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Practical Applications for Clinical Demand and Operations Planning

Randy Schwemmin
Genentech Clinical Demand and Supply Planning

Biotech Supply Chain Academy

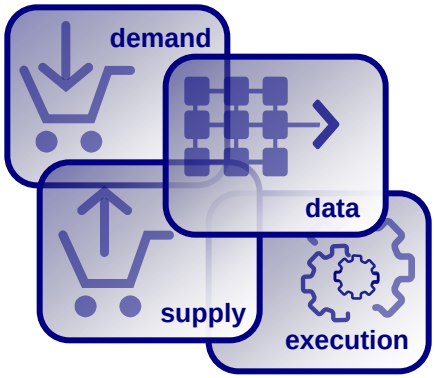
8 November 2011

Agenda

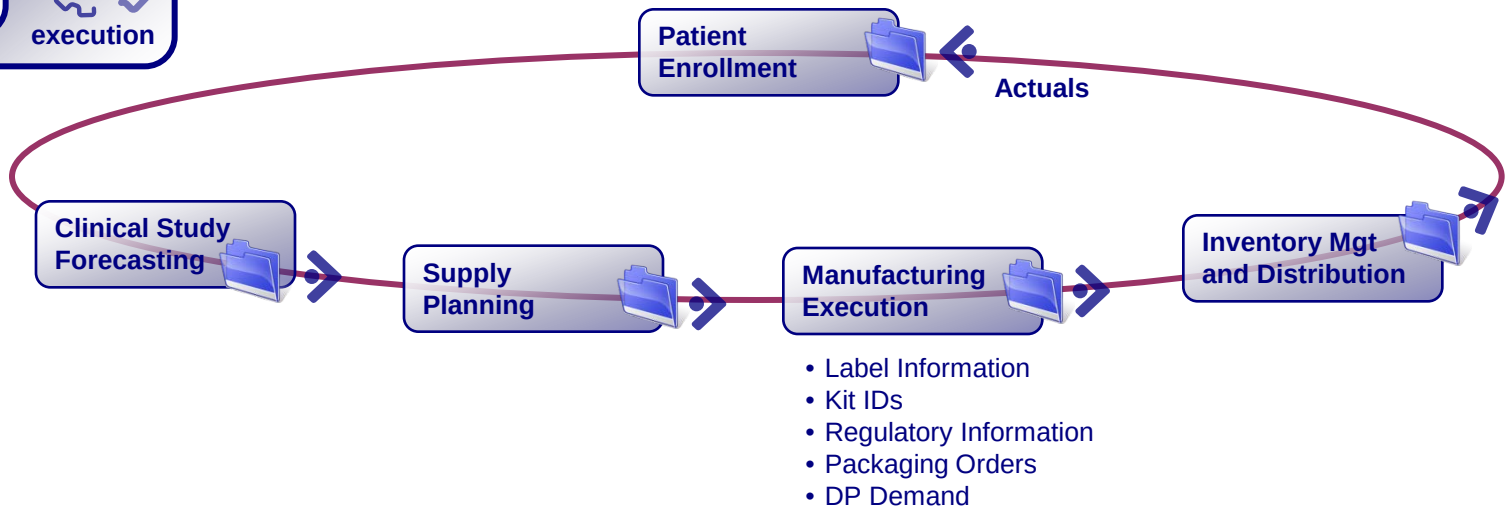
- Vision for Clinical Supplies
- Demand and Supply Planning Process Overview
- Lead Times and Horizons Drive CD&OP
  - Demand Timeline
  - Supply Timeline
- Conclusion

Vision for Clinical Supplies

Full visibility of our products in the Supply Chain



In order to reliably meet our commitments (compliance, quality, speed, agility, and costs) we need full transparency in the process, an integrated data flow and an automated process.

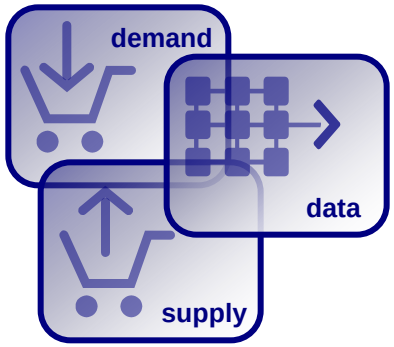


Improved reliability – right drug in the right place at the right time, every time.

Reduced distribution costs and lower material wastage.

Single set of data so everyone can do their job right the first time.

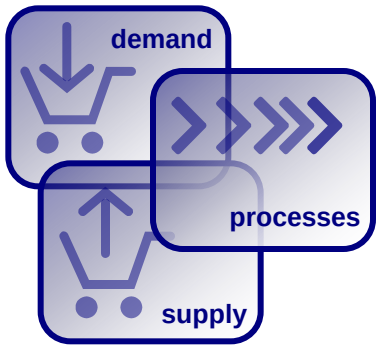
All demand and inventory for a product in a single system.



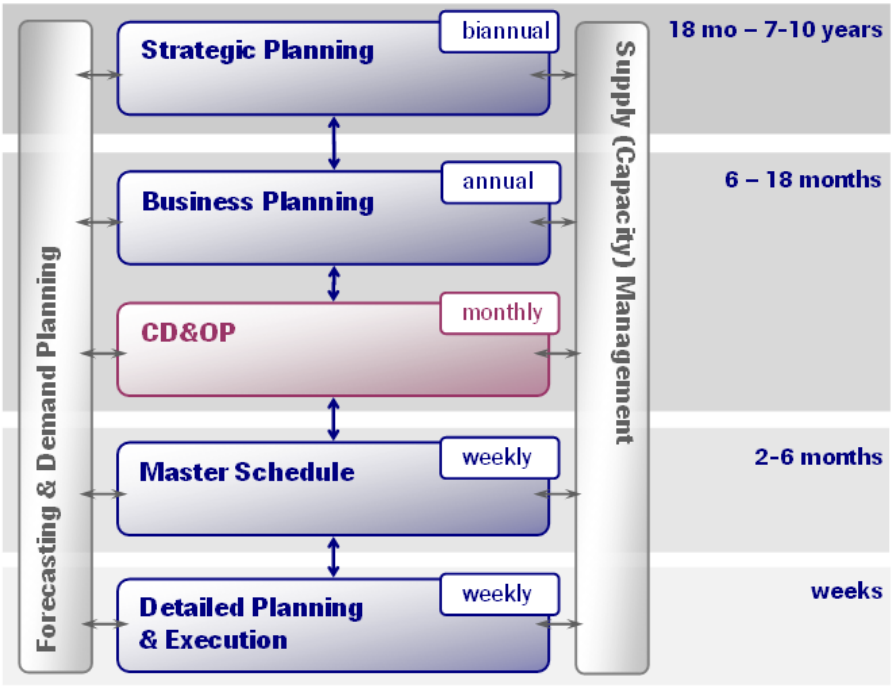
Connecting Clinical Study demands with TDT demands for upstream production - linking all demand and inventory for a product in a single system.

- Improved demand signals.
- Total network demand visibility – improved capacity management.
- Improved Mfg capacity management.

Ensuring aligned demand and supply



Execution of a ‘Clinical Demand and Operations Planning’ process (CD&OP) through an integrated global business management process



- **Transparency to supply costs and improved reliability in financial performance.**
- **Single source of data and alignment with Finance processes.**
- **Transparency to data and longer term capacity requirement visibility.**

Clinical Supply Vision

an integrated
planning and execution process
for clinical supplies

to meet all clinical trial and development requirements while driving business value through efficient use of our resources.

- Full visibility of product in our supply chain.
- All demand and inventory for a product in a single system
- Ensuring aligned demand and supply

Demand and Supply Planning Process Overview

Our Clinical Supply Chain process links information and operations across the company to ensure no patient goes without

DEMAND	SUPPLY	DISTRIBUTE & RESUPPLY
Our process takes in all demands for our clinical products as well as other study drugs (comparators): 1. GNE Sponsored Trials 2. Investigator Sponsored Trials 3. Partner Demand 4. R&D / Tox Demand 5. CMC Demand 6. Commercial Product Demand for Clinical Capacity	And converts it into integrated production plans in SAP for all of our products (both internally produced as well as contract manufactured): 1. Commercial product intermediates 2. Drug Substance 3. Drug Product 4. Finished Goods 5. Other Study Drug procurement 5. Movement to our primary depots	Upon release our products are held at our warehouse, depot, and subdepot locations based on inventory policies used both to resupply sites as well as trigger replenishment production: 1. SAP 2. IVRS 3. Manual processes for non-IVR trials and partner shipments

The CD&OP Cycle Steps

Step 1 – Demand Review

- Clinical - Include all GNE & IST Trial, Partner, PR&D, Tox
- Provides feedback to customers on the stability and quality of their inputs and requests

Step 2 – Pre-Supply Meeting

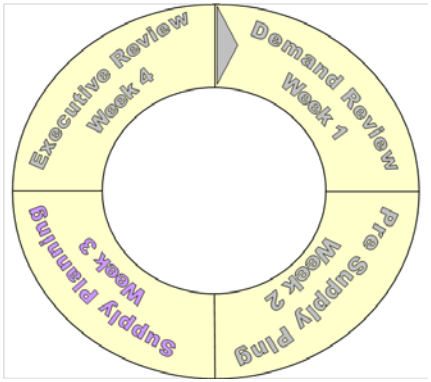
- Working sessions where plant schedulers and global planner review the orders coming into the horizon
- Most issues are resolved here before taken to the next step

Step 3 – Supply Planning

- Endorses the monthly supply plan
- Monitors the health of the clinical supply processes
- Reviews root cause analysis of major supply misses (i.e. interruptions in patient dosings)

Step 4 – Executive CD&OP Review

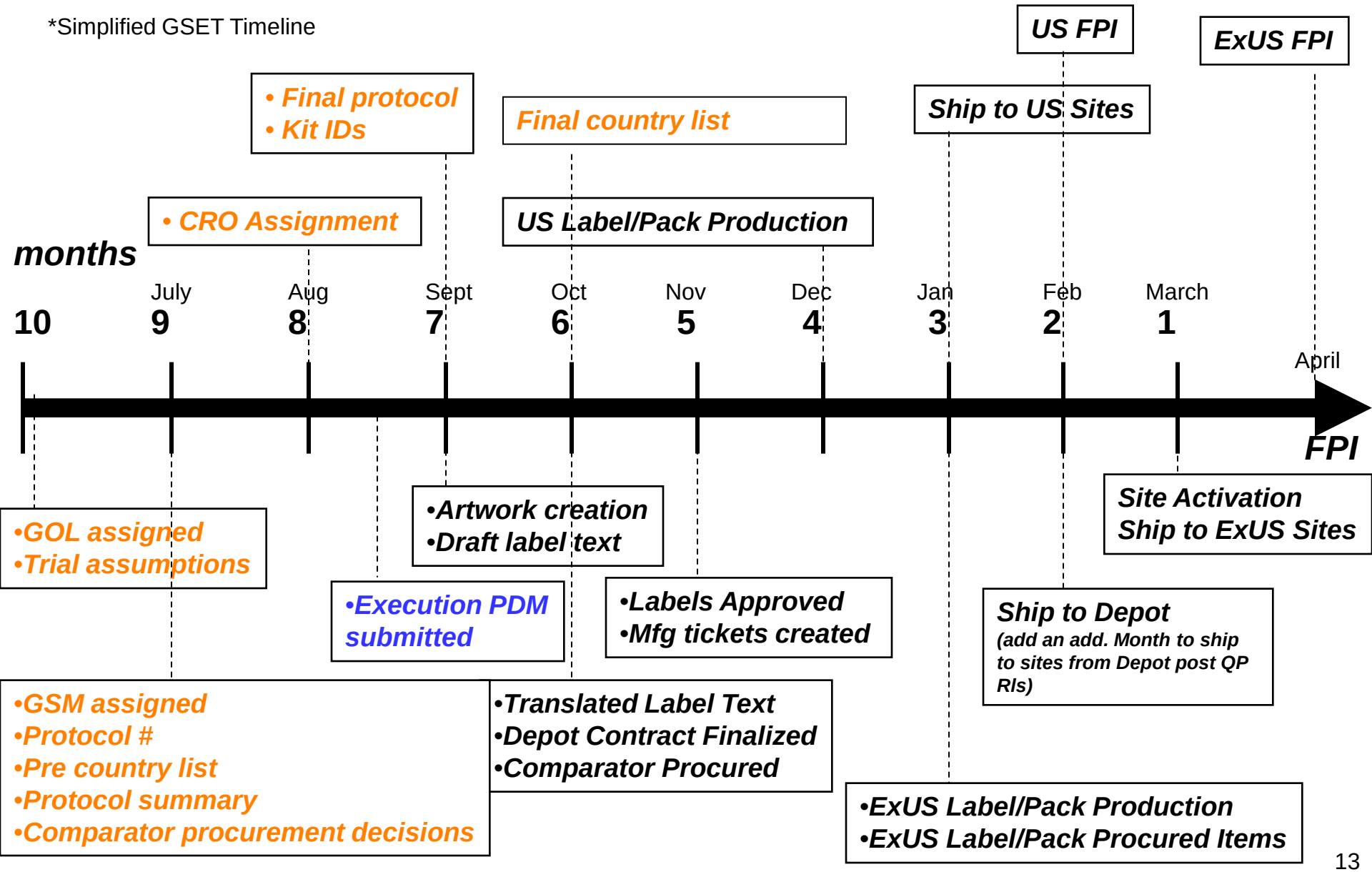
- Owns clinical asset strategy
- Governs major clinical supply initiatives (like integration)
- Reviews annual production budgets, resource plans, and capacity targets
- Align supply and production plan with business plan



Lead Times and Horizons Drive CD&OP - Demand Timeline

Timeline of activities required to successfully enable trial supply (NOTE: assumes drug product is available)

*Simplified GSET Timeline



Why is the data needed?

- *Trial Assumptions (FPI, LPI, FSA, # of patients, dosing arms, kit configuration)* – Needed to define the planning SKUs that will be used for the trial, enter demand in the system and create initial supply plans
- *Protocol Summary* – Needed by Inventory Order Operations to appropriately set up shipment contracts and licensing needs
- *Protocol #* - Needed to create planning SKUs and submit the execution PDM
- *Pre Country List* – Needed to begin depot selection and contract agreements. Needed for label text creation
  - Pre country list should be extensive but within reason taking into consideration:
    - The added work and resources required by Regulatory Label Development to create labels for countries eventually not pursued
    - The added work and contract costs for depot selection and set up for Mfg Collaborations and Inventory Order Operations
- *Comparator Procurement Decisions* – Needed to create the appropriate planning SKUs and to engage Procurement, Mfg Collaborations & IOO to identify source of supply and distribution requirements
- *CRO Assignment* – Needed to ensure the final country list can be identified prior to label approval. Needed to define procurement strategies. Needed to finalize the protocol.
- *Final Protocol* – Needed as confirmation that no more trial changes are expected – it represents our time fence point. Changes after this point put supply timelines and activities at risk
- *Kit IDs* – Needed to be able to order labels for label/pack job
- *Final Country List* – Needed to finalize the label and place the order with the vendor in time to support label/pack dates
  - Final country list should be a subset of pre country list. New country additions reset the timeline to the start

Impact of different types of delays

Type of Delay	Impact
Study Design/Protocol Summary Decisions	• Bulk inventory and allocation of API to DP cannot be accurately evaluated to support the trial (Planning) • Evaluation of the appropriate distribution network and contract requirements cannot be set up (Mfg Collaborations & Distribution) • May impact ability to meet FPI due to inability to schedule production, complete label requirements, procure material, etc (Planning, Mfg, Labels, Procurement)
Protocol Number	• Prevents submission of execution PDM to kick off creation of artwork/label, tickets, etc (Planning) • Impacts ability to set up the IVRS which can cause delays in release of material or shipments (Distribution)
CRO Selection	• Causes delay in final country selection which impacts artwork/label creation, depot selection/contracts, etc (Labels, Distribution) • Regulatory submissions may be delayed (Regulatory) • Delays decision on comparator strategy (Procurement)
Country List	• Evaluation of the appropriate distribution network and contract requirements cannot be set up (Mfg Collaborations & Distribution) • Label artwork creation can be delayed or resources could be wasted on unneeded countries (Labels) • Prevents submission of execution PDM to kick off creation of artwork/label, tickets, etc (Planning)
Comparator Drug Decisions	• Delays depot selection dependant on labeling requirements for the comparator chosen (Mfg Collaborations & Distribution) • Impacts purchasing selection options (Procurement)

Demand Review Excerpt: Near Term Changes to Trials

Trials in upcoming 6 months that have had a change in FSA or FPI

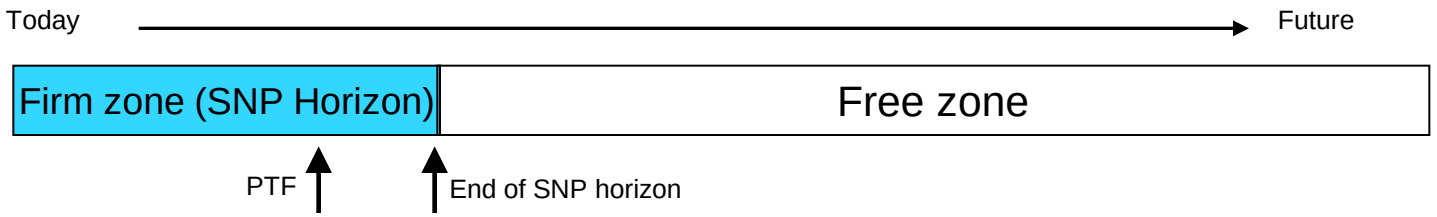
ID	Phase	Status	Multi-country?	FSA Last Month	First Site Activated Planned	FSA Change	FPI Last Month	First Patient In Planned	FPI Change	Last Patient In Planned	Comments
1	Phase I	Placeholder	No	0		0	11/1/2010	10/1/2010	-31		No Impact
2	Phase I	Approved	No	07/06/2010	09/17/2010	73	07/19/2010	10/04/2010	77	03/23/2012	Trial pushed out due to initial supply from Formatech. Rescheduling fill at differen't CMO.
3	Phase II	Approved	Yes	08/17/2010	08/12/2010	-5	11/02/2010	11/02/2010	0	06/14/2011	No Impact
4	Phase II	Approved	Yes	10/21/2010	10/25/2010	4	11/15/2010	11/15/2010	0	10/31/2011	No Impact
5	Phase I	Approved	No	9/17/2010	10/18/2010	31	10/18/2010	11/18/2010	31	11/19/2010	No Impact
6	Phase I	Planned	No	9/15/2010	11/12/2010	58	11/15/2010	11/30/2010	15	5/15/2012	No Impact
7	Phase II	Approved	Yes	10/20/2010	11/19/2010	30	12/1/2010	12/27/2010	26	6/27/2011	No Impact

4 month TF

6 month TF

Lead Times and Horizons Drive CD&OP - Supply Timeline

Some Time Fence Definitions



What is a Planning Time Fence?

Defined period of time where the production schedule is considered locked (2 mo for SSF/CMO pack)

Why establish a PTF?

To provide stability to production schedule and supporting functions focused upon execution/readiness activities to meet the schedule

What is an SNP horizon?

Defined period of time where APO will not automatically plan production receipts (3 mo for SSF/CMO pack)

Why establish a SNP horizon?

To leverage APO planning functionality up until the point where order stability is required

Why have time gap between PTF and SNP horizon?

To allow for MPP to control orders in time bucket currently under review for feasibility through CD&OP

Packaging Lead Time sets the Time Fence on the Supply Side

Product Planner:

1. "Firm order" for month crossing PTF includes quantity & lot allocation
2. Maintain accurate long-term plan
3. Specifies due date on MTO orders or initial supply to meet FPI goals

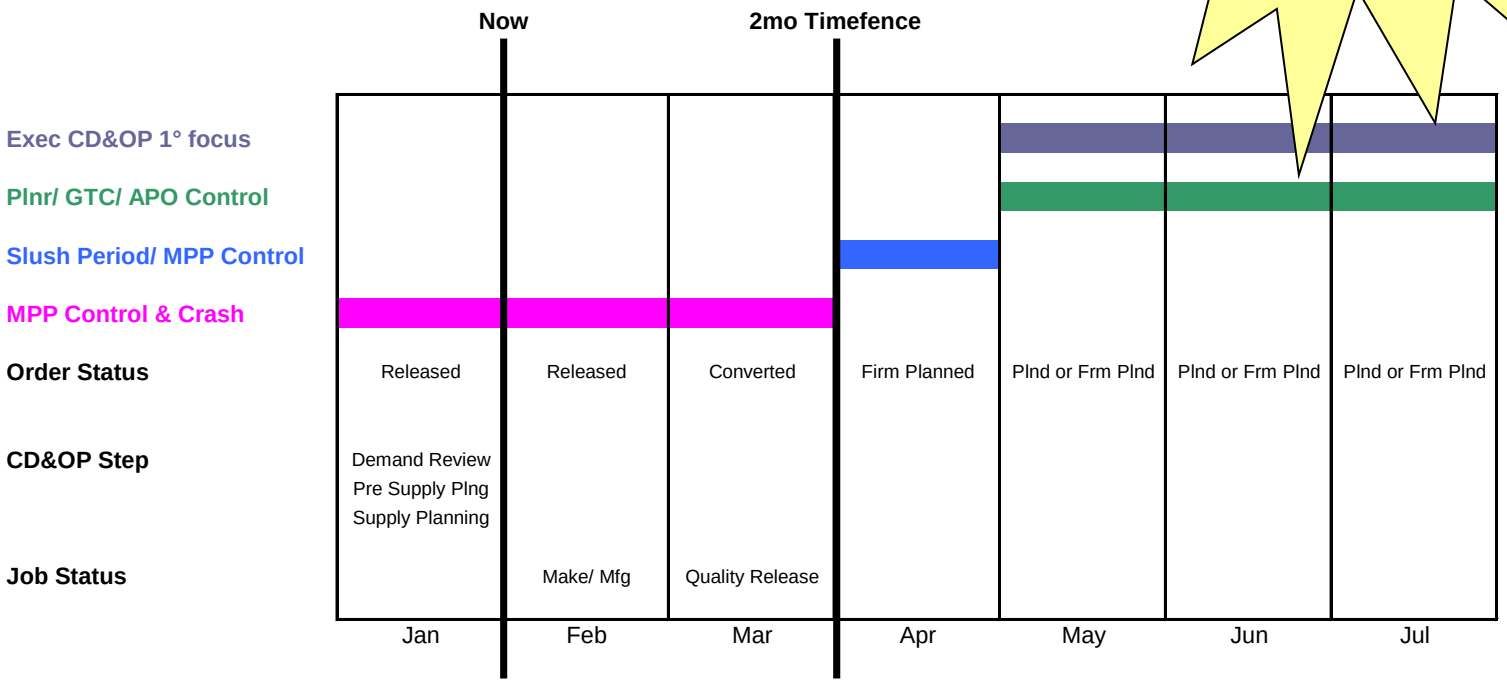
Master Planner:

1. Sets priorities for jobs within given month crossing PTF
2. Ensuring plan matches site capabilities
3. Negotiates with GTC/Planner to level load capacity

CD&OP:

1. Endorses time fence violations (CRASH requests)
2. Endorses low inventory risk (drop below target)
3. Process for outsourcing jobs as capacity relief
4. Process for network decision making

Ties Together:
1) Roles & Resp
2) TF for Decision Making
3) SAP Order Mgmnt



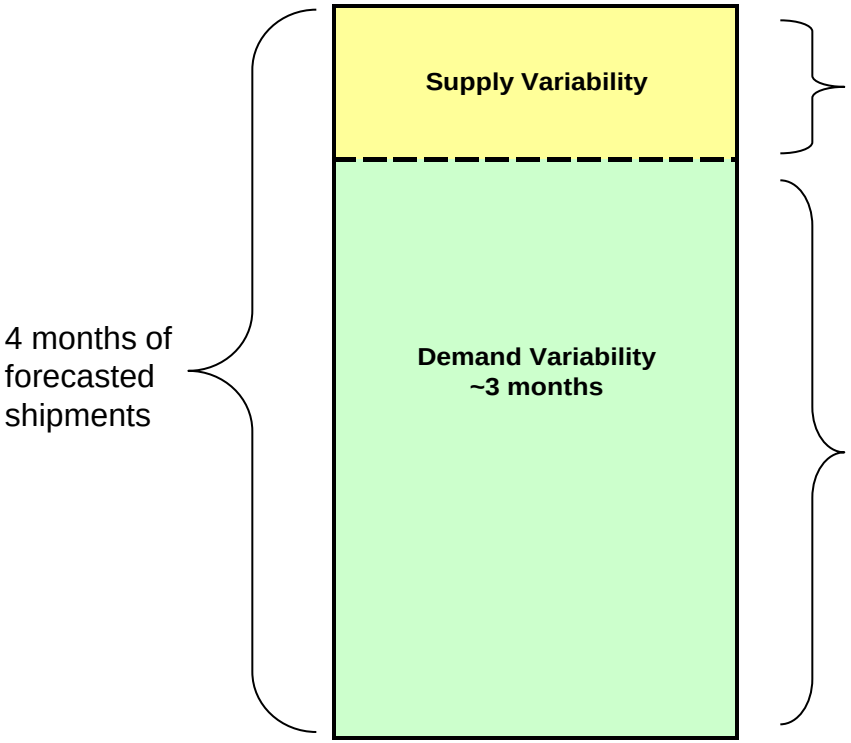
Set Safety Stock Levels to Cover Supply and Demand Variability

Safety Stock must cover both demand and supply variability over the “Supply Lead Time” or Planning Time Fence

Policy for Safety Stock

120 day minimum balance @ Primary Depot (fed inventory directly from packaging source)

60 day minimum balance @ Secondary depot (fed inventory from primary depot)



Release variability (pack and/or vial lot)

Schedule variability (readiness, competing priorities, optimization, etc.)

Logistics delays/issues (QP release, depot receipt time, etc.)

Patient enrollment

Dose assumptions (patient weight, other)

Location of enrollment (country assumptions)

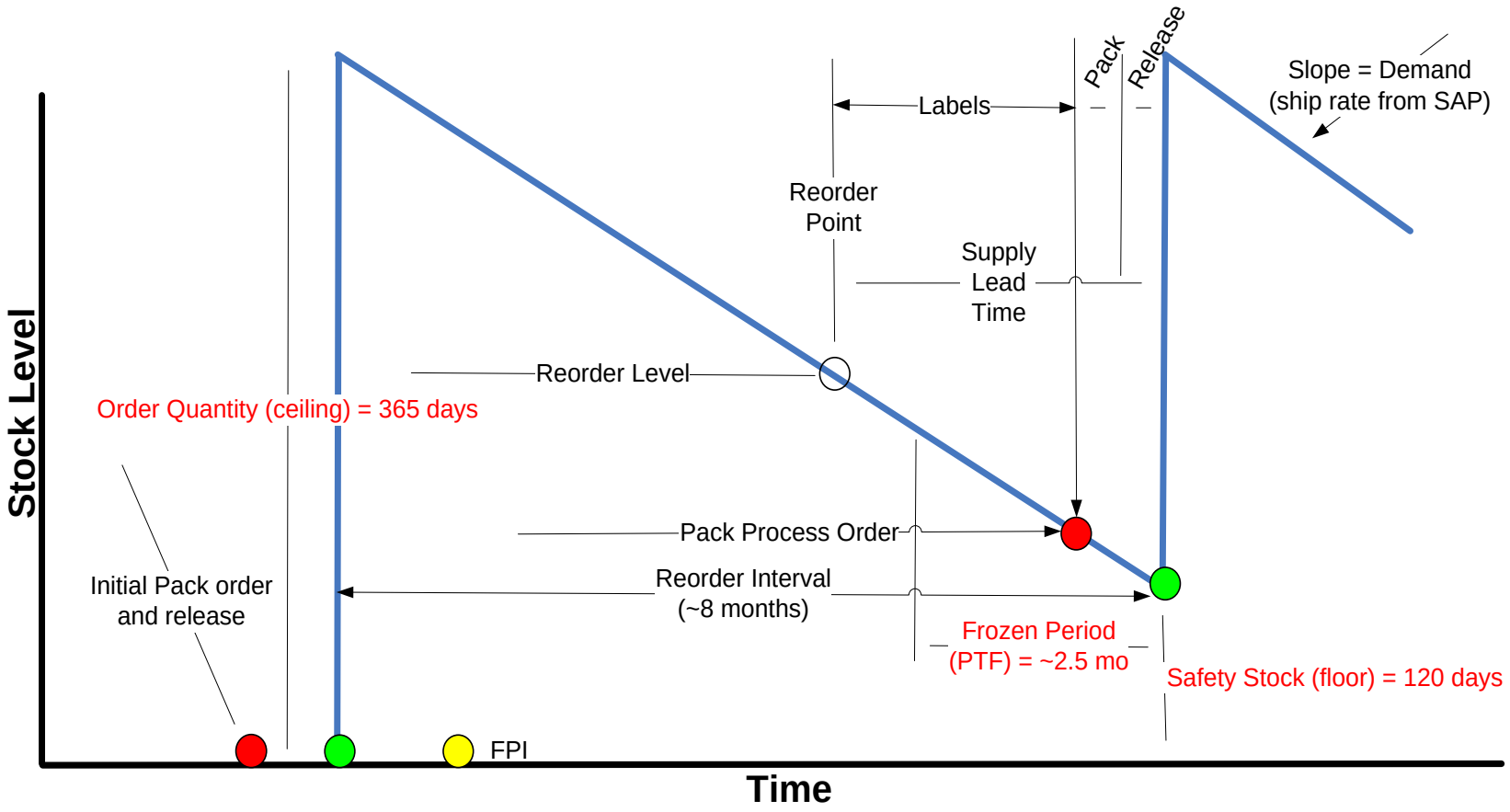
Site activation rate assumption

Changes to protocol (increased number of patients/sites)

APO planning parameters are established per item with default values

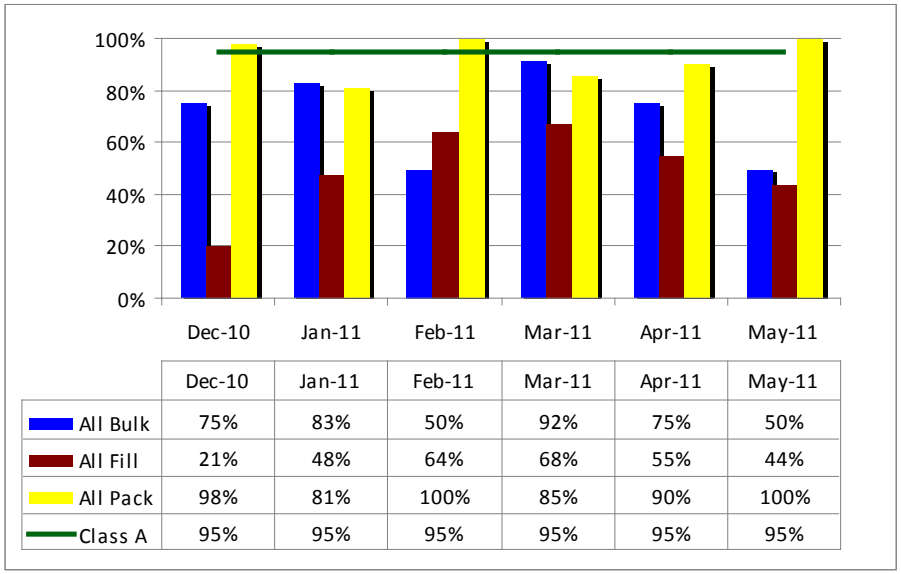
- Re-Order Days Required = sets the safety stock minimum quantity based upon future demand
- Target Days Required = sets the order quantity to restock inventory based upon future demand

Default APO parameters established for various item classifications (MTS, MTO, OSD, other?)
For most common MTS item: Re-Order Days = 120 (60) and Target Days = 365 (180)



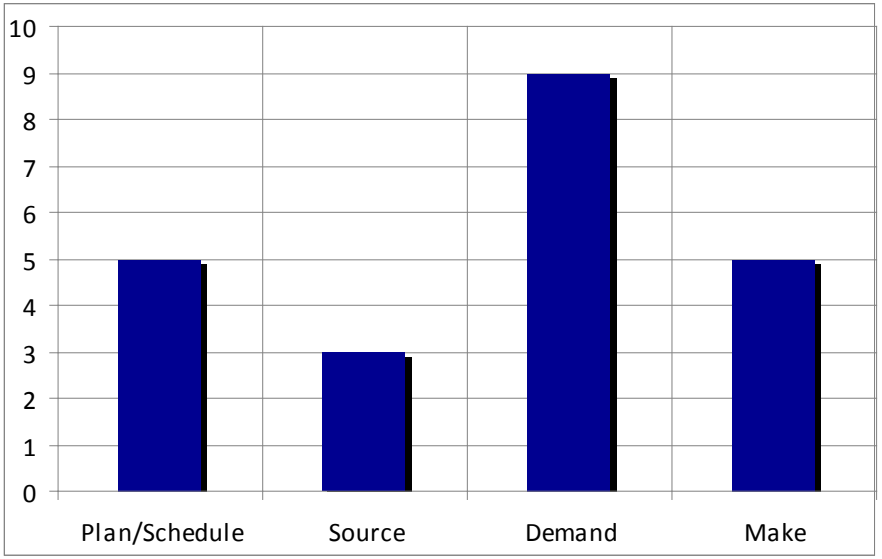
Production Plan Stability Measures Violations of the Planning Time Fence

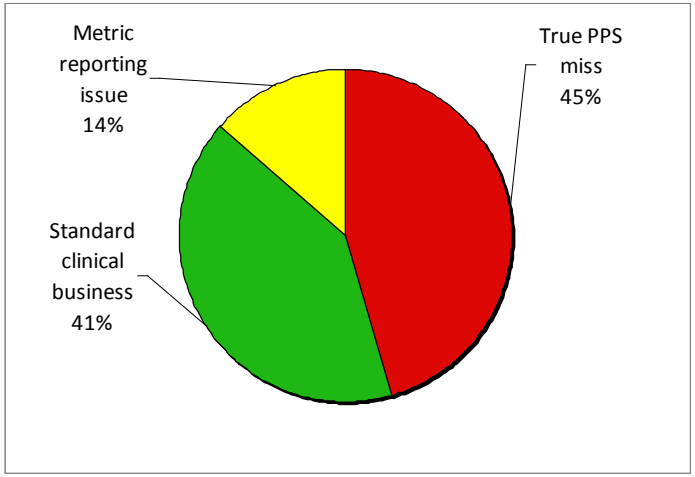
Packaging plan achieved target.



	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11
All Bulk	75%	83%	50%	92%	75%	50%
All Fill	21%	48%	64%	68%	55%	44%
All Pack	98%	81%	100%	85%	90%	100%
Class A	95%	95%	95%	95%	95%	95%

Unadjusted miss reason codes fell into 4 categories





Metric reporting issues require validation that only planned order data is being

COMMENTS:

- 41% of all crashes to the May 2011 plan were approved in advance.
- Order management issues allowed some delayed lot disposition to appear as PPS
- RCA analysis is being performed at Pre-Supply Planning meetings.
- Verifying “metric reporting” issues

Conclusions

- Clinical Demand and Operations Planning is a powerful communication method for balancing clinical needs with supply capability.
- The tools and steps used in CD&OP are simple and effective (IT investment not required), but doing it right is easier said than done!
- Understanding lead times in detail builds credibility with customers.
- Using those lead times as the time fences gives the process a starting point to ask for stable inputs, analyze process health, and improve capabilities.

Questions?