We'll begin soon.

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Project Management in The Medical Device Field

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Engineering the extraordinary

06MAY2022
Michael O'Connor

Michael O'Connor

Senior Research Program Director, Program Management, Enabling Technologies

Top 5 strengths

1. Achiever
2. Discipline
3. Context
4. Individualization
5. Learner

PROJECT MANAGEMENT

About

36 Years
Research, Development, Science, Technology, Innovation, Quality, Regulatory, Clinical etc.

32 Years
In Medical Devices

Fun facts

- I have a twin sister
- Music lover – play percussion and learning piano
- First job: Soccer referee
- Down time: Family, reading, gardening landscaping, fitness, soccer

Vision

- Deliver global program management…
  - Successful program teams
  - Successful outcomes
  - Improved patient lives

Core beliefs

"Project Managers are the most creative pros in the world; we have to figure out everything that could go wrong, before it does"

Fredrick Haren

"Life is like riding a bicycle. To keep your balance, you must keep moving"

Albert Einstein

Experience

- Senior Program Director, Program Management, Enabling Technologies
- Director Strategy and Project Management, Corporate Science and Technology
- Senior Program Manager, Corporate Quality and Regulatory
- Senior Manager, Compliance and Audit, Neuromodulation

Education

- Ph.D.: Civil Engineering, University of Maryland, College Park, A. James Clark School of Engineering
- MSc: Technology Management, University of St. Thomas
- MSc: Project Management, University of Wisconsin-Platteville
- MBA: Business Management, University of Phoenix

Lived here

- Twin Cities of Minnesota
  - Global Travel
    - Canada
    - Mexico
    - Europe
    - China
    - India
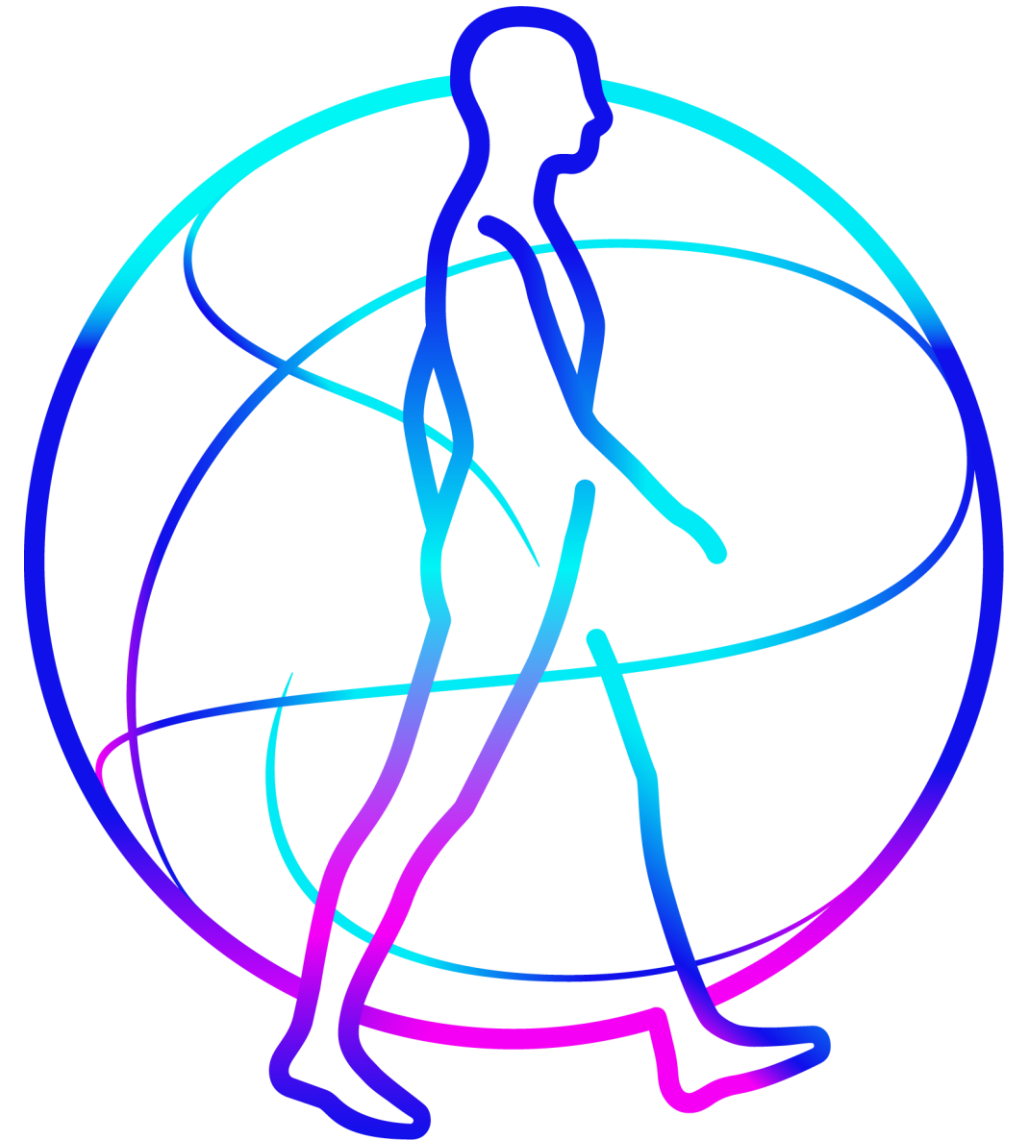   - South America
    - Middle East

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Project Management in The Medical Device Field

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Agenda:

- Medical Device Project Context

- Planning - Scope

- Resources

- Cost

- Schedule

- Stakeholders

- Risk

- Execution

- Project Completion

- Lessons Learned

- Summary

Medical Device Project Context

- What is a Medical Device?
  - They can be as simple as a band-aide or as complex as a pacemaker

- Determine if your product meets the FDA definition

- Determine if your product is a 510(K) or PMA submission

- Are there Similar Products on The Market?

- Does it have Mobile Application or Software?

- Will this be Sold Globally?

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Medical Devices Project Context

Project Management in The Medical Device Field | May 06, 2022
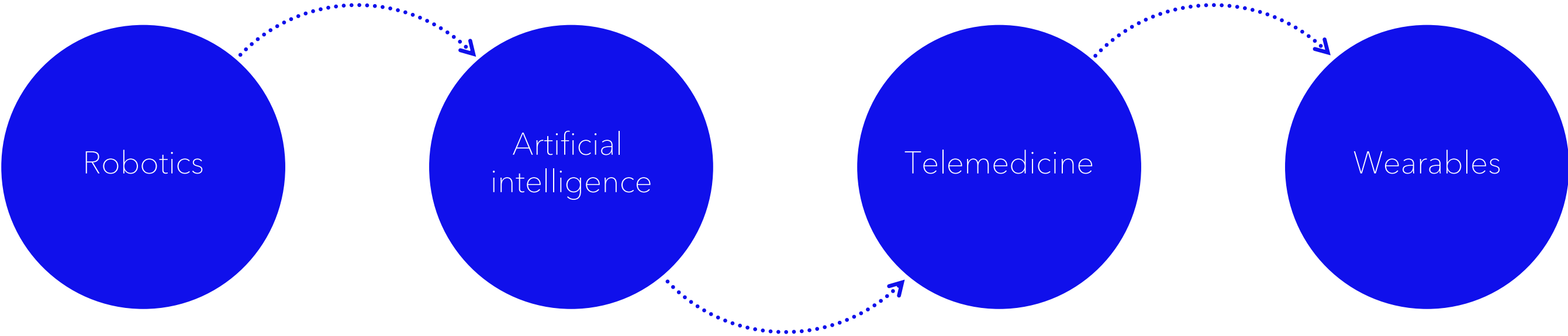
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Planning - Scope

- Planning, Roadmap for Success
  - Most Important Step
  - Cross Functional Team
  - Requirements and Voice of the Customer (VOC)
  - Phase Approach
  - Major Tasks in Each Phase
  - Sub Tasks in Each Phase
  - Cross Functional Team

- Scope
  - Defining What You are Going To Do
  - Defining What You Will Not Do
    - Features
    - Manufacturing
    - Sales
    - Market
    - Regulatory
    - Technology
    - Suppliers
    - Etc.

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Medical Device Marketing Trends

Robotics → Artificial intelligence → Telemedicine → Wearables

Project Management in The Medical Device Field | May 06, 2022
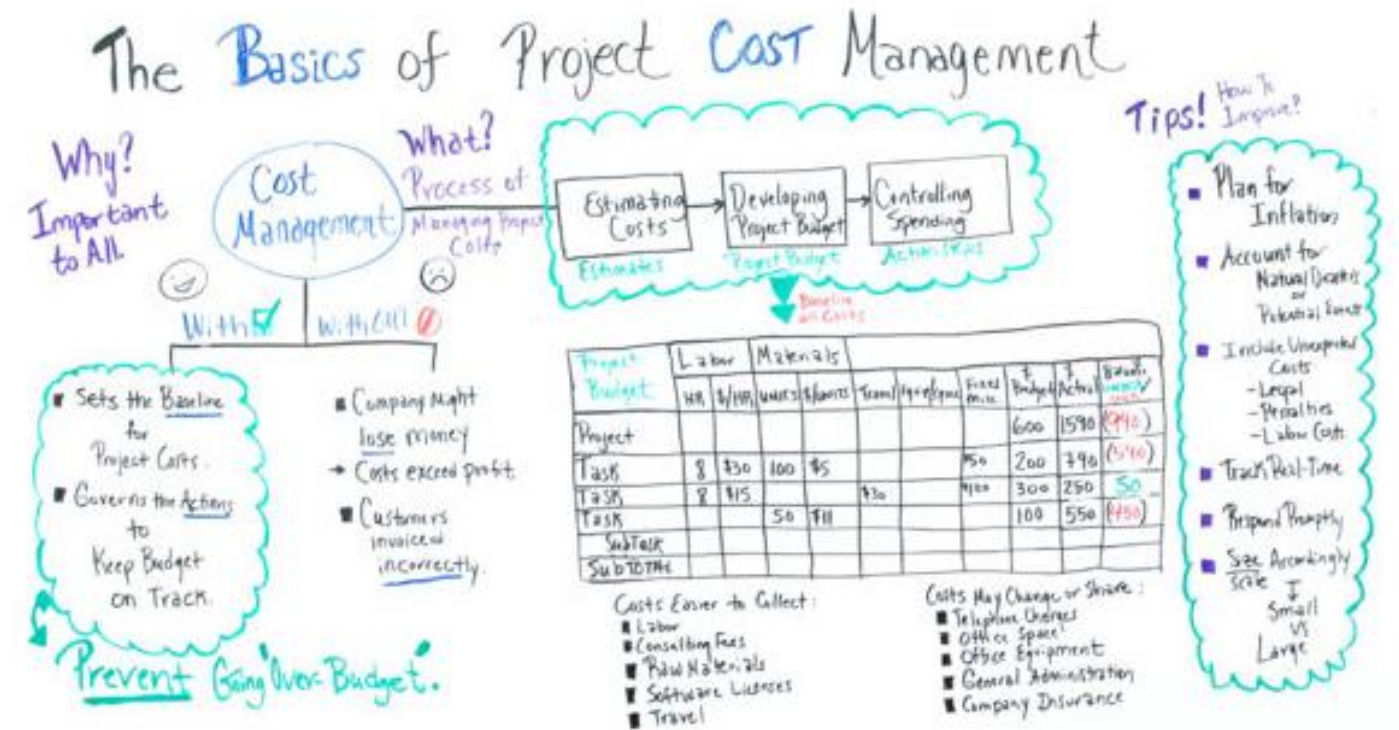
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Resources

- Resources
  - How Do You Get the Right People on Your Project
    - Expertise
    - Background
    - Experiences
    - Knowledge
    - Face to Face and Virtual
    - Office Setting or Co-Located Space
    - Training
    - Networking
    - Finance or Software System
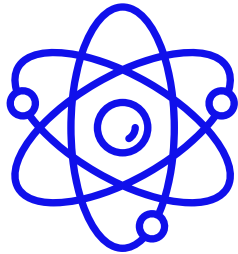   - Contractors vs. FTE

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Cost

- Cost
  - Can be Very Difficult to Estimate a New Device or Technology
  - Typically, this is a Weekly or Bi-Weekly Call with Finance Partner
  - Build in Some Back Up Cost for Risks and Unknowns
  - Typically, a Rolling Forecast
  - Regulatory Cost, Example EUMDR
  - Global Markets and Cost of Business
  - Sustainability, Packaging, Sterilization
  - Testing, Possible New Tests
  - Professional Consultants
  - Failure
  - Clinical Trials
  - Legal
  - Innovation, Skunk Works

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Medical Devices by The Numbers

16.5M

Project Managers Globally

100K+

Medical Device Manufacturing
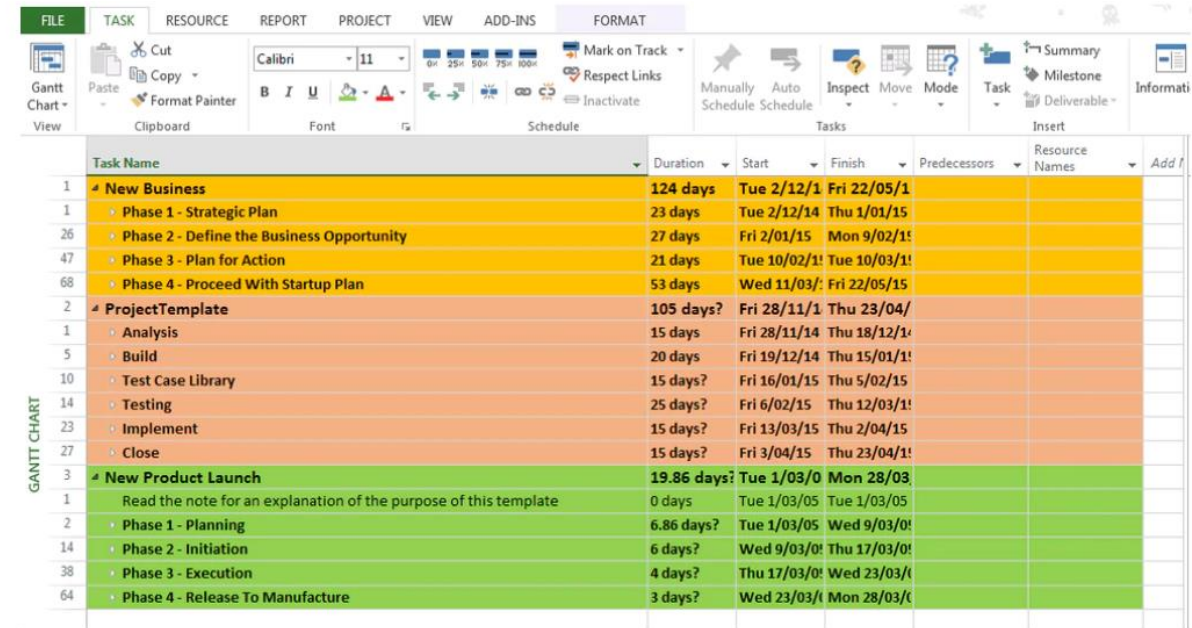Employees in USA

2M

Different Types of Medical Devices
Globally

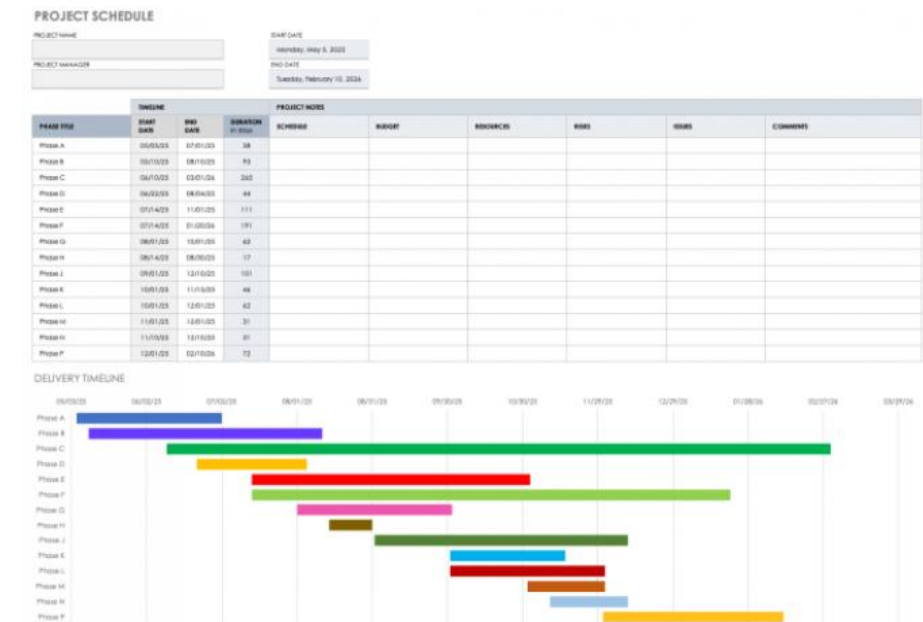Medtronic

Schedule

- Schedule
  - Part of the Output of Planning
  - Technology, Software
    - MS Project
    - Anaplan
    - Planisware
    - Planview
    - Smartsheet
  - The Team Needs to be Comfortable With The Technology
  - All Team Members Have Access
  - Need to Have the Ability to Take a Snapshot and Easily Place into A PPT
  - Reviewed at Each Team Meeting

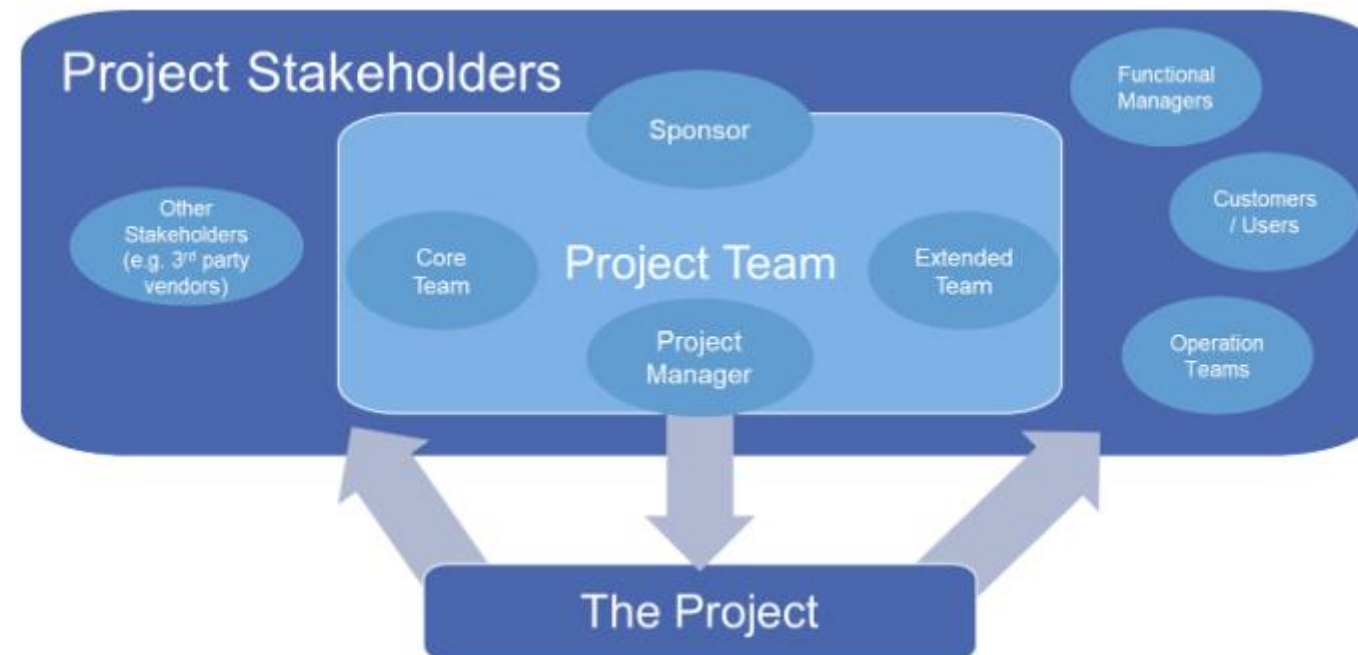MS Project Master Schedule

Project Schedule Template

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Stakeholders

- Stakeholders
  - PMI Defines Project Stake Holders As *"Individuals and organizations who are actively involved in the project, or whose interests may be positively or negatively affected as a result of project execution or successful completion"*
  - Need to Identify Stakeholders
  - Develop a Communication Plan with Each Stakeholder
  - This Can Be One of The Most Difficult Parts of A Project
  - When There are Risks or Issues, Working With a Known Stakeholder is a Much Smoother Process
  - Networking
  - Stakeholder Plan
  - Status Reports

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Risk

- Risk
  - Identify Risks Early and Visit Them Often
  - Analyze Potential Impact
  - Assign Priority
  - Mitigate Risks
  - Monitor Risks
  - Important Area of Medical Devices
    - Reliability
    - No Harm to The Patient, Operators or Environment
  - Risk Burn Down
  - Failure Mode and Effects Analysis
  - Software

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"BEING A PROJECT MANAGER IS LIKE BEING AN ARTIST, YOU HAVE THE DIFFERENT COLORED PROCESS STREAMS COMBINING INTO A WORK OF ART."

GREG CIMMARRUSTI

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Execution

- Execution
  - *Project Execution is The Stage of The Project Where Everything Your Team has Planned is Put Into Action*
  - Carry Out The Details of Your Project Plan
    - Schedule
    - Cost
    - Resources
    - Communication
    - Risk
    - Change Mangem4ent
    - Quality
    - Etc.
  - Update as Needed
  - Deliver Products or Services to Your Customers
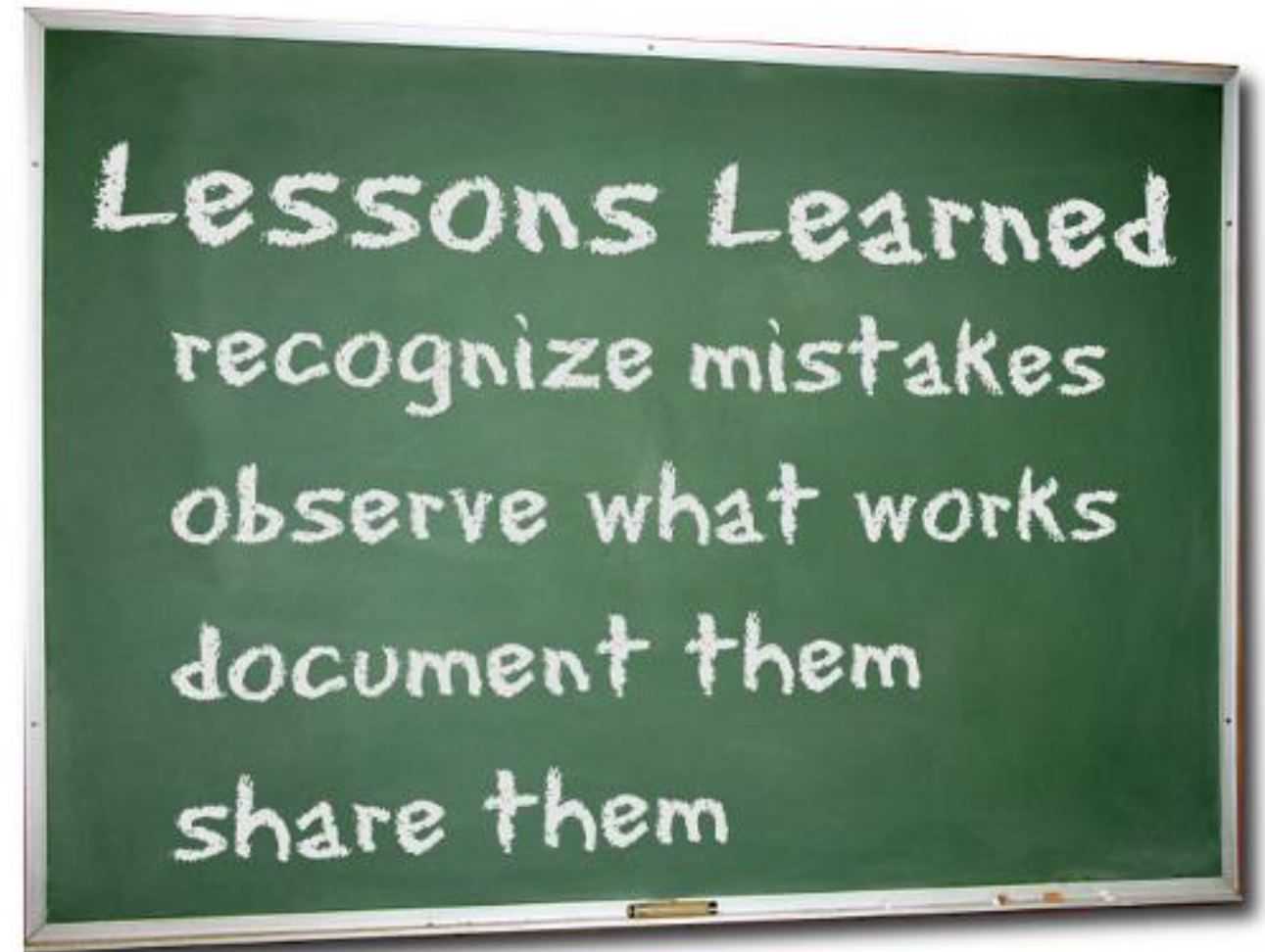
Power Skills

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Project Completion

- Project Completion
  - Successful Achievement of the Project Goal
  - Documentation Archived
  - Outcomes and Results
  - Resources, Next Positions
  - Reflection
  - Add or Document to Yor Resume/CV
  - Survey?
  - Celebrate

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Lessons Learned

- Lessons Learned
  - Document Both Positive and Negative Experiences
  - Lesson Learned Template
  - Analyze
  - Archive
  - Easy Retrieval
  - Present to Stakeholders, Brief Overview
  - Set Up for Easy Reading and for Future Products

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"Project Management Principles Must be Applied in Planning and Executing Successful Medical Device Development Projects." (David Kolesar, MDDI)

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Summary

- Summary
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  - Planning - Scope
  - Resources
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  - Schedule
  - Stakeholders
  - Risk
  - Execution
  - Project Completion
  - Lessons Learned
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Thank You

Contact

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Q&A

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