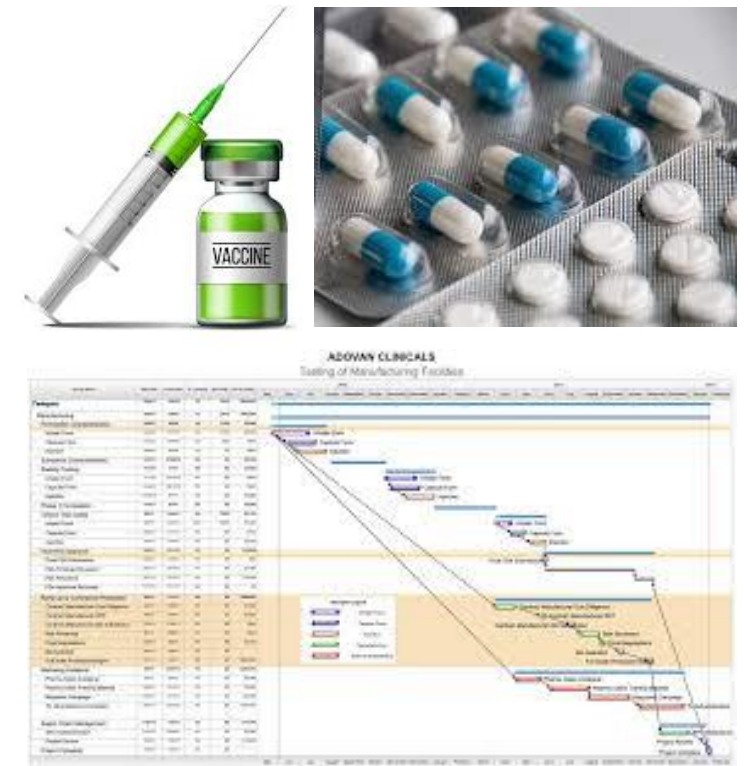


Pharmaceutical PROJECT MANAGEMENT

Bradford Powell PhD PMP
5 Oct 2022



Agenda

- Entry to PM
- PMI Business Acumen
- FDA and drug development
- Case studies
 - Communications
 - Assumptions
 - Culture
- Conclusions

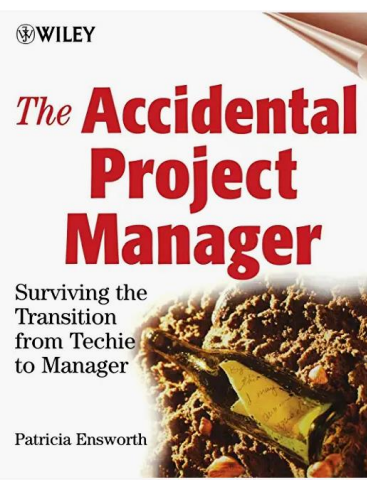
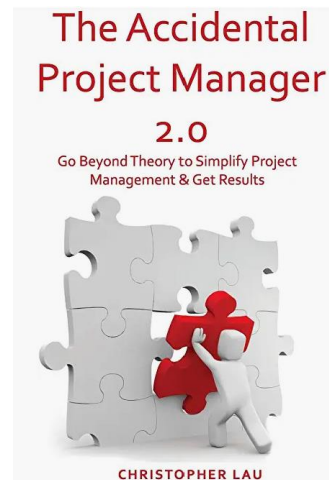
PRESENTATION DISCLAIMER

This presentation is intended for educational purposes only and does not replace independent professional judgment. Statements of experience, facts, and opinions expressed are solely those of the author unless expressly stated to the contrary. The events and organizations described herein are representations and not actual. No professional organization, body, or society has endorsed or approved this presentation, or assumes responsibility for the content, accuracy, or completeness of the information.

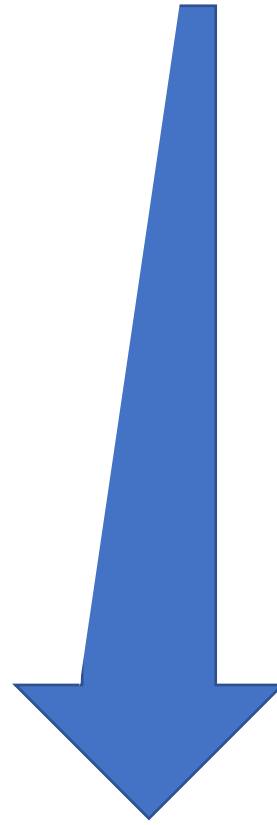
Accidental Project Manager



- Didn't originally pursue PM
- Technical or Leadership skills
- Assigned 'initiatives' to manage
- Operating own business
- **Opportunity: +2.2M PM/year to 2027**



Certified Project Manager

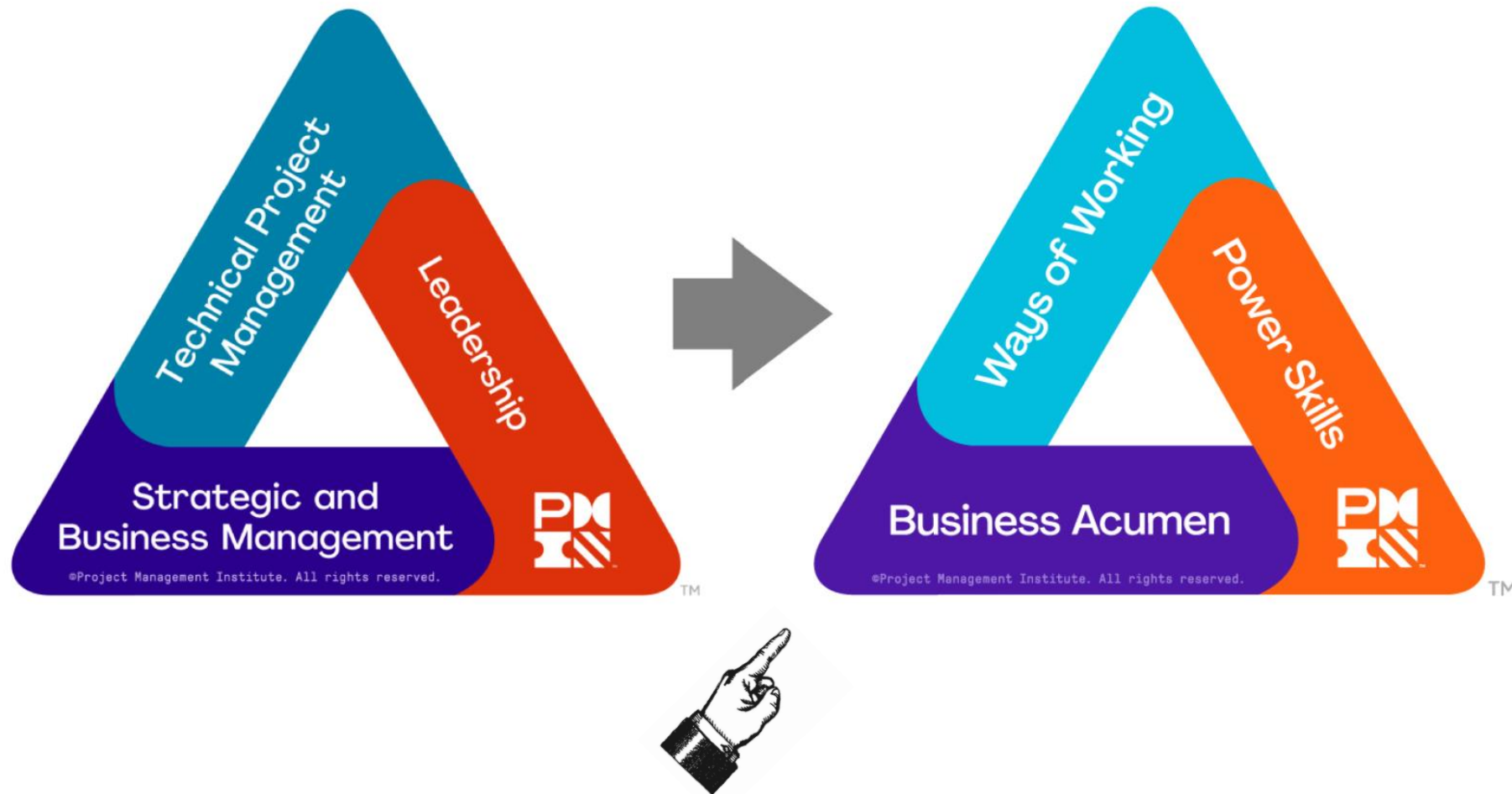


- Laboratory Aid, Team Lead
- Process & Method Validation
- S&T Laboratory Head
- Instructor/Coach
- PD Shared Management
- QA/QC support
- Director of Analytical Sciences
- General Manager
- Consulting Business

PM / PMO



The PMI Talent Triangle® is Evolving



PMI Business Acumen

3.4.4.2 QUALITIES AND SKILLS OF A LEADER

Research shows that the qualities and skills of a leader include but are not limited to:

- ◆ Being a visionary (e.g., help to describe the products, goals, and objectives of the project; able to dream and translate those dreams for others);
- ◆ Being optimistic and positive;
- ◆ Being collaborative;
- ◆ Managing relationships and conflict by:
 - Building trust;
 - Satisfying concerns;
 - Seeking consensus;
 - Balancing competing and opposing goals;
 - Applying persuasion, negotiation, compromise, and conflict resolution skills;
 - Developing and nurturing personal and professional networks;
 - Taking a long-term view that relationships are just as important as the project; and
 - Continuously developing and applying political **acumen**.

PMBOK® 6th Ed, page 61

PMI Lexicon of Project Management Terms has no entry for business acumen.

<https://www.pmi.org/-/media/pmi/documents/registered/pdf/pmbok-standards/pmi-lexicon-pm-terms.pdf?v=5c542105-b1b0-4d8f-855a-694463d27816>

PDUs Claimed [?]

PMP®



Knowledge of and expertise in the industry or organization that enhances performance and better delivers business outcomes.

Ways of Working [?]

Power Skills [?]

Business Acumen [?]

Total PDUs

0.00

0.00

0.00

0.00

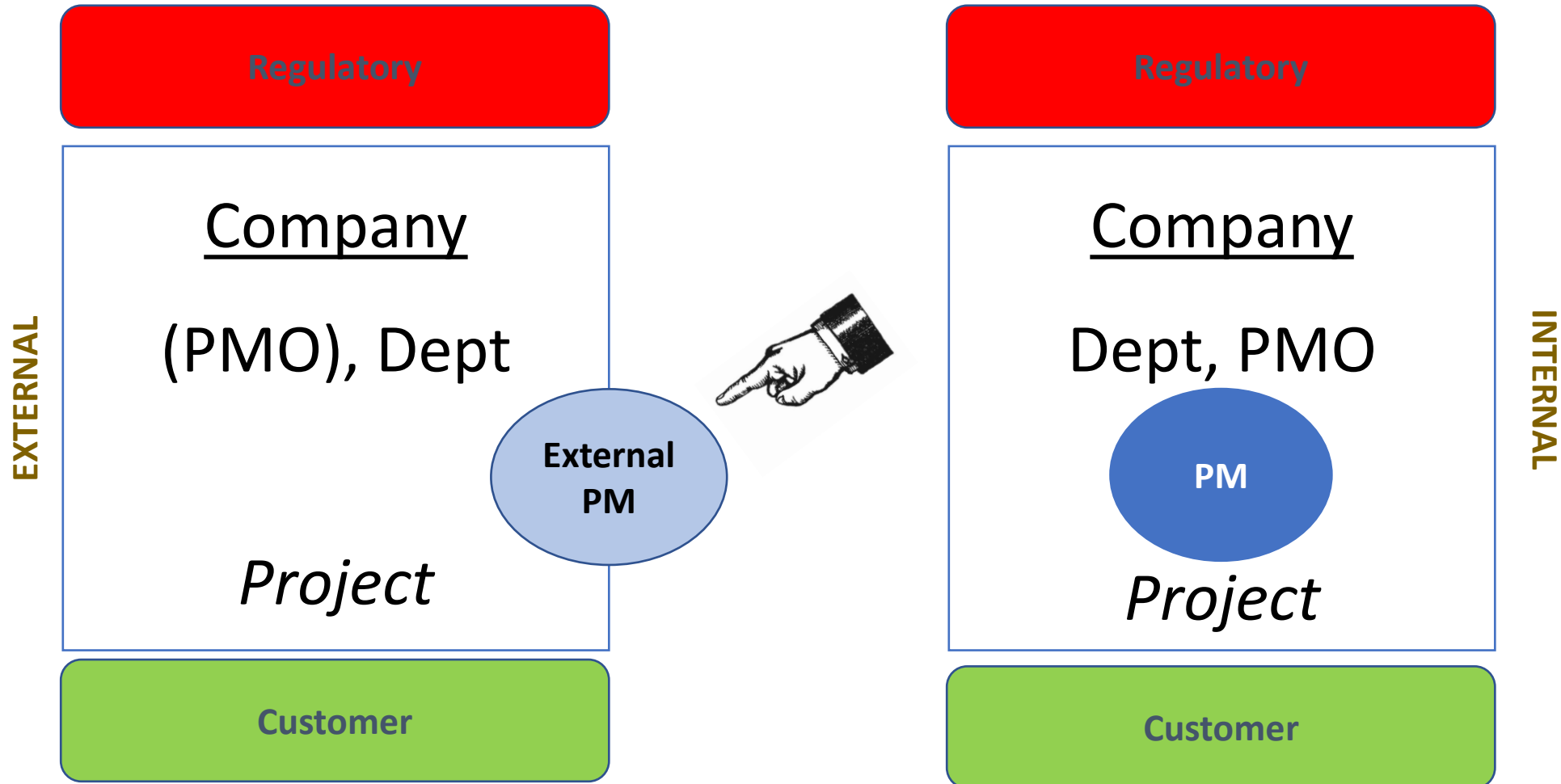


Political or Business Acumen

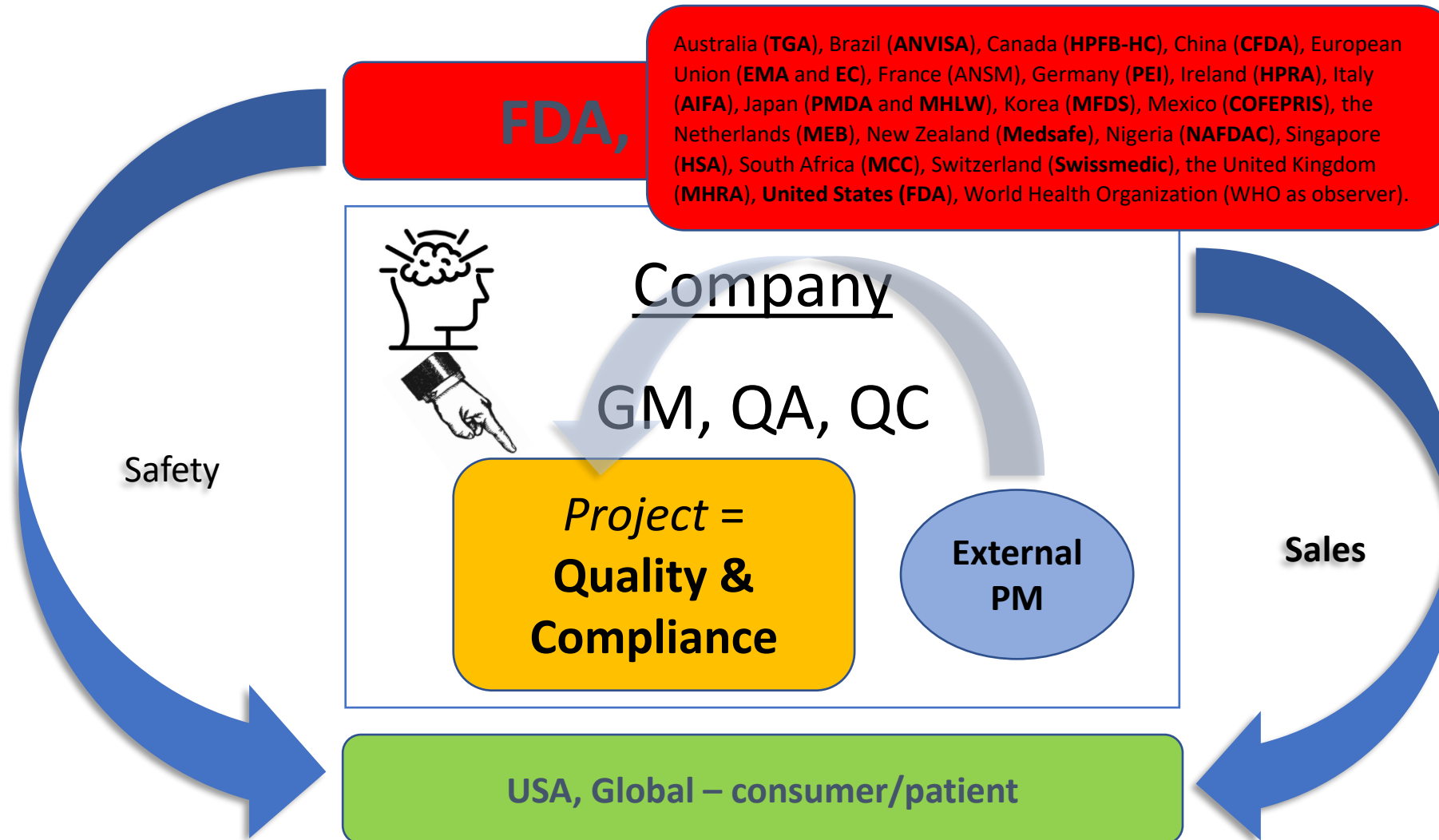
1. Map out the political landscape of your organization
2. Identify the key influencers and "political alliances"
3. Develop professional relationships with those in positions of influence
4. Join important groups and alliances
5. Respect everyone around you
6. Develop your knowledge base and credibility
7. Exercise your power wisely and choose your battles carefully

Power Broker

Two Modes of Project Manager



Pharma Project Management



Known Project Performance Factors

- Strategy
- Controls
- Risks & Rewards
- Preventions & Corrections

Hidden Project Performance Factors

- Plan the work – Work the plan
- First Law of Holes – stop digging
- **Key to Project Success – People**
- Root Causes – people (and water)

- 
- Talk
 - Listen
 - Think
 - Act
 - Feel
 - Believe

Strategy

Work

Goal

Controls

* Communications * Assumptions * Culture

Adjustments

People

Listen, Talk, Write, Think, Act,
Feel, Believe, Resist, Defend,
Agree , Support, Share, Champion

Human Nature vs Your Project

Parkinson's Law – Work expands so as to fill the time available for its completion.

Schedule, Cost, Resources

Murphey's Law – If anything can go wrong, it will.



Risk, Quality, Management Plans

Manson's Law – The more something threatens your identity, the more you will avoid doing it.

Culture...Trust, Inclusion, Safety ?



Signs, Symptoms, Sources

Communications – information is incomplete, inaccurate, conflicting, absent, indirect, late, wrong

Assumptions – unknown constraints, dependencies, risks

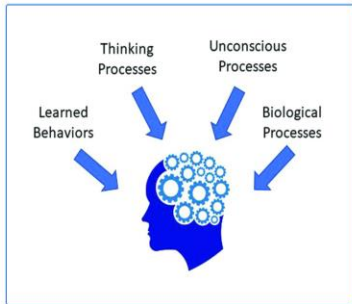
COMPANY

^ **Culture** – us/them, in/outsider, silos, customs/norms, habits, appearance, perceptions, style/language

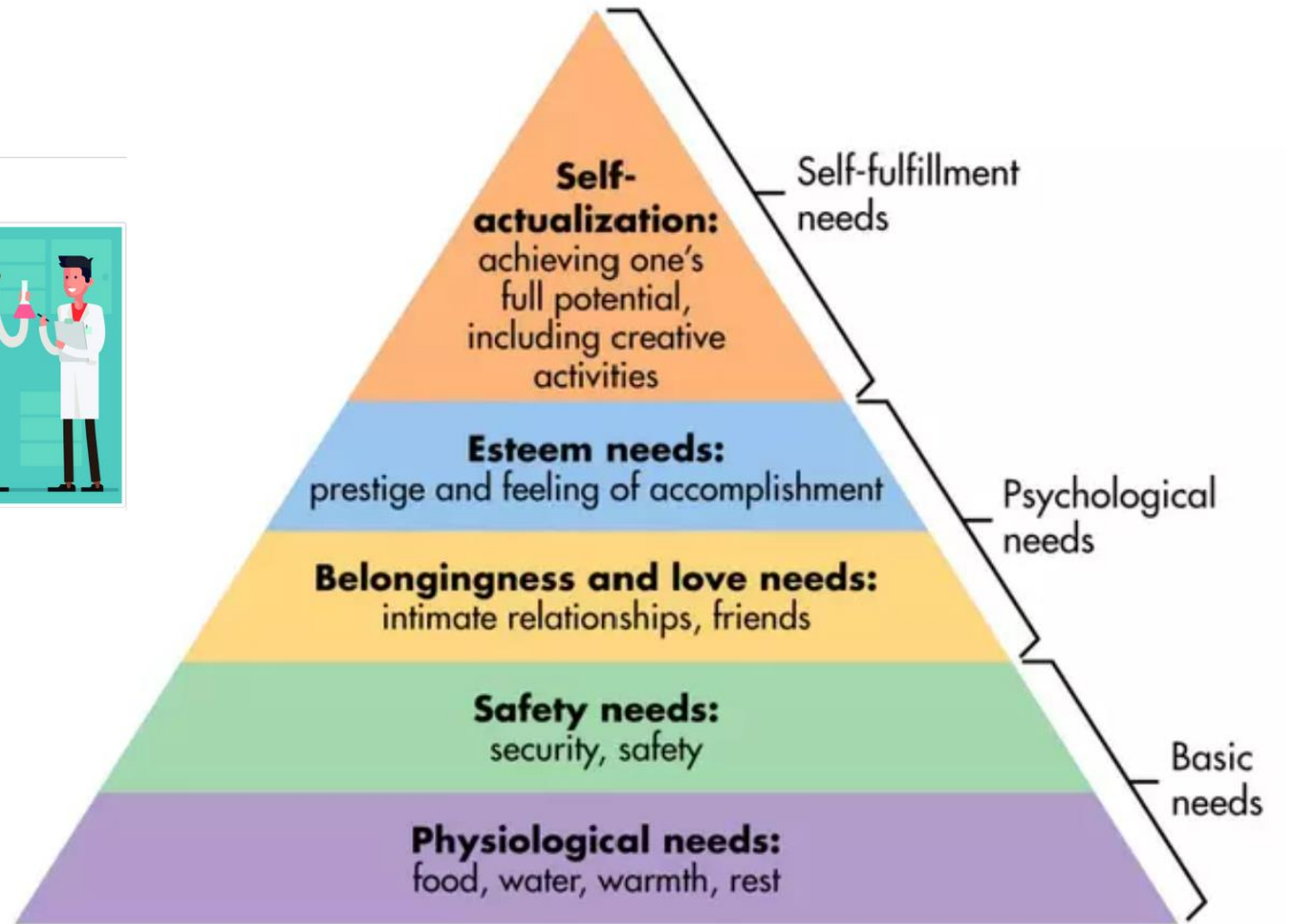
A Hierarchy of Stakeholder Needs



Google Site Search



<https://www.simplypsychology.org/maslow.html>



A Hierarchy of Team Needs

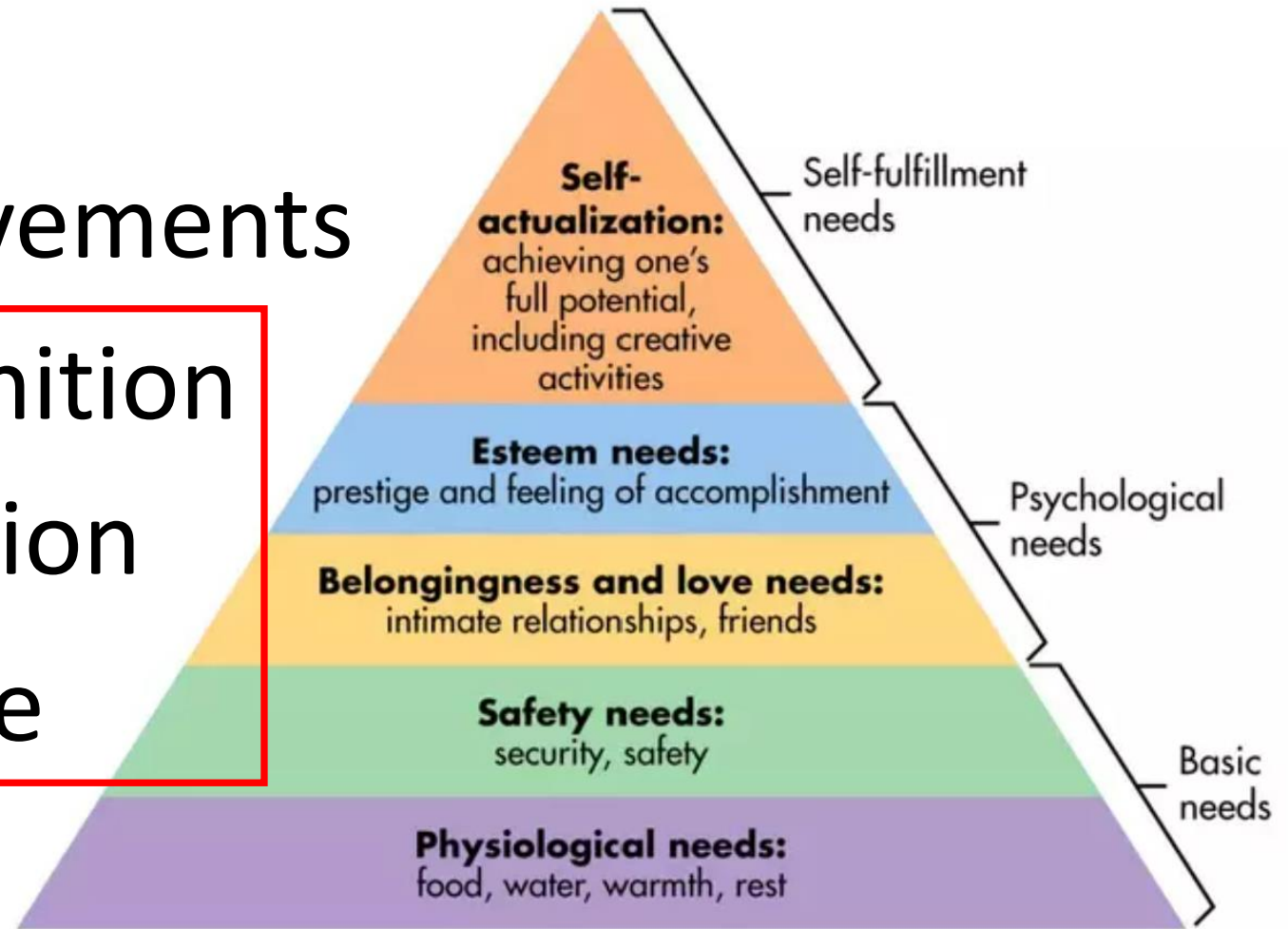
Project Achievements

Recognition

Communication

Workspace

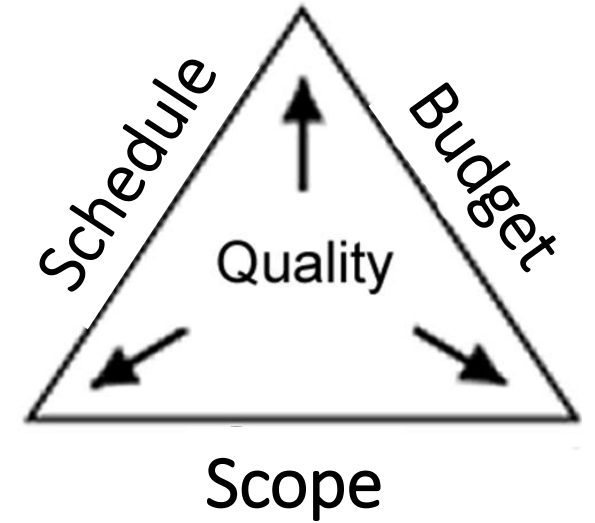
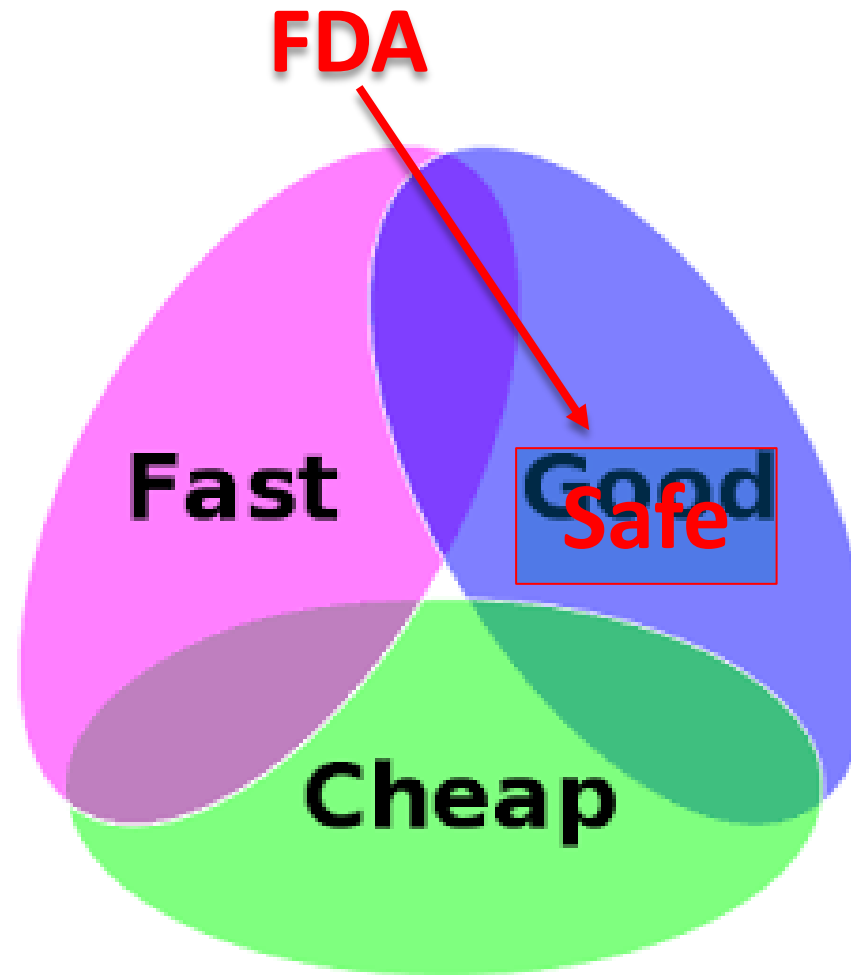
Income



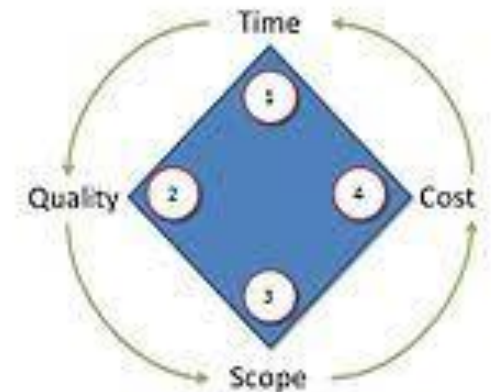
Project Constraints



SQERT Project Management



The Project Diamond
(Used to be the Iron triangle)



Bio/Pharma Quality Projects

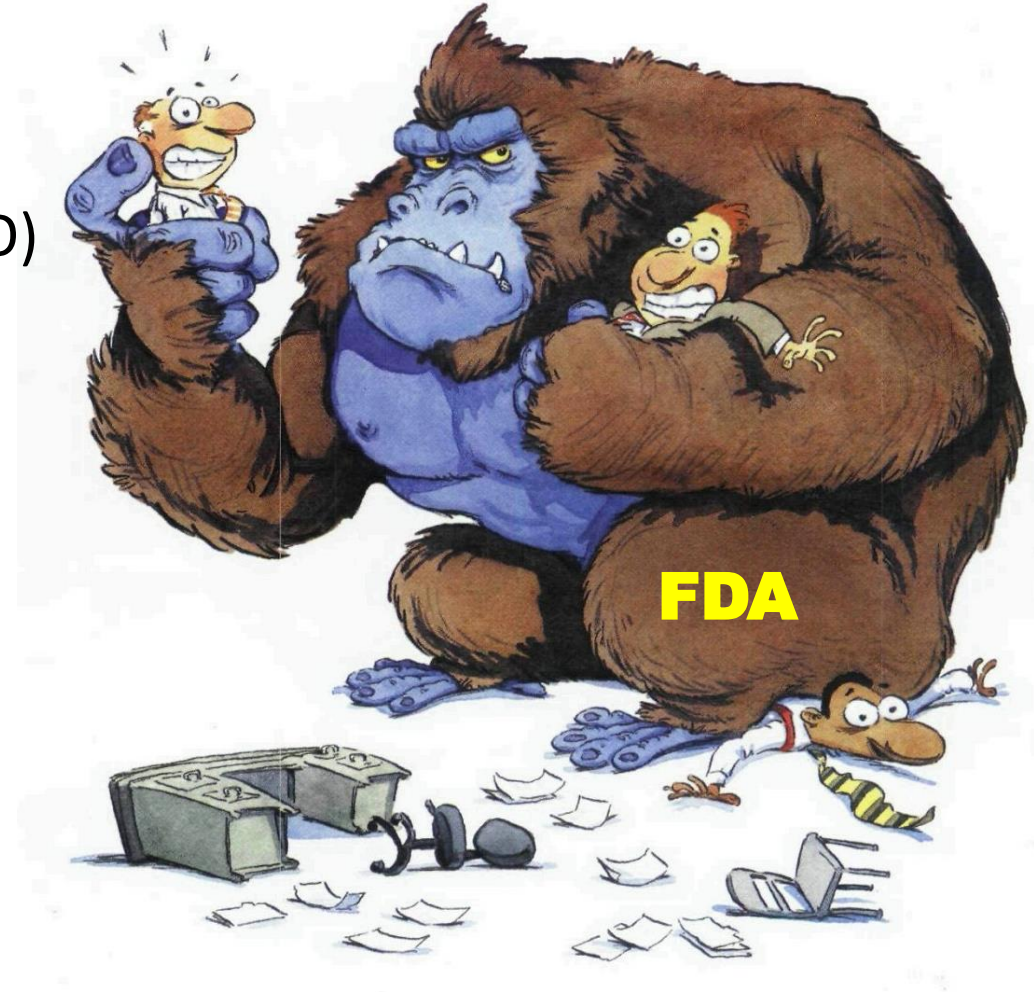
Objective(s) – meet requirements of regulatory ‘customer’ AND maintain ongoing operations

Scope – Support Management & QA (w/o client PMO)

Purpose – Adapt processes to comply with upgraded regulation; Response to recent inspection outcome (483, warning letter, consent decree); Improve operations

Schedule – Monthly reports, Re-inspection (back to business asap)

Constraints – Insufficient understanding, capability; unwillingness to design & implement changes independent of production



Drug product quality

Cost of Poor Management



- \$ 1B/Each New Drug
- Opportunity Costs
- Failed Drugs
- Higher Marketing & Sales Costs
- Delayed Treatment to Patients



The Path of Regulatory Action

FDA responses $\propto$ risk/benefit

- immediate threat to health/safety
- pattern of non-compliance
- criminal offense



Compliance & Enforcement



FDA inspection > 483 + EIR > classified as VAI or OAI >
Warning Letter > Recall > Product Seizure /Field action >
Embargo, Injunction (temporary or permanent), Prosecution > Debarment

Oral Solid Dose Hold Time Validation

OSD = tablet, capsule, pill ingested then dissolved in the digestive system for delivery to the body

Mission – Validate hold times and conditions for OSD manufacturing process at full scale (previously 1/20th scale).

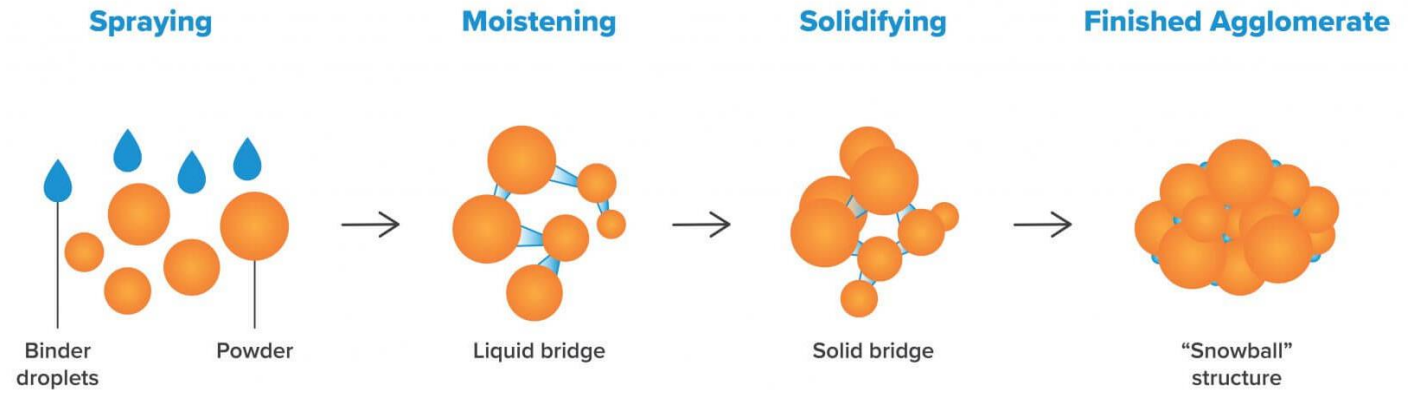
* PM Role *
Support Mgt

Objective – Adapt processes and testing to comply with upgraded FDA ‘mandate’ (improved regulation).

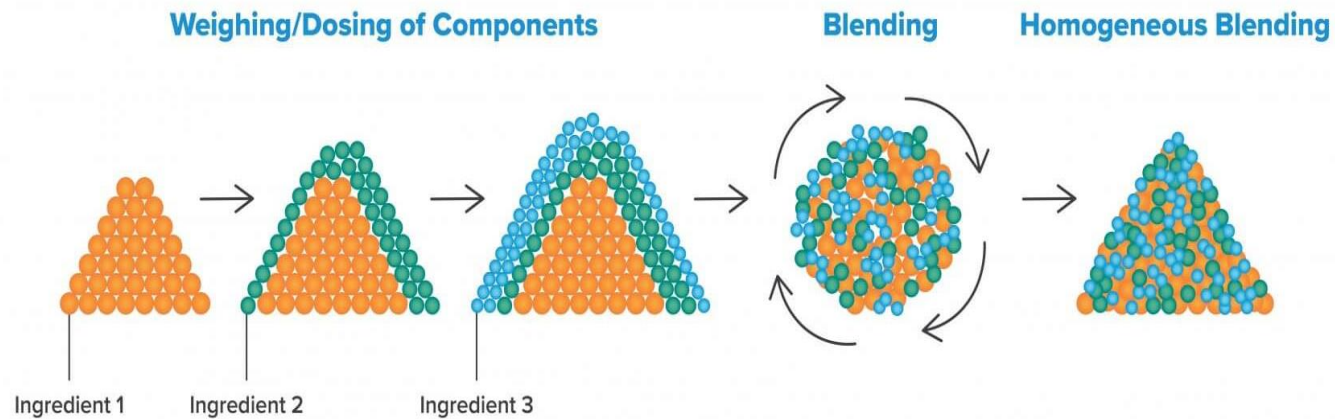
Approach – Revalidate OSD drug products, leveraging worst-case scenarios to establish acceptable ranges of conditions for process holds.

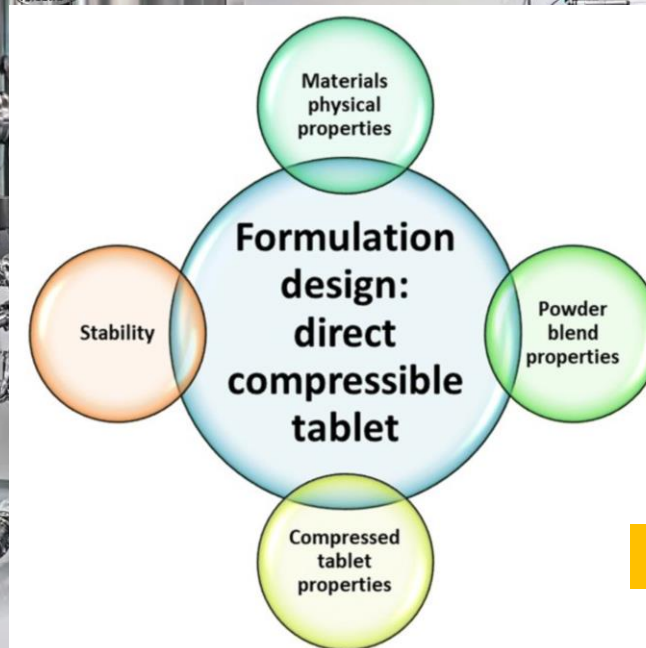
Schedule – Monthly reports, re-inspection 1 year later

Without
Client PMO



OSD

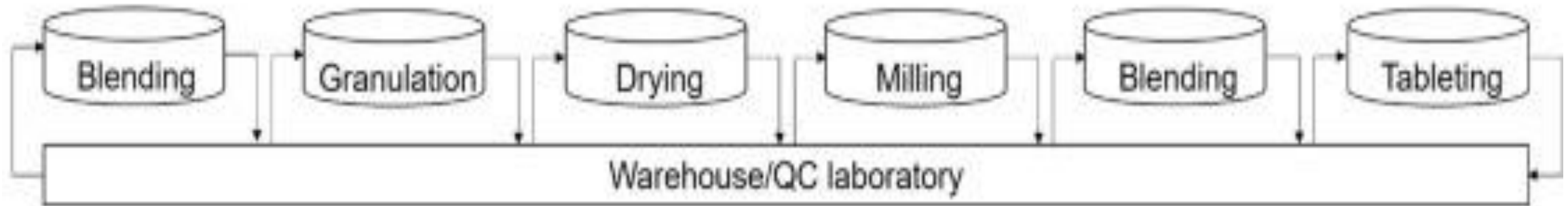




https://www.youtube.com/watch?v=VBqZrnGSB_8

OSD Manufacturing Process Validation

Batch manufacturing



Hold

Hold

Hold

Hold

Hold

Hold

Confirm allowable times between steps, at a pre-established range of conditions, in Actual Containers

Risks Realized

T/H monitor devices mounted, calibrated... then moved.

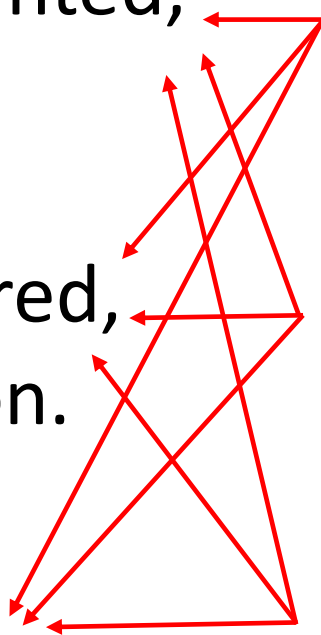
Hold tanks cleaned, secured, set ... then into production.

Raw material containers ordered ... obsoleted by

Communications – information

Culture – norms & habits

Assumptions – unknown



Quality/Efficiency/Production Build-out

Compounded pharmaceuticals 503A/B = small scale production, manual, standard recipes

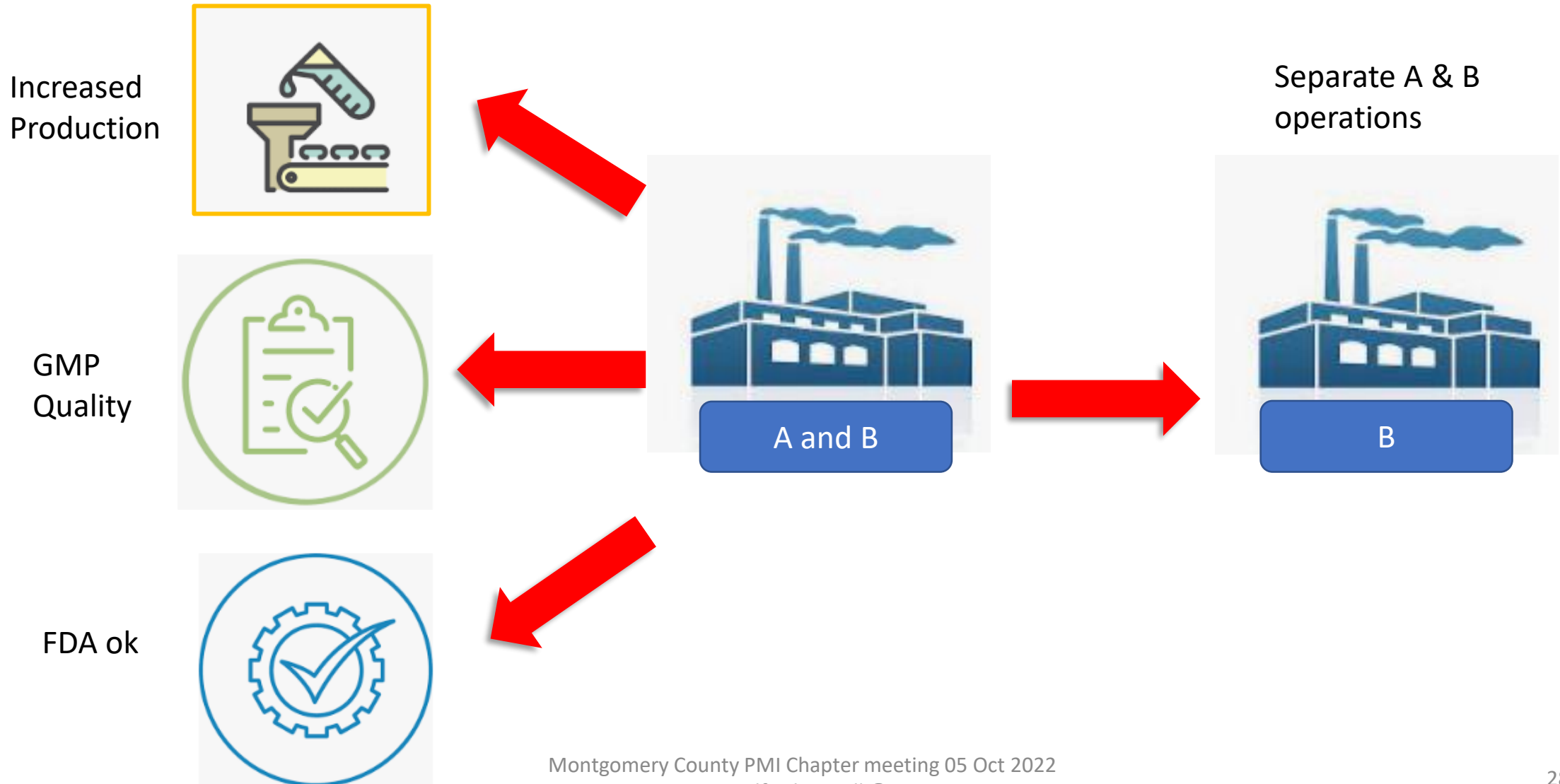
Mission & Objectives – 1. Overhaul site **quality system** to meet new regulations; 2. Build **new plant** to separate A and B side businesses; 3. Increase **production efficiency** and quality.

Situation – Past 483's and warning letter required immediate adaptation to comply with multiple new FDA regulations; **inspection imminent**.

Approach – 1. Review org, docs, staff, **adjust as warranted**; 2. Design, build, **commission second production site**; 3. Study and engineer improved **packaging and production processes**.

Schedule – Annual reports, re-inspection 1 year later

Multiple Interdependent Projects





“Sure, we need more research in alchemy, necromancy, and sorcery, but where is the money going to come from?”



Establish a Shared Vision
with Common Language, then confirm often

Site Quality System Improvement

Biologics = human enzymes recovered from serum, purified, tested, packaged

Mission & Objectives – 1. Review and improve site quality system to meet basic GMPs; 2. Prepare for pending inspection.

Situation – Past 483's and warning letters required strategic overhaul to modernize quality system for current regulatory requirements.

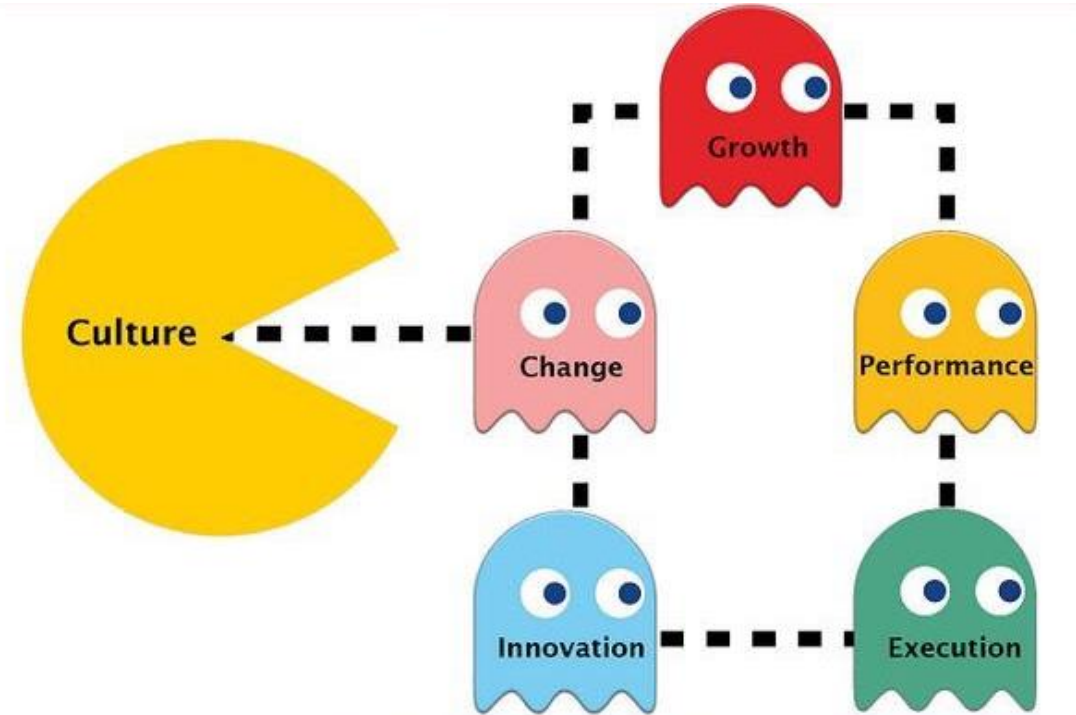
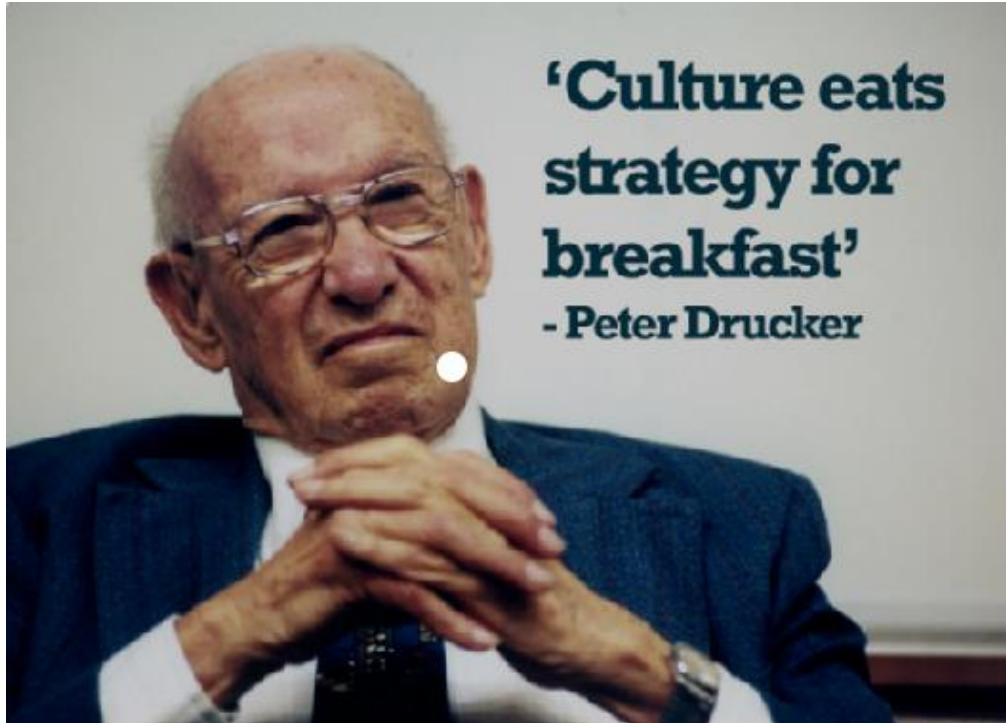
Approach – 1a. Gap analysis; 1b. Design and implement improvements in one product area; 1c. Extend to subsequent products; 3. Train staff and guide with mock inspections.

Schedule – Weekly, Monthly & Final/Close-out reports, re-inspection pending

Conflicting Stakeholder Norms & Goals



Culture, Values & Beliefs Rule



What's the fix for Company Culture?



Solutions

Communications – Ensure information is understood in both directions and distributed to all relevant stakeholders
[Communications Management Plan, Stakeholder Management plan]



Assumptions – Continuously research & confirm expectations;
Trust & verify [Requirements Document, Risk Management Plan]

Culture – Discover, understand and adapt to company norms & power structure to nurture agents of change.

Some Helpful Tips & Tools

Develop, Monitor and UPDATE Plans for Stakeholders, Risks, Communications

- Communications Plan
 - Active conduit
 - Touch Point Mtgs
 - Stakeholder Register
 - Be inclusive
 - Engender Trust
 - What & Why
- Risk Plan - Assumptions List
 - Internal and External
- Change Agents
 - Champions

'Project Method'



- ✓ People Power Projects
- ✓ Requirements
- ✓ Organize
- ✓ Jell
- ✓ Execute
- ✓ Control
- ✓ Transfer



Ray Fronhoefer, "Accidental Project Manager Zero to Hero" 2021



Final Thoughts



Focus on people in all stages and every moment of the project lifecycle

Remember to include yourself



He who knows all the answers has not been asked all the questions. Confucius, 551 – 479 BCE

And if any man think that he knoweth any thing, he knoweth nothing yet as he ought to know.
Corinthians 18:2, 53–54 CE

Those who cling to perceptions and views wander the world offending people. Buddha, 563 - 483 BCE