Wave Transfer Planning

Strategies to Transfer Manufacturing Operations to a Newly Built International Pharmaceutical Facility

Presented by:
Medical Technology / PMA Team

The Pharma Team

Jennifer Cipollini

Senior Manager, Project Management

Jennifer has long-standing experience leading project managers in the transfer of new pharmaceutical products from R&D into GMP manufacturing locations. Last year, she embarked on a new role driving global transfer of pharmaceutical products to a new manufacturing site overseas.

Tim Stoll

Senior Director, Manufacturing Strategic Projects

Tim is an accomplished real estate and construction management professional with over 5M SF and $2B of development and construction work successfully completed. An expert communicator with strong leadership skills, able to distill complex technical issues into clear strategies and lead successful execution of real estate strategies.

PMA's Team

Angel Arvelo **PMP, LEED AP**
Senior Director

Angel has extensive experience delivering large complex projects for clients in multiple industries. His experience includes work with oil and gas, pharmaceutical/GMP, life science, alternative energy, power generation & utilities, civil infrastructure, as well as commercial development projects.

Blake Cuneo
Senior Consultant

Blake's experience has been focused in the pharmaceutical, residential, and civil infrastructure industries. As a result of his experience, Blake has developed a specialization in scheduling and consulting, project and construction management, and overall project controls.

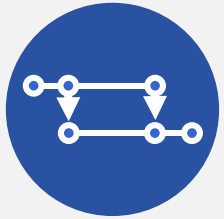
Presentation Agenda

A Little Background
Project Details
Life Cycle → Product Wave Planning

Wave Plan Optimization
Identify bottlenecks and evaluate strategies

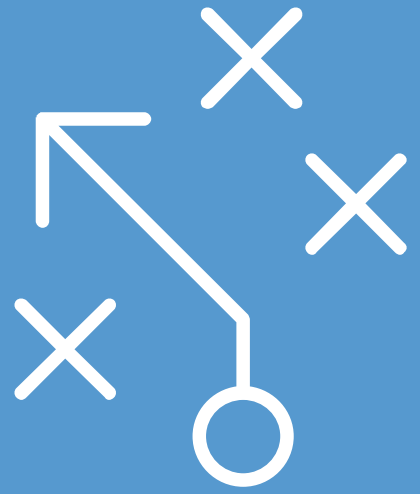
Planning Approach
Methodology

Business Case and Decision Making
Drive Smart Decisions Based on Data



Leveraging NetPoint
Interactive Planning and real-time

Conclusions



A little Background

Project Details

Business objective:

To increase global manufacturing capacity

Program Scope:

Includes the transfer of operations and systems to new facility

- *Manufacturing process*
- *Technical knowledge*
- *Support systems*
- *Personnel Training*

- ✓ Program in a highly regulated pharmaceutical industry
- ✓ Renovation of existing manufacturing plant and expansion to a new green site

Project Details

Collaboration between different business units, operational sites, functional departments and supporting functions within the company

Planning Objectives

Need to develop strategies to support business needs in new market

Detailed plan to balance limited resources and prioritize needs

Risk Management is key to the success of the project

Balance project objectives with operations and marketing objectives

Make Smart Business Decisions based on hard data

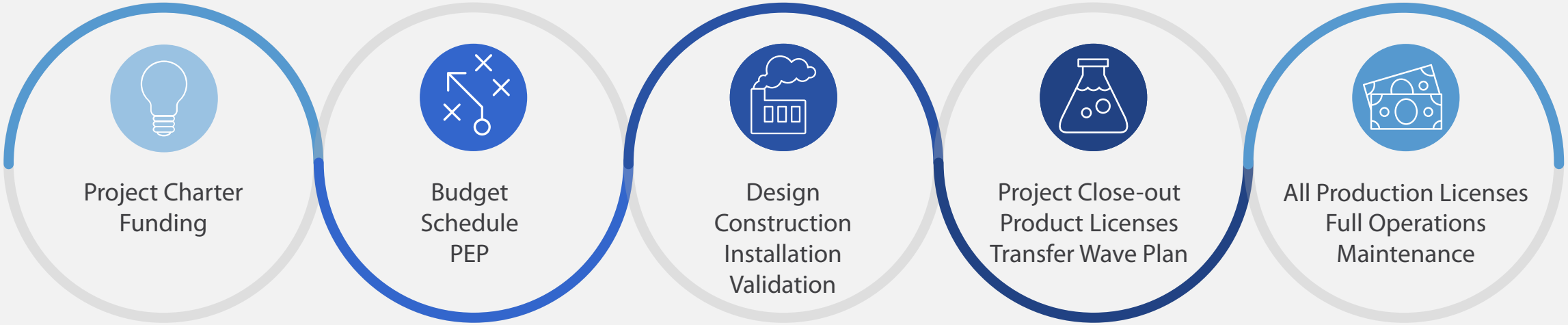
Establish key operation milestones

Some Interesting Metrics

- Existing manufacturing site offers a portfolio of **100+ products**
- **60%-70% of the staff** assigned to the project are currently supporting the different phases of the wave transfer work
- Estimate is that the Master Schedule will ultimately include **45% - 50% of activities** related to the transfer scope
  - *Permitting / Construction:* ***20% - 30%***
  - *Engineering:* ***8% – 10%***
  - *Procurement:* ***3% - 5%***
  - *Others:* ***10% - 15%***

Life Cycle Phases

From Approval to Full Operations (all products)



01 Project Initiation

02 Project Planning

03 Project Execution

04 Control & Monitoring

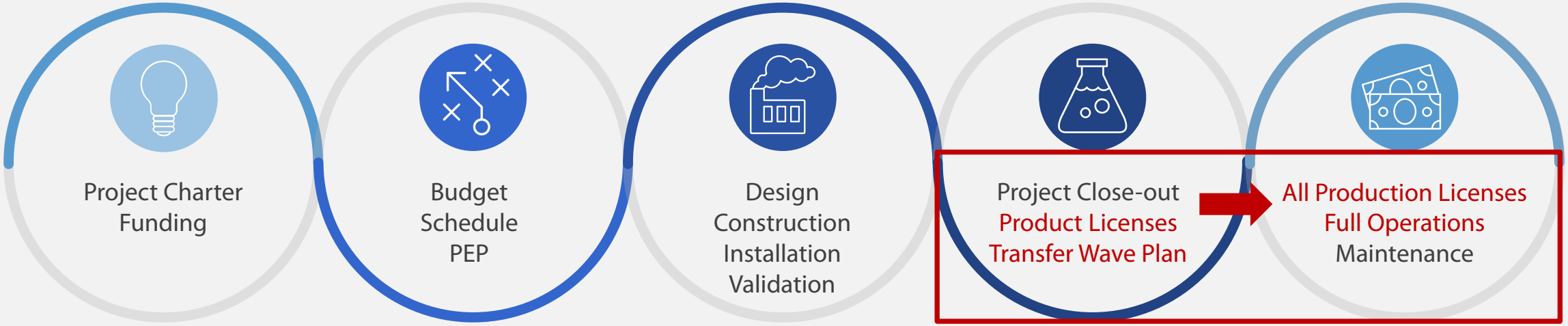
05 Project Close-out

06 Product Wave Transfer

07 Operations & Maintenance

Life Cycle Phases

From Approval to Full Operations (all products)



01 Project Initiation

02 Project Planning

03 Project Execution

04 Control & Monitoring

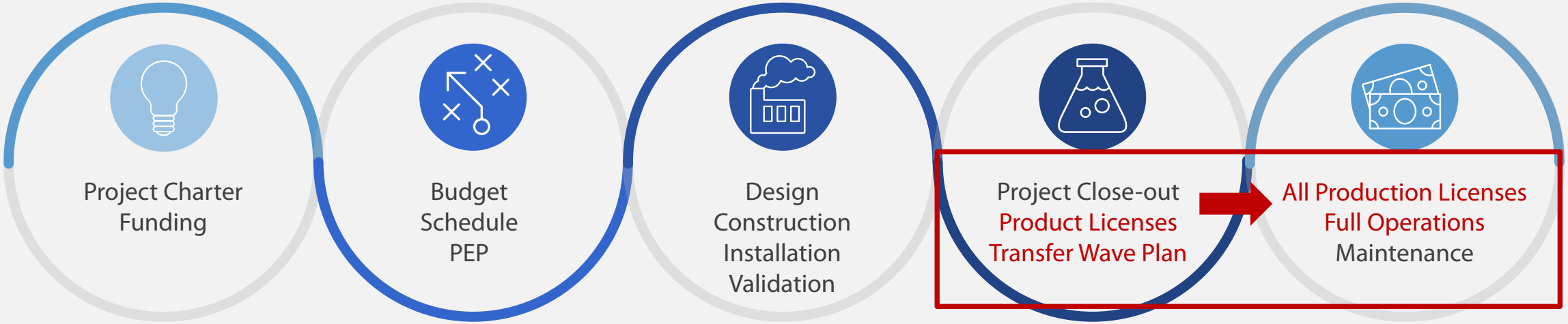
05 Project Close-out

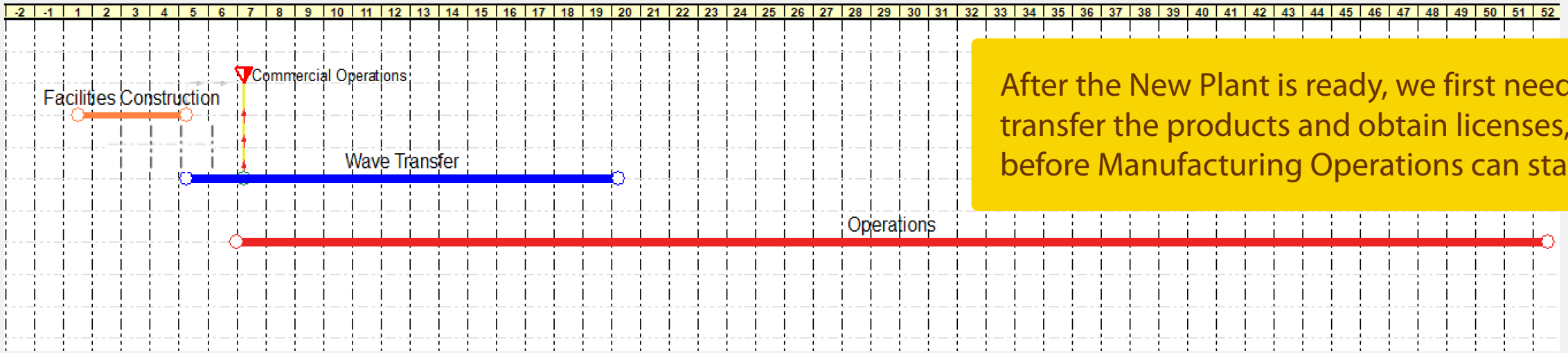
06 Product Wave Transfer

07 Operations & Maintenance

Life Cycle Phases

From Approval to Full Operations (all products)





After the New Plant is ready, we first need to transfer the products and obtain licenses, before Manufacturing Operations can start

Case Study – Product Wave Transfer Planning

Develop Transfer Plan → Balance Priorities / Strategy

Product Wave Transfer Planning

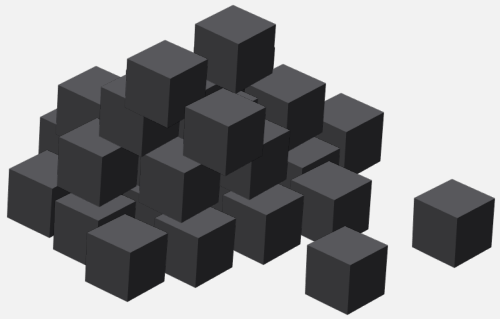
Facilities Ready for Manufacturing

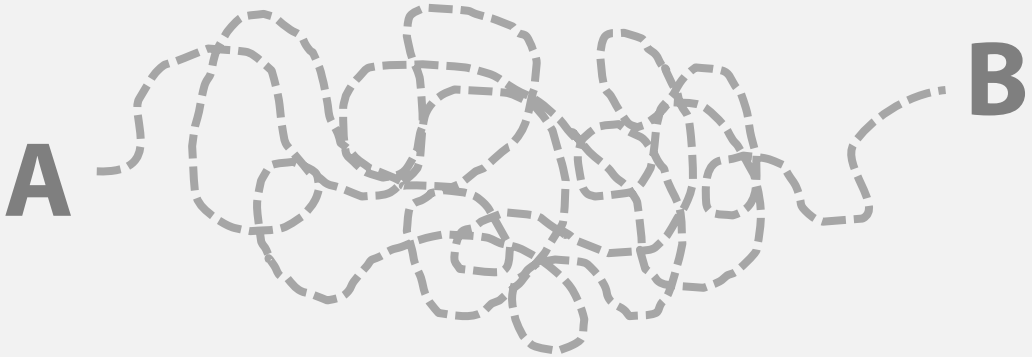
Produce 1st Product

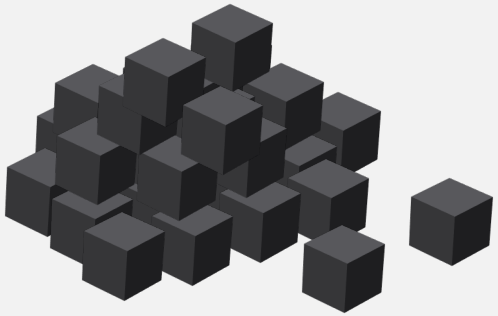
Receive 1st License

Start Commercial Ops

Complete Transfer All Products

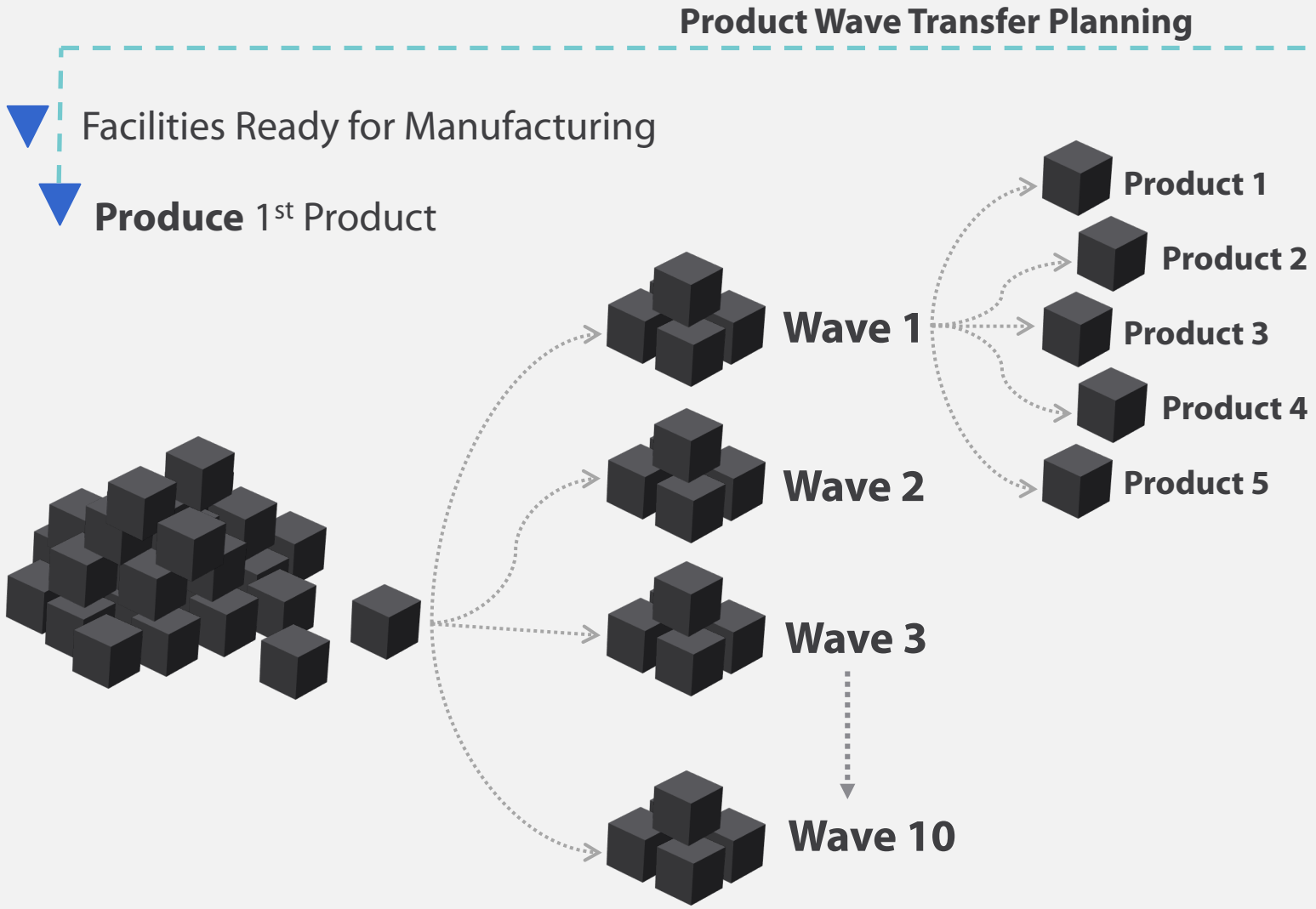






Case Study – Product Wave Planning

Group Products in Waves Based on Transfer Plan

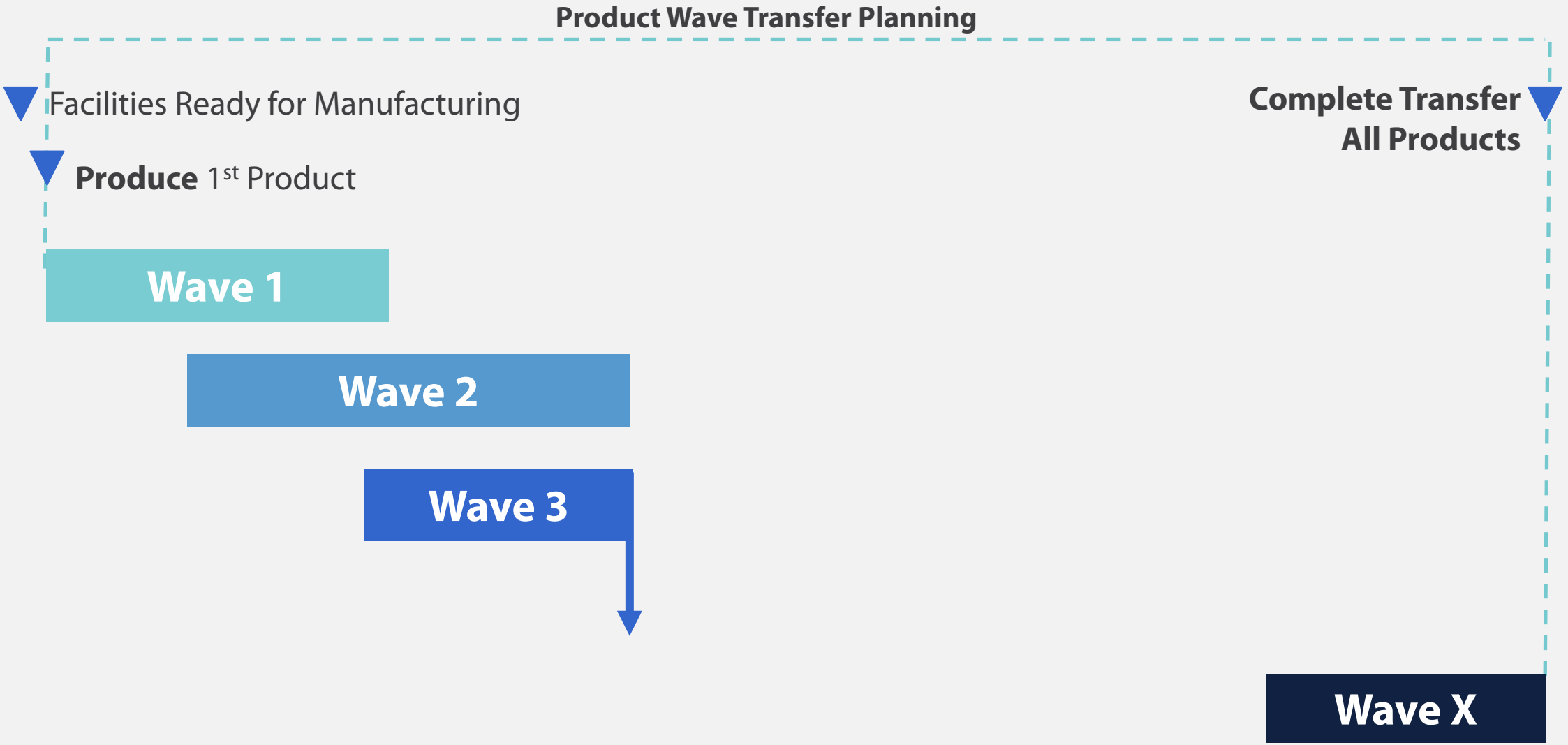


Parameters

- ✓ Business Needs
- ✓ Manufacturing Process
- ✓ Material Sourcing
- ✓ Registration Strategy
- ✓ Risks: Threats & Opportunities

Case Study – Product Wave Planning

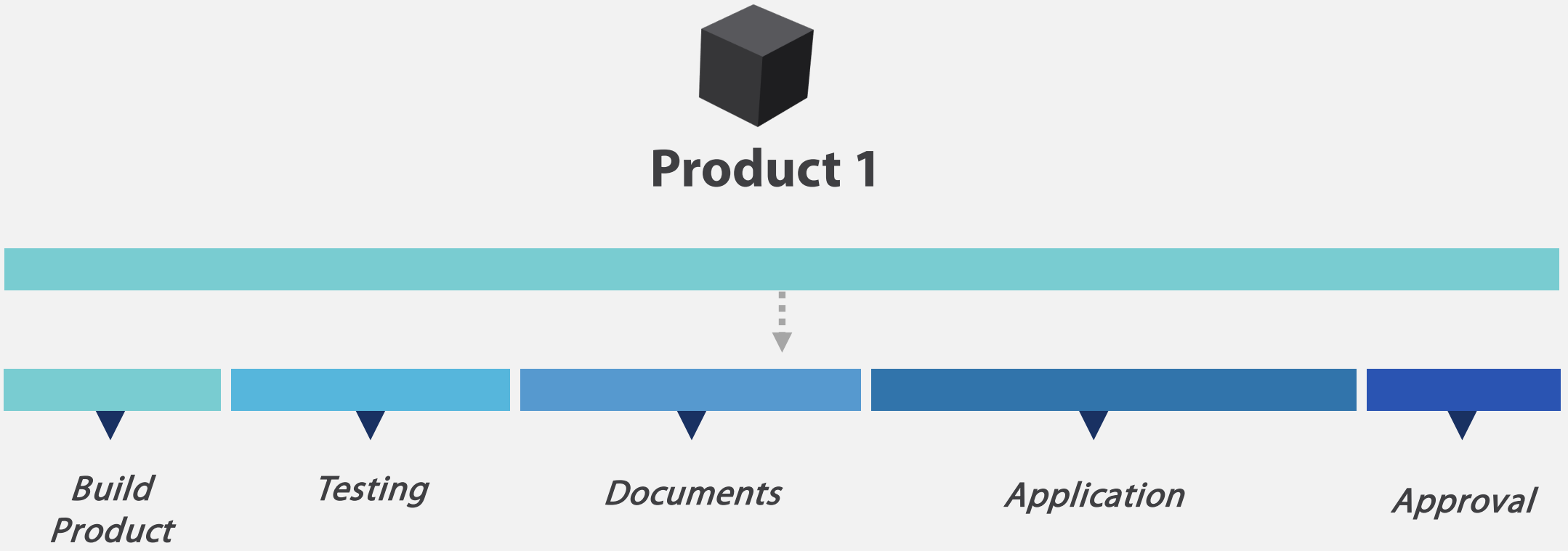
Develop Detailed Schedules for All Waves



Planning Approach

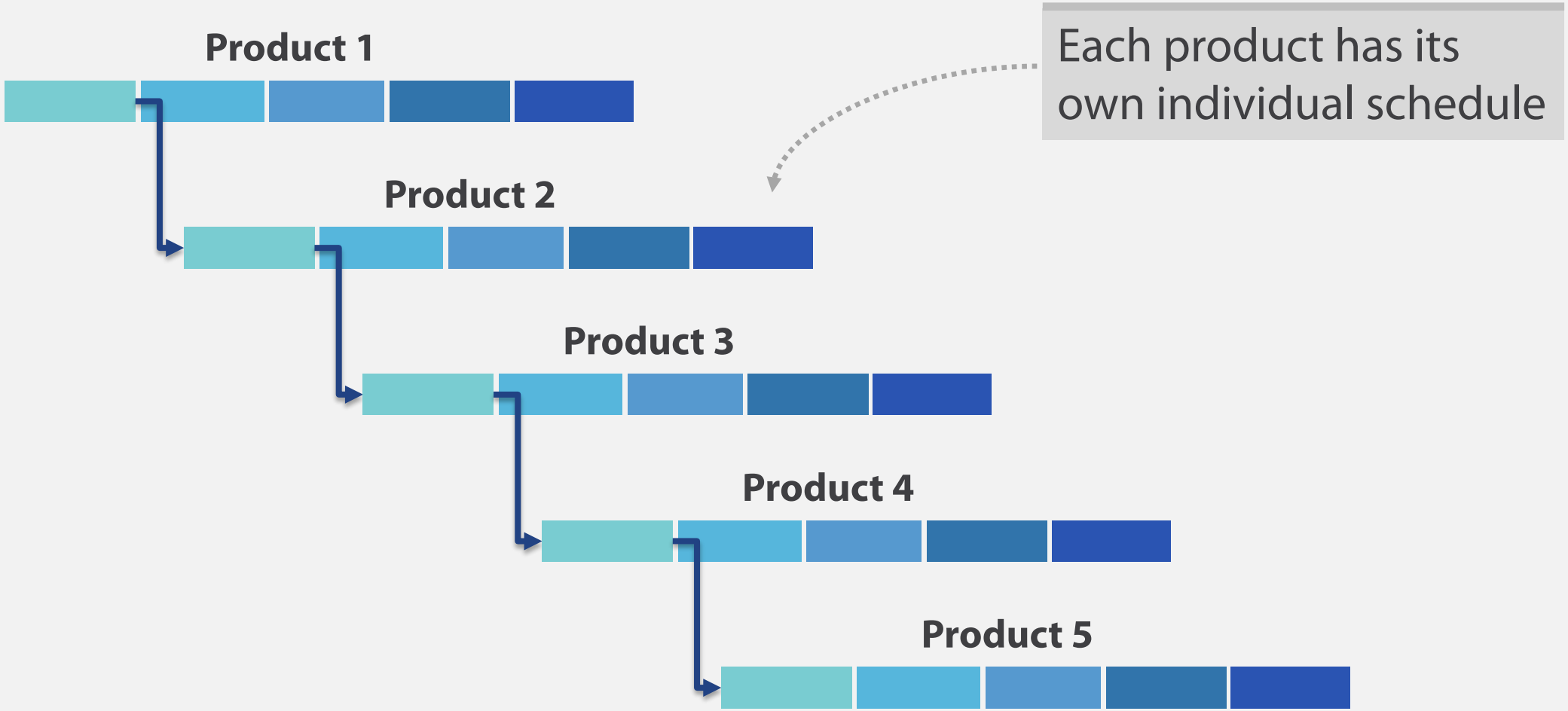
Planning Approach

Timeline of a Product



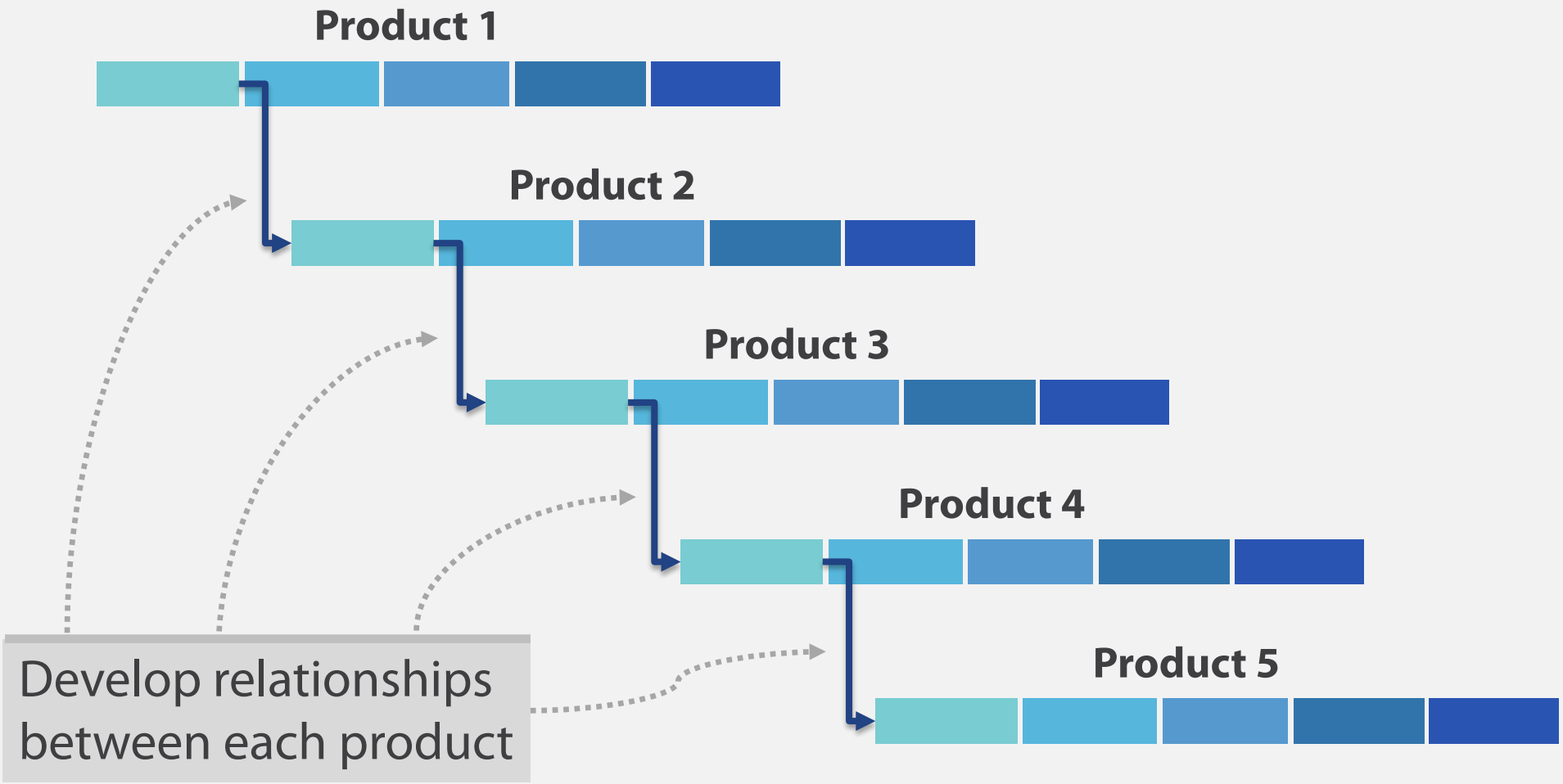
Planning Approach

Timeline of a Product



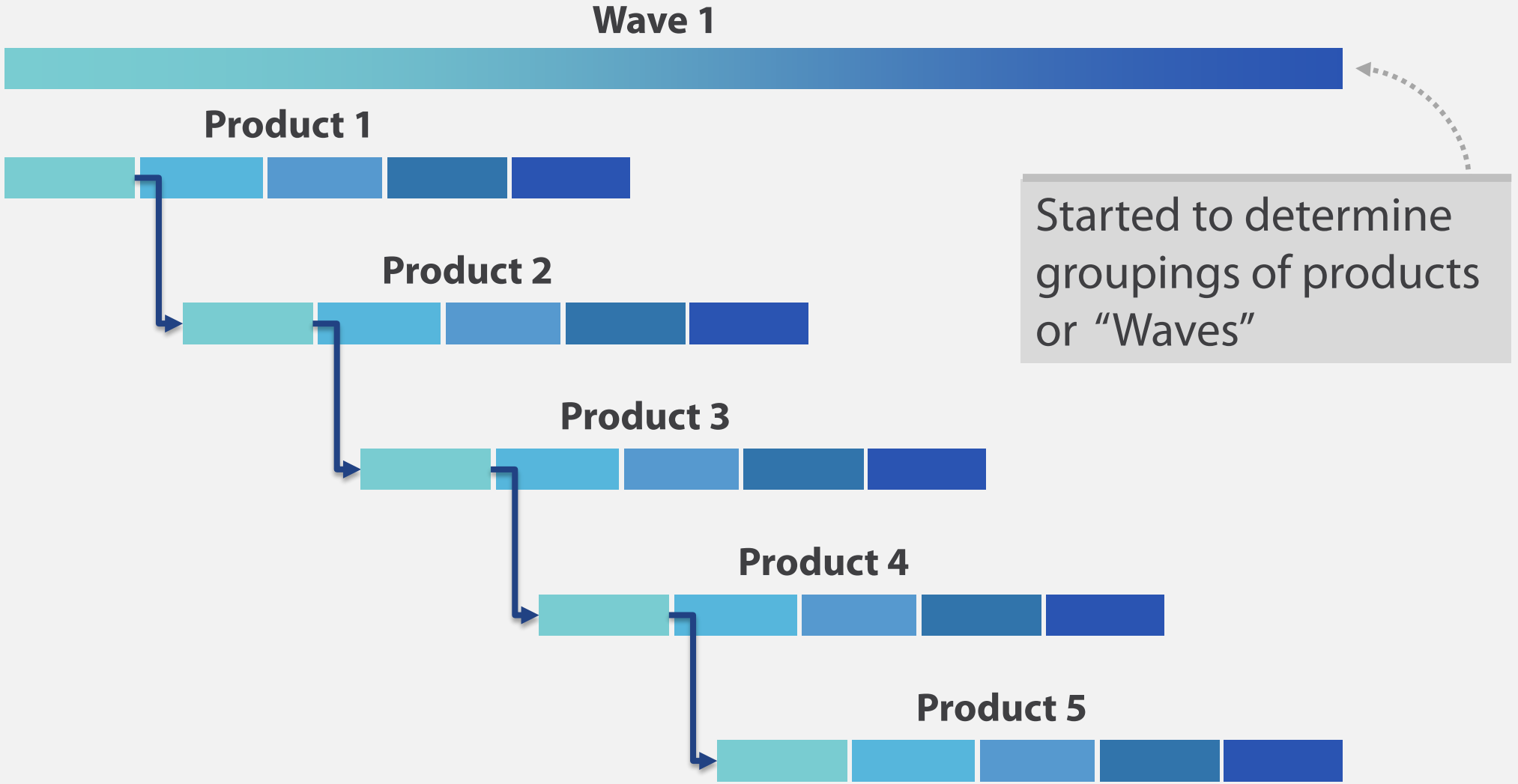
Planning Approach

Timeline of a Product



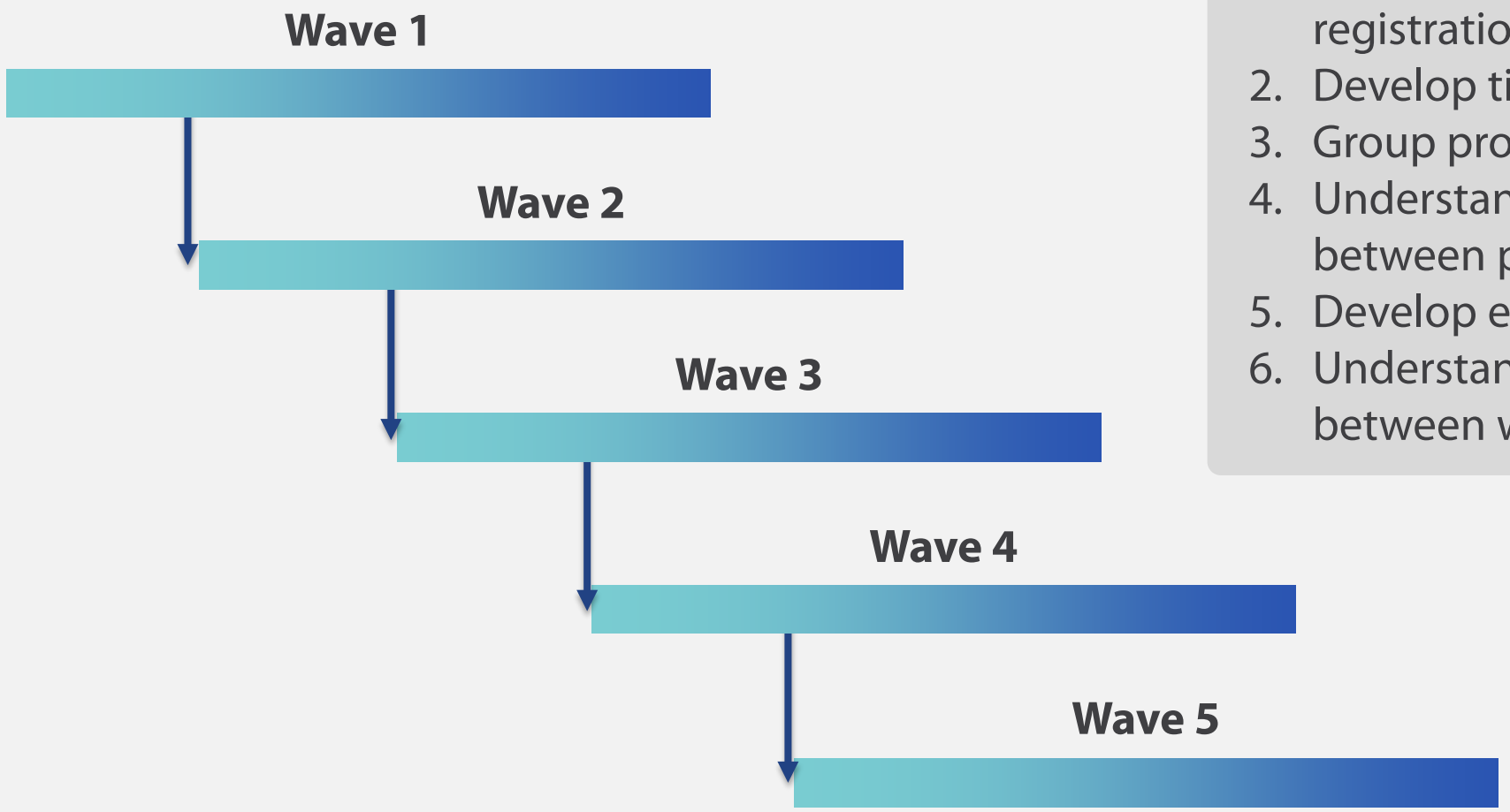
Planning Approach

Timeline of a Product



Planning Approach

Timeline of a Product



Wave Planning Steps:

1. Identify Key Phases for product registration
2. Develop timeline for products
3. Group products in waves
4. Understand driving factors between products
5. Develop each wave timeline
6. Understand relationships between waves

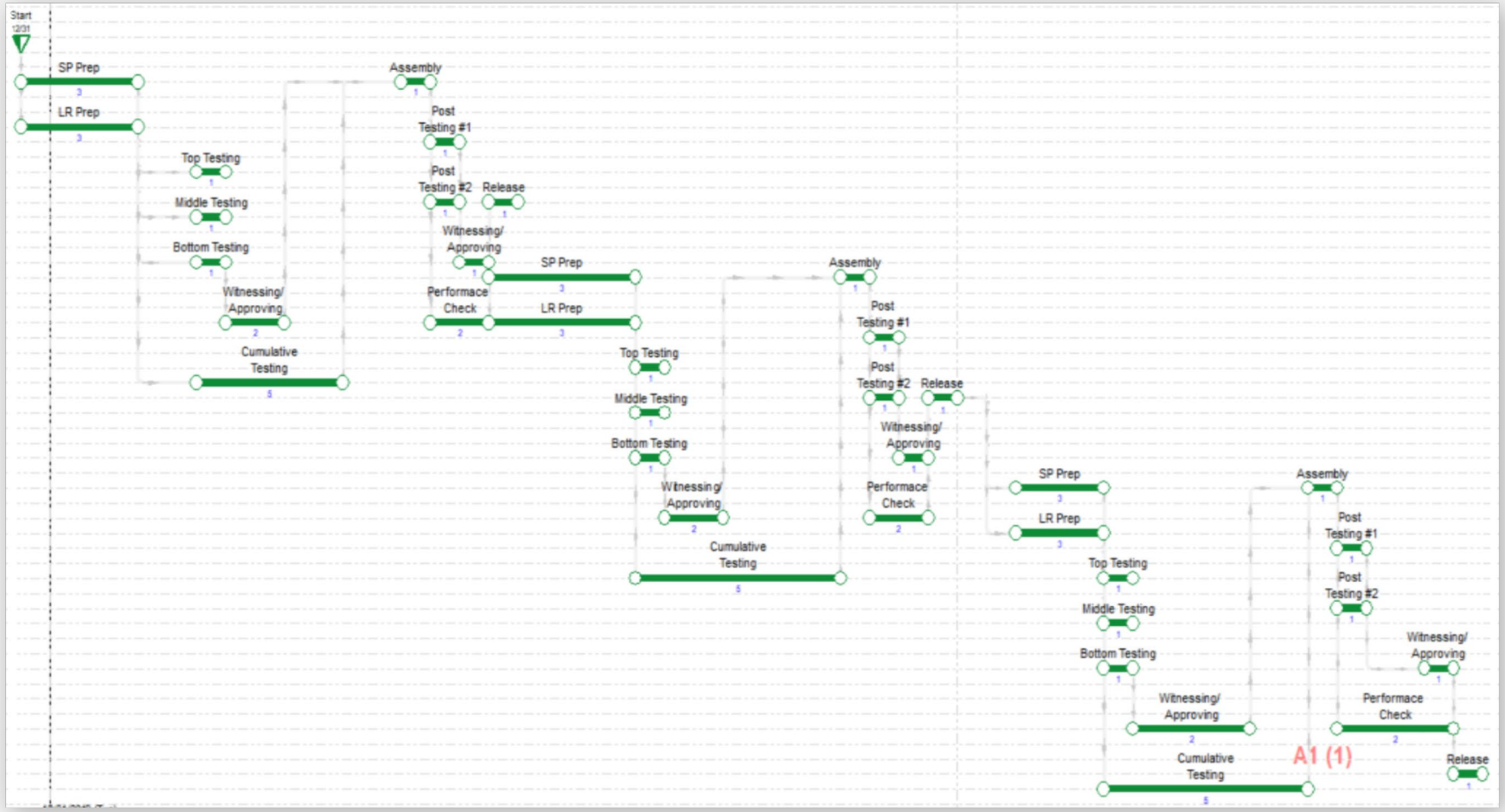
Leveraging NetPoint

Leveraging NetPoint

Phased Schedule Development

Leveraging NetPoint

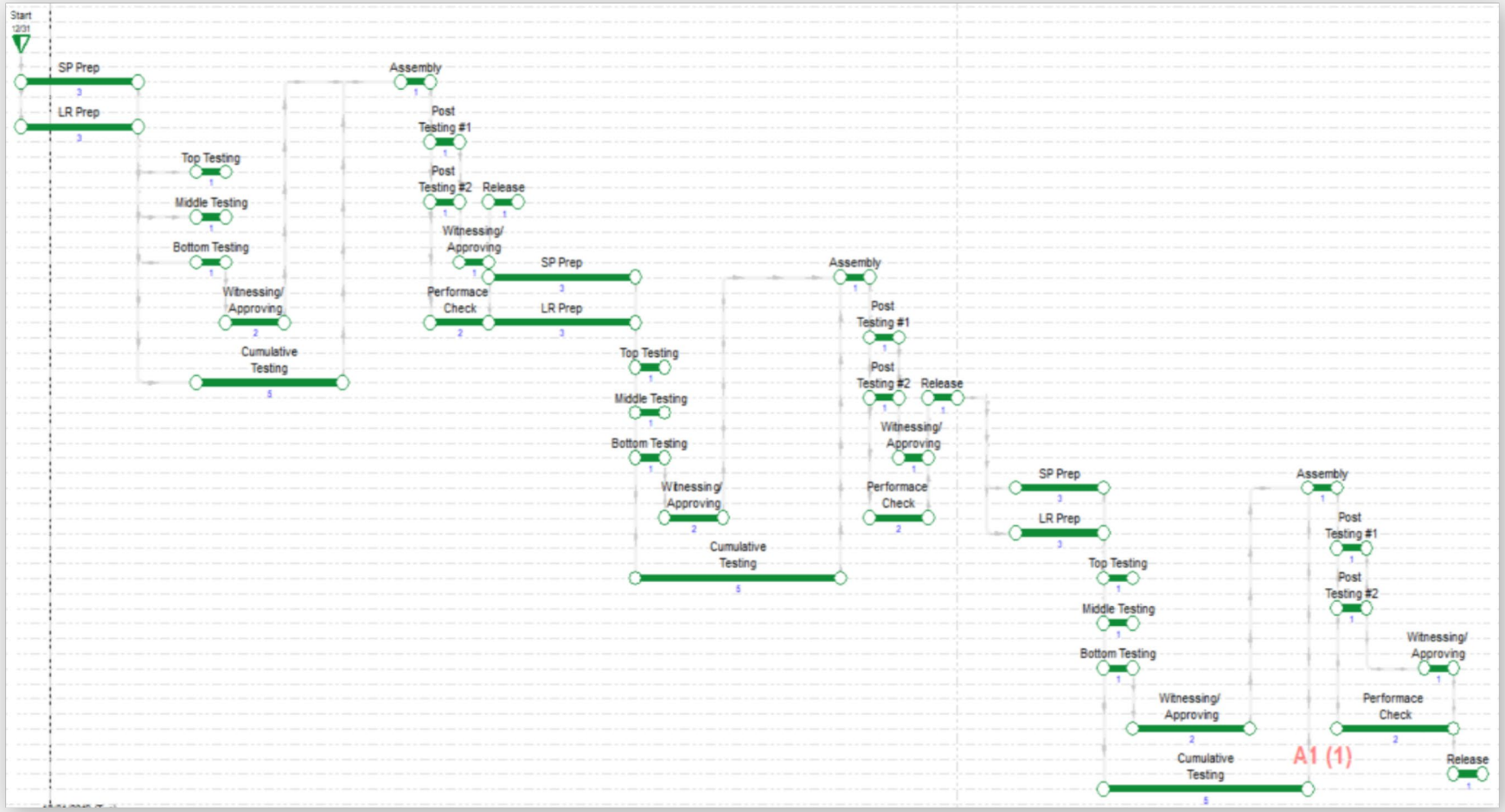
Phased Schedule Development



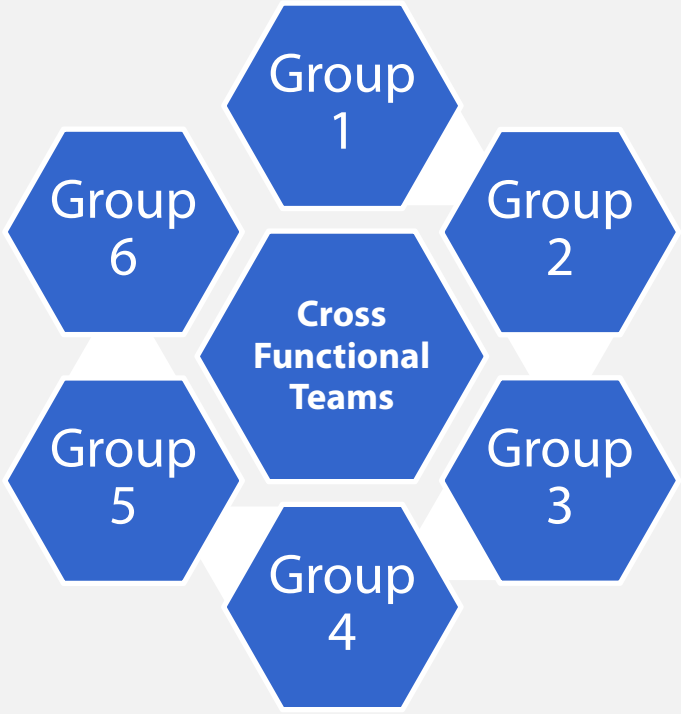
- ✓ Engage cross functional SME's in detail planning
- ✓ Develop detailed (daily) schedule for current phase
- ✓ Identify relationships (hard/soft logic)
- ✓ Load resources to each activity for equipment and labor

Leveraging NetPoint

Phased Schedule Development

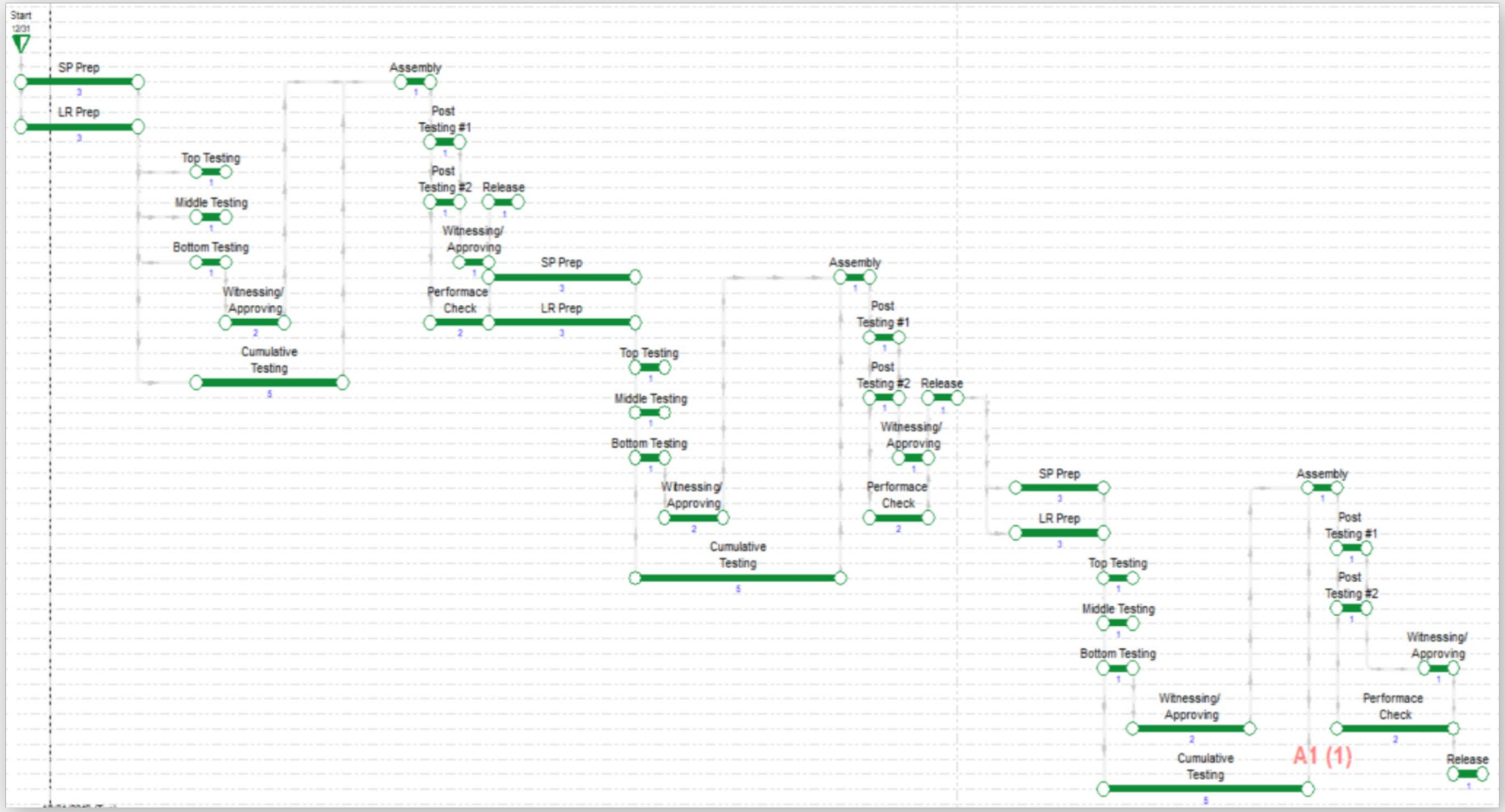


Cross Functional Team Collaboration

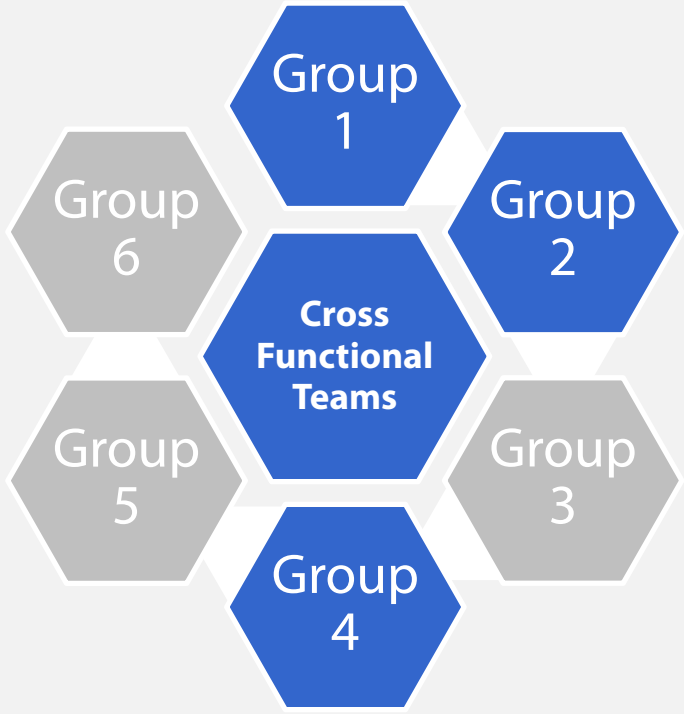


Leveraging NetPoint

Phased Schedule Development



Cross Functional Team Collaboration

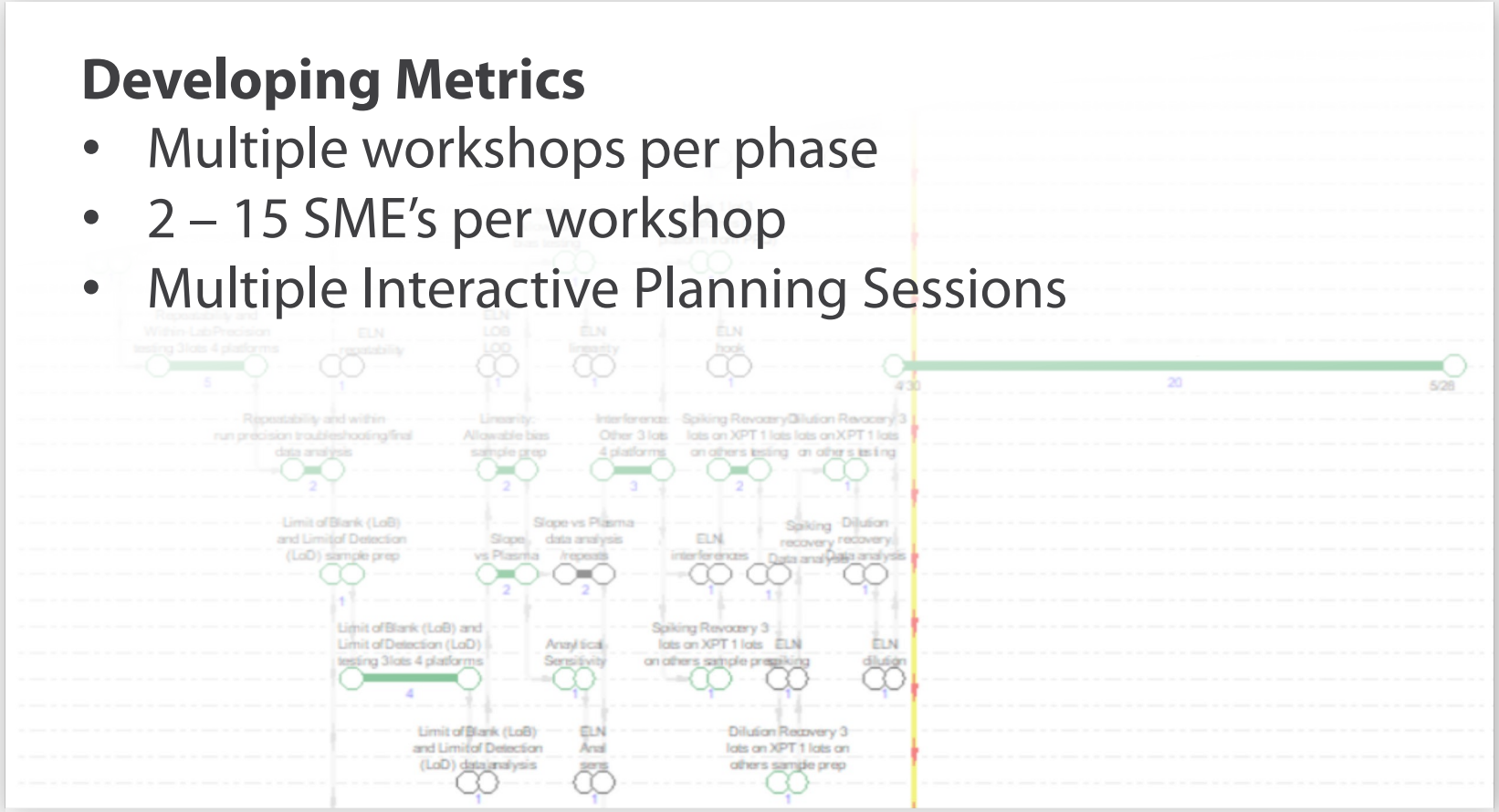


Leveraging NetPoint

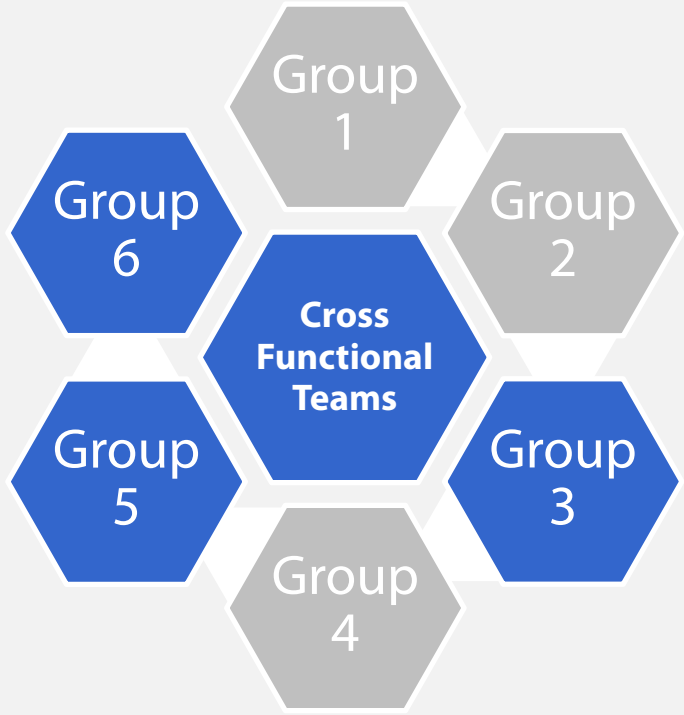
Phased Schedule Development

Developing Metrics

- Multiple workshops per phase
- 2 – 15 SME's per workshop
- Multiple Interactive Planning Sessions

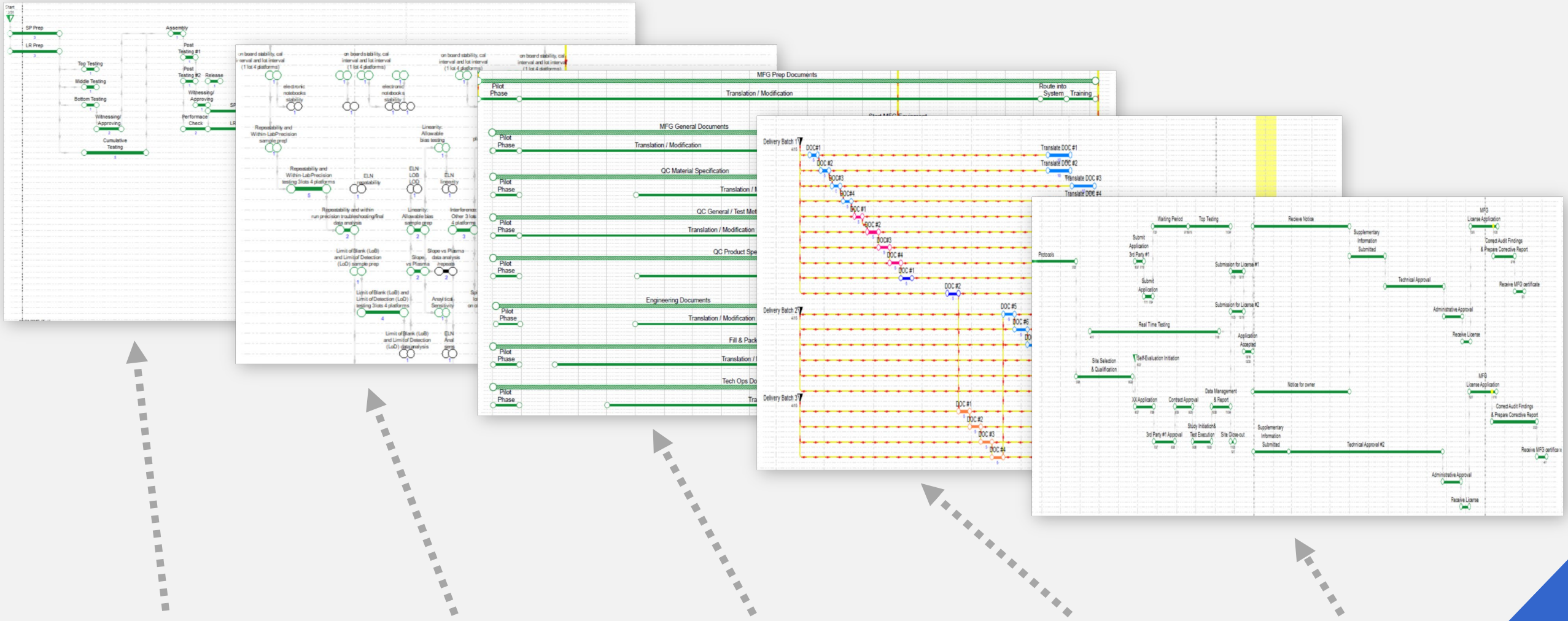


Cross Functional Team Collaboration

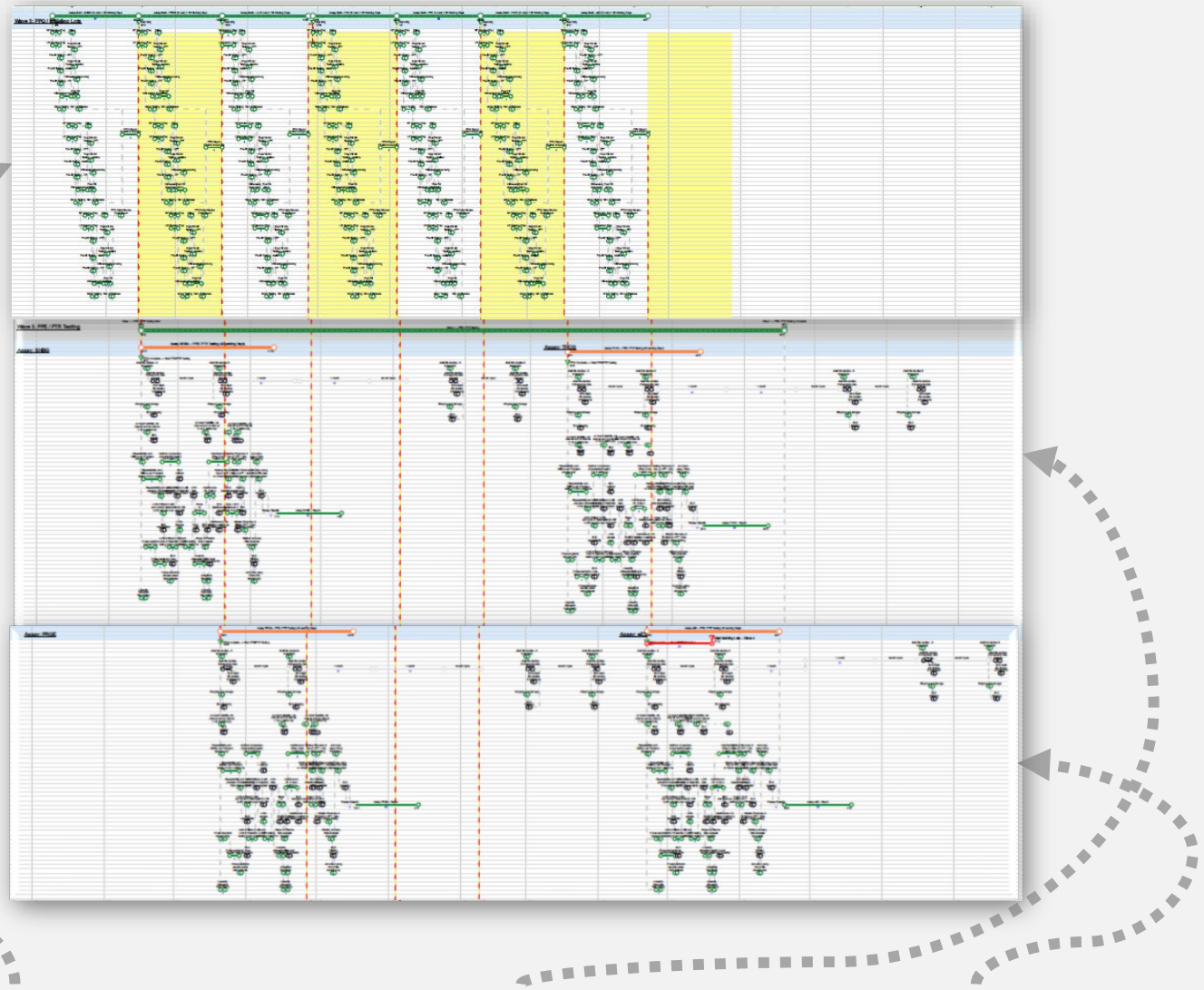


Leveraging NetPoint

Phased Schedule Development



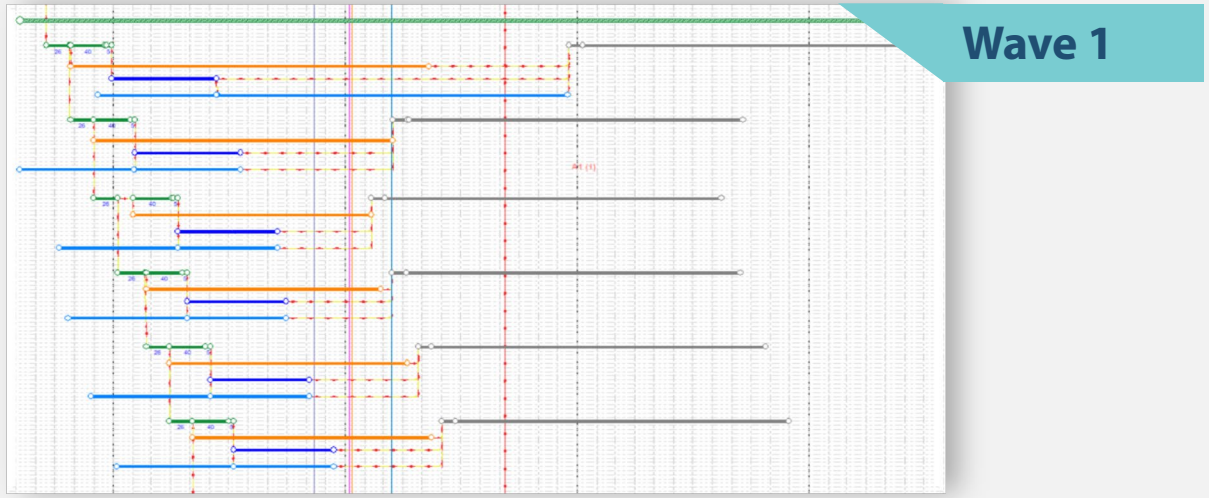
Putting It All Together



Identified relationships between product phases

- ✓ Adjusted logic as necessary
- ✓ Monitored resources

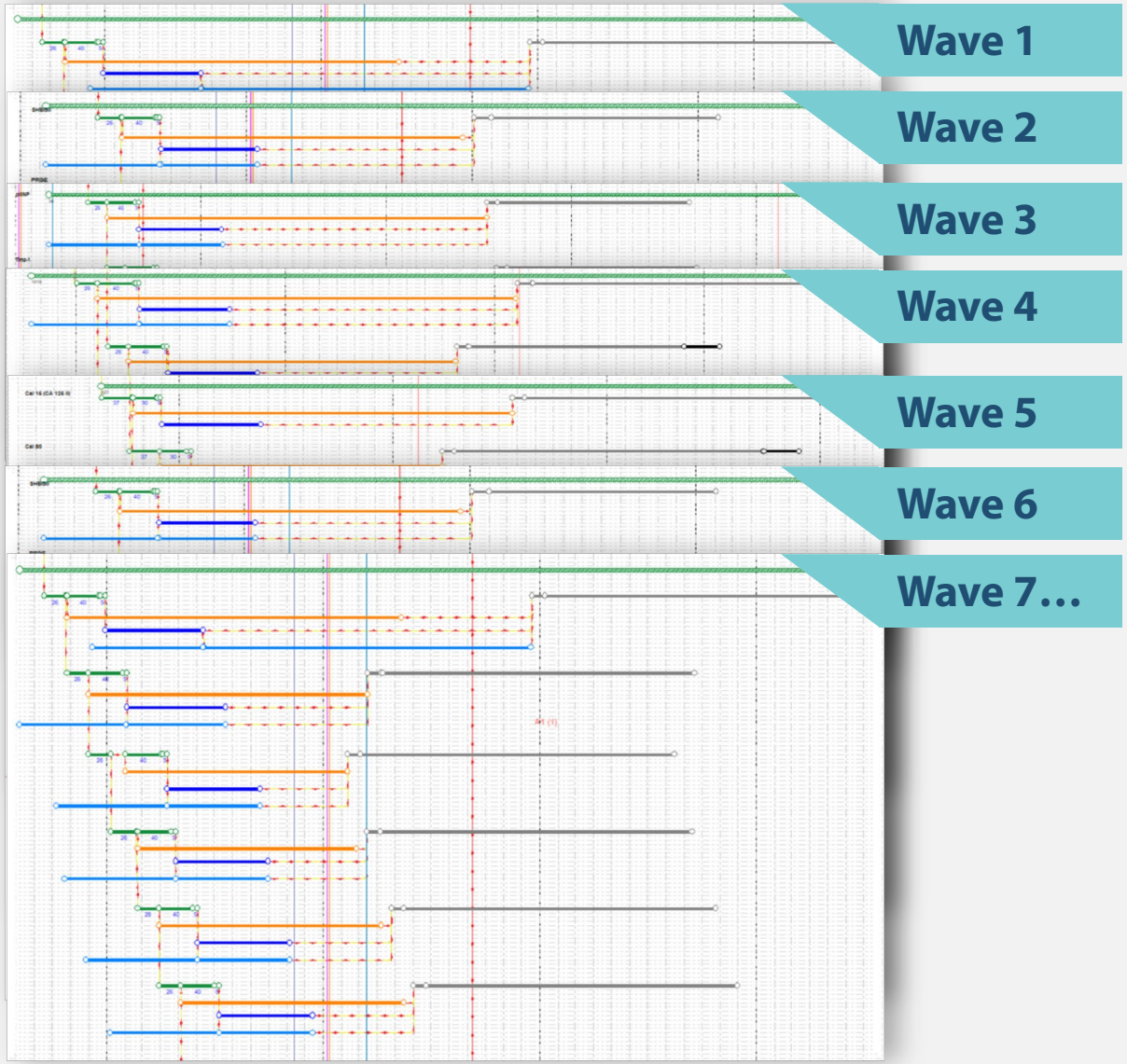
Putting It All Together



Identified relationships between Products → Single Wave Schedule

- ✓ Adjusted logic as necessary
- ✓ Monitored resources

Putting It All Together



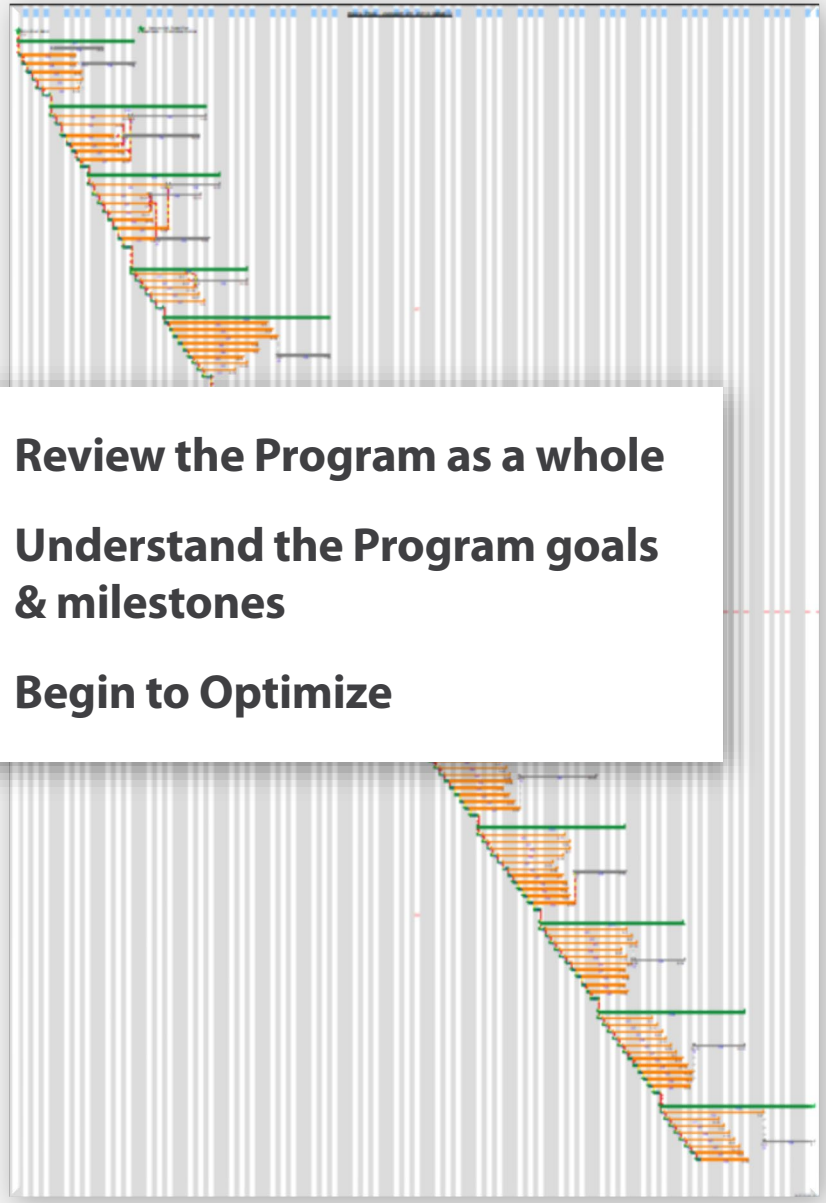
Identified relationships between Products → Single Wave Schedule

- ✓ Adjusted logic as necessary
- ✓ Monitored resources

Identified relationships between Waves

- ✓ Adjusted logic as necessary
- ✓ Monitored resources
- ✓ **Created a complete Wave Transfer Plan**

Putting It All Together



- ✓ **Review the Program as a whole**
- ✓ **Understand the Program goals & milestones**
- ✓ **Begin to Optimize**

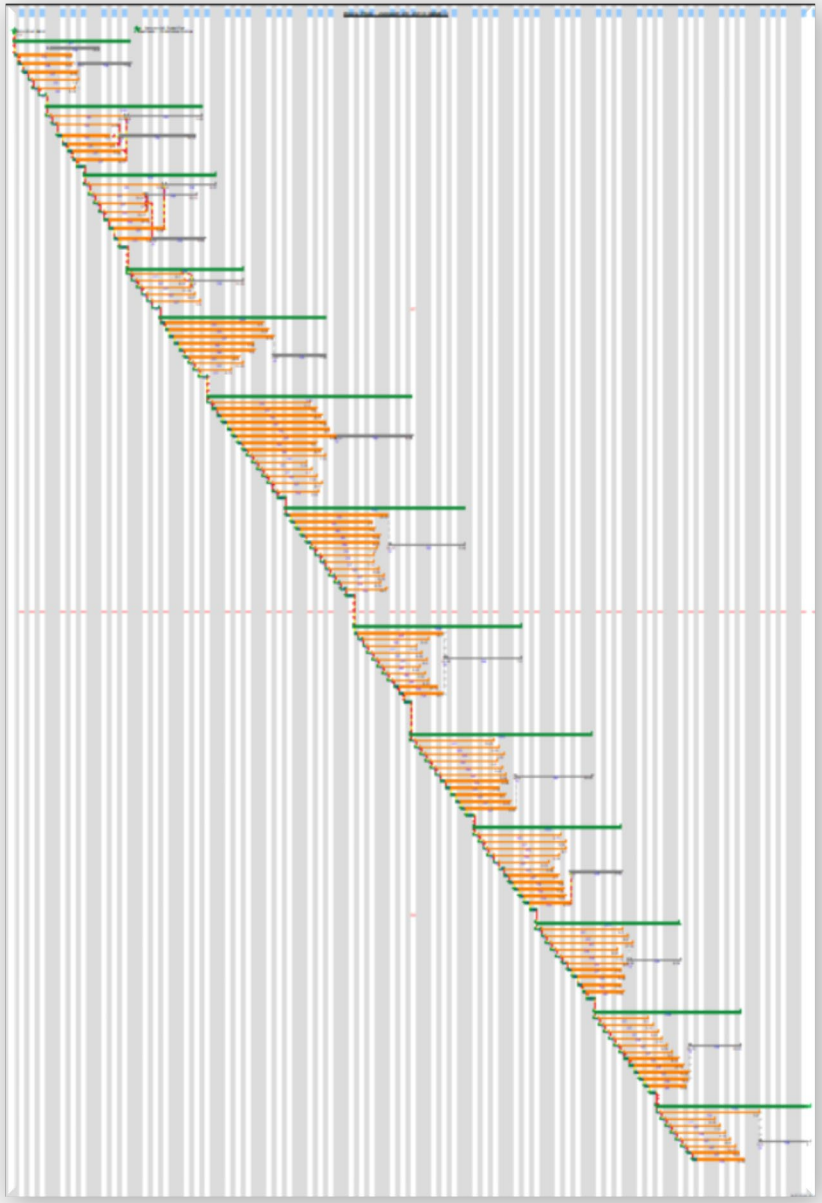
Identified relationships between Products → Single Wave Schedule

- ✓ Adjusted logic as necessary
- ✓ Monitored resources

Identified relationships between Waves

- ✓ Adjusted logic as necessary
- ✓ Monitored resources
- ✓ **Created a complete Wave Transfer Plan**

Putting It All Together



Developing Metrics

of Activities

- *30 – 75 activities per phase*
- *5 phases per product*
- *~10 products per Wave*
- *~10 total Waves*

of NetPoint Files

- *Detailed files for each phase (w/ resources)*
- *Created "templates" for product groupings*
- *1 NP file per Wave*

of Resources

- *Approximately 65% Equipment & Labor*
- *Approximately 25% Labor Only*

Wave Plan Optimization

Wave Plan Optimization

CONTINUOUS IMPROVEMENT

Evaluate/Define strategies to improve overall transferring plan while balancing project needs:

- ✓ Marketing
- ✓ Business / Revenue
- ✓ Manufacturing
- ✓ Sourcing
- ✓ Manpower
- ✓ Training
- ✓ Cost
- ✓ Schedule
- ✓ Risk exposures

01

Refine Product / Wave Order

Review proposed product order and provide recommendations to optimize overall timeline

02

Review Resource Assignments

Evaluate resource needs and identify bottle neck → propose strategies to overcome limitations

03

Conduct Schedule Risk Assessment

Evaluate impacts of schedule uncertainty to transfer plan duration / key project milestones using NetRisk

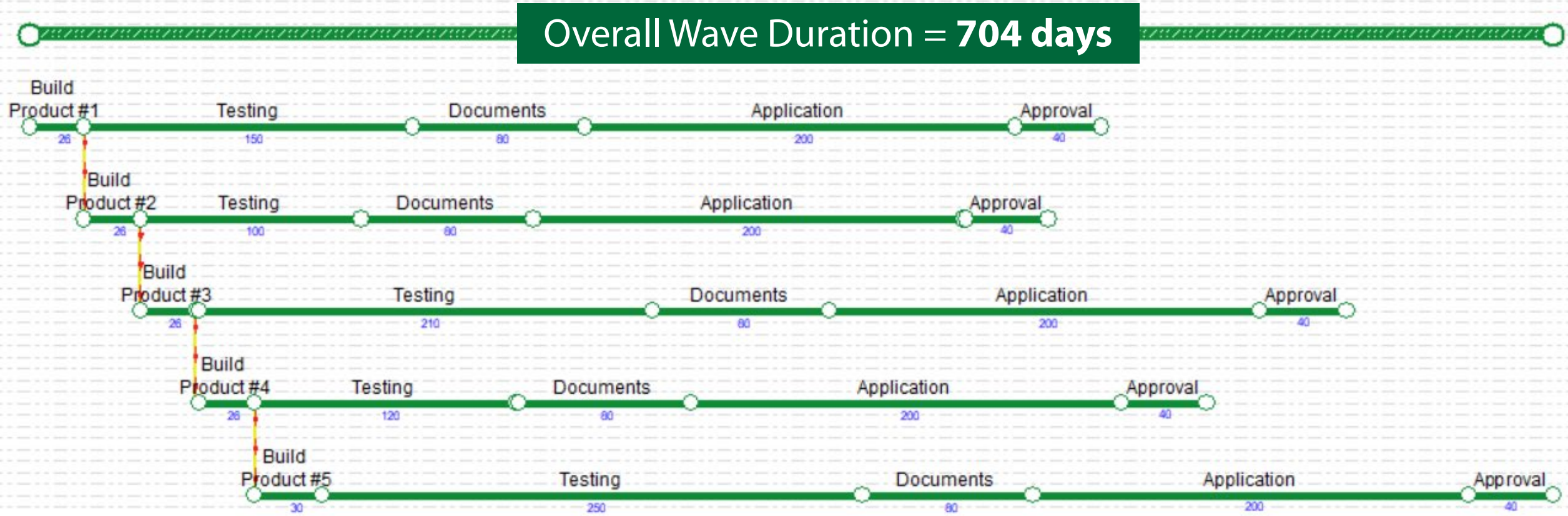
04

Risk Reponses Planning, Control & Monitoring.

Develop risk response strategies to minimize threat impacts and maximize opportunities. Control and monitor effectiveness of plan

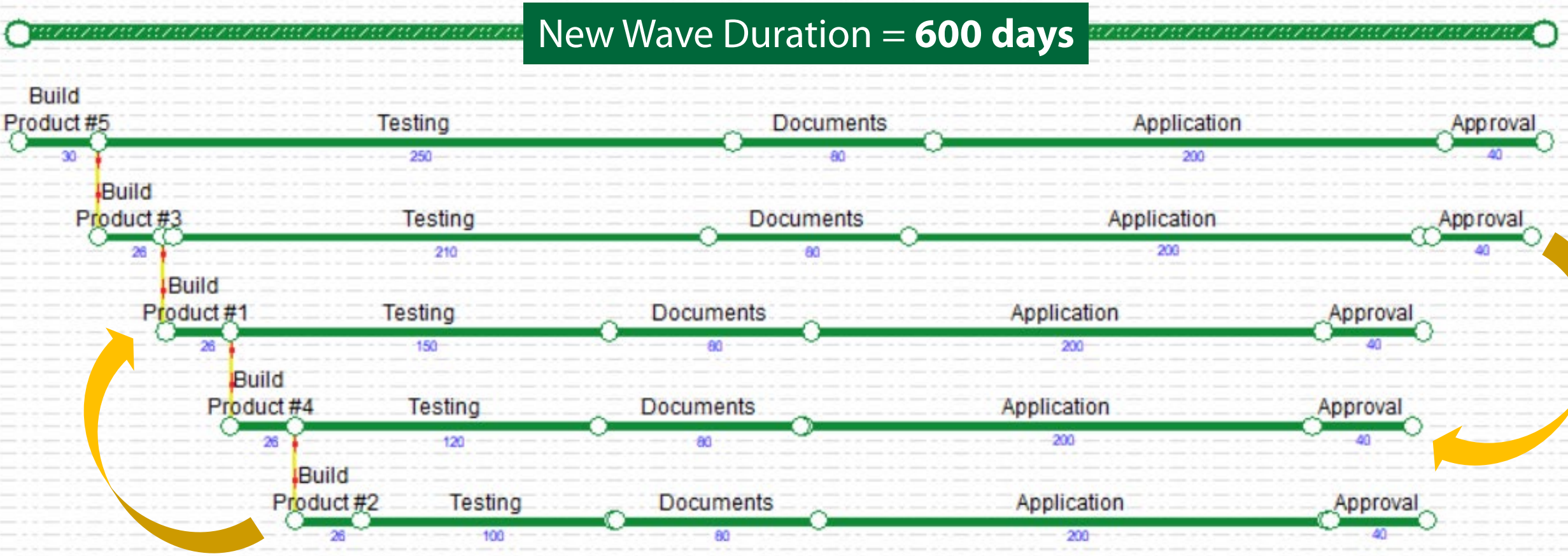
01 Refine Product Order

Order of the Product does affect the overall timeline



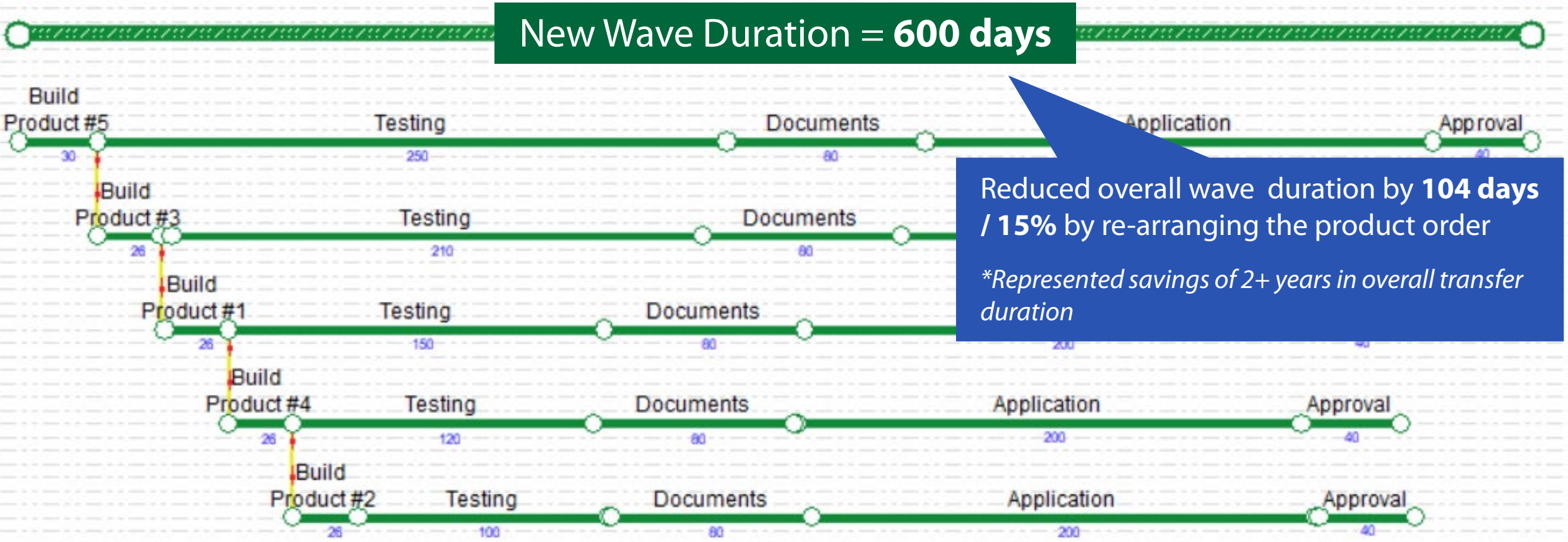
01 Refine Product Order

Order of the Product does affect the overall timeline



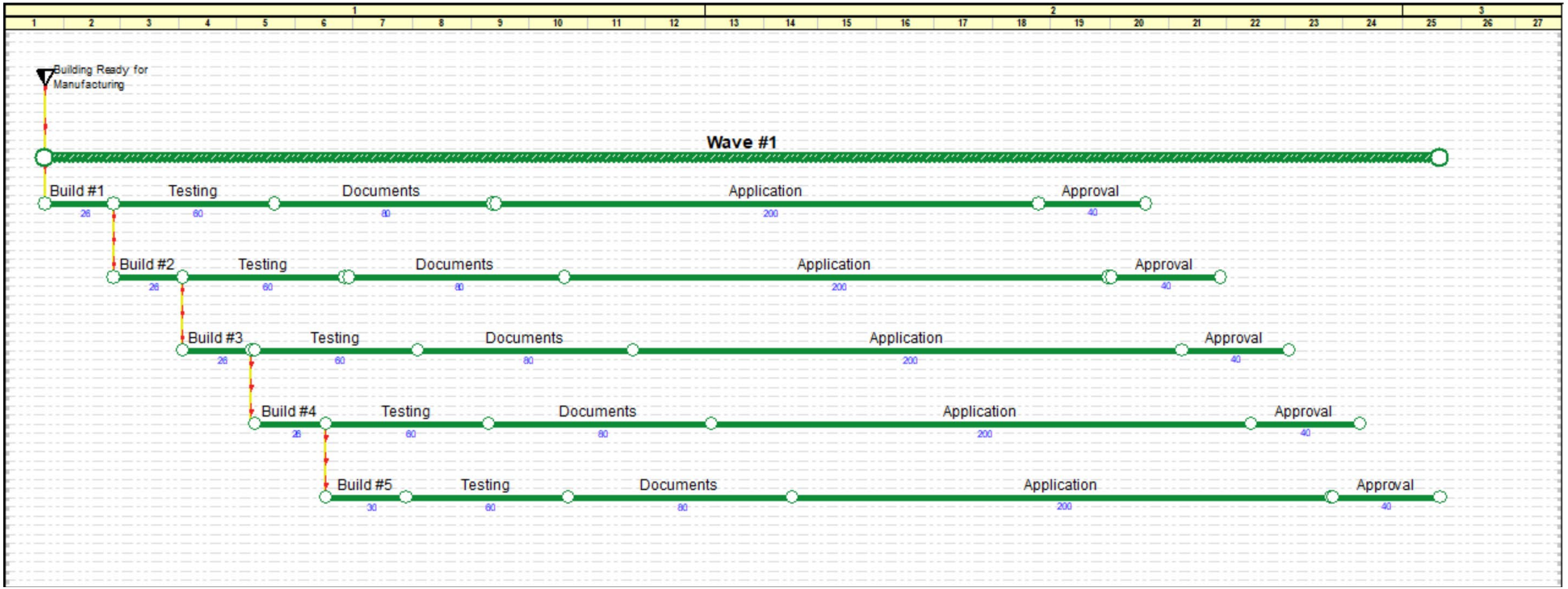
01 Refine Product Order

Order of the Product does affect the overall timeline



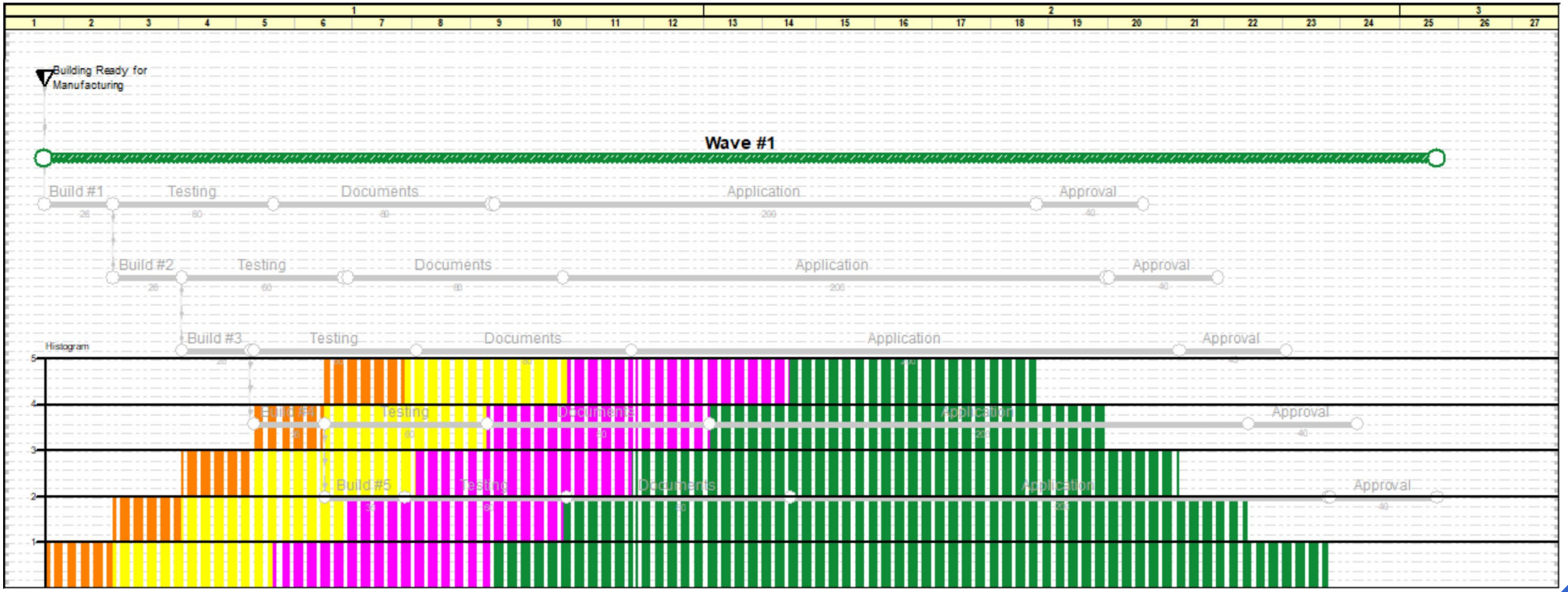
02 Review Resource Assignments

Equipment and Labor needed to support wave transfer → limiting factor



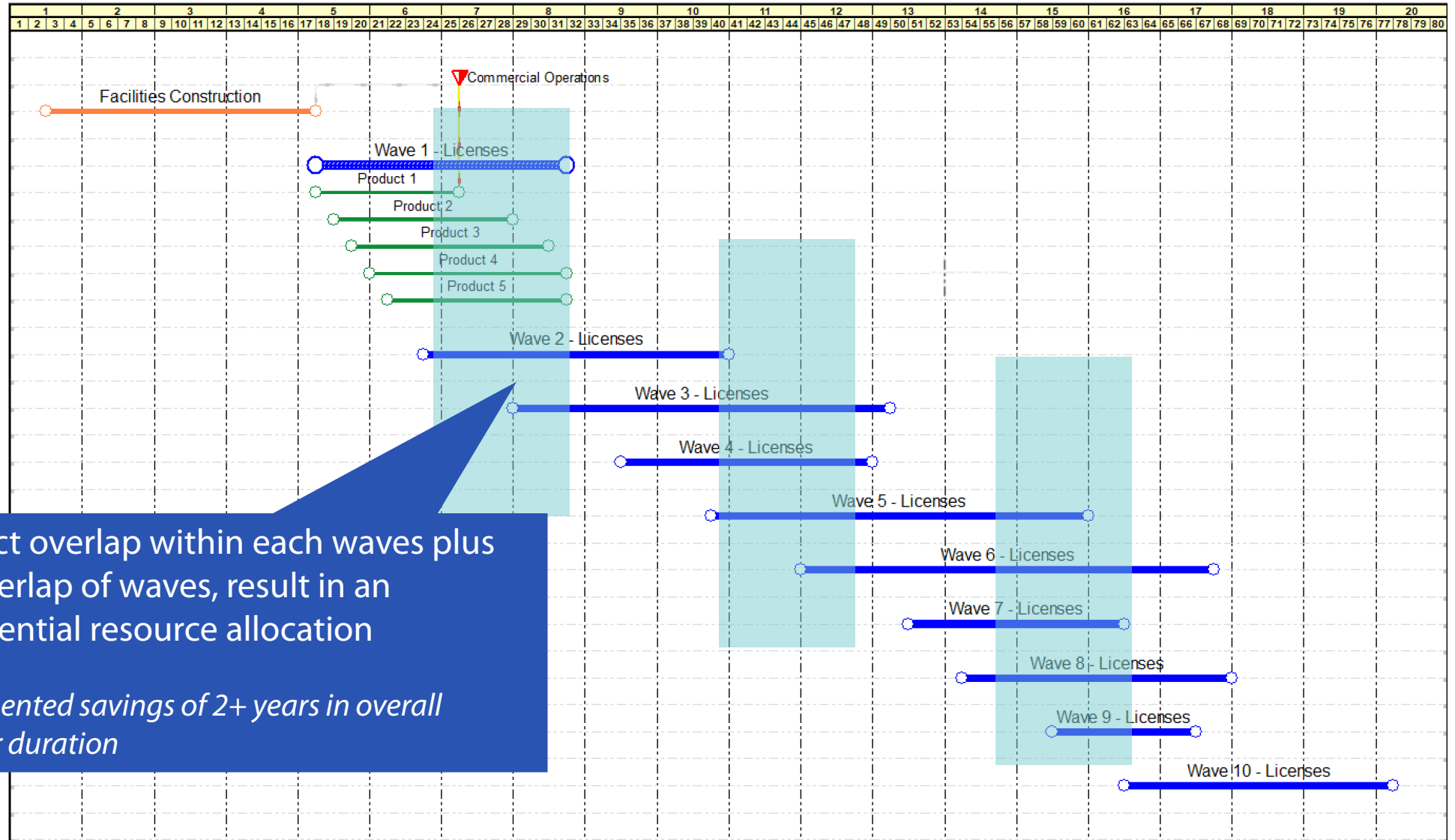
02 Review Resource Assignments

Equipment and Labor needed to support wave transfer → limiting factor



02 Review Resource Assignments

Equipment and Labor needed to support wave transfer → limiting factor

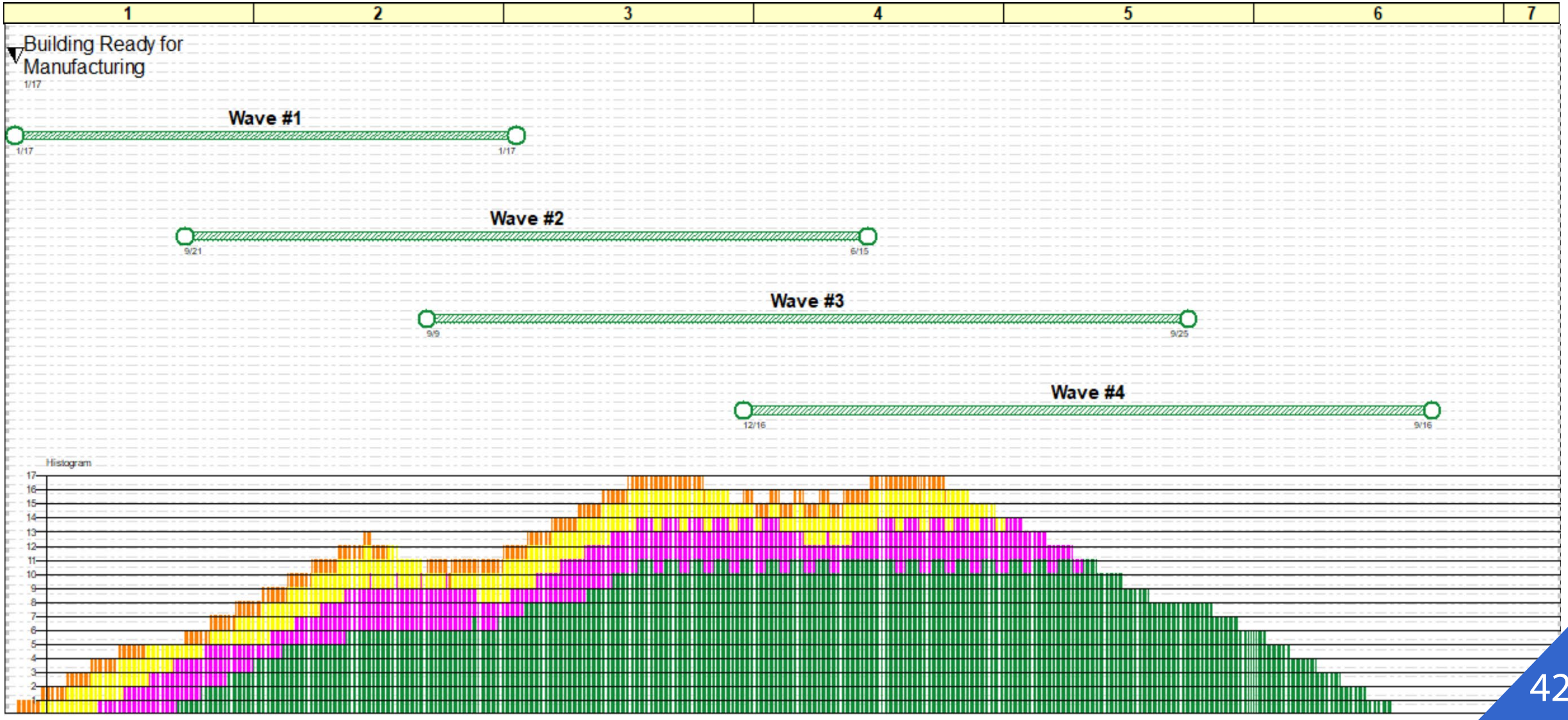


Product overlap within each waves plus the overlap of waves, result in an exponential resource allocation

**Represented savings of 2+ years in overall transfer duration*

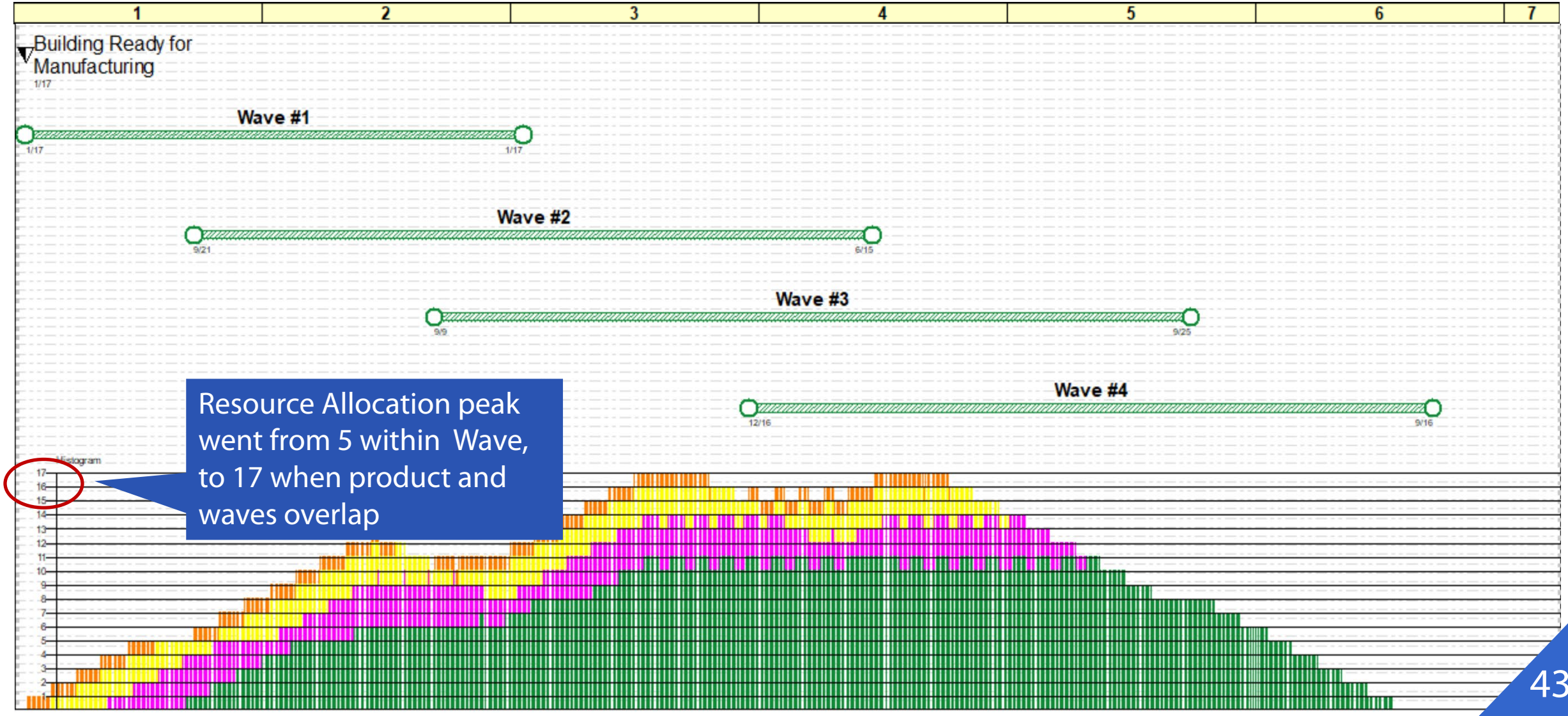
02 Review Resource Assignments

Equipment and Labor needed to support wave transfer → limiting factor



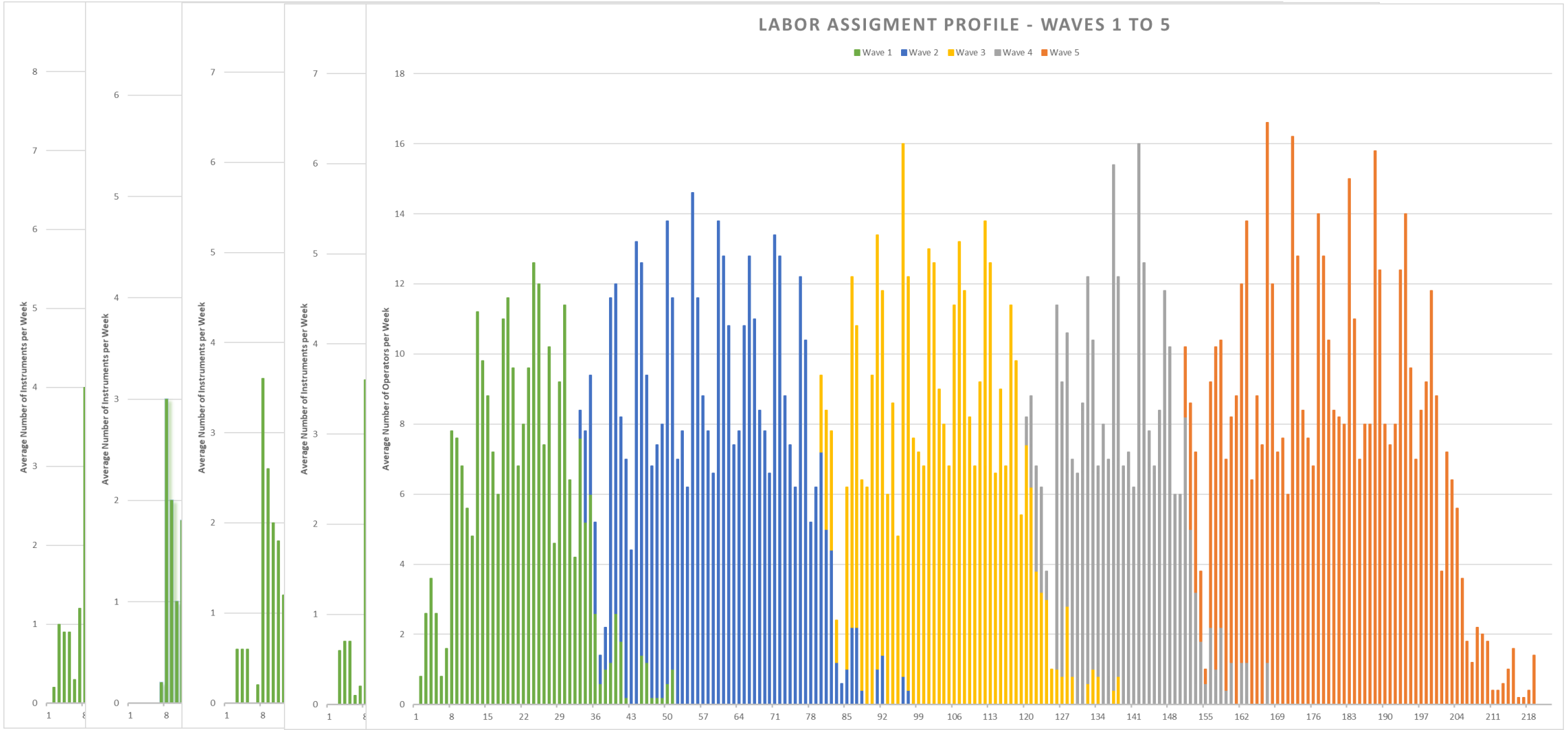
02 Review Resource Assignments

Equipment and Labor needed to support wave transfer → limiting factor



02 Review Resource Assignments

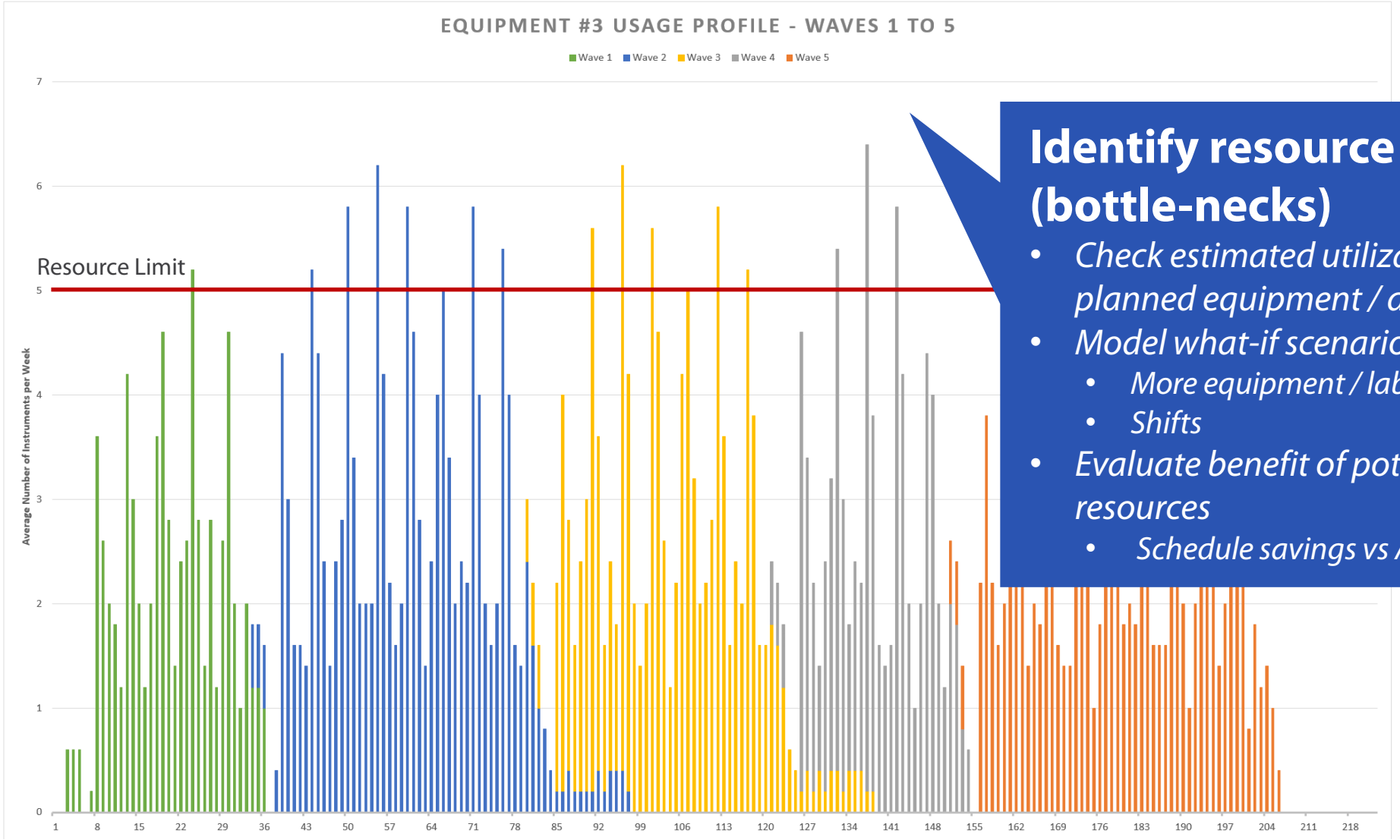
Created resource allocation charts for each equipment & operators



02

Review Resource Assignments

Created resource allocation charts for each equipment & operators

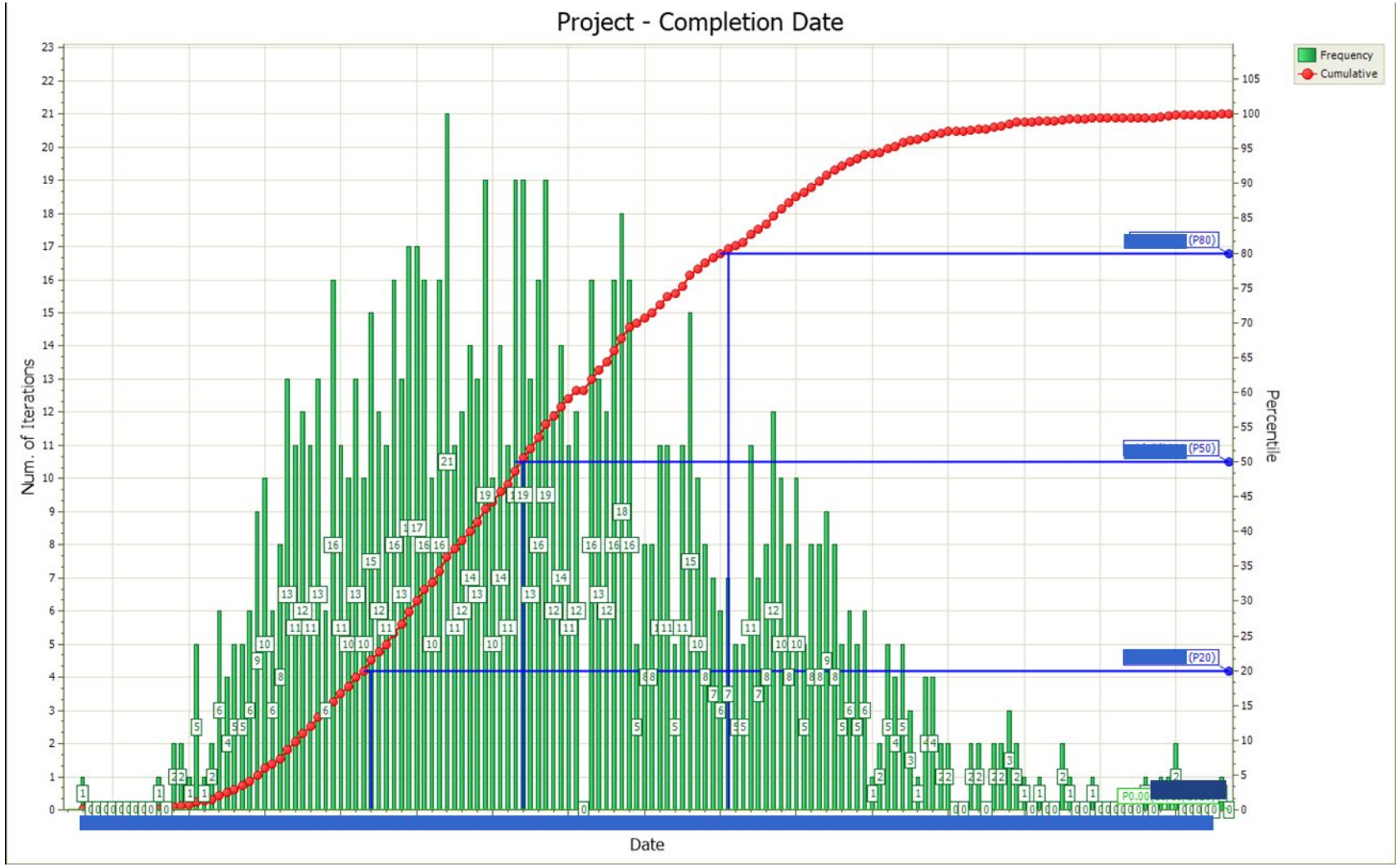


Identify resource limitations (bottle-necks)

- *Check estimated utilization peaks vs. planned equipment / design*
- *Model what-if scenarios*
  - *More equipment / labor*
  - *Shifts*
- *Evaluate benefit of potential additional resources*
  - *Schedule savings vs Added Cost*

03 Conduct Schedule Risk Assessment using NetRisk *(on-going effort)*

Factor Uncertainty → Risk Drivers & Duration Ranges



Benefits

- **A** Evaluate impacts of variability in manufacturing and testing procedures.
- **B** Understand compounded effect from product/wave prioritization and resource allocation, together with schedule uncertainty
- **C** Visibility of Cruciality, Criticality, Priority Index and Sensitivity.
- **D** Provide back-up data for decision making

04

Risk Response Planning, Control & Monitoring *(on-going effort)*

Strategies to manage risks, mitigate threats and maximize opportunities

Risk Response Planning

Establish strategies to minimize threats and maximize opportunities impacts.

Opportunities	Threats
Exploit	Avoid
Enhance	Transfer
Share	Mitigate
Accept	Accept

Monitoring and Controlling

- Implement risk response plans, control and monitor status of identified risks
- Continue to identify and evaluate potential new risks impact
- Evaluate the effectiveness of the risk response planning

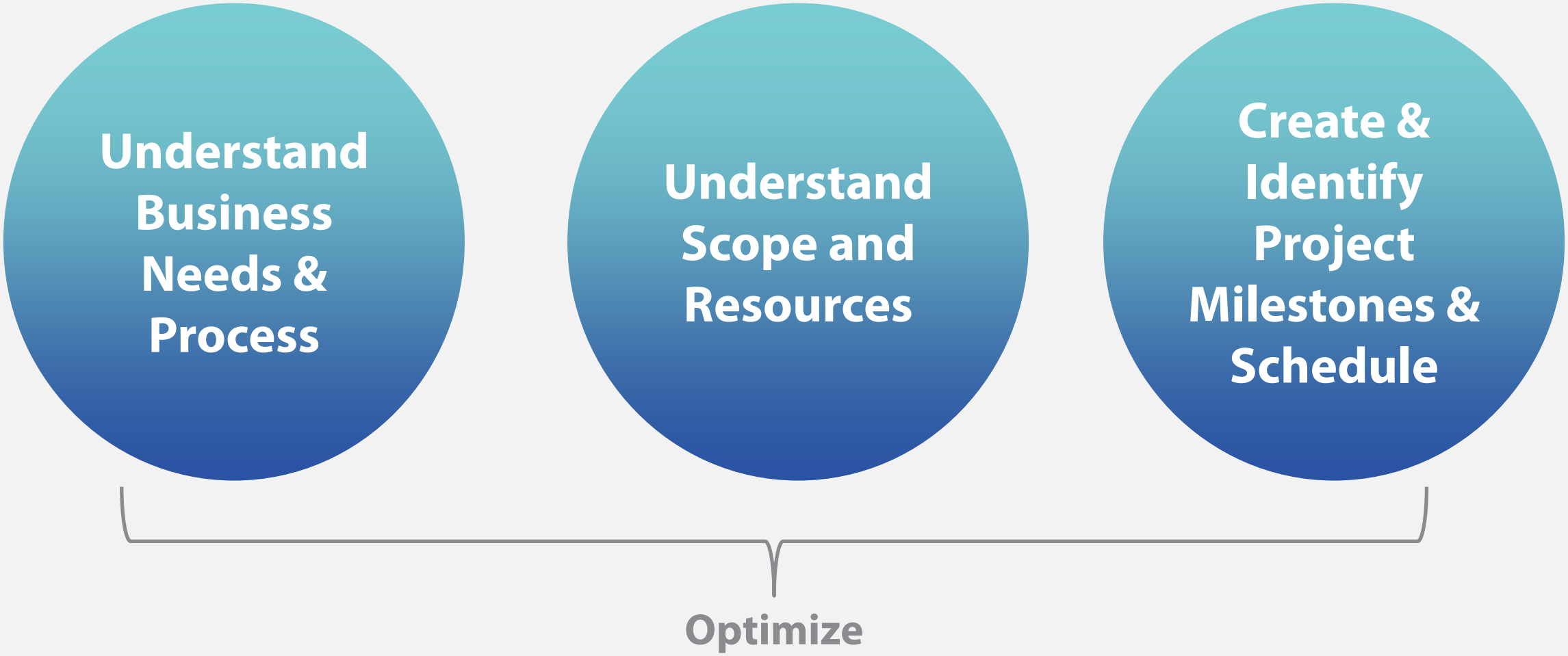
Decision Making

Project Need for Strategic Decisions

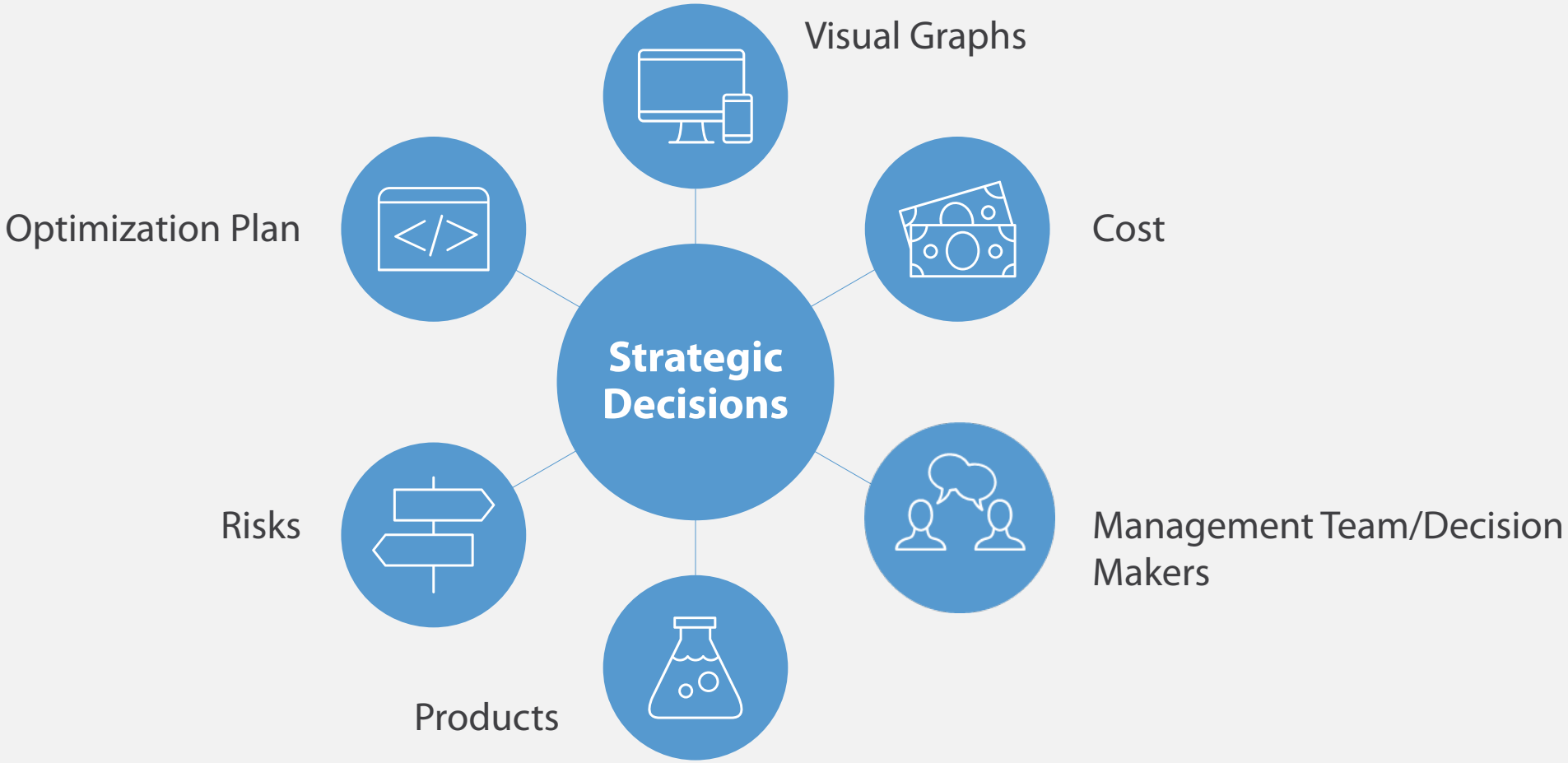
Strategic understanding, thinking, and optimization are critical to strategic decision making.

To successfully transfer products globally to a new manufacturing facility, we must make time for these activities.

Optimization Requirements



Decisions, Decisions



Options & Optimization

With understanding the business needs and process, strategic options can be developed in NetPoint to **optimize** schedule and cost:

01

Option one

Adding or removing resources or working shifts

02

Option two

Moving product transfer sequence

03

Option two

Creating parallel and simultaneous activities

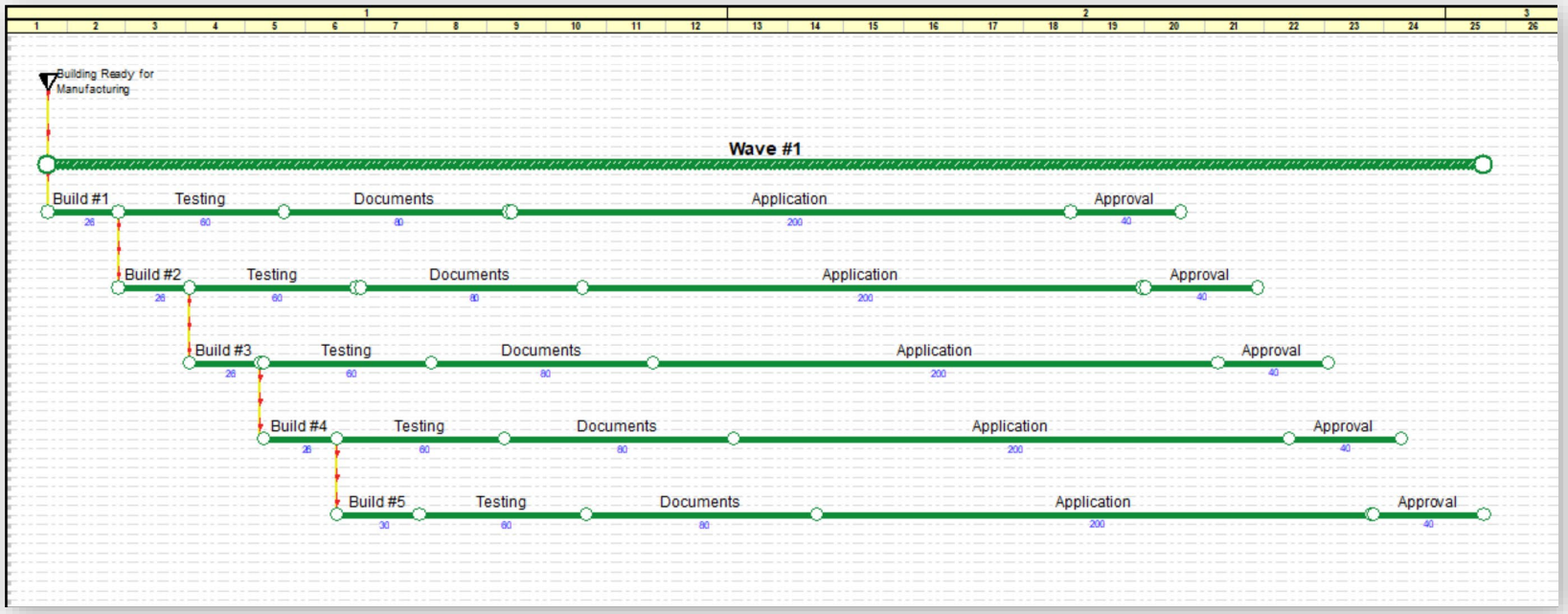
04

Option 4, etc.

Different combinations of options 1-3

Product Availability Projections

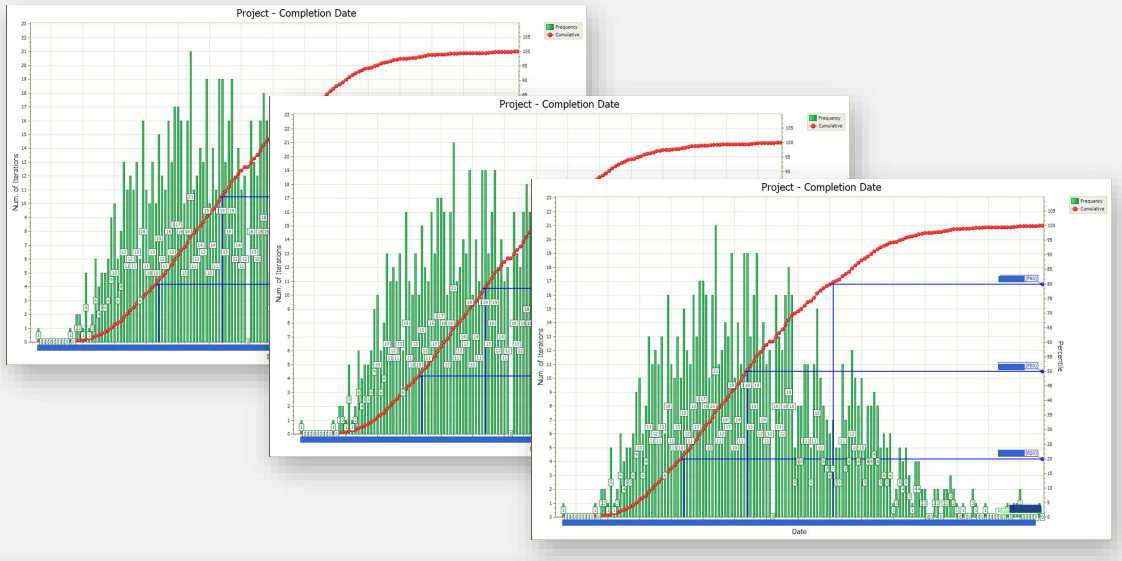
Adjust Business Case projection based on probabilistic schedule



A Deterministic completion date for each product

Product Availability Projections

Adjust Business Case projection based on probabilistic schedule

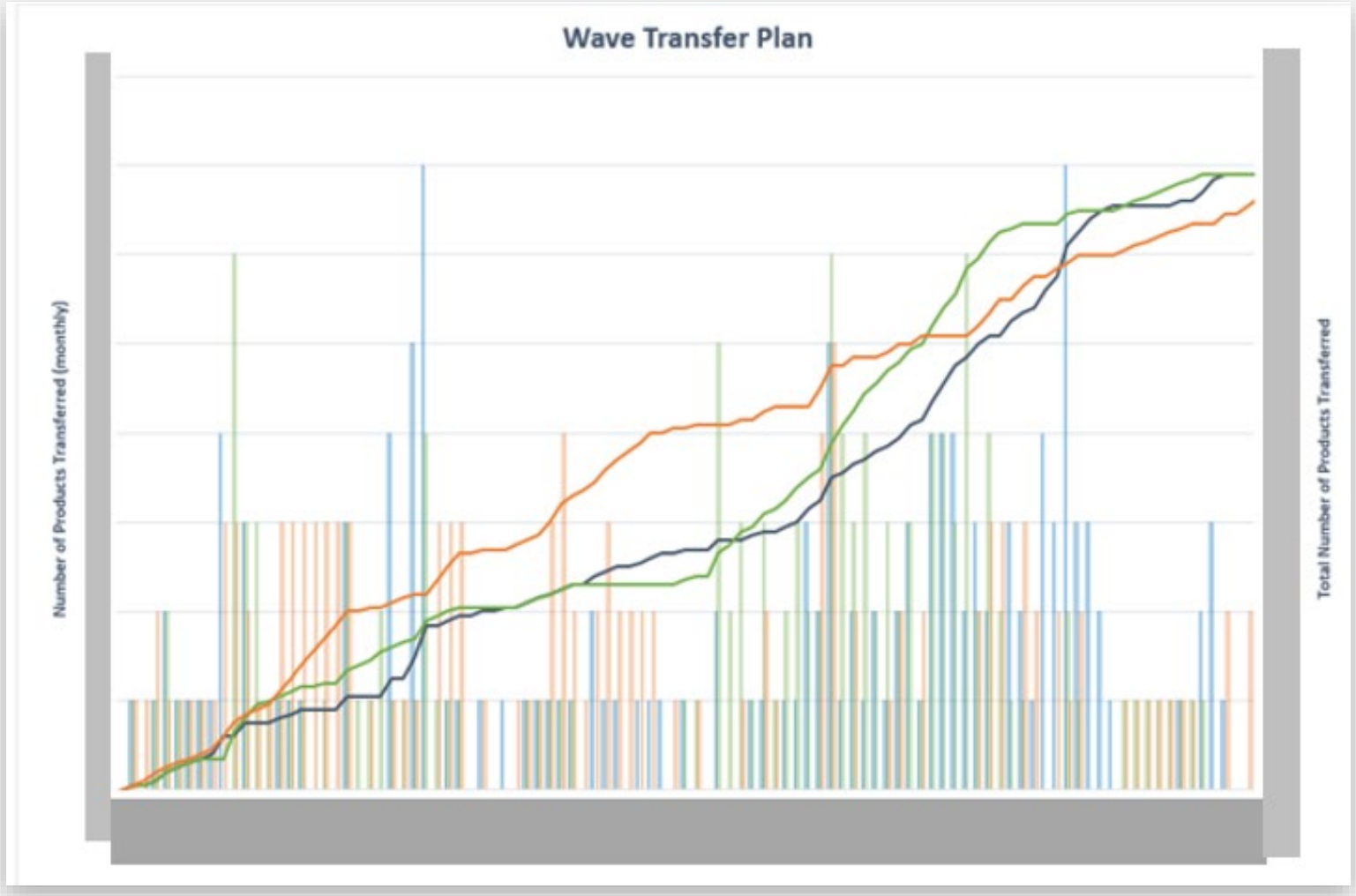


	Deterministic	Probabilistic		
Product	Completion Date	P20	P50	P80
Product #1				
Product #2				
Product #3				
Product #4				
Product #5				
Product #6				
Product #7				
Product #8				
Product #9				
Product #10				

- A Deterministic completion date for each product
- B Probabilistic completion date for each product → define confidence level (P20/P50/P80)

Product Availability Projections

Adjust Business Case projection based on probabilistic schedule



- A Deterministic completion date for each product
- B Probabilistic completion date for each product → define confidence level (P20/P50/P80)
- C **Product Availability Projections**
  - → Volume projections
  - → Revenue projections
  - Marketing Plan
  - Business Case
  - Staff Planning
  - Sourcing Plan

Determination of Benefit and Cost

Perform a cost benefit analysis for each product

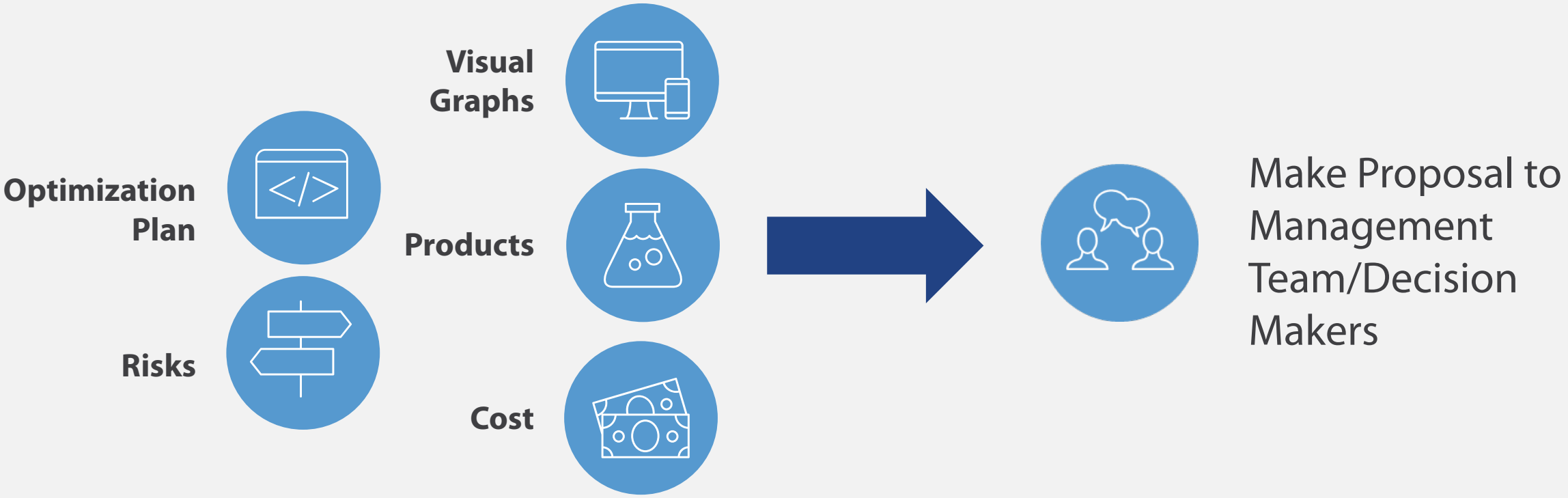
Product	Benefit				Total Benefit	Cost			Total Benefit-Cost =
	Revenue	Qty Shipped		Total Benefit		SPC	Class	Total Cost	
		FY18	Q1 FY19						
A	$$$$	4	4	8	16	1	2	3	**13**
B	$	5	5	10	20	1	2	3	**17**
C	$$	4	4	8	16	1	2	3	**13**
D	$	5	5	10	20	1	2	3	**17**
E	$$$$$$	4	3	7	14	2	2	4	**10**
F	$$	4	4	8	16	1	2	3	**13**
G	-	5	5	10	20	1	2	3	**17**
H	$$$	5	4	9	18	4	2	6	**12**
I	$$$	5	5	10	20	1	2	3	**17**
J	$	4	4	8	16	1	2	3	**13**

A. Calculating Total Benefit based on Revenue and Product Shipped

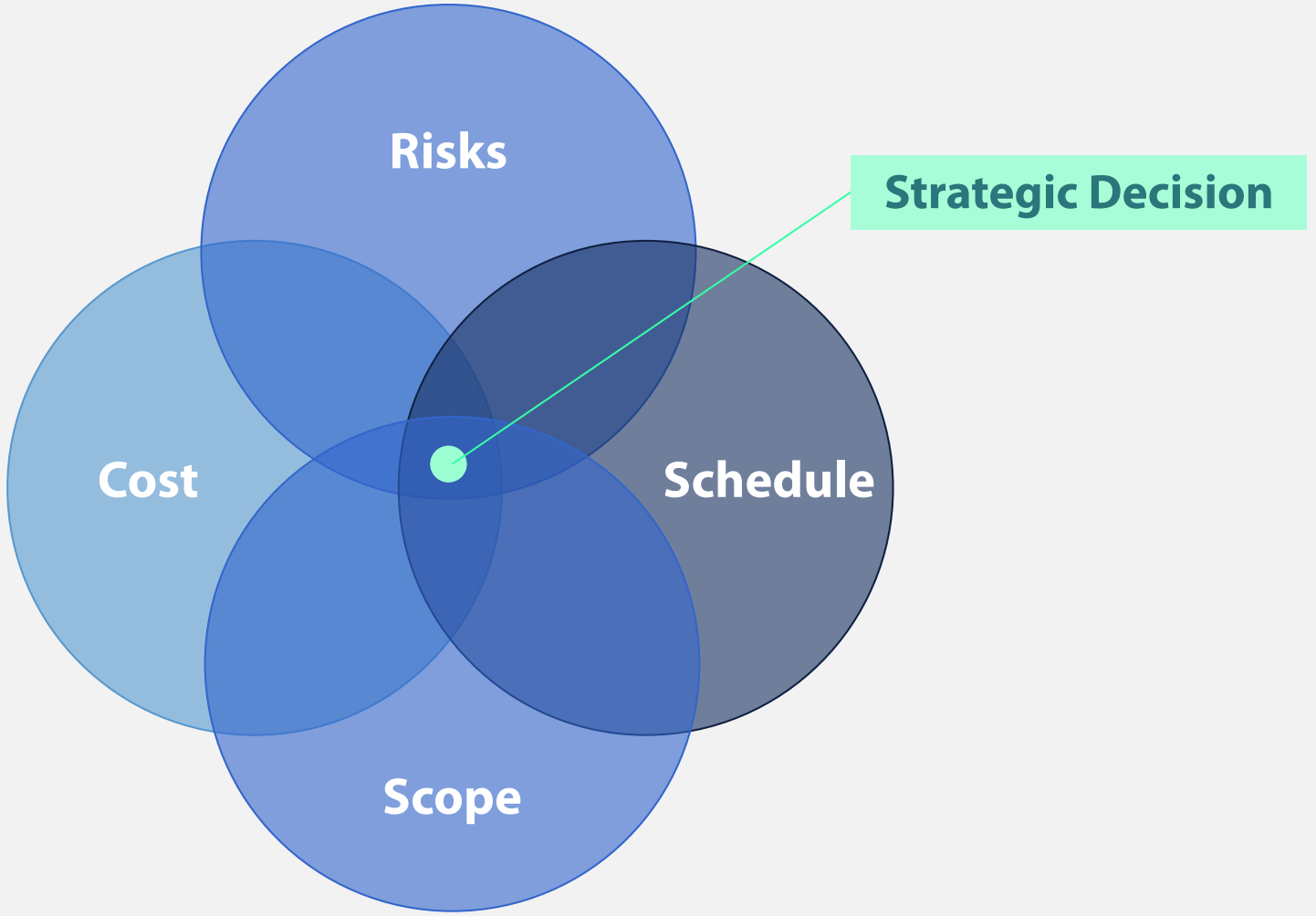
B. Calculating Total Cost based on SPC and external factors

C. Calculating Total Benefit-Cost to apply to optimizations

Time to Make Decisions



Strategic Decision Made



Conclusions

Conclusions

NetPoint is a tool used by the team
to create reliable execution plans.

Conclusions

NetPoint is a tool to communicate
strategy and drive collaboration.

Conclusions

NetPoint is a tool to communicate strategy and drive collaboration.

Strategic Plans

- Executive Leadership
- Investment Committee
- Business Unit Leadership
- Project Leadership

Tactical Plans

- Quality Control and Technical Operations
- International Operations
- Procurement and Logistics support team
- Design and Construction team

Q & A Time

Thank you – Any Questions?

Jennifer Cipollini
Senior Manager, Project Management
linkedin.com/in/jennifer-cipollini-mba-a45aa546

Tim Stoll
Senior Director, Manufacturing Strategic Projects
https://www.linkedin.com/in/tistoll/

Angel Arvelo
Senior Director, PMA Consultants
www.linkedin.com/in/arvelo

Blake Cuneo
Senior Consultant, PMA Consultants
linkedin.com/in/blake-cuneo-40372480