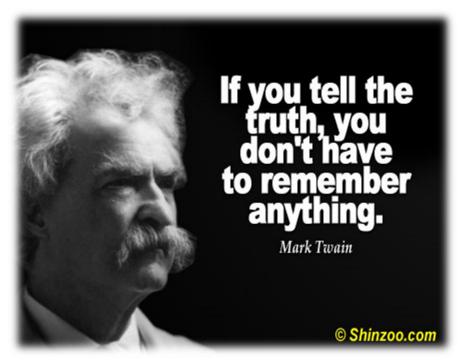
Maintain your Personal Integrity

INTEGRITY IS DOING THE RIGHT THING. EVEN WHEN NO ONE IS WATCHING.





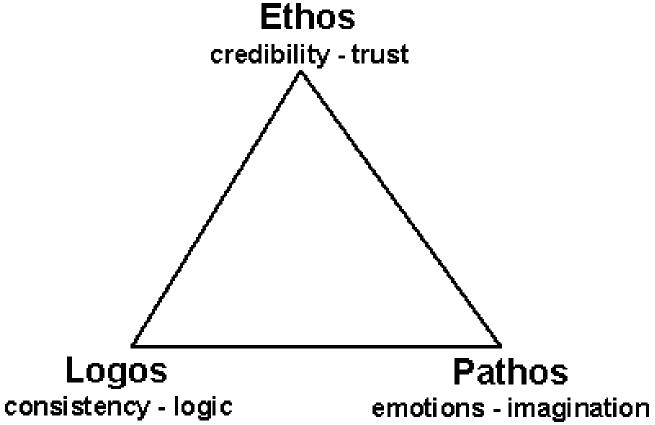
Honesty



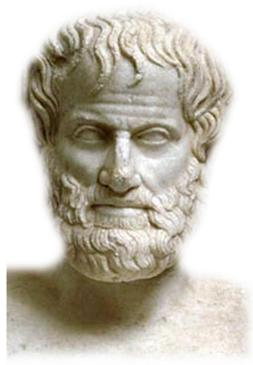
honesty is hard work. Spider Robinson



Aristotle Rhetorical Triangle



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Ability to Communicate

Oral Communication

- Ethos-Logos-Pathos
- Know your audience
- Focus on the point
- Show respect
- Be yourself



Ability to Communicate

Written Communication

- **Technical Writing**
 - Know your audience
 - Get to the point and return frequently
 - Don't skip the outline!
 - Good logical flow- "tell a story"
 - No slang
 - Proof read



E-mails

- Title should include requested action
- Read it over before sending
 - Out loud is OK!
- Avoid bCC



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Ability to Learn

"Anyone who stops learning is old, whether twenty or eighty. Anyone who keeps learning stays young".

- Henry Ford



If you're not learning, you are not growing

Your knowledge and experience increases your value to the company

Your knowledge and experience broadens your opportunities or promotions

Make learning a lifestyle



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Ability to Change

Prepare each day for a possible change

- Schedule change
- A new task
- Unforeseen circumstance
- A problem



Enjoying success requires the ability to adapt. Only by being open to change will you have a true opportunity to get the most from your talent.

- Nolan Ryan



Prepare yourself for the big changes

- A new promotion
- A new company



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TIPS FOR THE JOURNEY



Know your Regulations

FDA, Safety, Environmental

ICH- International Conference on Harmonization

cGMP- ICH Q7, 21 CFR parts 210/211

"cGMPs provide for systems that assure proper design, monitoring, and control of **manufacturing** processes and facilities."

www.fda.gov

Q7 Good Manufacturing **Practice Guidance for Active Pharmaceutical Ingredients**

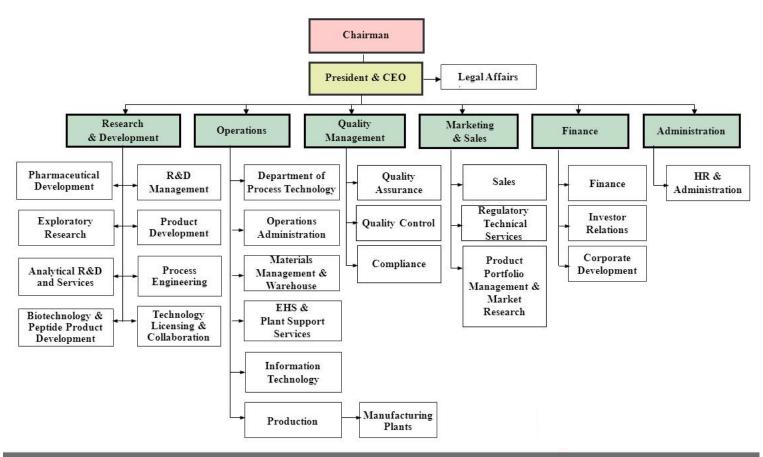
Guidance for Industry

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) September 2016 ICH

Revision 1



Understand and Respect Roles



Learn to use an organizational chart Learn the proper channels to get things done Approach at same organization level if possible

Understand approval process



Know how to work as a team



Trend toward specialization

Teamwork is critical to business success

"To me, teamwork is the beauty of our sport, where you have five acting as one. You become selfless."

Coach Krzyzewski



"Talent wins games, but teamwork and intelligence wins championships."

Michael Jordan



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Experience in Operations/Manufacturing is Invaluable



All departments depend on operations

Operations is where the money is made

Experience in operations will help you in any job within the organization





Learn Problem Solving Skills

DMAIC – Define, Measure, Analyze, Improve, Control

Define

Identify the true problem (what, when, where, what extent)

Measure

What is the extent. What told you there was a problem.

Analyze

Use appropriate problem solving tools

Fishbone Diagram

- 5 Whys
- Fault Tree Analysis

Improve

Identify appropriate countermeasures
Benefit vrs Effort

Control

Have a control plan Measure after implementation of countermeasures



Pointers:

Stuck in the corral or looking beyond

GEMBA, GEMBA – Get up and GO SFF!!

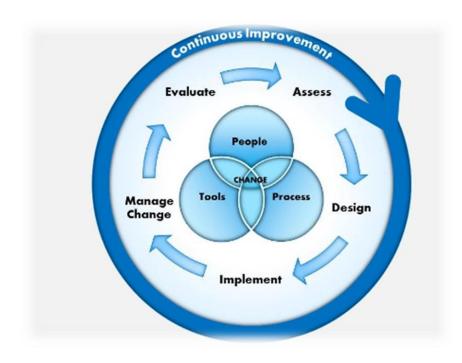
Break it down in small manageable pieces

Zoom Out – Does my solution apply to other problems or Potential Problems?



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Know the Proper Route for Change



Need to "Manage" change

- Change Control Procedures
- Proper path for introducing change
- Proper methods for validating the change

Know the targets for change

- Structured process and tools to lead people through change
- Communication Plan
- Why is the change needed?
- How will the change affect the target?



Seek Good Leadership/ Learn from Bad Leadership

10 Leadership Lessons from George Washington

- 1) He believed in his men
- 2) He was a man of exemplary character
- 3) He treated other with the utmost respect
- 4) He held men accountable
- 5) He loved his men
- He placed the welfare of his men ahead of his own
- 7) He was personally invested in the cause
- 8) He did not waver from his guiding principles
- He was a man of deep faith who demonstrated that via his actions
- 10) He took his responsibilities seriously





"The ultimate measure of a man is not where he stands in moments of comfort and convenience, but where he stands at times of challenge and controversy."

Martin Luther King Jr.



Maintain Confidentiality

Internal

- Reviews and HR protected
- Patient information
- Information told to be confidential
- If you do not need to know
 do not seek



External

Client information Financials

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Watch social media





Learn to Teach



Professor Zheng Ji Nanjing University

Founder of Nutritional Science in China

You never really know anything until you have to teach it!

"To teach is to learn twice over."

Joseph Joubert

"Who dares to teach will never cease to learn"



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Networking is Essential

Helps you in:

Developing in your current job Getting into new jobs

Remember we are a small industry Do not burn bridges

Types of Networking:

On-line- Linked-in

Professional Associations- ISPE

Email assistance

Manage your contacts!





Taking a position is not always about money or if you are good enough...

"Begin with the end in mind"

Stephen Covey

First Question: Does this fit my professional goals?

What are your professional goals?

As you begin your career, assess what you enjoy doing.

Do not say an automatic "no" to an opportunity (even if you do not consider yourself a Subject Matter Expert)

"Take healthy risks!"

my lovely wife

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"Take risks: if you win, you will be happy; if you lose, you will be wise."



"If somebody offers you an amazing opportunity but you are not sure you can do it....Say Yes....then learn how to do it later!"

Richard Branson



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Anchors Aweigh



20 years from now you will be more disappointed by the things you didn't do than by the ones you did. So throw off the bowlines, sail away from the safe harbor, catch the trade winds in your sails.

Explore.

Dream.

Discover.



Mark Twain

