Managing Multiple Partners in Product Development

Strategies for Success

June 10th, 2025

greenlight guru

HaA PD
MEDICAL DEVICE DEVELOPMENT

nqa
ISO 13485
MEDICAL DEVICES

About HaA Product Development

HaA PD is a full-service ISO-13485 certified, USA focused, international, strategic medical device development partner for hundreds of Class I, II, and III medical devices.

For over 25 years, our organization has partnered with medical device companies of all sizes to bring their vision from concept to commercialization, while reducing cost and time to market.

Services:

- Market Research
- Regulatory Strategy & Compliance
- Human Factors/Usability
- UX & UI Design
- Industrial Design
- Prototyping
- Engineering
- Quality Assurance
- Manufacturing Optimization

What You Will Learn

By the end of this session, participants will be able to:

- **Identify strategies to establish an efficient and effective project team** that aligns with and supports overall project goals.
- **Adopt a success-oriented mindset** at project initiation to optimize outcomes and drive progress.
- **Implement methods to ensure alignment within the project team** to promote cohesive efforts and goal achievement.
- **Develop effective communication practices** within the team to enhance collaboration and maximize productivity.

Common Problems

Responsibility Overlap

"Next-Phase" Thinking

Team Misalignment

Inefficient Communication and Organization

Problem # 1:
Responsibilit
y Overlap

"I know there is strength in the differences between us. I know there is comfort where we overlap."

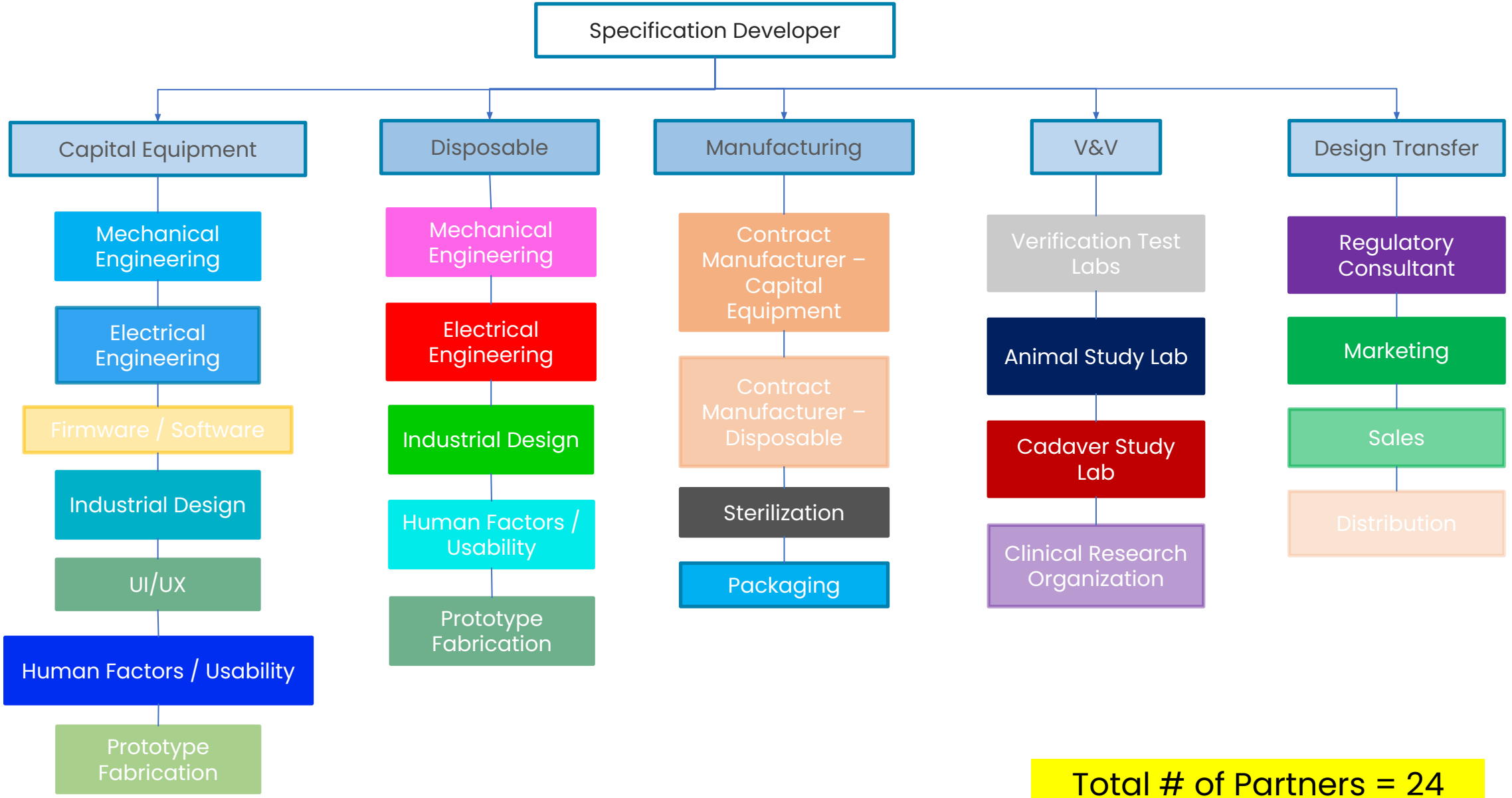
- Ani DiFranco

Balance the comfort and strength

The Complexities of Medical Device Development

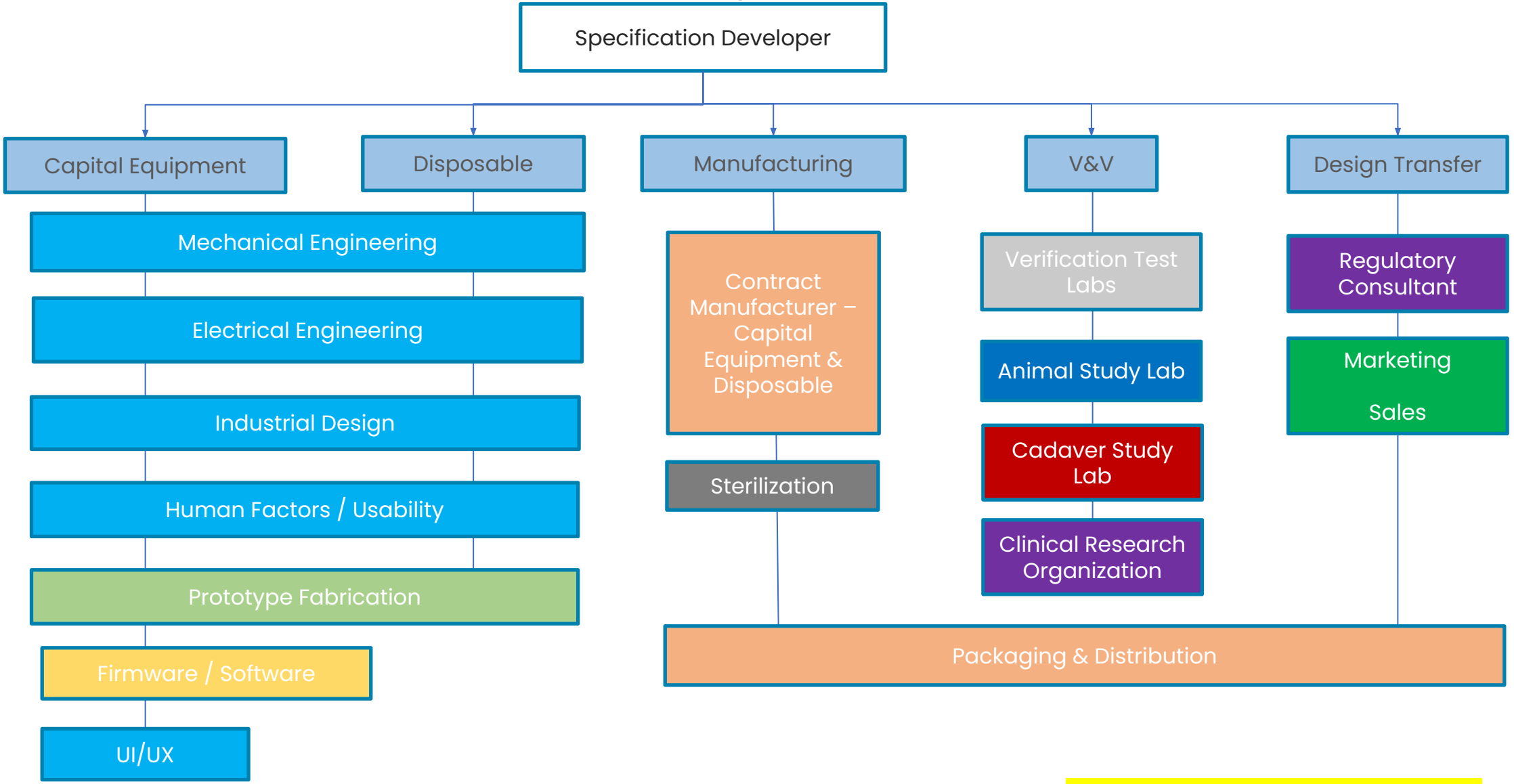
- A complex process with multiple key constituents required for success
- Highly regulated industry that requires expertise in more than just product development (IP, Regulatory, Clinical, etc)

Typical Project Partners Example - Electromechanical Device with Software and Disposable Handpiece



Total # of Partners = 24

Streamlined **Project Partners Example –** Electromechanical Device with software and disposable handpiece



Total # of Partners = 10

Considerations for Streamlining Partners

Advantages

- ✔ Less management stress
- ✔ More cost & time effective
- ✔ Fewer handoffs
- ✔ Less overhead

Watchouts

- ✔ Less specialized expertise
- ✔ Fewer checks and balances
- ✔ More copy-paste mentality/technical debt

Recommendation: Reduce partners to avoid overlap, but add oversight and overlapping skills for core technology areas.

HaA Partner Map Tool: Capabilities of Potential Partners

HaA **Partner Map Template**

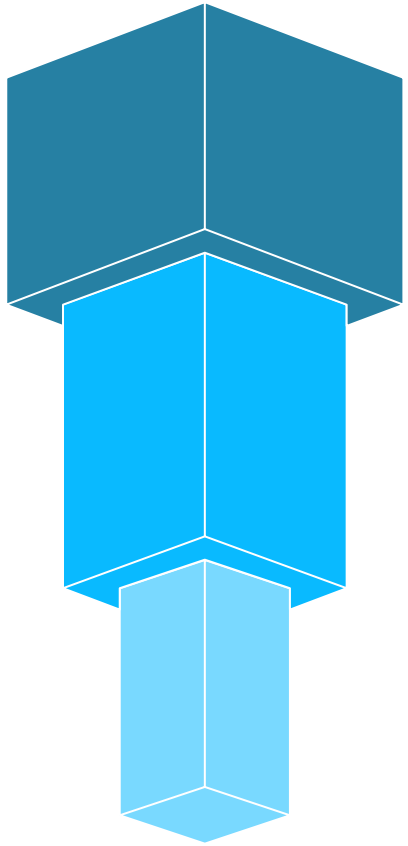
Categories	Sub-Categories	Capabilities	In-house	Potential Partners						
				Partner A	Partner B	Partner C	Partner D	Partner E	Partner F	Partner G
Mechanical Engineering	3D Printing	Stereolithography (SLA)		X	X					
		Selective Laser Sintering (SLS)		X	X					
		Direct Metal Laser Sintering (DMLS)		X	X		X			
		Multi Jet Fusion (MFJ)		X			X			
		Fused Deposition Modeling (FDM)								
		Carbon Digital Light Synthesis (DLS)			X					
		Micro 3D Printing			X					
		Continuous Fiber Fabrication (CFF)								
		Laser Powder Bed Fusion (LPBF)								
		PolyJet			X					
	Product Design	Thermal Analysis	X				X			
		Tolerance Analysis	X				X			
		Strucutral Analysis	X				X			
		Material Selection	X	X						

Compare capabilities and if you have a lot of capability overlap, then you can reduce the number of partners you use

Understanding Partner Personas

	Planners	Reactors	Perfectionists
Project Approach	Selects partners early	Reacts to needs in the moment	Design freeze before engaging partners
Decision Making	Unifies teams, quality-based decisions	Time & money based decisions	Analysis paralysis due to information
Decision Makers	Designated decision maker	Power of One	Board of decision makers
Project Efficiency	Parallel effort, most efficient	Jugglers	Linear effort, least efficient

Typical Design Outcomes Based on Persona



Perfectionists

Every feature imaginable
Fragile design
Not repeatable for manufacturing

Reactors

Add features based on the "Power of One"
Lose stability

Planners

Minimal set of features
Robust
Repeatable

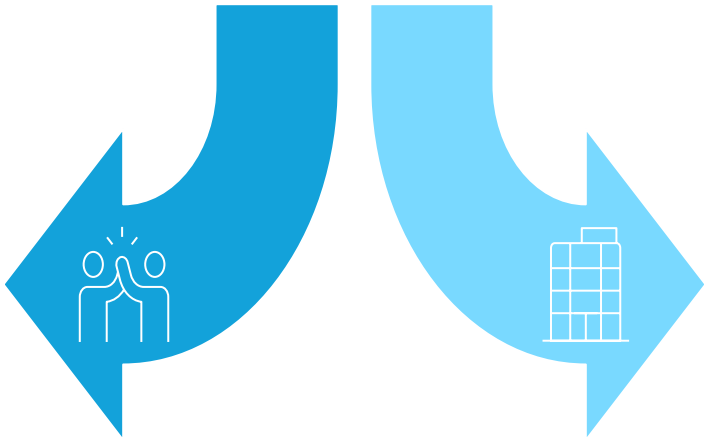
Partner selection tips

- **Second-sourcing** – find alternative, back-up suppliers who can assist help shorten lead times or increase capacity
- **Engage material suppliers / distributers –** leverage partners recommended by material manufacturers
- **Build relationships –** Meet suppliers before you need them. Keep a list of possible suppliers

Which Partner Size To Target?

Small Company

- Quicker communications
- Partner loyalty
- Production scale-up risk
- Expertise may reside in one or two individuals



Large Company

- More overhead
- Slow to ramp up
- More expertise in-house
- More robust quality system

Questions to ask your partners

Topic	Questions to Ask	Where to Document
IP	Who owns IP related to the product? Who owns IP related to the processes? Do you use any patented processes? Are any of your processes trade secrets? Are there any licensing fees for any processes?	Manufacturing Agreement
Quality	Is sub-supplier information shared? What documentation is provided with parts? Example CofC? What kind of QMS do you have? How are approvals done?	Quality Agreement
Operations	What are your typical lead times? Overall time & cost to get product to production? What operations are outsourced? How does your project queue work? Any way to expedite? What quantity ranges are you best setup for? Where are raw materials sourced from? Do resources stay on a project until completion?	SOW, Supplier qualifications
Communications	How do you like to communicate (email, phone, Zoom, etc)? What is the best frequency for communications? How and where to document communications?	Project plan
Technical	What are the core technical skills? Do technical skills reside in one or two individuals? Can you expand your capabilities in the future?	SOW, Supplier qualifications

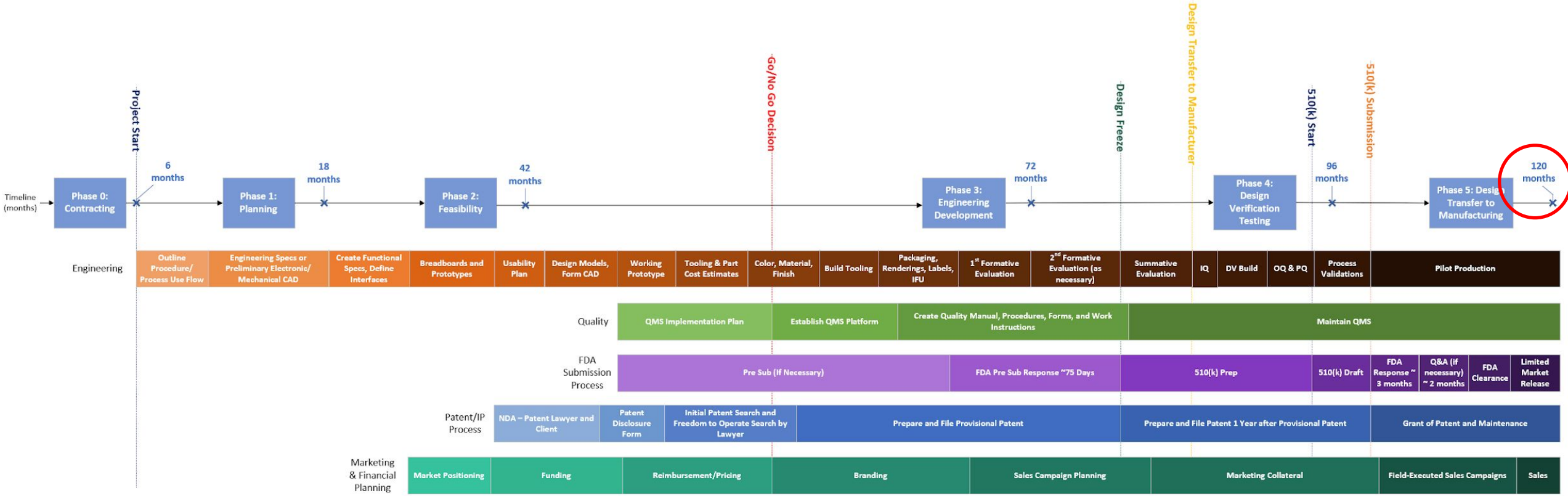
Problem # 2:
”Next-Phase ” Thinking

"Reality is made up of circles but we see straight lines."

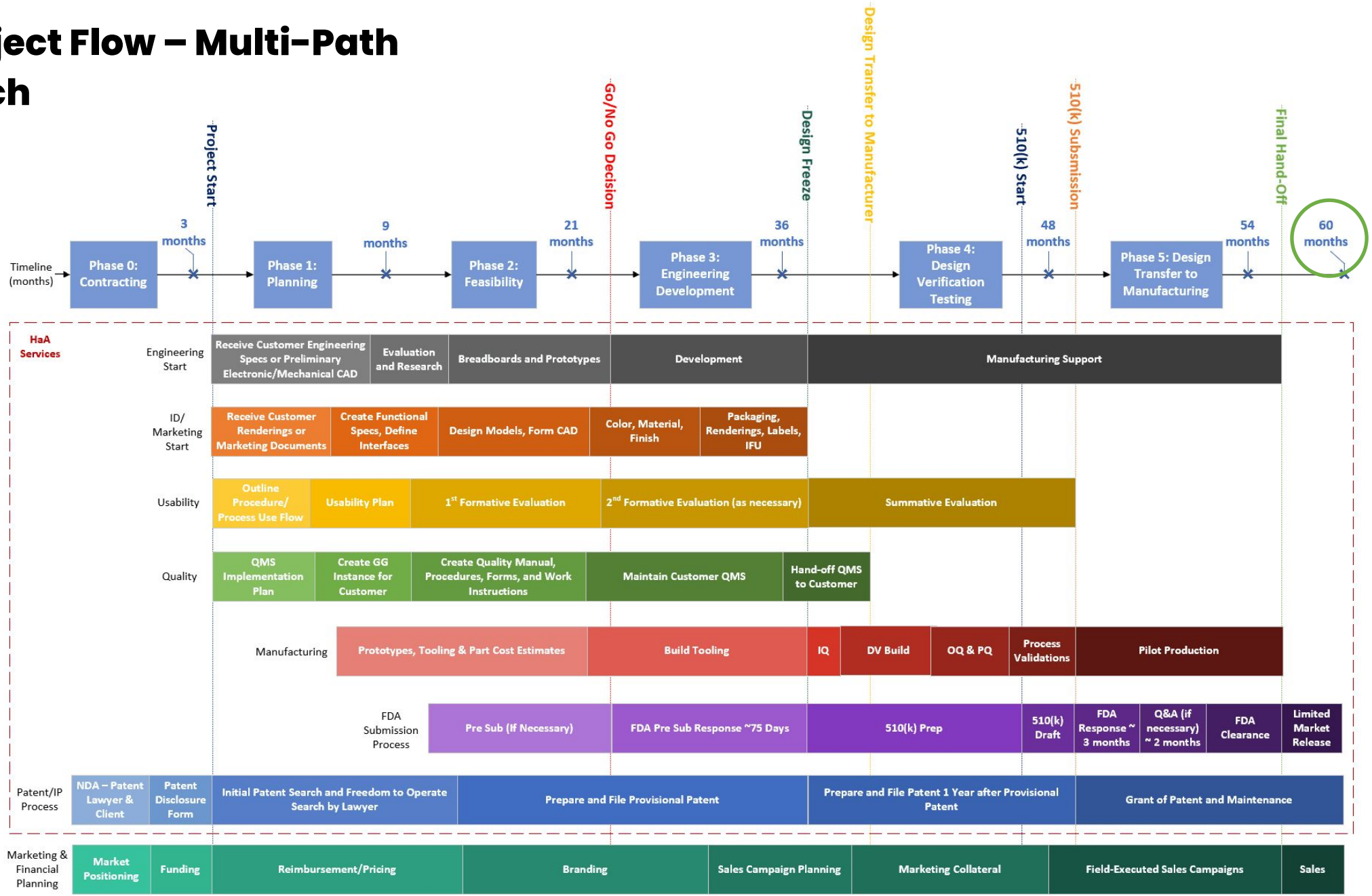
- Peter Senge

Pay attention to how things interact

Typical Project Flow – "Next-Phase" Thinking



HaA Project Flow – Multi-Path Approach



Tips for Successful Multi-Path Project Management

At start of project

- Define user needs
- Plan testing
- Establish user group
- Consider all perspectives

Throughout project

- Design – Prototype – Test
- Risk management
- Continuous update of documentation
- Regulatory engagement

Problem # 3:
Team Misalignment

"If everyone is moving forward together, then success takes care of itself."

- Henry Ford

Good alignment equals good outcomes

Why Defining Partner Scope Upfront is Critical to Success

Setting clear requirements for your partners at the start of a project:

Forces you to think about the project long-term rather than one phase at a time

Avoids Project Start-Stop Cycles

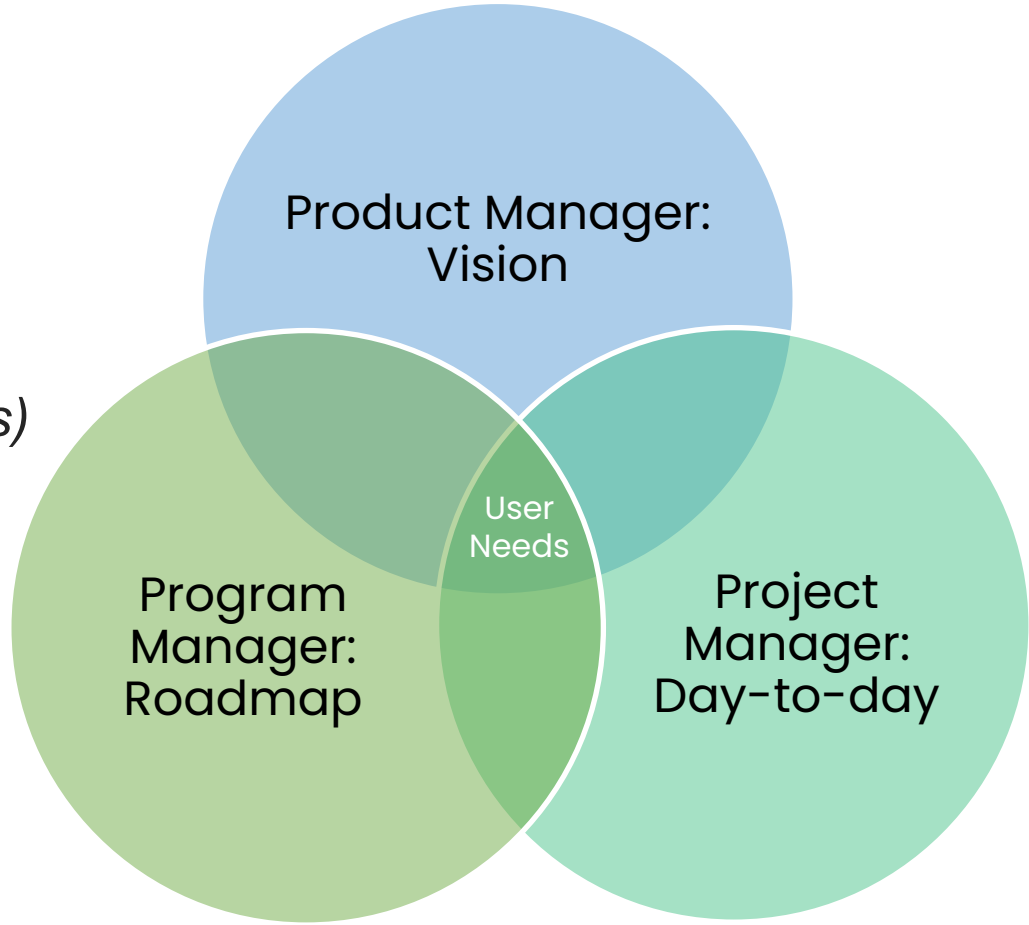
Reveals Costly Out-of-Scope Work

The Different Types of Managers in Product Development

Product Manager = manages scope of a product *(Marketing role)*

Program Manager = manages strategy of a product portfolio *(Responsible to manage priorities)*

Project Manager = manages individual project (TYPICALLY LEADS TEAM: *Responsible to manage partners & budget*)



Alignment of Teams for Successful Projects

1. **Alignment Exercise**
   Make sure everyone is heard

2. **Active Listening**
   Listen to all partners throughout the project

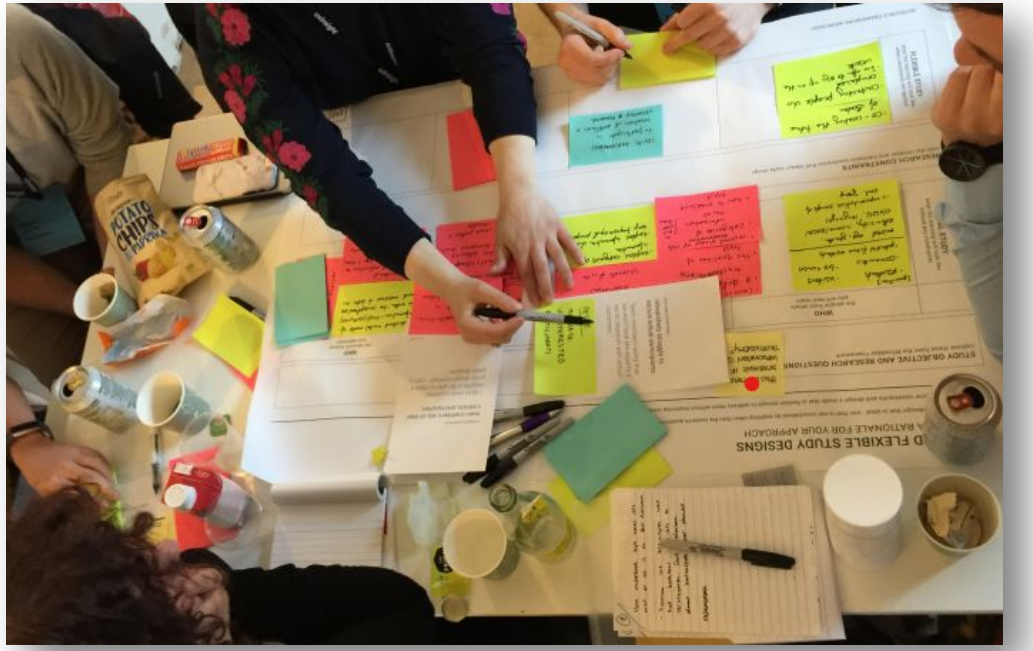
3. **Celebrate Small Wins**
   Acknowledge minor achievements to boost morale

4. **Maintain Motivation**
   Keep the team engaged and focused on goals

5. **Achieve Project Success**
   Reach the goal with a strong team effort.

Team Alignment Exercise

- The goal is to reveal questions at the beginning of the project and the process by which answers can be obtained.
- The outcome is to get everyone's questions out in the open and determine a plan to answer them.
- Assumptions are challenged and sources of information are revealed along with the team's confidence level in their sources.



Create Your Quality Agreement at Project Start

Section 1: Scope
- Agreement between which partners?

Section 2: Purpose
- Which regulations are being followed? GMP?

Section 3: Project Description
- Overview of the partner roles

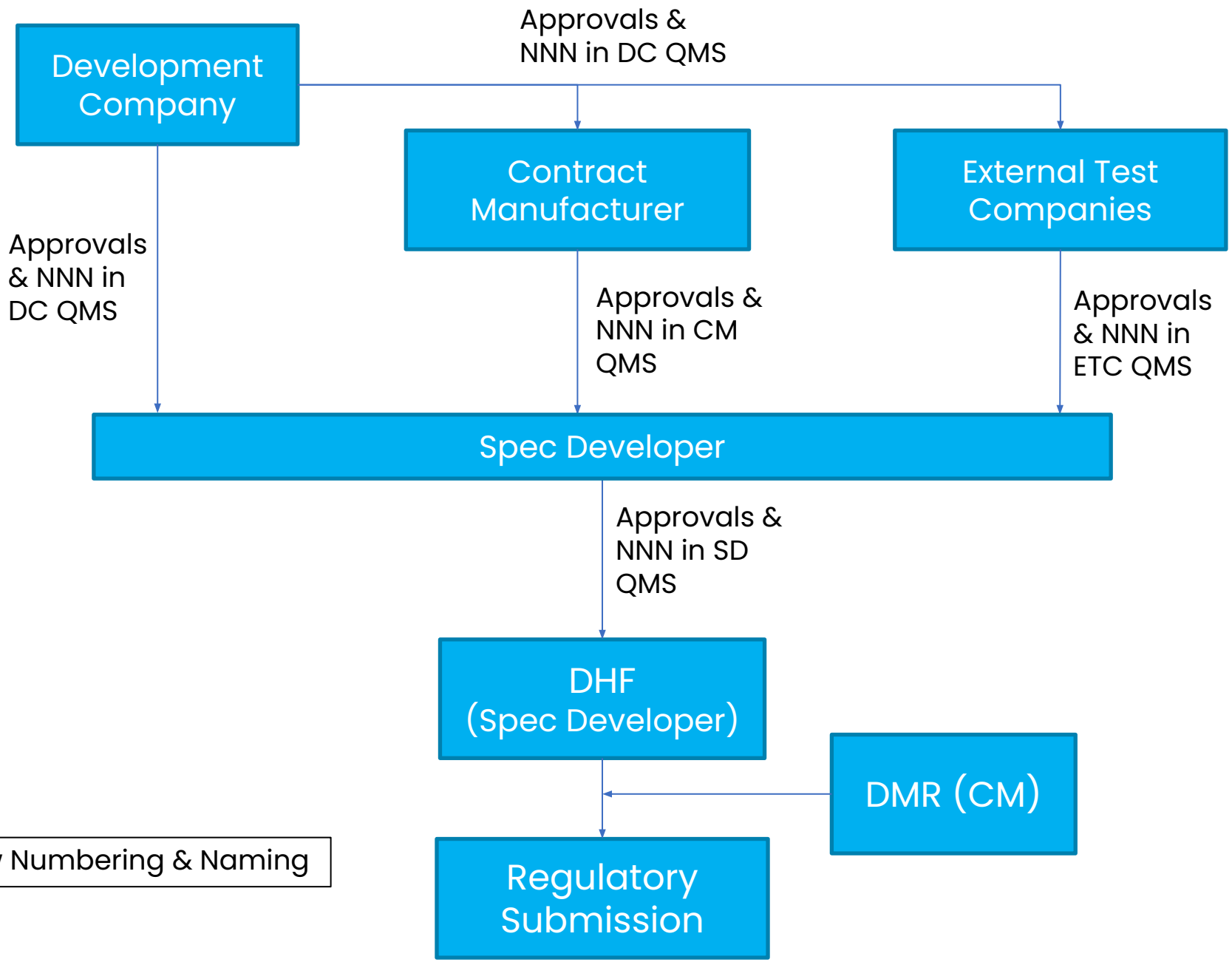
Section 4: Quality System
- Project will follow which quality system(s)?
- Who owns the DHF?
- Whose design controls and risk controls?
- Who will be conducting supplier audits?
- Whose part numbers will be followed?
- Paper-based or electronic QMS?

Section 5: Modifications
- Change management, approvals

Section 6: Responsibilities
- Table laying out responsibilities per regulatory requirements ↓

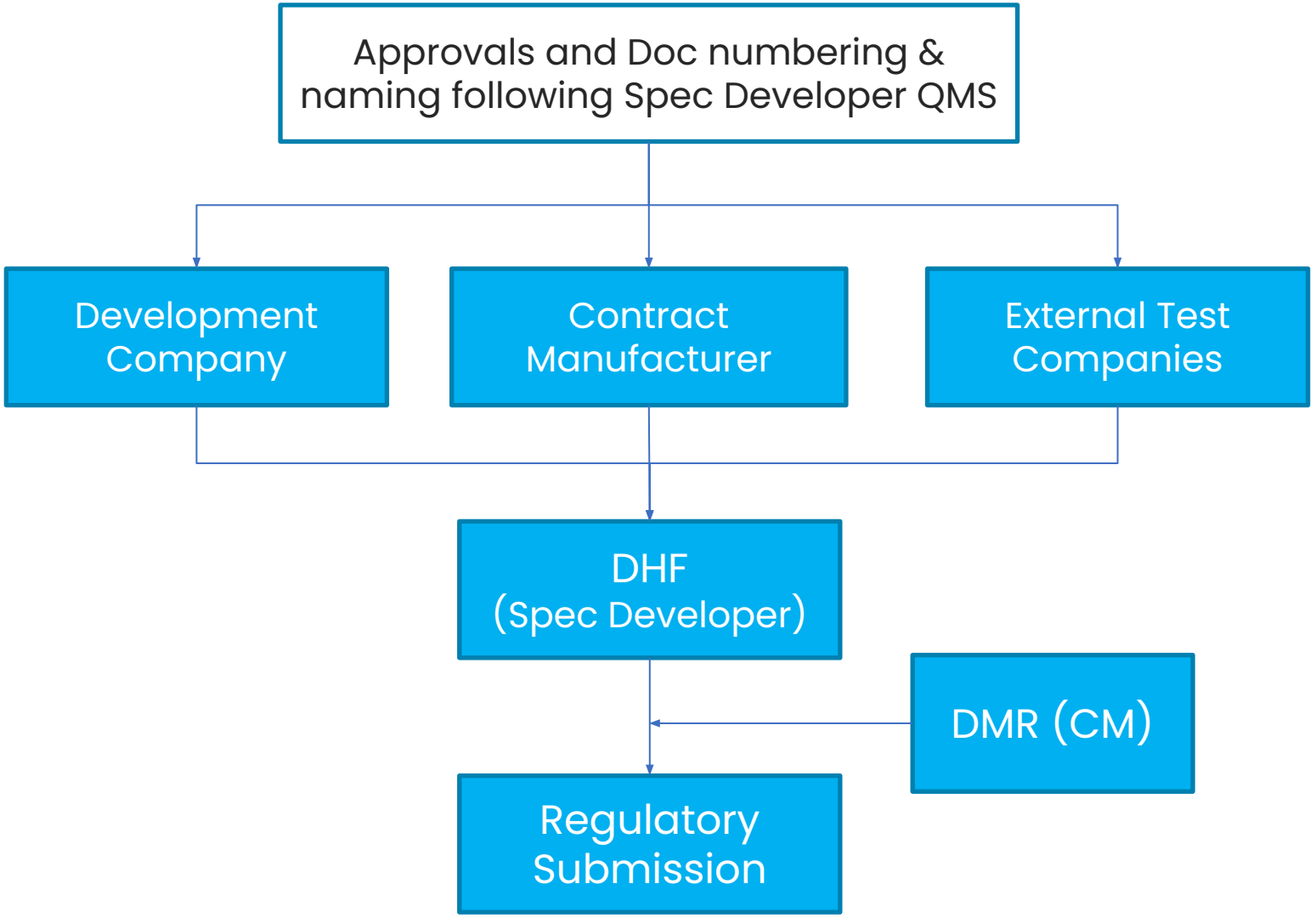
Requirements per 21 CFR Part 820	Responsible Partner	Comments
820.5	All Partners	e.g. procedure reference
820.20 (a)	Partner A	
820.20 (b)	Partner A	
…		

Typical Partner Deliverables Flowchart – *No Up-Front Planning*

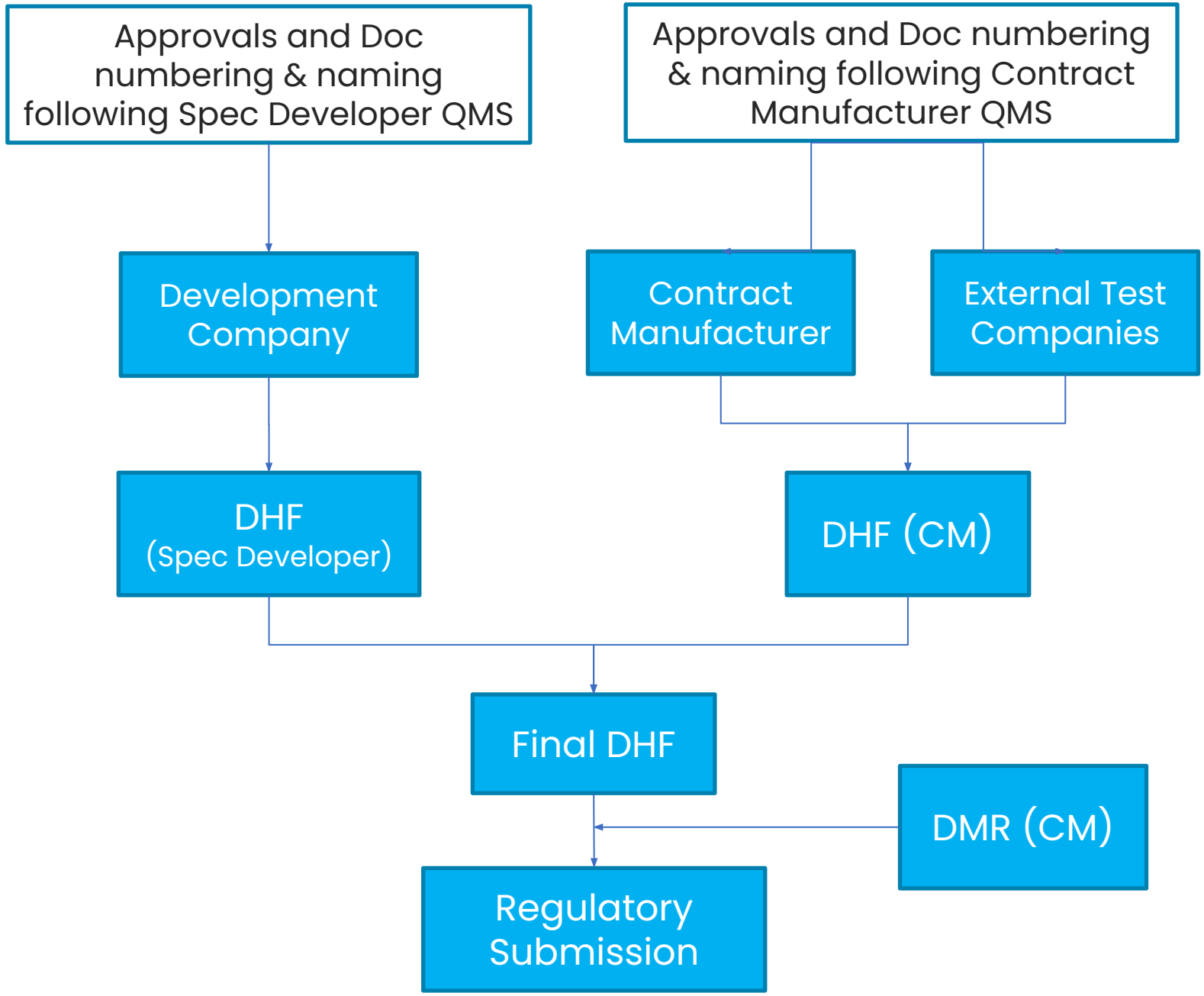


NNN = New Numbering & Naming

Simplified Partner Deliverables Flowchart – *Large Company*

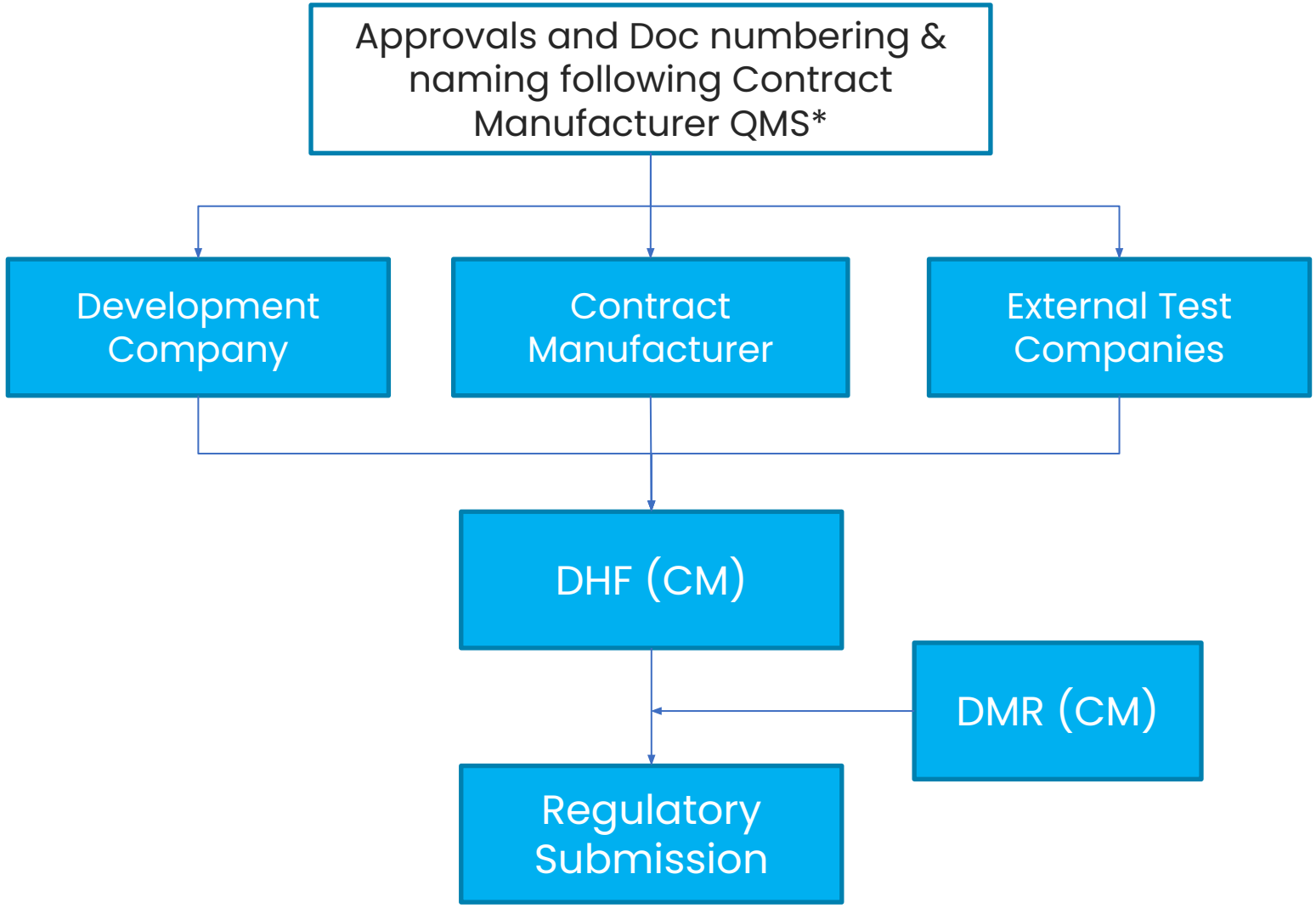


Simplified Partner Deliverables Flowchart – *Mid-Sized Company*



Simplified Partner Deliverables Flowchart – *Startup Company*

* Note: This typically requires a large-sized CM company



Problem # 4:
Inefficient Communication & Organization

"Everyone has a plan until they get punched in the face"

- Mike Tyson

When plans change, communication is crucial

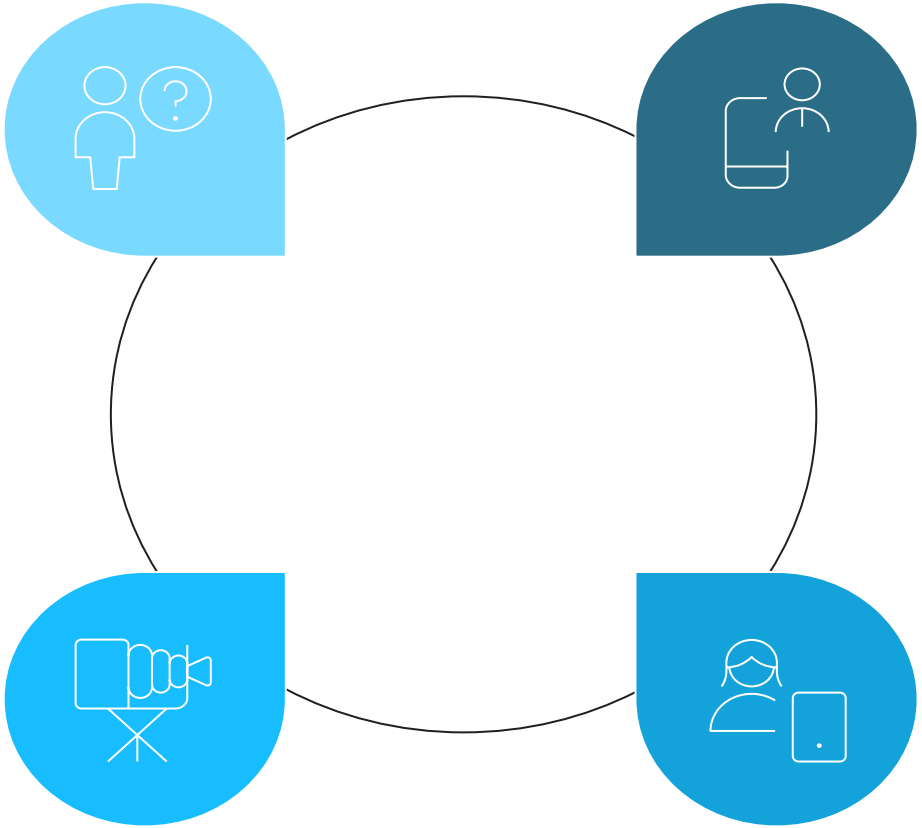
Strategies for Effective Partner Communication

User Needs

Reminding partners of user requirements and training on procedure

Single Point of Contact

Establishing a primary contact for efficient decision-making



Visual Aids

Enhancing understanding through videos and images

Backup Contacts

Ensuring communication continuity with secondary contacts

Project Scheduling Strategies

Break Down Schedules

Divide large schedules into smaller mini-projects

Define Deliverables

Set specific deliverables for each mini-project

Layout Project

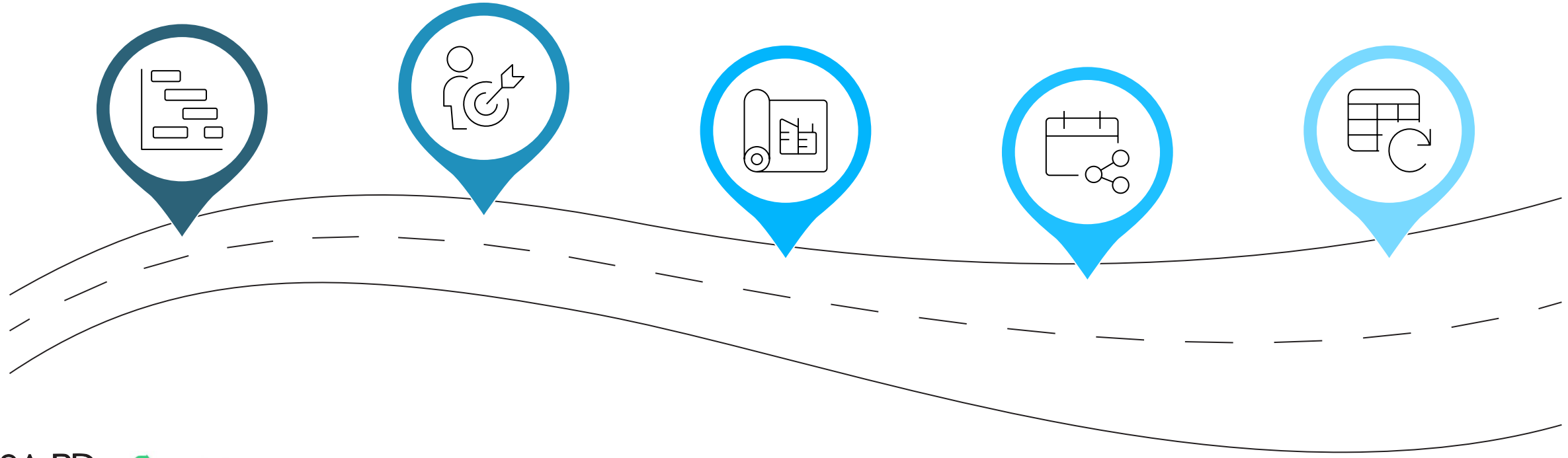
Create a detailed project layout with diminishing detail

Share

Make the schedule accessible online for stakeholders

Update

Regularly update the schedule to reflect progress



Managing Deliverable Approvals and Transfers Between Quality Systems

The time it takes to close out each project phase can be significantly reduced if you establish:

- **Who** requires review/approval for each deliverable
- **How** deliverables from partners will be shared

How to Expedite Partner Approvals

Approving partners need to be able to:

- approve Change Orders as a reviewer
- complete assigned trainings
- view shared documents

Note: Ensure approving personnel has proper understanding of what they're approving

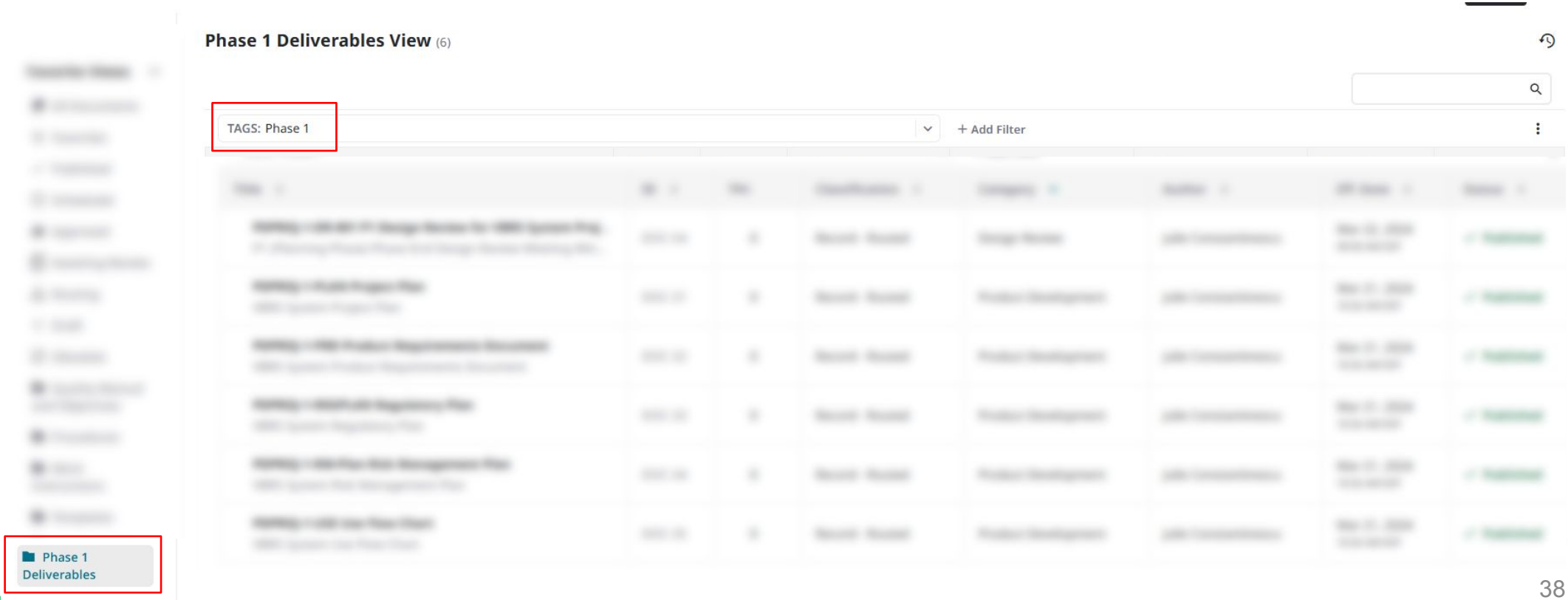
In GG, invite any external partner that requires approval on documents with "**Lite**" user access and "**External**" User Type

	Name	Email	Status	Job Title	Roles	User Type	User Access
☐	Gary Gagnon	gary@ggproductsllc.com	Active			External	Lite
☐	Kevin Stack	kjs2787@gmail.com	Active		Executive Management	External	Lite

Organizing Project Folders

- Decide on central storage location for partner deliverables (e.g. SharePoint)
- Establish project folder structure at the start
- Ensure up-front visibility, access, and understanding by everyone

- In GG, Utilize **Tags** and **Shared Folder Views** to organize deliverables by Phase

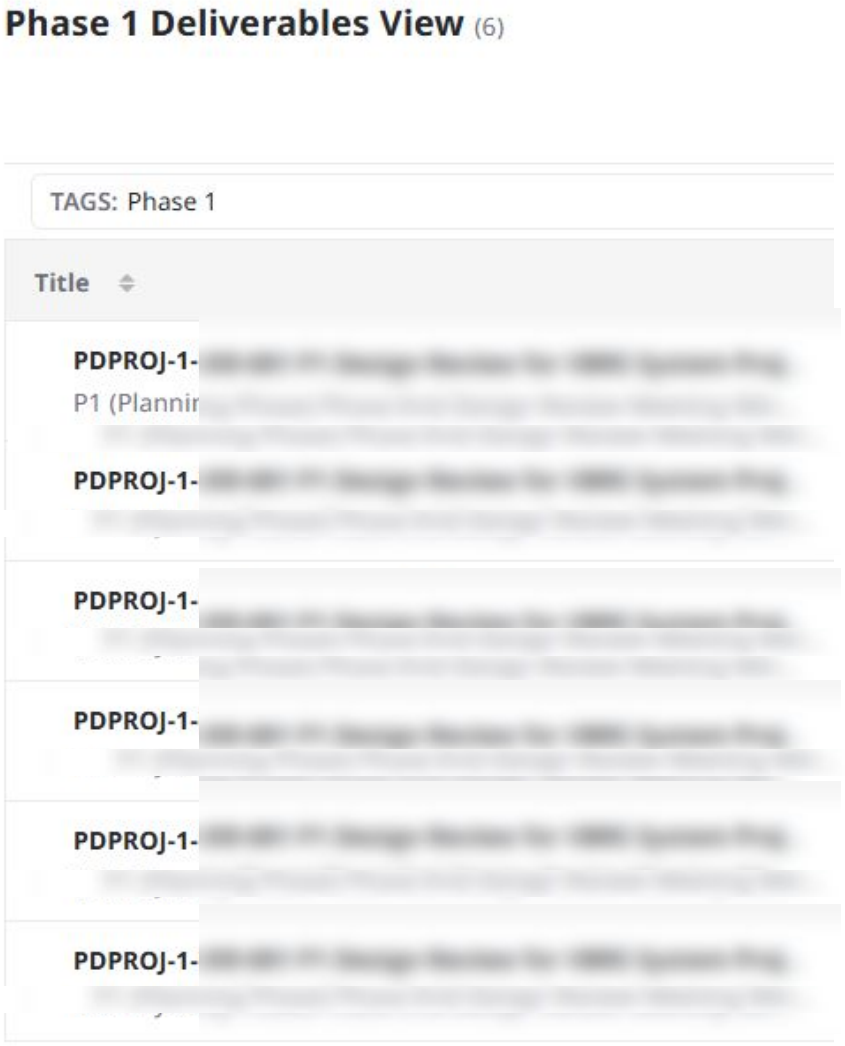


Consistent Numbering & Naming Conventions

- Agree on naming convention for deliverables at the start and stick with it throughout the project
- **Especially important for CAD part and drawing names / numbers**

Examples:
- PDPROJ-X-01 Quality Agreement
- DHF-X-01 Quality Agreement

- Assign deliverable ID numbers at the start of project & ensure understanding by all partners



Deliverables Tracker: Keep Partners Aligned and Aware

Example 1: Project following spec developer QMS

DHF	PDPROJ-1							
Phase	Planning							
Doc #	Deliverable	Document Creator	Current Rev	Document Editor(s)	Document Reviewer(s)	Deliverable Status	Document Location	Comments
1	Quality Agreement	Partner A	0	Partners B, D	All Partners	In Progress	SharePoint > Phase 1 > Working Folder	
2	Project Plan	Partner A	0	Partners B, D	All Partners	In Progress	SharePoint > Phase 1 > Working Folder	
3	Regulatory Plan	Partner A	0	Partners B, D	Partners B, D, E	In Progress	SharePoint > Phase 1 > Working Folder	Has predicate been finalized?
4	Risk Management Plan	Partner A	0	Partners B, D	Partners B, D, E	Not Started	SharePoint > Phase 1 > Working Folder	
5	User Needs Document	Partner B	1	Partner A, C, D, E	All Partners	Ready for Review	SharePoint > Phase 1 > Working Folder	Review UNs #4-7 in particular
6	Initial Product Requirements	Partner B	0	Partner A, C, D, E	All Partners	In Progress	SharePoint > Phase 1 > Working Folder	
7	Phase End Review Report	Partner A	0	None	All Partners	Not Started	SharePoint > Phase 1 > Working Folder	

This tracker should be populated with deliverables and responsibilities at the start of the project!

- Reduced burden on project manager
- Unique document IDs shared with team
- Track approvals

<u>Final Deliverable Identifiers:</u>
Quality Agreement = PDPROJ-1-01
Project Plan = PDPROJ-1-02
…

Tailoring Deliverable Trackers to fit Project Types

Example 2: Project following *both* spec developer QMS and contract manufacturer QMS
--> Tailor tracker by adding a column to distinguish deliverables by DHF

DHF	PDPROJ-1 (Spec Developer) or DHF-4 (CM)								
Phase	Launch Phase								
DHF	Doc #	Deliverable	Document Creator	Current Rev	Document Editor(s)	Document Reviewer(s)	Deliverable Status	Document Location	Comments
DHF-4	31	Process Validation Report	Partner E	1	Partners A, D	Partners A, C, D	Ready for Edits	SharePoint > Phase 5 > Working Folder	Draft of Rev 1 complete
DHF-4	32	Final DMR	Partner E	0	Partners A, B, D	All Partners	In Progress	SharePoint > Phase 5 > Working Folder	
PDPROJ-1	33	Production & Post-Production Risk Management Plan	Partner A	0	Partner B, C	Partners B, C, E	In Progress	SharePoint > Phase 5 > Working Folder	
PDPROJ-1	34	Risk Management Report	Partner A	0	Partner B, C	Partners B, C, E	In Progress	SharePoint > Phase 5 > Working Folder	
PDPROJ-1	35	Phase End Review Report	Partner A	0	None	All Partners	Not Started	SharePoint > Phase 5 > Working Folder	

<u>Final Deliverable Identifiers:</u>
Process Validation Report = DHF-4-31
Production & Post-Production Risk-Management Plan = PDPROJ-1-33
…

Prototype Tracker: Plan and Manage Prototype Fabrication

DHF	PDPROJ-1										
Last Updated	05/09/25										
								Describe prototype or breadboard			
Activity	Date Needed	Activity Responsibility	Prototype Fabricator(s)	Sterilization Required?	Packaging Required?	Functionality Required?	Quantity	Drawing #	Rev #	Description	Comments
Feasibility Testing	07/10/25	Partner A	Partners D & F (packaging)	No	No	Yes	2	DRW-001	0	Breadboard needed for preliminary industrial design considerations	
Formative Usability Study	09/12/25	Partner C	Partners D & F (packaging)	No	No	Yes	15	DRW-005	2	Working prototoype for formal formative	
Bench Testing	10/24/25	Partner A	Partner D	No	No	Yes	10	DRW-006	1	Force and performance testing	
Pilot Animal Study	01/05/26	Partner E	Partner D	No	No	Yes	10	DRW-012	5		
Design Freeze											
Biocompatibility											
Cadaver study											
Summative Usability Study											
DV build 1											
DV build 2											
Animal Study											
Summative Usability Study											
Clinical Study											
Marketing Samples											
Molding Process Dev											
Molding OQ											
Molding PQ											
Assembly PD											
Test Method Validations											
Total							37				

This tracker should be populated with activities and responsibilities at the start of the project!

- Enables traceability
- Alignment of multiple manufacturers
- Reduce waste
- Helps plan testing

Decision Log: Track & Evaluate Decision Impact on Partners

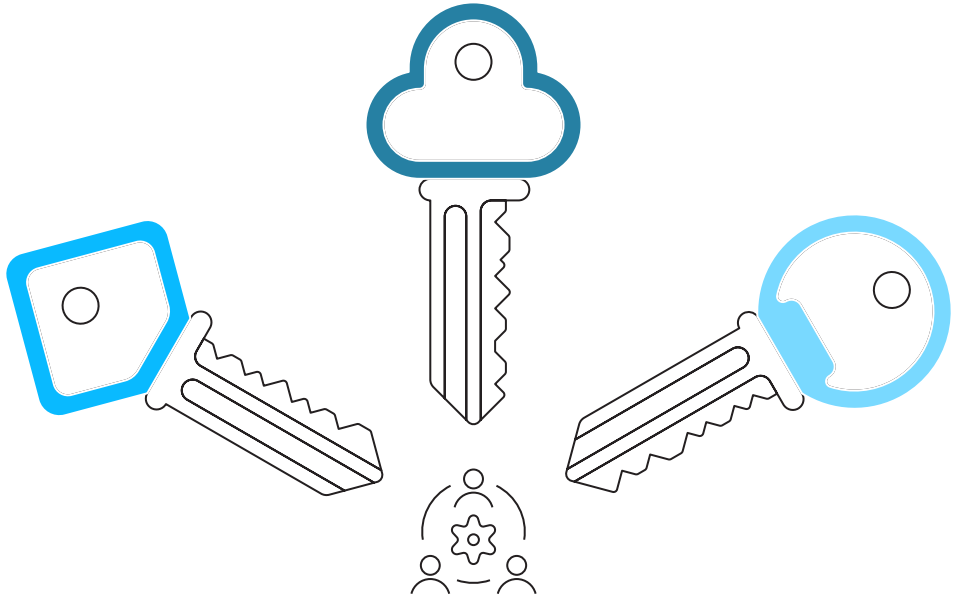
DHF	PDPROJ-1									
Phase	Planning									
Date	Request Description	Requesting Partner	Source	Category	Project Manager Decision	Impact Partner A	Impact Partner B	Impact Partner C	Status	Additional Comments/Notes
5/5/2025	Add material information to drawing	Partner B	Meeting	Engineering	Partner A to complete request	Edit drawing	Update part number	None	Implemented	
5/15/2025	New PCB does not fit into existing housing. Modify housing to make fit.	Partner C	Meeting	Engineering	Partner A to complete request	Redesign housing	Update test fixtures	None	In Process	Additional product feature caused board size to increase. Looked into other options but nothing else would satify requirements.
6/3/2025	Re-do handle design as a result of formative testing	Partner C	Meeting	Usability	Partner A to complete request	Redesign handle	Update test fixtures	Plan next formative with updated handle	In Process	Users felt "awkward" handling the deployment mechanism

- Assess the impact of decisions
- Cross-partner visibility
- Reduce delays and backtracking

Keys to Successful Project Collaboration

Partner Selection

Leverage your existing network and ovoid overlap.
Ask relevant questions.



Planning

Early establishment of partner scope and responsibilities.
Tackle activities in parallel.

Communication

Establish a single point of contact and log progress.
Ensure cross-partner visibility throughout the project.

Partner Management

Recap – Solutions to Common Problems

Responsibility Overlap

- Streamline partners where possible
- Ask strategic questions

"Next-Phase" Thinking

- Tackle activities in parallel
- Select partners early
- QMS Flexibility

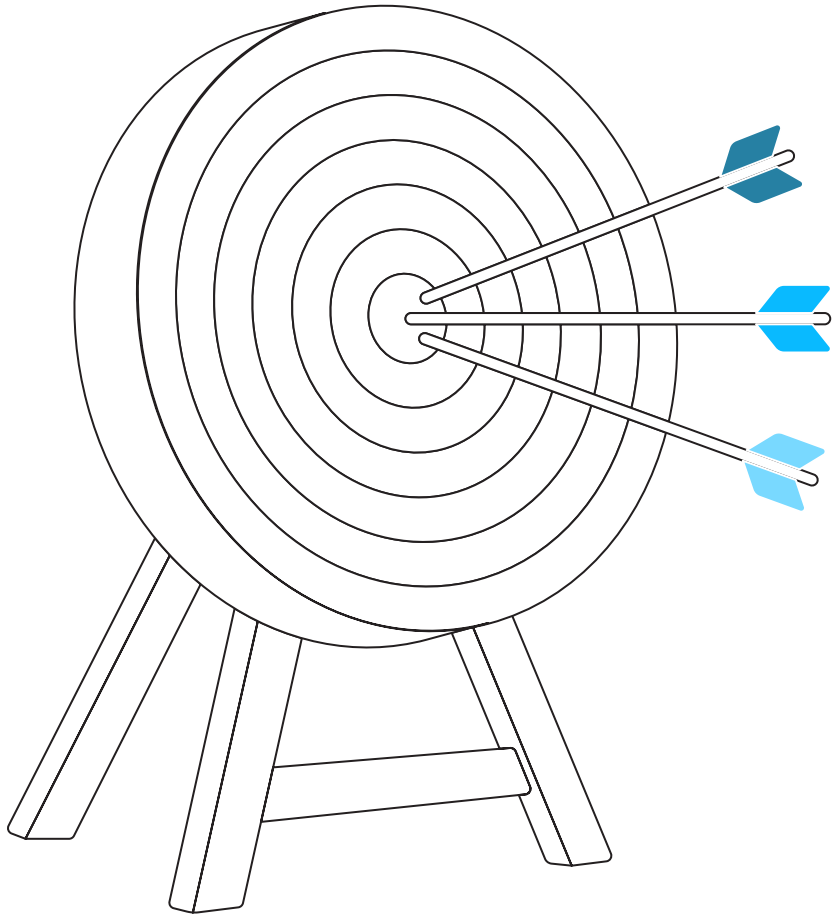
Team Misalignment

- Establish partner scope and points of contact early
- Define decision making roles
- Outline deliverable flowcharts
- Team alignment exercise

Inefficient Communication & Organization

- Central and accessible location for deliverables
- Plan partner approvals ahead of time
- Log deliverable progress & decision making

Your Next Steps



Team Alignment

Verify that your team is aligned and everyone understands the user needs

Set up trackers

Monitor progress and decisions

Create a partner map

Visualizes partner capabilities to help streamline number of partners

Thank You!

Questions?

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