



# Analyzing Physical Barriers in Antibody Manufacturing:

*Capacity Planning for the Manufacture of  
Antibody Drug Substance*

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Ralph Lambalot, PhD  
Plant Manager  
Abbott Bioresearch Center  
Worcester, MA

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# Presentation Objectives

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- Factors influencing capacity utilization at Abbott Worcester
- Capacity planning scenarios for the long, mid and near term
- Overcoming the physical barriers of plant capacity
  - Production capacity/throughput
  - Equipment efficiency
  - FTE efficiency

# Abbott Biologics API Manufacturing Facilities



## Abbott Bioresearch Center (ABC) Worcester, MA

- Fully integrated site from Discovery through API manufacture
- Manufacture preclinical, clinical and commercial API for Abbott and Third Party Clients



## Abbott Biotechnologies Ltd (ABL) Barceloneta, PR

- Commercial Humira API mfg
- Expansion capacity for future commercial demand
- Small volume parenteral fill line

# Factors Influencing ABC Capacity Utilization

## 1. Backfilling a Blockbuster



**Abbott Bioresearch Center (ABC)  
Worcester, MA**



**Abbott Biotechnologies Ltd (ABL)  
Barceloneta, PR**

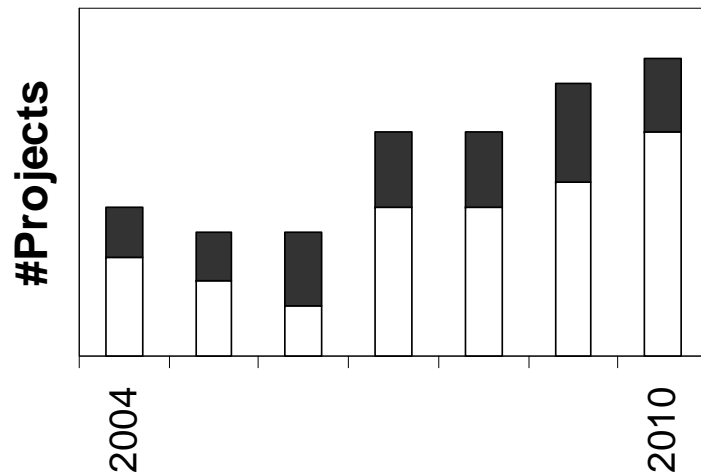
Filling the void following  
HUMIRA Tech Transfer

**HUMIRA  
API Mfg  
Primary Site**

# Factors Influencing ABC Capacity Utilization

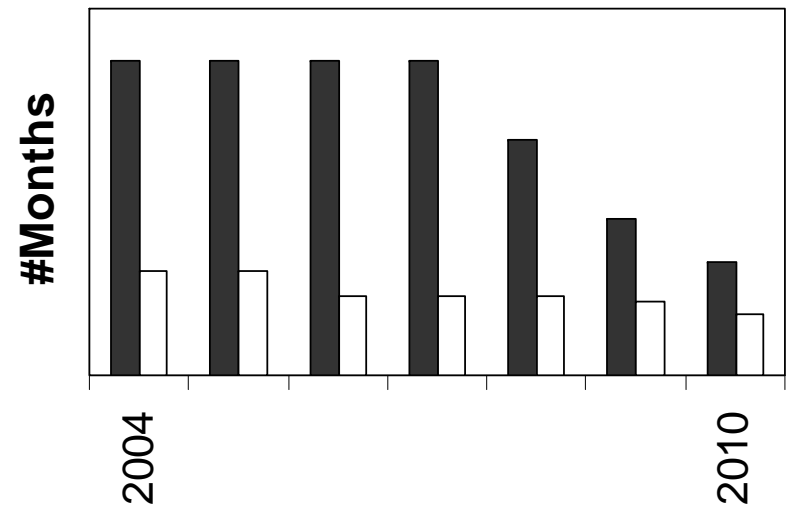
## 2. A Shift Toward Increased Clinical Mfg

**Clinical vs. Commercial Project Distribution**



- ↑ # clinical projects
- ↑ # new product introductions

**Average Campaign Duration**



- ↓ campaign duration
- ↑ # changeovers

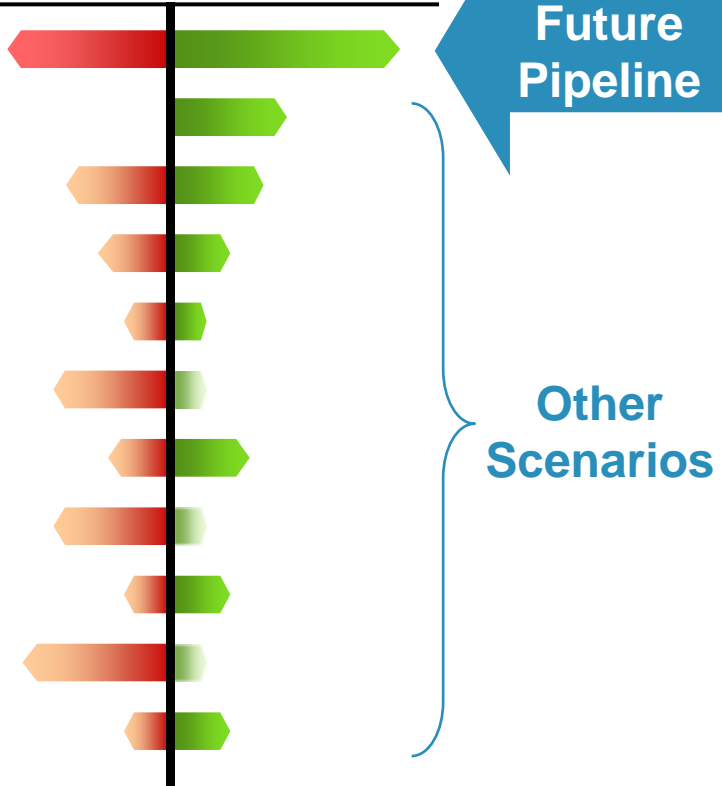
*Requires flexible capacity with shorter cycle times*

# Factors Influencing ABC Capacity Utilization

## 3. Future Demand Projections

### 2012-19 Small Suite Demand\*

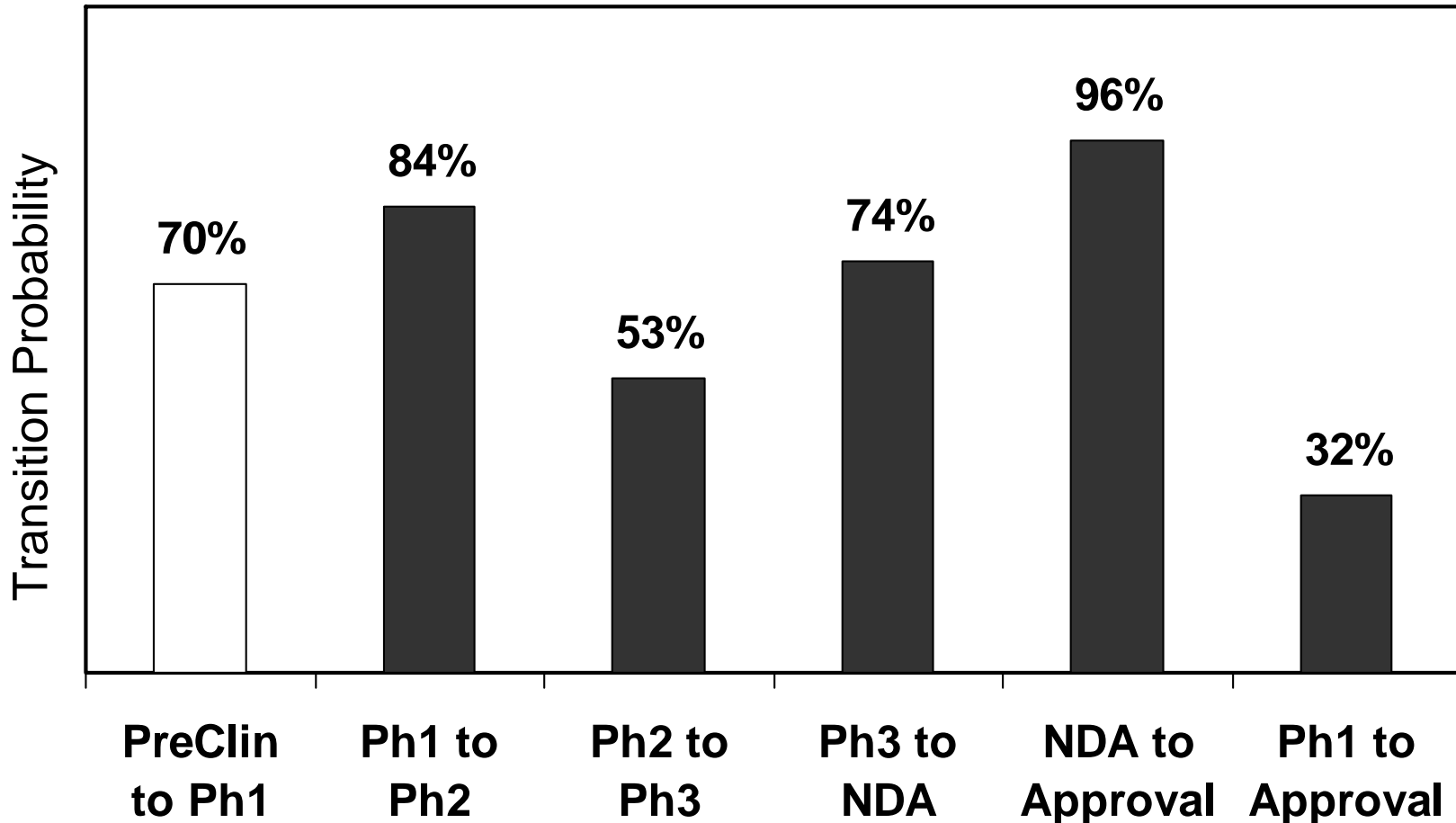
less ← Base Case → greater



- 10 Year Demand Forecast
  - Arrow length indicates volume change
  - Arrow shade indicates likelihood
  - Darker shade denotes more likely
- Future pipeline shows the greatest uncertainty relative to base case assumptions
- Preparation for upside case will require greater flexibility from existing facility

# Development Risks

## Probabilities of Successful Phase Transitions



*Black bars: DiMasi et al., Clinical Pharmacology & Therapeutics, March 2010 Vol 87(3) pp.272-277*

*White bar: KMR Group Pharmaceutical Benchmarking Forum*

# Identifying Physical Barriers to Capacity

## *Capacity Planning Time Horizons*

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Future Capacity & Demand Planning (2xLRP)



**10 Year**

Long Range Planning (LRP)



**5 Year**

Sales & Operations Planning (S&OP)



**2 Year**

# Future Capacity & Demand Planning (2xLRP)

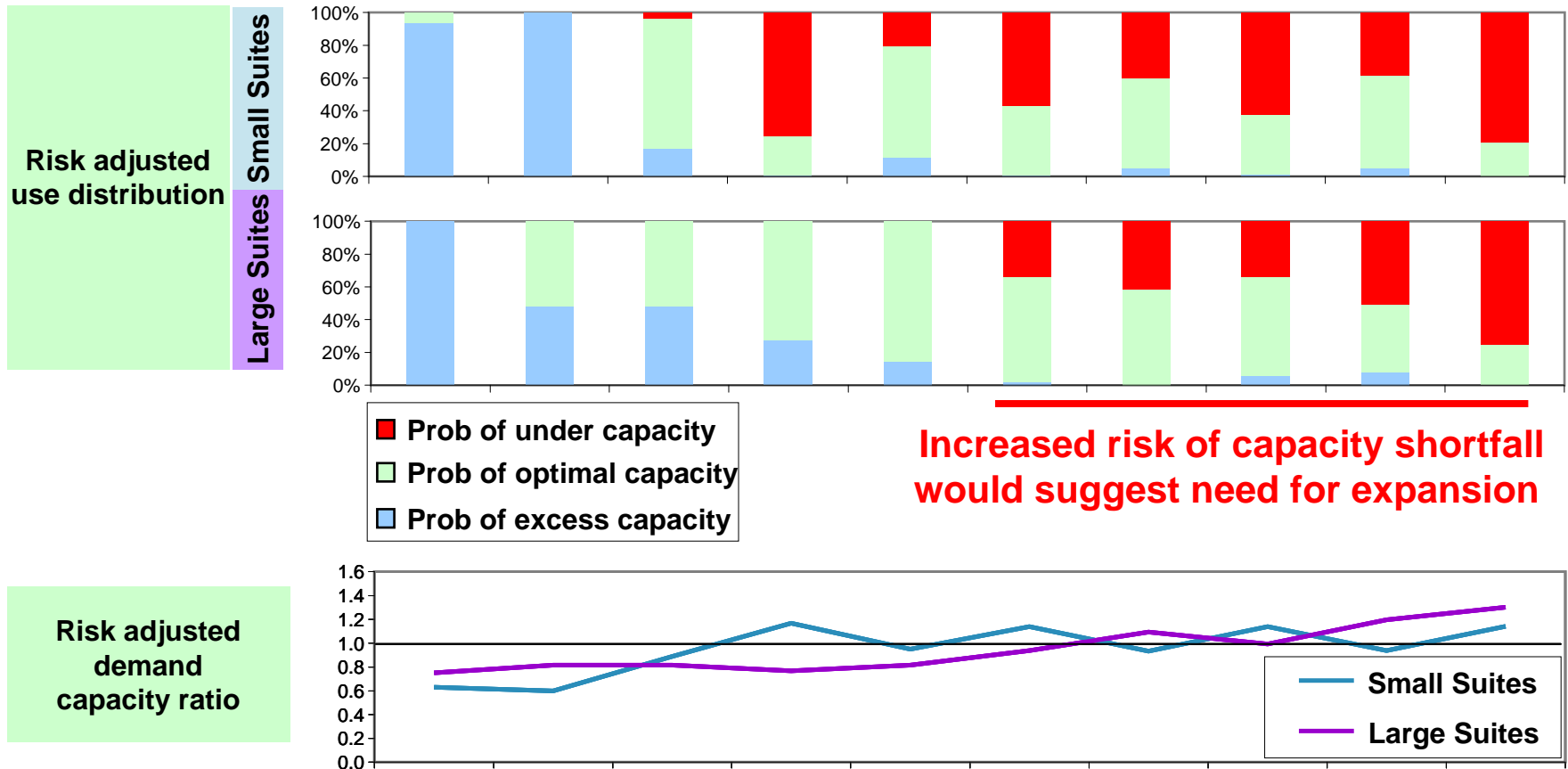
## 10 Year

- 10 Year Rolling Window
  - Quarter level schedule granularity for data inputs
  - Refreshed periodically as situation warrants
  - Incorporates risk adjusted demands for future portfolio
  - Provides for dynamic scenario planning to develop probability forecasts
    - i.e. probability of being under capacity, at capacity and above capacity
  - Drives timing of large capital investments and “make vs buy” decisions

# 10 Year Demand Forecast

## Upside Scenario

Driven by early development portfolio impact to pre-clinical/clinical capacity

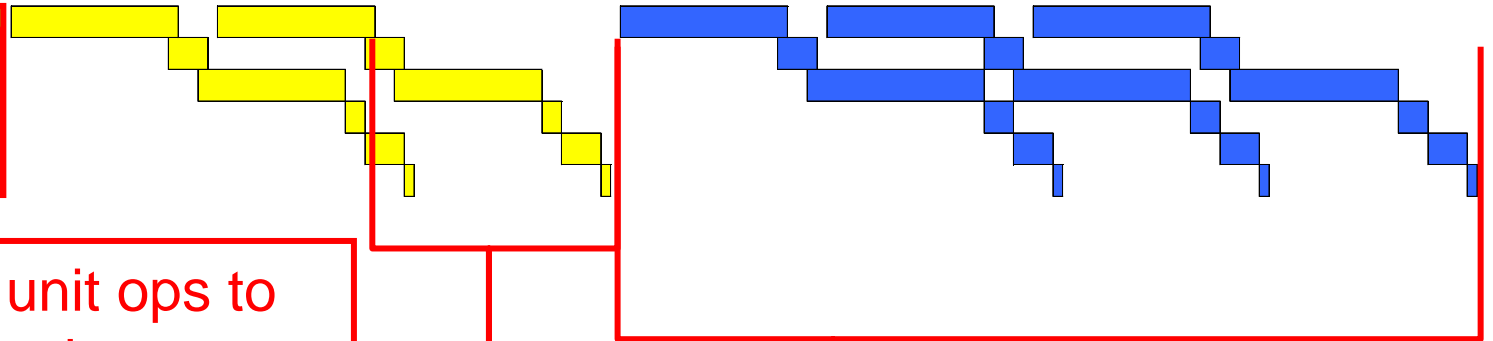


# Expansion Strategies: Pre-Clinical/Clinical Capacity

## *Hedging for the Upside Scenario*

JAN                      FEB                      MAR                      APR                      MAY

Single Reactor Suite	INOC
	SEED
	FERM
	CAPTURE
	PURIFICATION
	BOTTLING



1. Decouple unit ops to accelerate changeover

2. Reduce suite changeover time

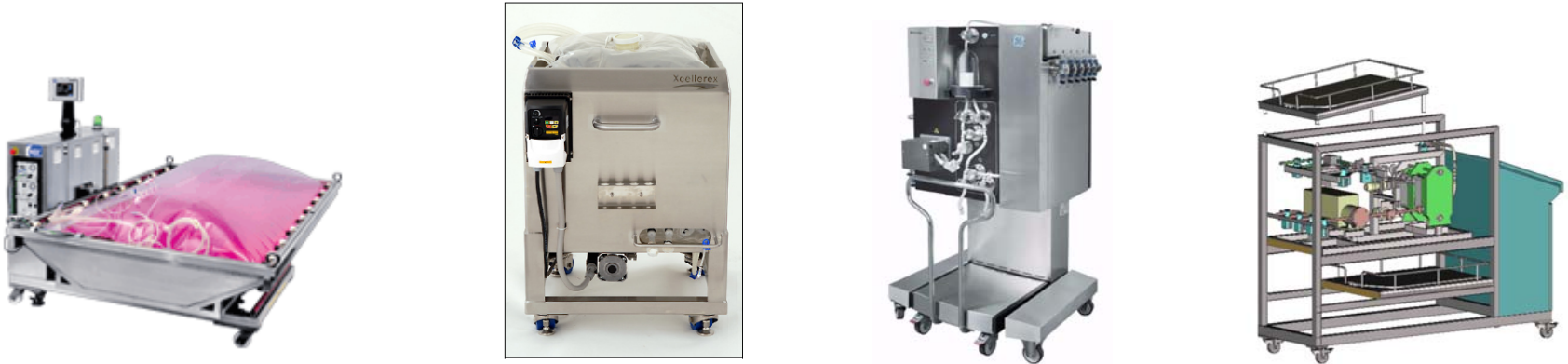
3. Reduce campaign duration/#runs, increase #projects through suite

4. Augment existing capacity with disposables

- Campaign 1
- Campaign 2

# Expansion Strategies: Pre-Clinical/Clinical Capacity

## *500L Disposable Suite*



- Production of tox material and/or Phase I GMP material
- Maximized utilization of disposable technology across all unit operations

# Additional Implementations of Disposables

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- Core Support
  - Buffer & Media bags
  - Filters
- Upstream Operations
  - Shaker & Spinner Flasks
  - Wave Bags
  - Sample systems
- Downstream Operations
  - POD Filters
  - Mixing Systems, up to 1000L
  - Q Membranes
- Some of the Benefits
  - Reduce tankage requirements
  - Reduce QC micro testing
  - Minimize changeovers
  - Reduce water usage
  - Reduce maintenance
  - Reduce clutter
  - Free space

# Long Range Planning (LRP)



## 5 Year

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- 5 Year Rolling Window
  - Quarter level schedule granularity
  - Refreshed annually
  - Financial forecast
    - Capacity absorption
    - Headcount growth/attrition
    - CMO activities
  - Capital investment plan
    - Capacity expansion
    - New equipment
    - Continuous improvement & compliance initiatives

# Sales & Operations Planning (S&OP)



## 2 Year

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- 4 – 24 Month Rolling Window
  - Week level schedule granularity
  - Refreshed monthly through S&OP meeting cycle\*
    - week 1      Portfolio Review
    - week 2      Demand Review
    - week 3      Supply Review
    - week 4      Management Business Review / Financial Reconciliation
- 0 – 4 Month Firm Planning Zone
  - Monitored weekly at Schedule Review meetings
  - Ensures proper scheduling of resources – people and equipment
  - Drives New Product Introduction (NPI), Master Resource Plan (MRP), and Master Production Schedule (MPS)

*\* Oliver Wight Class A Integrated Business Planning Process*

# Rough Cut Capacity Plan

## Executing the Strategy

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
500L						Ph1			Ph1			Ph1		Ph1		Ph1		Ph1		Ph1				
3000L	Ph1			Ph2					Ph1			Ph1		Ph1		Ph1		Ph1		Ph1				
3000L	Registration										Registration						Ph2			Ph1				
3000L	Commercial										Ph3					Ph3						Ph2		
6000L	Commercial			Registration					Commercial											Pre-Approval Inspection				

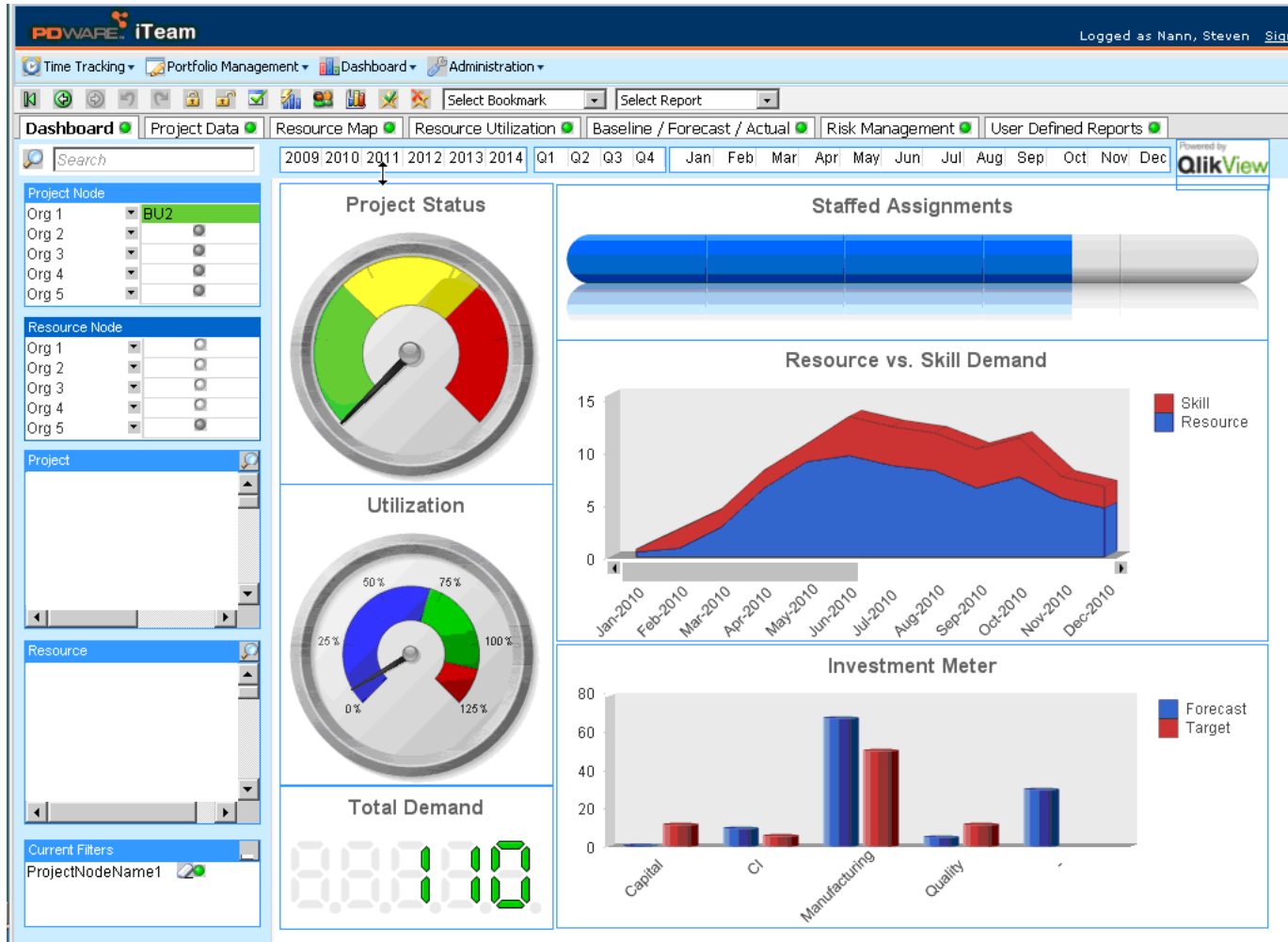


Current Month

Confirmed  
 Pending

# PDWare

## Building a Better FTE Capacity Model



# Summary

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# Acknowledgements

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  - Dave Wilson
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  - Melissa Semple
  - Carrington Edmunds
- **Class A S&OP Team**

