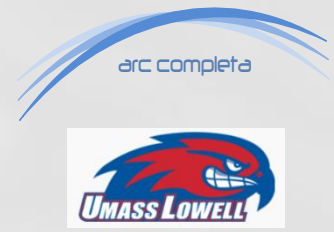


Enlightened Bites Entrepreneurship Series

Moving from Tactical to Strategic Planning

Prepared by:
Gary J. Ainsworth
Principal Consultant
Arc Completa, Inc.

A Conundrum...

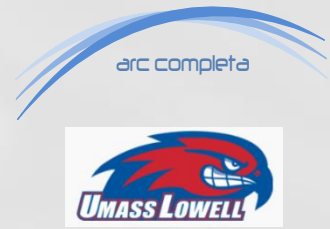


**“While Product Development
needs unencumbered freedom to
realize its most creative work,**

**Operations needs a controlled
process to realize its most
creative work”**

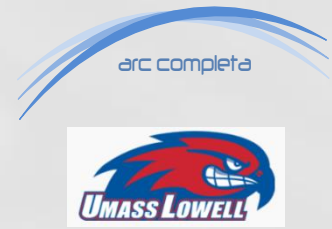
Gary J. Ainsworth

Why do we offer this information



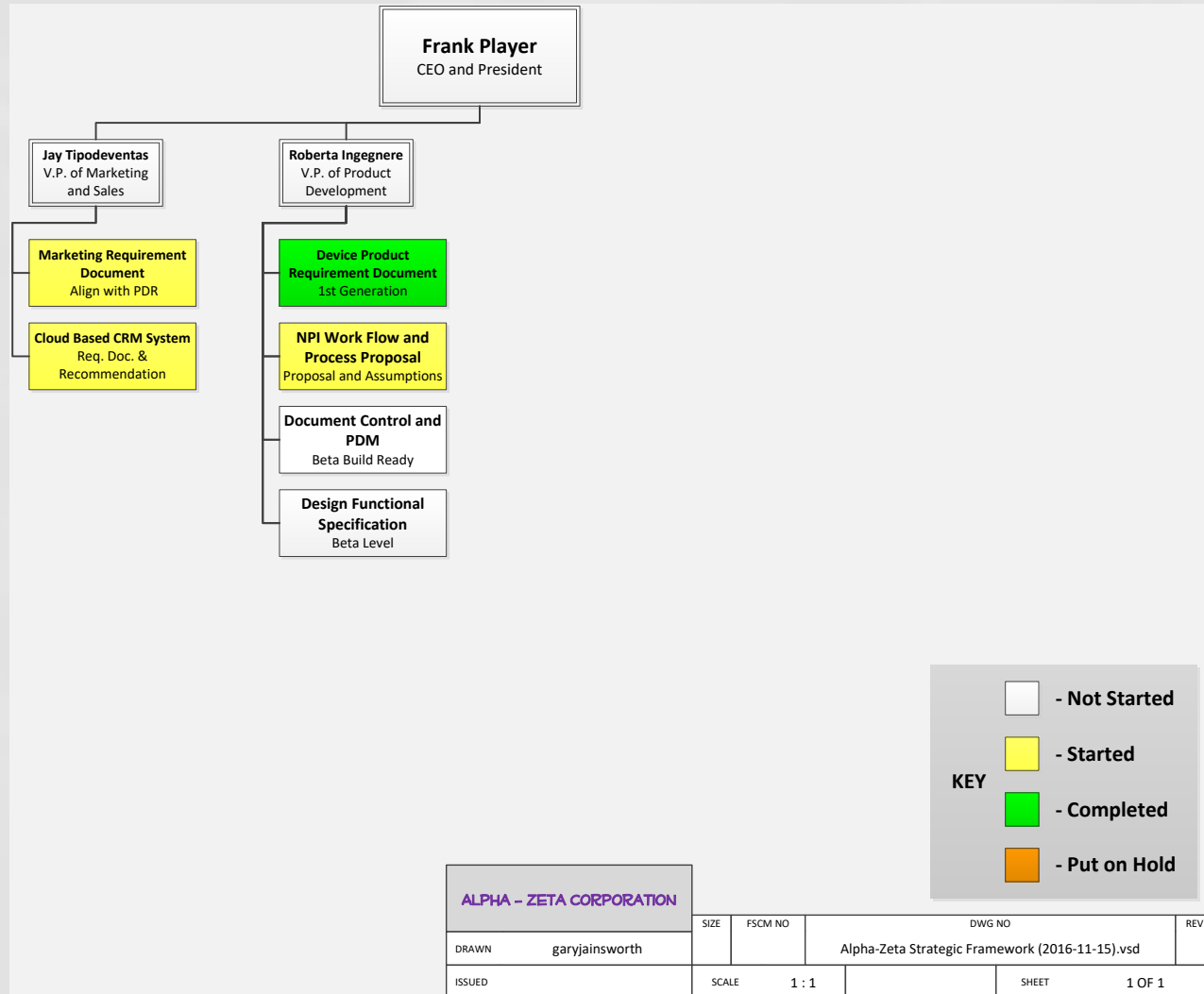
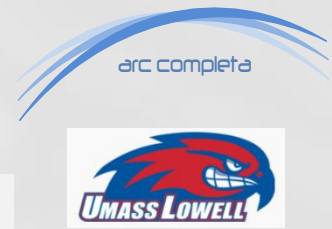
- Because of the Start-Up Challenge
 - The clock is ticking – Start-ups are in a constant non-profitable cash burn scenario
 - No precedence in knowing what might be important or what has the highest risk
 - Literature Search and Basic Research are the norms
 - Low or No Production Volumes to gain understanding of critical requirements
 - Every Build Counts to create collective knowledge base, but infrastructure is often absent and unable collect critical knowledge
 - Simultaneous Knowledge Accumulation in product and process development, test, and manufacturing
 - Inexperienced management team, needing to focus limited resources with strong personalities
 - Poor community habits, including inconsistent communication of direction and priority
 - Great innovators are not necessarily great organizers and managers
 - Investors need concise, quantitative messaging on results and committed work against milestones

Previous Session



- Identify and Capture Validated Work
- Use 3 Lists and 3 Loops to organize and drive completion of validated work
- Consider Work as **Tasks** versus **Projects** versus **Initiatives**
 - **Tasks**
 - Longer than couple of days, but small in scope, risk, or impact, but that is still important
 - **Projects**
 - Outward Looking Work that requires planning, resources, and coordination that a customer values
 - **Initiatives**
 - Inward Looking Work that requires planning, resources, and coordination that improves how the business performs
- Understand the nature of validated work and how they follow basic rules by your ability to complete the work with what resources:
 - Daily Lists
 - Tactical Lists
 - Strategic Lists and Frameworks

Functional Strategic Framework

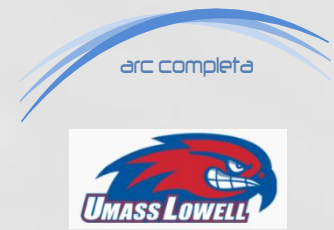


Typical Department Task-Project-Initiative List



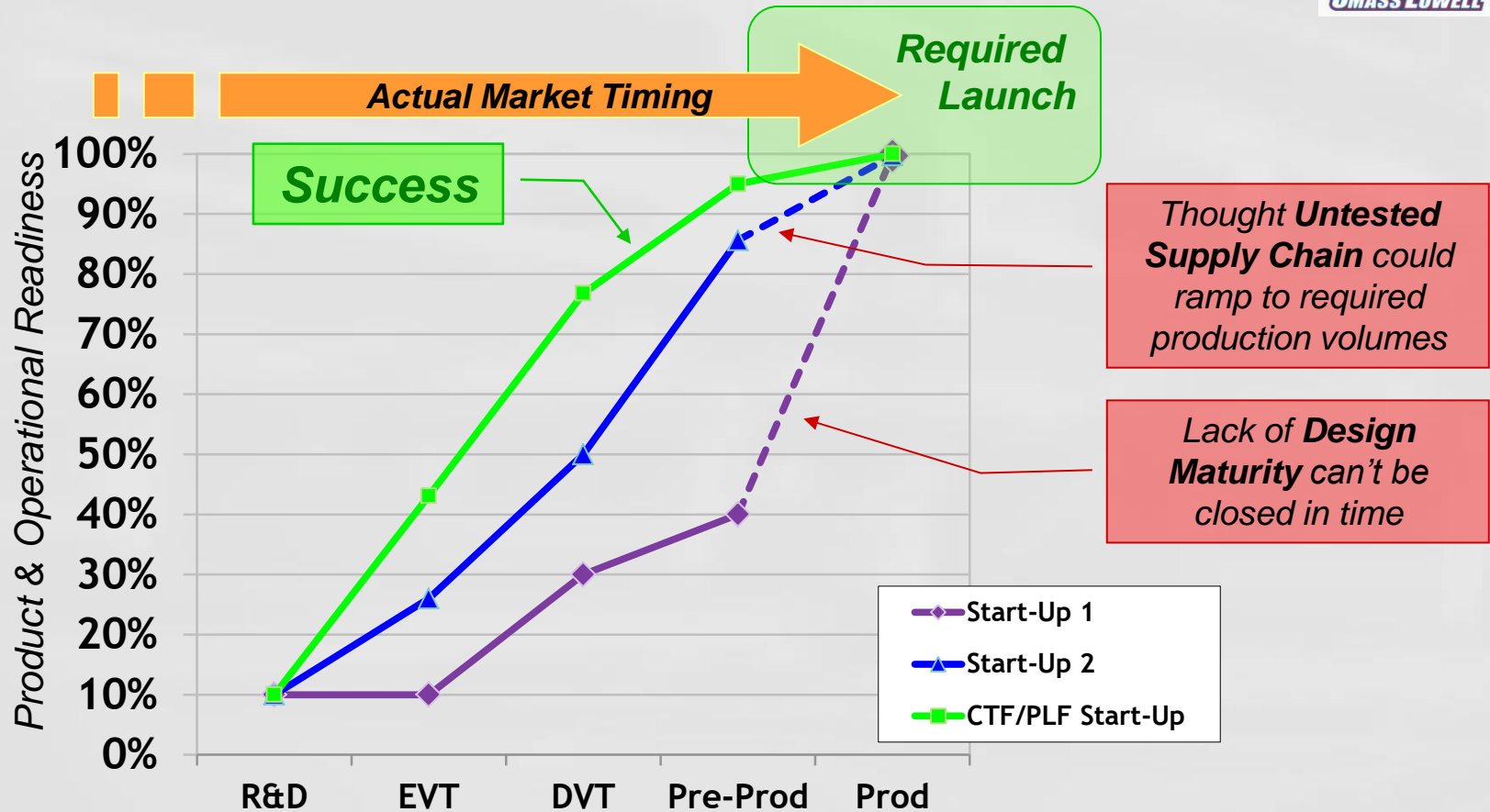
Roberta Ingegnere	V.P. of Product Development	
Role	The Vice President of Product Development has management responsibility and accountability for the Product Development Group to help the company achieve its goals. They are responsible for strategically driving the pro-active development of the road map of products and services to be offered by the company. Additionally, they are responsible for tactically organizing, implementing, and maintaining all of the day-to-day activities and personnel needed to manage the company's current product and service offerings in a manner which efficiently and effectively communicates to our clients and our employees the appropriate expectations of timeline, pricing and functionality of such offerings.	
Scope	<ul style="list-style-type: none"> Manages entire Product Life Cycle process, ensuring technology, process, reliability, and regulatory roadmaps are understood and valid. Assure accurate proper product realization process selection, and operation process loading to assure customer requirements are met (product realization includes purchasing, individual manufacturing processes used, handling, preservation, packaging, and shipment). Assure that customer technical requirements are fully understood and/or anticipated for all new product orders and any ambiguous requirements are resolved before accepting an order. Participates in quotations review to provide insight on potential risks because of violation of design rules Documents "lessons learned" to ensure that future products are developed more effectively 	
Tasks	1. Task: Hire Senior Level Electrical Engineer with expertise in migrating sub-systems from analog to digital platforms <ul style="list-style-type: none"> Signal Processing and Firmware development is a requirement Temp to Perm will be considered 	11/1/2016 12/15/2016
	2. Task: Develop Board Presentation on "Make – Buy" decision breakdown from initial design review <ul style="list-style-type: none"> Must include BOM cost estimate One slide summary of commercially available roadmap and design alignment 	11/30/2016
	3. Task: Support newly hiring VP of Ops effort of Parametric Process Mapping of the Alpha units' fabrication process	12/30/2016
Projects-Initiatives	1. Project: Compose Medical Device Product Requirement Document <ul style="list-style-type: none"> Working with CTO, Sales and Marketing, and V.P. of Operations compose Top Level Product Requirement Document 	Complete
	2. Project: NPI Work Flow and Process Proposal <ul style="list-style-type: none"> With V.P. of Ops, create basic framework for PLC transitions and hand offs Establish PLC stage gates boundaries Propose top level PLC and NPI assumptions and process 	12/30/2016
	3. Initiative: Establish Document Control and PDM system requirement before moving to Stage 2 (Beta Builds); must including provisions for: <ul style="list-style-type: none"> BOM control Hardware content control CAD/PDM database control Firmware Control Extensions for process, reliability, and test documentation Extension for reports 	1/30/2016
	4. Project: Develop top level design functional specification and family tree construct to enable for first customer design review: <ul style="list-style-type: none"> System, Sub-System, and Component design capture Roadblock identification Parametric analysis of tolerance budgets 	1/30/2016

Typical Department Task-Project-Initiative List

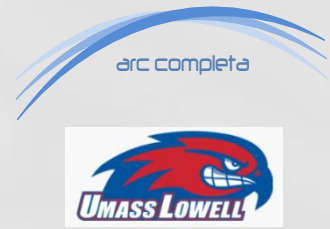


Jay Tipodeventas	V.P. of Marketing and Sales (New Hire)	
Role	The Vice President of Marketing and Sales plans, directs, and set the strategic direction of the sales and marketing program to maximize profit and increase product or service visibility. Direct the sales and marketing management staff in effective use and development of business plans and strategies. Works closely with V.P. of Product Development and V.P. of Operations to understanding the inherent technical and operational strengths of the company's product offering.	
Scope	<ul style="list-style-type: none"> Complies and contributes to the Product Life Cycle process, ensuring technology, process, reliability, and regulatory roadmaps are understood and valid from a customer perspective. Analyze sales statistics to determine sales potential, monitor customer preferences and inventory requirements. Ensure services are in compliance with professional and company policy standards. Plan, direct, and set the strategic direction of the sales and marketing program to maximize profit and increase product or service visibility. Direct the sales and marketing management staff in effective use and development of business plans and strategies. Develops objectives and policies for the sales and marketing department. 	
Tasks	1. Task: Identify existing sales funnel's contacts to date and make introductory calls a. Take opportunity to ensure that we have the correct contact information and all of the decision makers at the customer	12/20/2016
	2. Task: Develop Board Presentation on initial impressions of sales climate compared to your baseline experience a. Must contrast our competitors b. Must include initial impression on sales funnel maturation	11/30/2016
	3. Task: Meetings with the key company stakeholders: a. CTO b. V.P. of Ops c. V.P. of Product Development	11/30/2016
	4. Task: Review newly written Medical Device Product Requirement Document a. Meet with stakeholders to understand technology and operational basis b. Start to consider product and its value proposition c. Start to consider the Generic Buyer Profile	11/20/2016
Projects-Initiatives	1. Project: Compose Marketing Requirement Document a. Working with CTO, V.P. of Product Development and V.P. of Operations compose Top Marketing Requirement Document	12/30/2016
	2. Project: Research and Make Recommendation on Cloud Based CRM System a. Write functional requirements specification, ensuring hooks for existing system integration and usage are considered b. Complete research and RFQ cycle c. Make recommendation	1/30/2017

The Start-Up Challenge

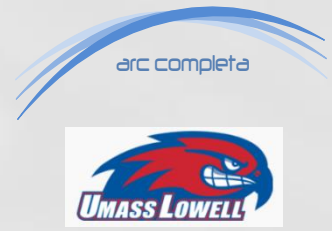


What we will achieve in this session



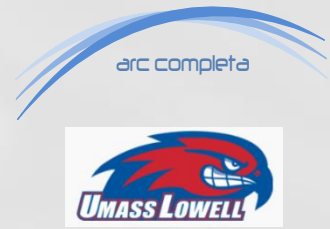
- Continue to consider how to use tactical and strategic tools
- Consider Simplified Product Life Cycles and how they are used to organize product and operations development efforts
- Consider how Strategic Frameworks and Product Life Cycles are related and coexist
- When do you move from R & D to Applied Development and Commercialization?

Creating Strategies



Why do I develop strategies
and where do they fit in?

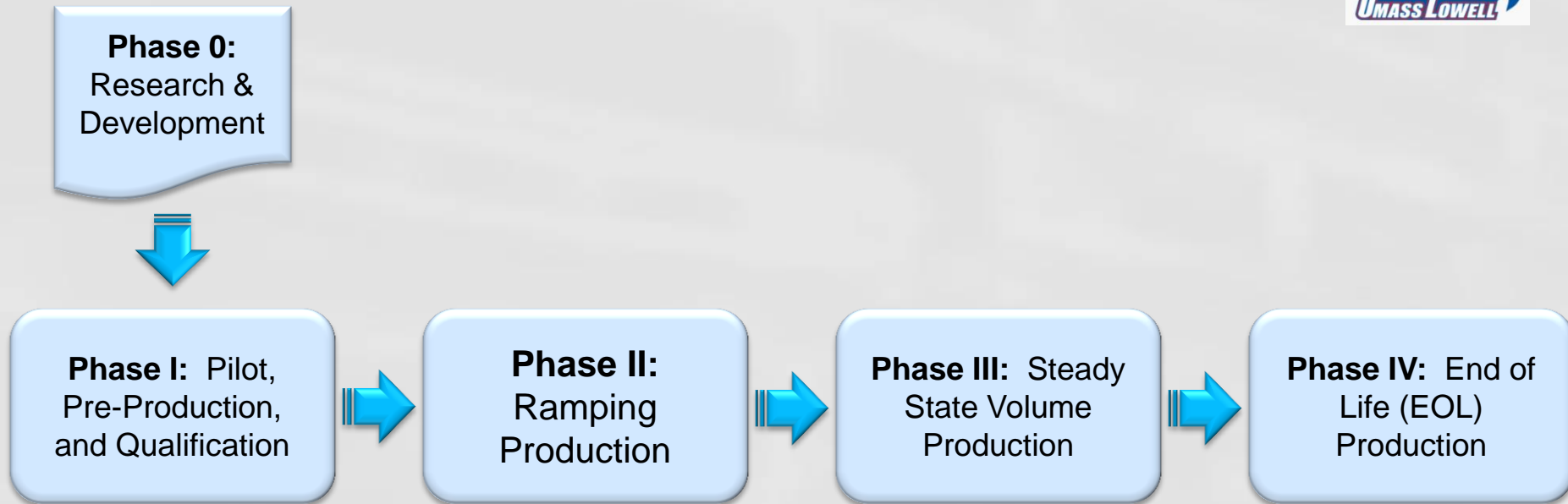
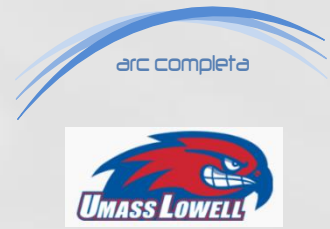
Some Definitions



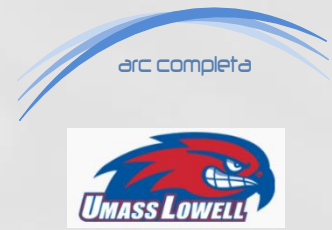
● Simplified Complex Hardware Product Life Cycle (PLC):

- **Phase I: Pilot, Pre-production, and Qualification** – A high cost, low volume effort to establish design intent, process and design capability (Yields and CpK), and qualification against customer requirements, before the decision must be made to fund increased investment to realize production potential. Time to market is the goal of the phase. The expense and capital consumed during this phase are basically sunk costs, and may or may reflect or represent the final intrinsic cost.
- **Phase II: Ramping Production** – High investment phase, where capacity is being brought on-line and qualified to the original performance baselines from Phase I. Time to Profit is the goal of this phase. Economies of scale and process refinements start to drive the cost structure towards the final intrinsic cost. The designed in yield starts to be realized more often than not, and efforts continue to close and eliminate major start-up yield issues.
- **Phase III: Steady State Volume Production** – Demand is being fulfilled, with high efficiency and utilization. At this point intrinsic cost should be at its minimum. At the beginning, the net profit margin is highest, and by the end erosion has started. Sustainable and predictable production and fulfillment is the goal of this phase. Yields and product costs are basically representative of what the actual designed-in cost and yields are, regardless of models. Ability to affect change is limited because of the associated risks to customers, unless externalities require acute action.
- **Phase IV: End of Life (EOL) Production** – Because of newer, lower cost, higher performing offering (or competing technologies), planning is focused on last orders, and minimizing purchases to close out existing commitments. Margins have eroded to the point of loss, and the goal is to kill the product before a costly quality issue arises because of decreasing emphasis and resources.

Simplified Product Life Cycle (PLC)



Some Definitions



Technology and Operational Roadmaps

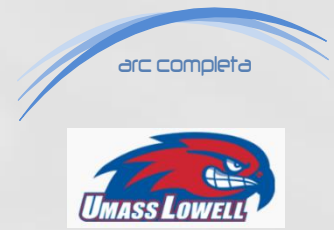
- Technological Improvements or development contrasted to time or generations of products
- Often drives economics of design decisions and assessment of overall risk and financial impact of change
- Technology for Technology's sake is usually not a valid business strategy
- Commercially available technology roadmaps often inform **Make - Buy** decisions

Tech E				
Tech D				
Tech C				
Tech B				
Tech A				
	Gen x	Gen x+1	Gen x+2	Gen x+3
Time →				

Platform Roadmaps

- An economic, technical, and operational strategy considering the new development, reuse or abandonment of investments in a product's features, means of manufacture and test, means of procurement, and scope of usage over generations

Some Definitions



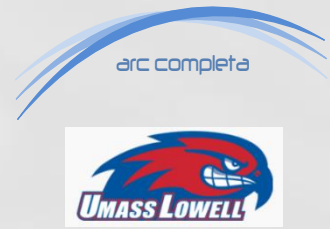
- Marketing Requirement Document (The What)

- Is a document that expresses the customer's wants and needs for the product or service
- What (new) product is being discussed
- Who the target customers are
- What products are in competition with the proposed one
- Why customers are likely to want this product
- When the Product or Product Variation is **NEEDED**

- Product Requirement Document (The How)

- Is a document containing all the requirements to a certain product.
- It is written to allow understanding of what a product should do
- It should avoid anticipating or defining how the product will do it in order to later allow designers and engineers to use their expertise to provide the optimal solution to the requirements.

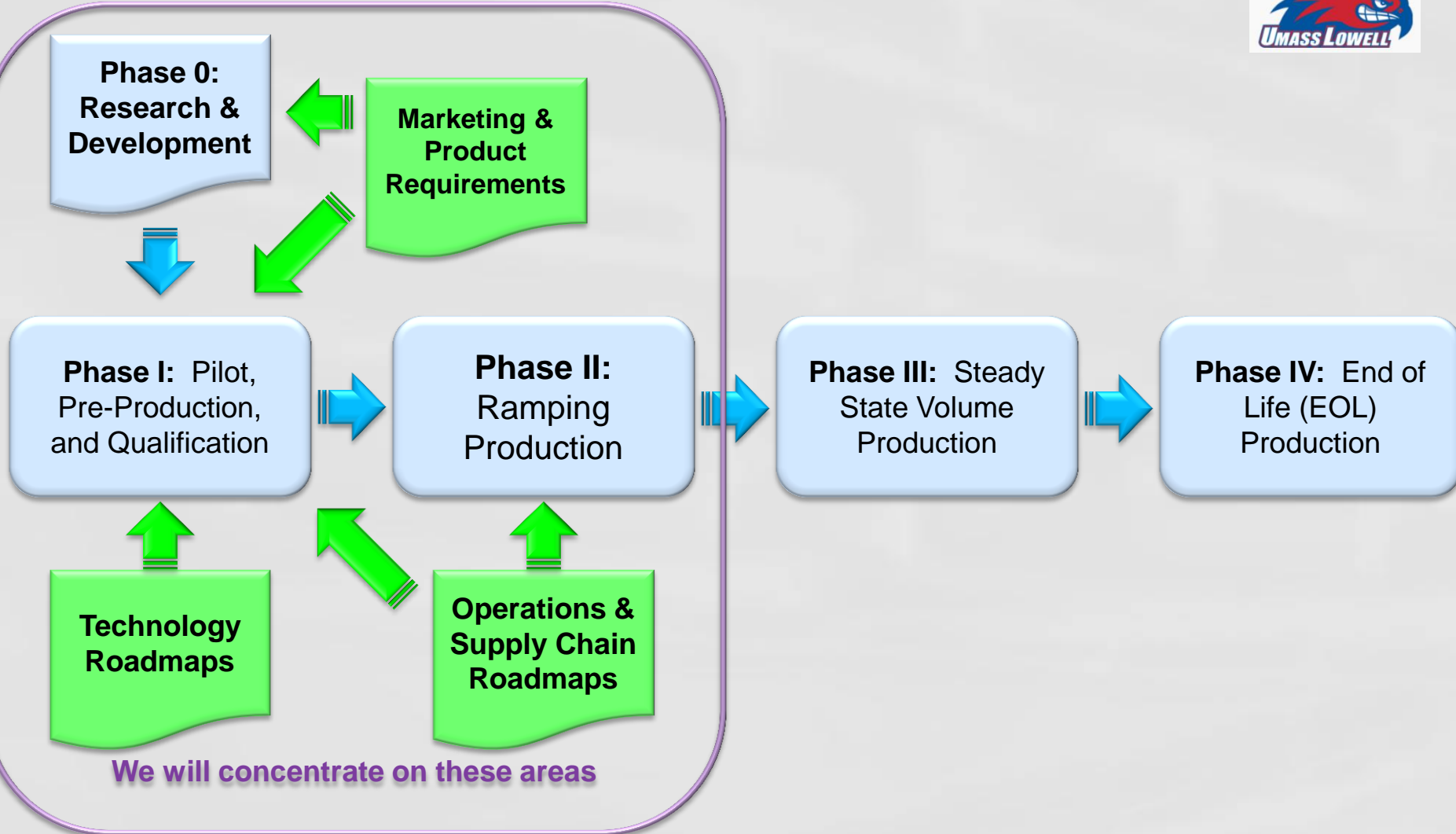
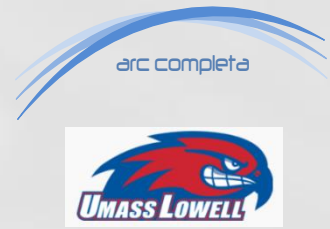
Functional Strategic Frameworks vs. Product Life Cycles



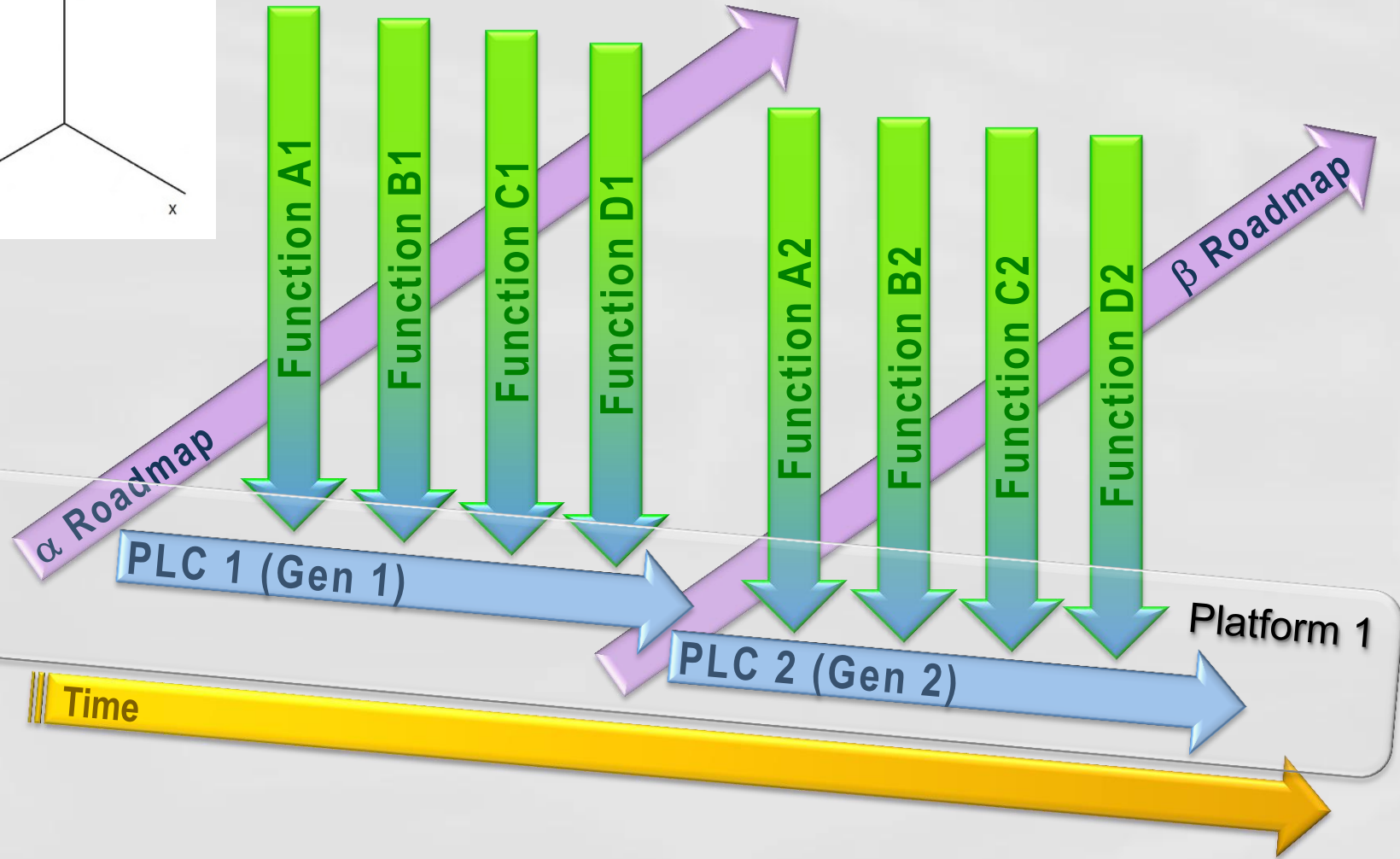
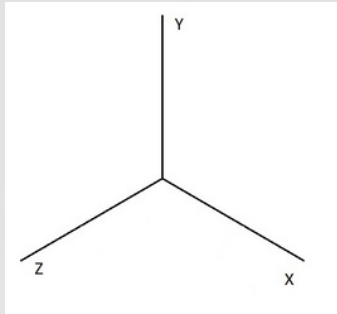
● Think of:

- Functional Strategic Frameworks as Vertical (y)
 - May be projects or initiatives that may be associated with a product or overall continual improvement
- Product Life Cycles (PLC) as Horizontal (x)
 - Stages of a product development from its birth to End of Life (EoL) obsolescence
- Technology and Operational Roadmaps as (z)
 - Defines technology's or processes maturity and cost, and frames the risk of adoption

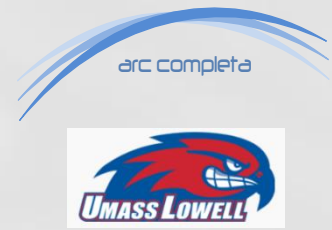
Simplified Product Life Cycle (PLC)



Functional Strategic Framework to Product Life Cycles to Roadmaps

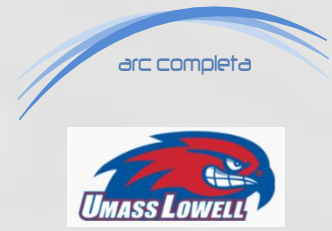


Basic Function of a PLC



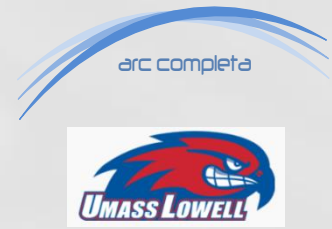
- Establish **Product Maturity** and **Performance Criteria & Gates** to ensure a product's development meets its MRD and PRD
- The character of a given phase or stage is based on the deliverables and milestones, which are often broken into **Builds**
- The objective measurement of performance against realistic and appropriate PLC targets is one of the best indicators of inevitable commercial success
- Another PLC's objective is to move the product's care and maintenance from product development resources to operations resources who will maintain the product and its application until end of life

Build Nomenclature



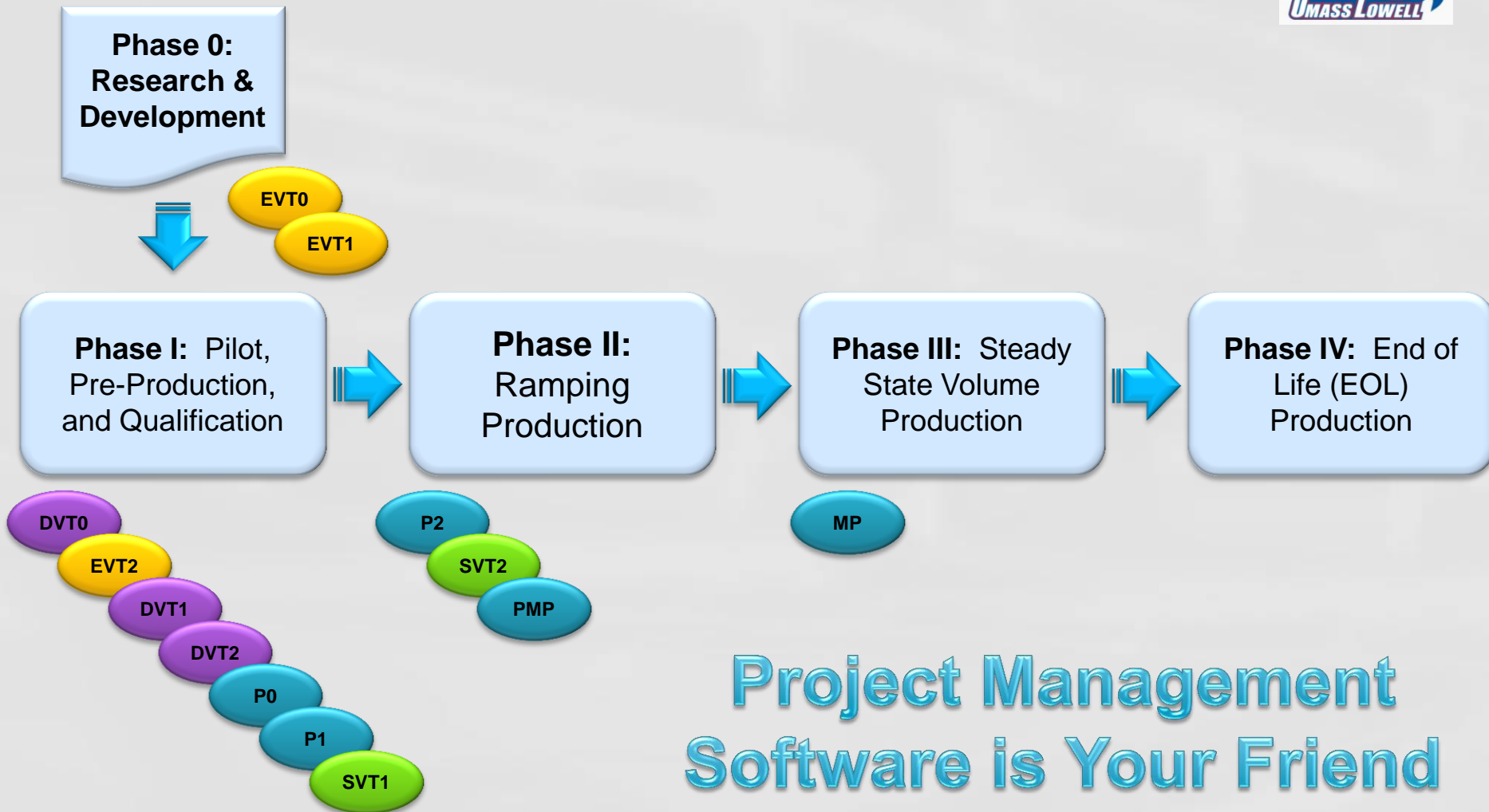
- Engineering Verification Builds (EVT, Typical Notation: EVT0, EVT1, EVT2, EVT3)
 - Validation of components and purchased sub-systems resulting in the contrast of design targets to actual performance to ensure higher confidence DVT builds
- Design Verification Builds (DVT, Typical Notation: DVT0, DVT1, DVT2, DVT3)
 - Validation of sub-system and early system builds resulting in the contrast of design targets to actual performance to ensure higher confidence SVT builds
 - Typically early production resources are starting to get involved
 - Results of these builds are often use in reliability testing, which now proceeds in parallel

Build Nomenclature



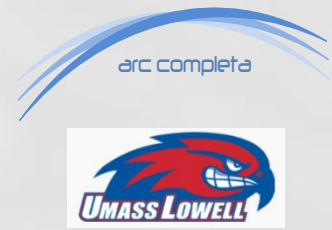
- System Verification Builds (SVT, Typical Notation: SVT0, SVT1, SVT2)
 - If Software/Firmware/Hardware integration is part of the product, SVT builds start to drive and integrate higher level functionality
- Production Verification Builds (PVB, Typical Notation: P0, P1, P2, PMP, MP)
 - Supply Chain and Production Resources are being tested and matured, from prototype and pilot efforts to qualified production capacity
 - Each build, while supporting other function's maturation efforts, is also driving continual improvement and capacity increases to reach the end of Phase 2 goal of Credible Deployed Capacity
 - Credible Deployed Capacity is usually an agreement on the target investment in capacity to fulfill all early production orders while sales increase because customer adoption
 - The quality of these P1, P2 , and PMP builds can usually allow limited customer SVT testing

Simplified PLC with Builds



**Project Management
Software is Your Friend**

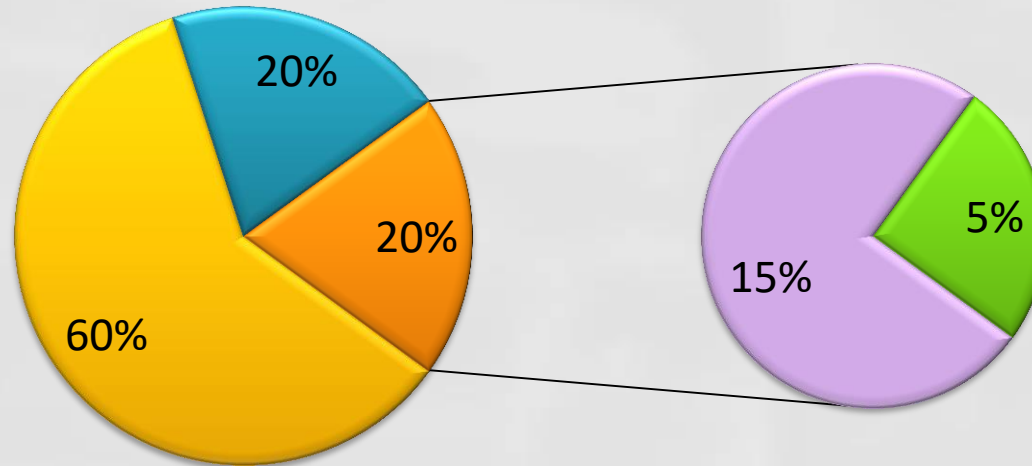
When can we leave Phase 0?



- You have a validated MRD, that has been researched and refined to the point it represents a first credible product offering that meets 80-90% of prime customers' needs
 - This is further validated by customers' willingness to help assess, test, and potentially invest with "Patient Money"
 - Your required **Launch Window** has been established and validated
- You have a credible PRD that defines how your product will meet performance requirements as defined by the MRD, which means:
 - Major new technologies have been demonstrated sufficiently and with consistent repeatable results using the commercially available technological or processing resources to prove **Design Intent**
 - Sufficient research has been completed to assess commercial availability of components, materials, and processing capabilities at the capacities you need for all build activities to allow commercialization to proceed
 - Sufficient research has been completed to ensure that there are no potential intellectual property infringements or required licensing
- A PLC framework with phases, builds and gate criteria has been developed with resource and time estimates support **Launch Window**

Qualitative Rule of Thumb

New Technology Saturation



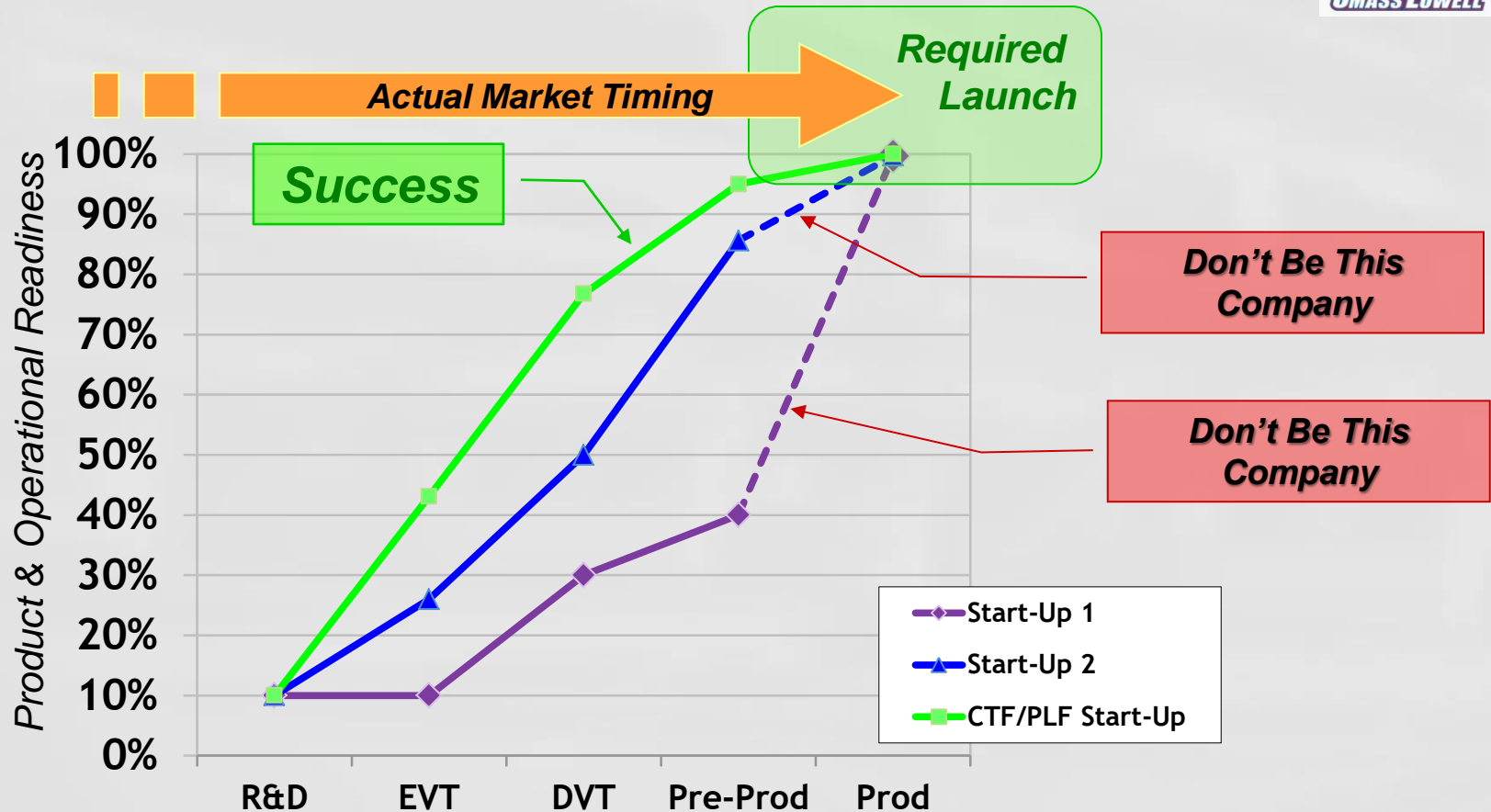
■ Commerically Available

■ Commerically Available, with Restrictions

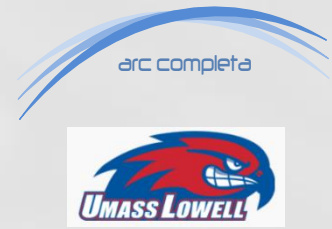
■ Derivative, But Higher Risk

■ New Art

The Start-Up Challenge



About Gary Ainsworth



My area of practice focuses on emerging technology product commercialization in hardware start-ups.

Also, I work with existing companies on new product introduction, operations, and product development performance improvement. In all instances I usually work in the gray area between R&D and Product Development -and- Operations and Supply Chain, employing methods to lower the inherent noise level allowing better decision making in a more accountable framework.

I'm currently working with UMMA Lowell's New Venture Business Development team and iHub on content around understanding start-up behaviors, leading to a higher probability of successful commercialization and profitability.

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