TYM Program
ACD Pilot Project
Report to Steering Group

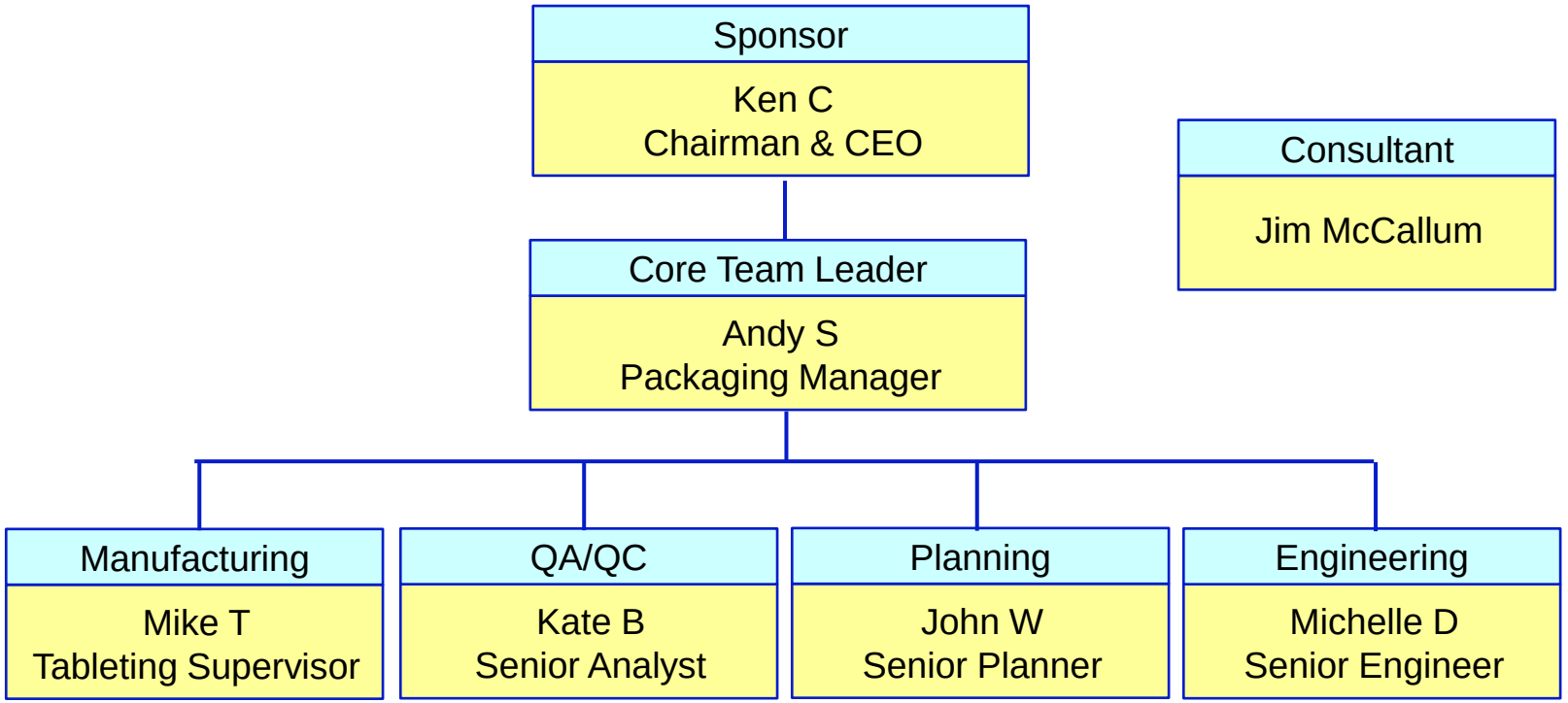
Sydney, January 2010

Agenda

- Introduction
- TYM Design
- Implementation Plan
- Business Case
- Discussion

Poster

TYM Core Team

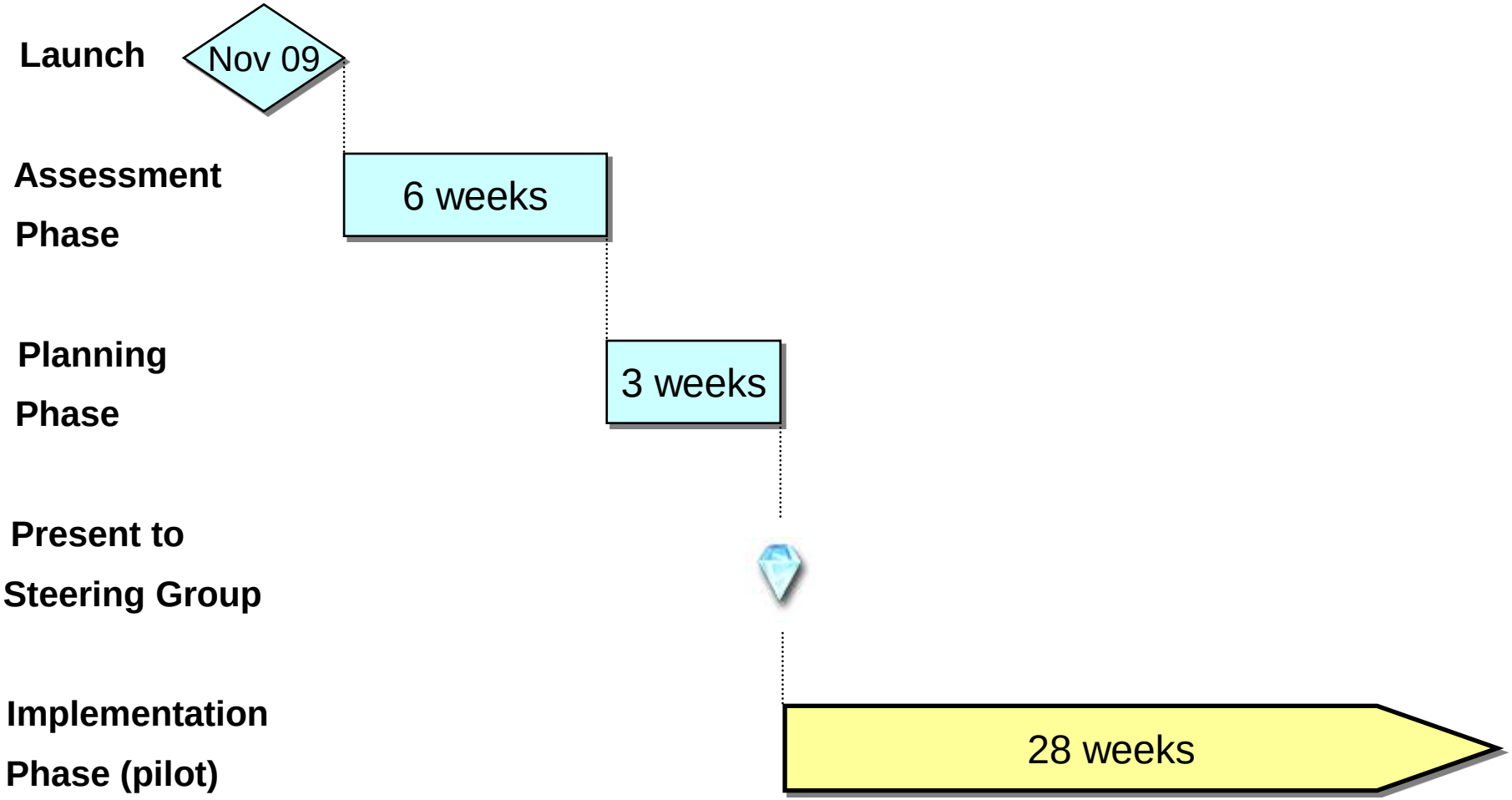


TYM Objectives

- Minimise Thruput Time / Lead Time
- Maximise Thruput Rate / Productivity
- Get it Right First Time

- **Key Enablers:**
- Synchronise Support Functions – QA/QC
- Planning & Scheduling
- People & Organisation

TYM Timescales



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Thruput Time – TPT / PLT

- Walk Thru for ACD:

	Current	
No of Steps	60	
No of Value Adds	6	
No of Non-Value Adds	54	
VA Process Time (batch)	37h	
TPT (Thruput Time)	32.3d	
PLT (Pipeline Lead Time)	64.1d	
Distance Moved	984m	

Thruput Time – TPT / PLT

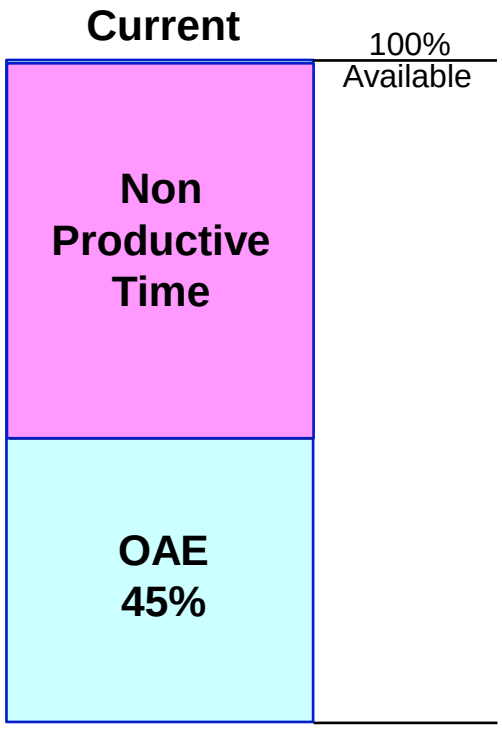
- Walk Thru for ACD:

	Current	TYM Practical Vision
No of Steps	60	41
No of Value Adds	6	6
No of Non-Value Adds	54	35
VA Process Time (batch)	37h	16.3h
TPT (Thruput Time)	32.3d	4d
PLT (Pipeline Lead Time)	64.1d	10d
Distance Moved	984m	502m

Thruput Time – TPT / PLT Vision for ACD

	Curr Cycle (h)	New Cycle (h)	TPT (d)	PLT (d)
Inbound				+5
Dispensing	2	2		
Granulation	1.5	1.5	1	
Tableting	20	8.6	1	
Packaging	16	5.7	1	
QA Release			1	
Outbound				+1
		Total	**4d**	**10d**

Thruput Rate – OAE in Tableting



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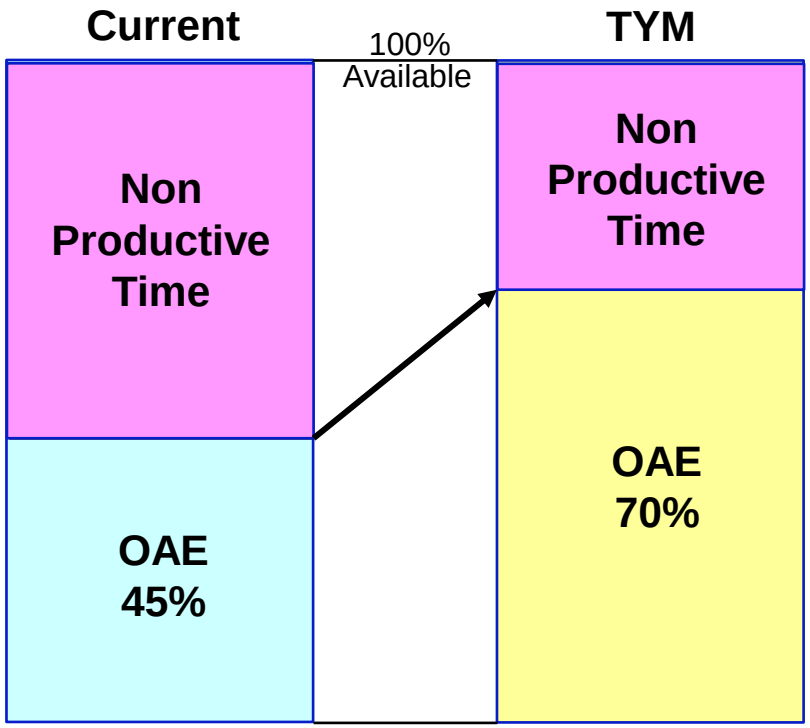

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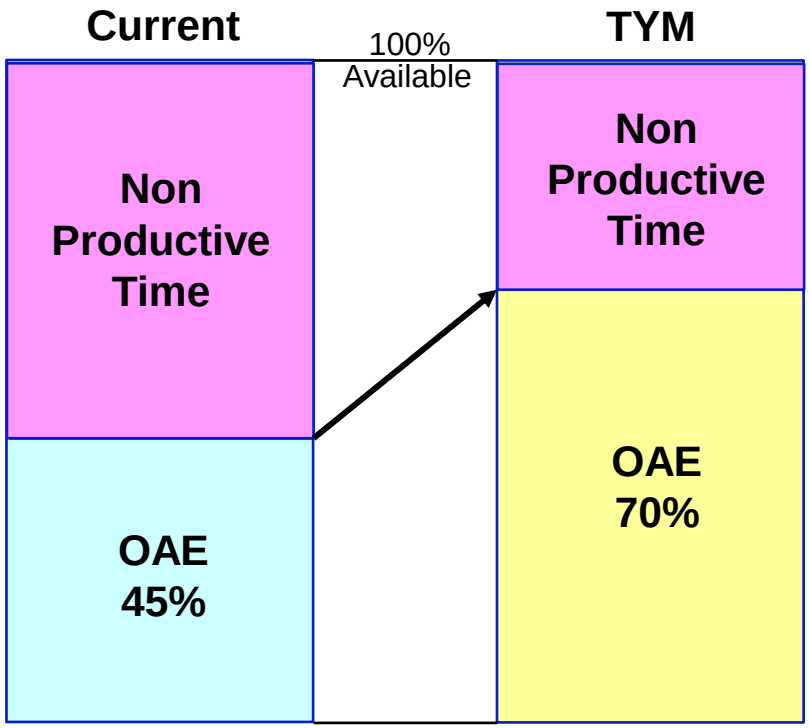
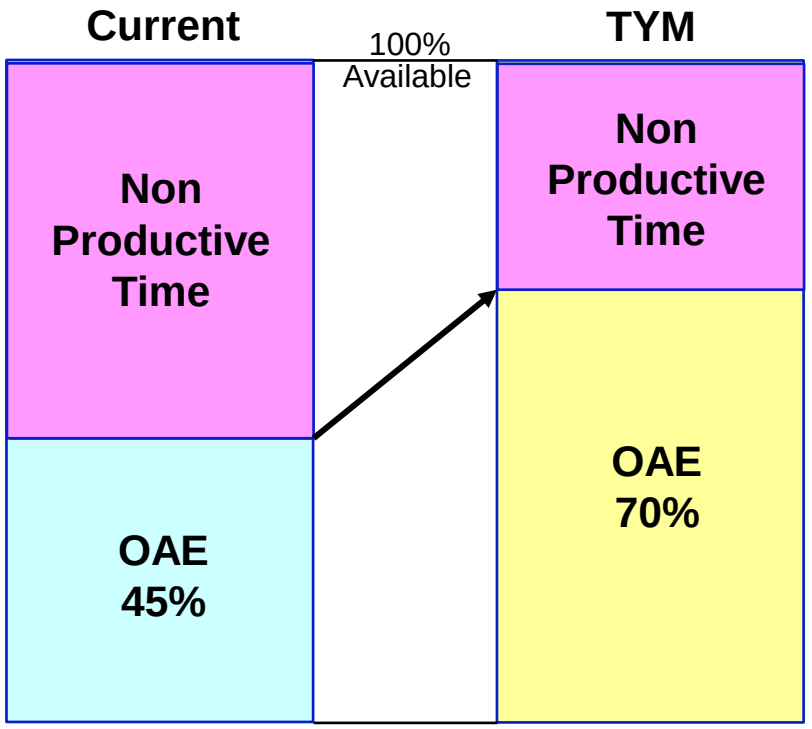


Improve OAE by -
Reducing Changeover Time
Reducing Stoppage Time
Running at Max Validated Rate
Running During Breaks

Thruput Rate – OAE in Tableting



Improve OAE by -
Reducing Changeover Time
Reducing Stoppage Time
Running at Max Validated Rate
Running During Breaks

Result is increase in TPR from
4 batches of ACD per week to
9 batches of ACD per week
with same equipment and
same resources

Thruput Rate – OAE in Tableting – Changeover Times

	Current	TYM	Reduction
Full Change	6h	1h 52m	69%
Lot Change	1h 30m	0h 29m	68%

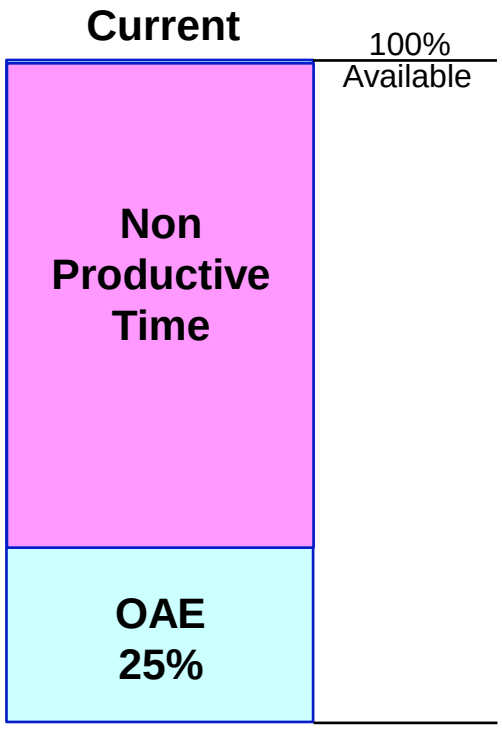
- Initial Video Analysis for ACD 20mg Changeover
- Includes changeover and cleaning
- Exchangeable pieces cleaned and kitted off-line
- Dedicated operator in cleaning room
- Additional operator from granulation during changeover
- Choreographed with intensive training

Thruput Rate – OAE in Tableting – Run Rate

Validated Range	Current	TYM	Increase
60k to 120k tab/hr	80k	120k	50%

- Test runs for ACD 20mg only
- Tested by increasing speed in 5k increments
- No apparent quality problems – all tablets to spec
- Additional samples taken during test runs for confirmation
- Yield levels >99% throughout
- Will apply same approach to other products

Thruput Rate – OAE in Packaging



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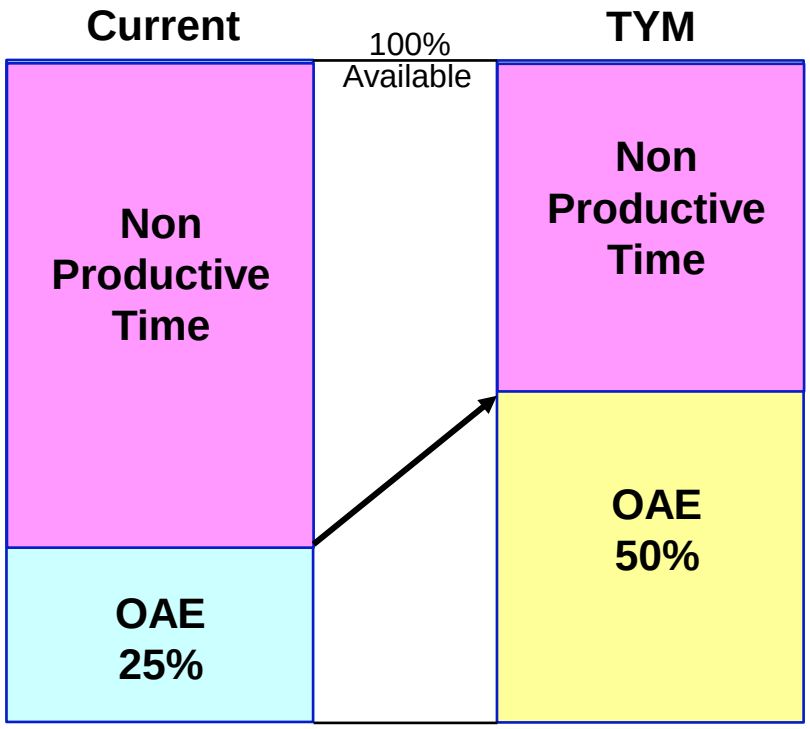

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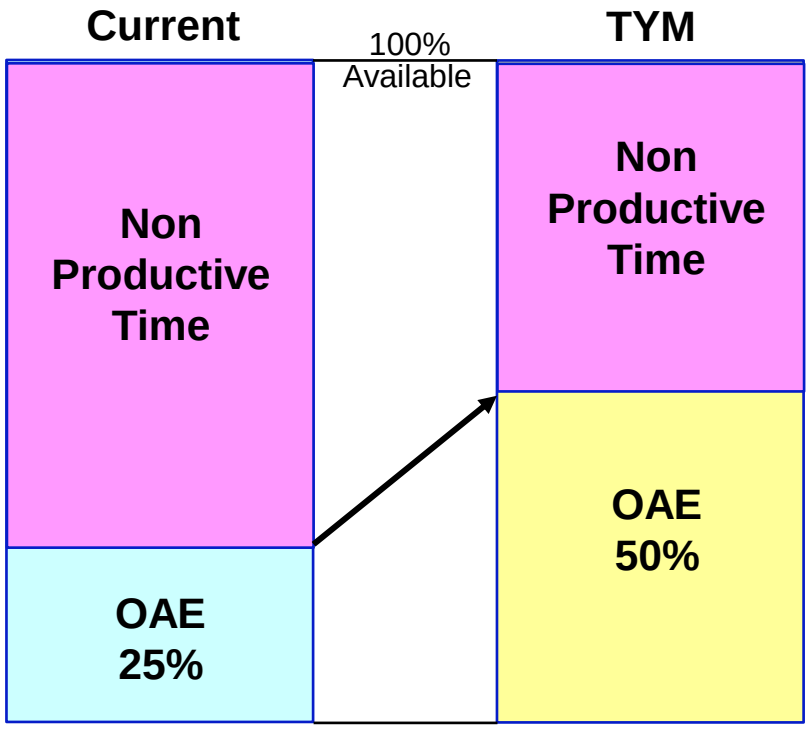

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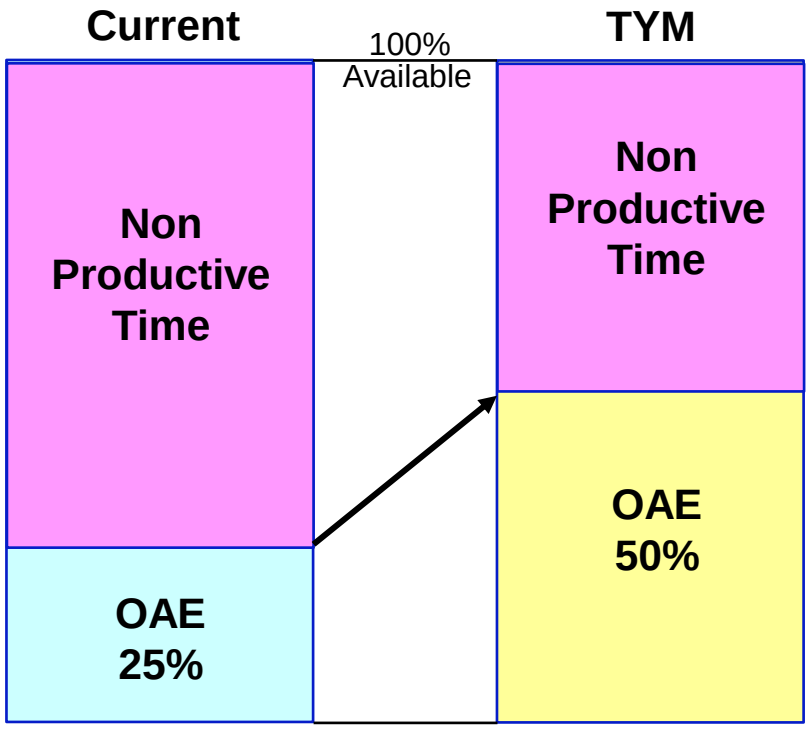
Training Multi-skilled Operators
Harmonising Pack Materials

Thruput Rate – OAE in Packaging



Improve OAE by –
Reducing Changeover Time
Reducing Stoppage Time
Running at Max Validated Rate
Running During Breaks
Training Multi-skilled Operators
Harmonising Pack Materials

Result is that
packaging line can also
handle 9 batches of ACD / wk
with same equipment and
same resources

Thruput Rate – OAE in Packaging – Changeover Times

- Initial Video Analysis for ACD 20mg Changeover
- Includes changeover and cleaning

	Current	TYM	Reduction
Full Change	6h 35m	2h 12m	67%
Lot Change	1h 42m	0h 38m	63%

Thruput Rate – OAE in Packaging – Harmonisation

- Initial Analysis for ACD Harmonisation
- Proposals in preparation

	Current	TYM
Bottle Dimensions	4	2
Leaflet Dimensions	4	1
Overwraps	6	0
Case Dimensions	4	1

Thruput Rate – OAE in Packaging – Stoppages (from Gamed)

Reason	Time (h:m)	Freq	%
Filler	8:55	124	11.14
Microstops	7:18	556	9.12
Labeller	3:57	18	4.93
Packer	2:57	38	3.68
Cartoner	2:18	46	2.87
Capper	2:04	23	2.58
Leaflet	1:09	14	1.43
Check Weigher	0:04	1	0.08
Bottle Feeder	0:01	1	0.03
Total	**28:41**		**35.86**

Note: Data from week 02

Right First Time – MBR Current Example (Liquids)

		Sign	Sign	Date
12. Transfer 1800l of purified water to the manufacture tank. Ensure that the temperature of the water is 15 – 25C. Ensure tank mixer is on at 55 – 80 rpm	Tank ID …… CMS Mixer ID …… Tank Mixer ID …… **2300004** K134 Purified Water Volume Check…… Temperature Check …… Tank Mixer On …… Tank Mixer Speed ……			

- Too many entries required
- Cramped signature and date spaces
- Prone to errors and omissions – currently only 50% RFT

Right First Time – MBR TYM Example (Liquids)

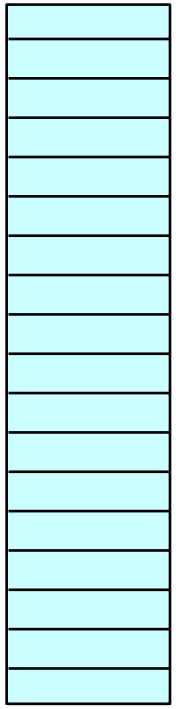
Step	Mat'l ID				Op'r	Check	Date
12A	**2300004**	Transfer 1800l of K134 purified water to manufacture tank	Tank ID	**T431C**			
12A	N/A	**Volume Check**					
12B	N/A	Ensure temperature of water is 15 – 25C	CMS Mixer ID	**M194**			
12B	N/A	**Temperature Check**					
12C	N/A	Ensure tank mixer is on at 55 – 80 rpm	Tank Mixer ID	**M197**			
12C	N/A	**Tank Mixer Speed Check**					

- Entries reduced from 28 to 12 (57%)
- Colour coded entries – blue for value – cannot move on till green complete
- Simpler, easier to follow, less chance of errors – aim for 100% RFT

Right First Time – Deviations

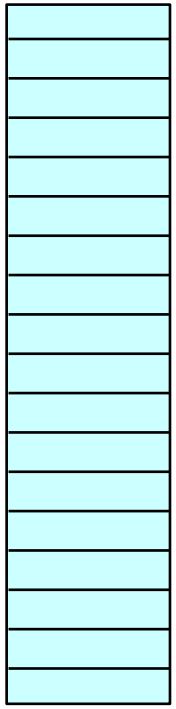
- Total of 21 deviations on ACD year to date – all avoidable – no batches rejected
- Establish and rank root causes
- Develop action plan for top five (in conjunction with Production and Quality)
- Train all parties in the solutions to top five
- Implement solutions (including control charts where appropriate)
- Have QA available on shop floor to help resolve deviations in <24h

QA/QC Synchronisation - QC Testing



Current
18 days

QA/QC Synchronisation - QC Testing



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Improve flexibility of analysts

Whiteboard for active planning

FIFO

TYM KPIs

Standardised procedures

Investment to speed response times

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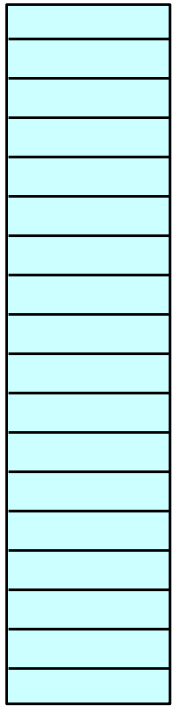

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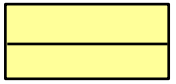

TYM
<2 days

QA/QC Synchronisation – QA Release

Current
5 days

QA/QC Synchronisation – QA Release

Current
5 days

Simplify MBR

Minimise Deviations

If batch record queue >1day take action

Replace batch at next rhythm if Deviations not resolved

QA/QC Synchronisation – QA Release

Current
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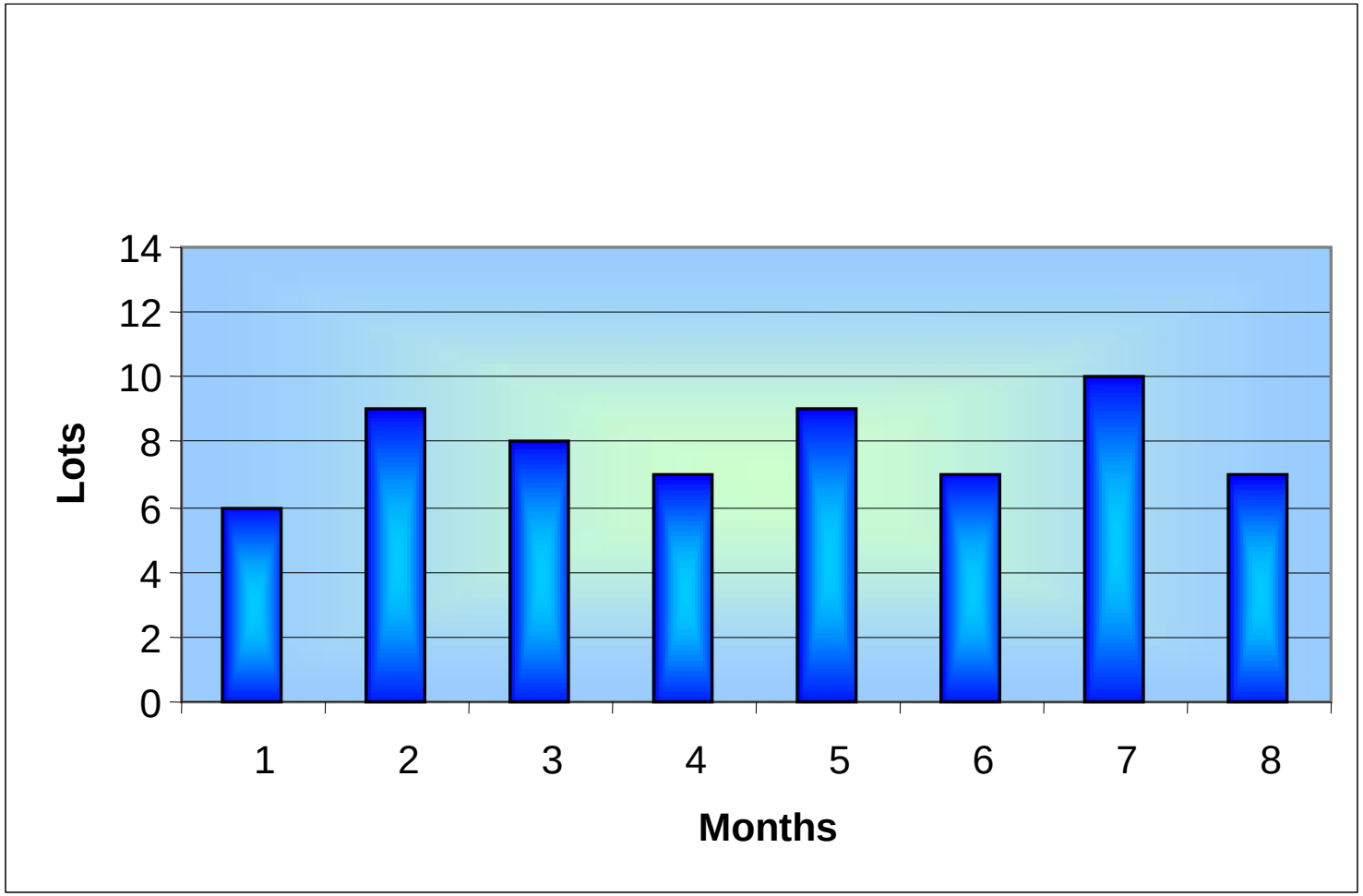
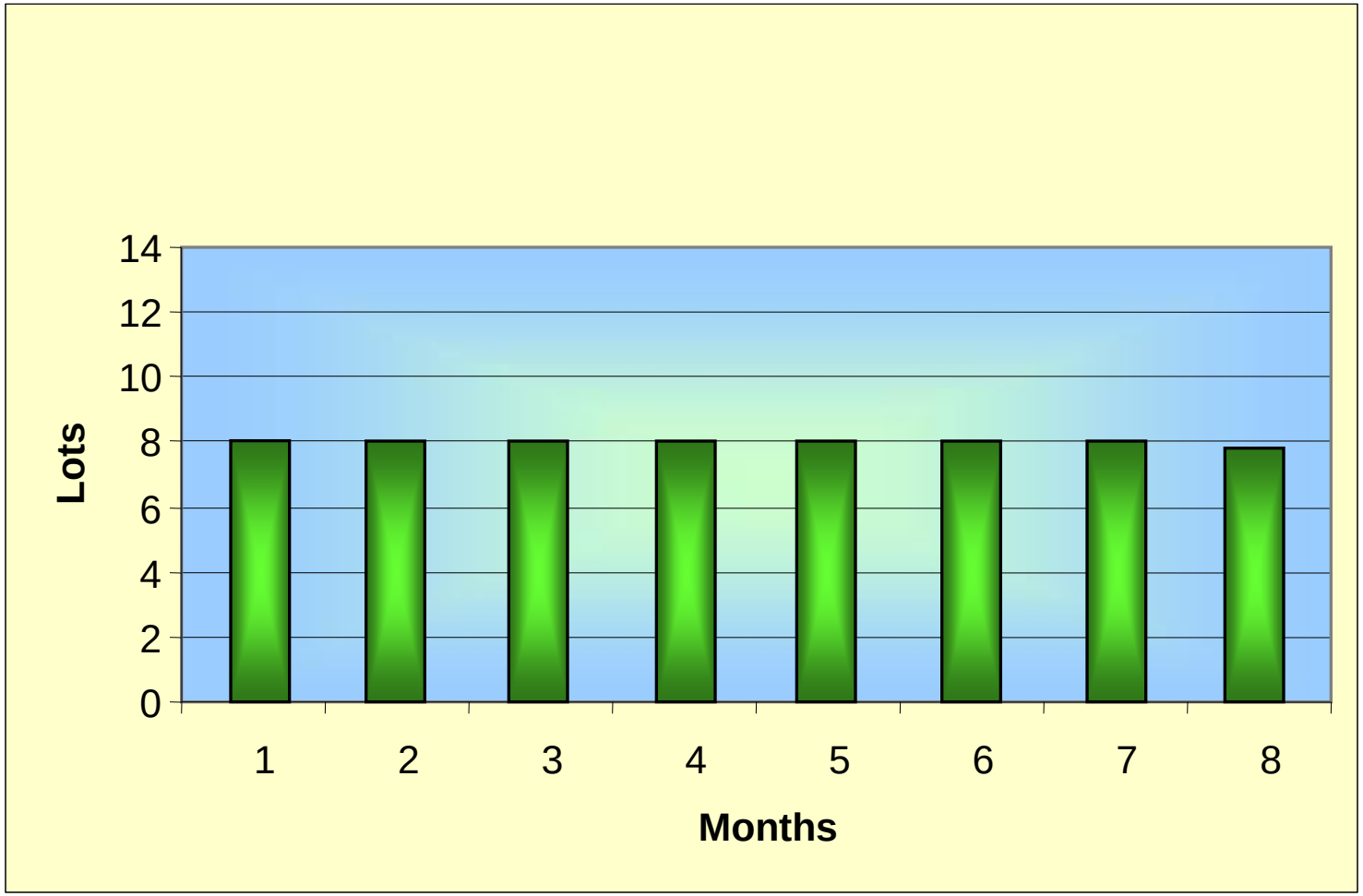
TYM
<1 day

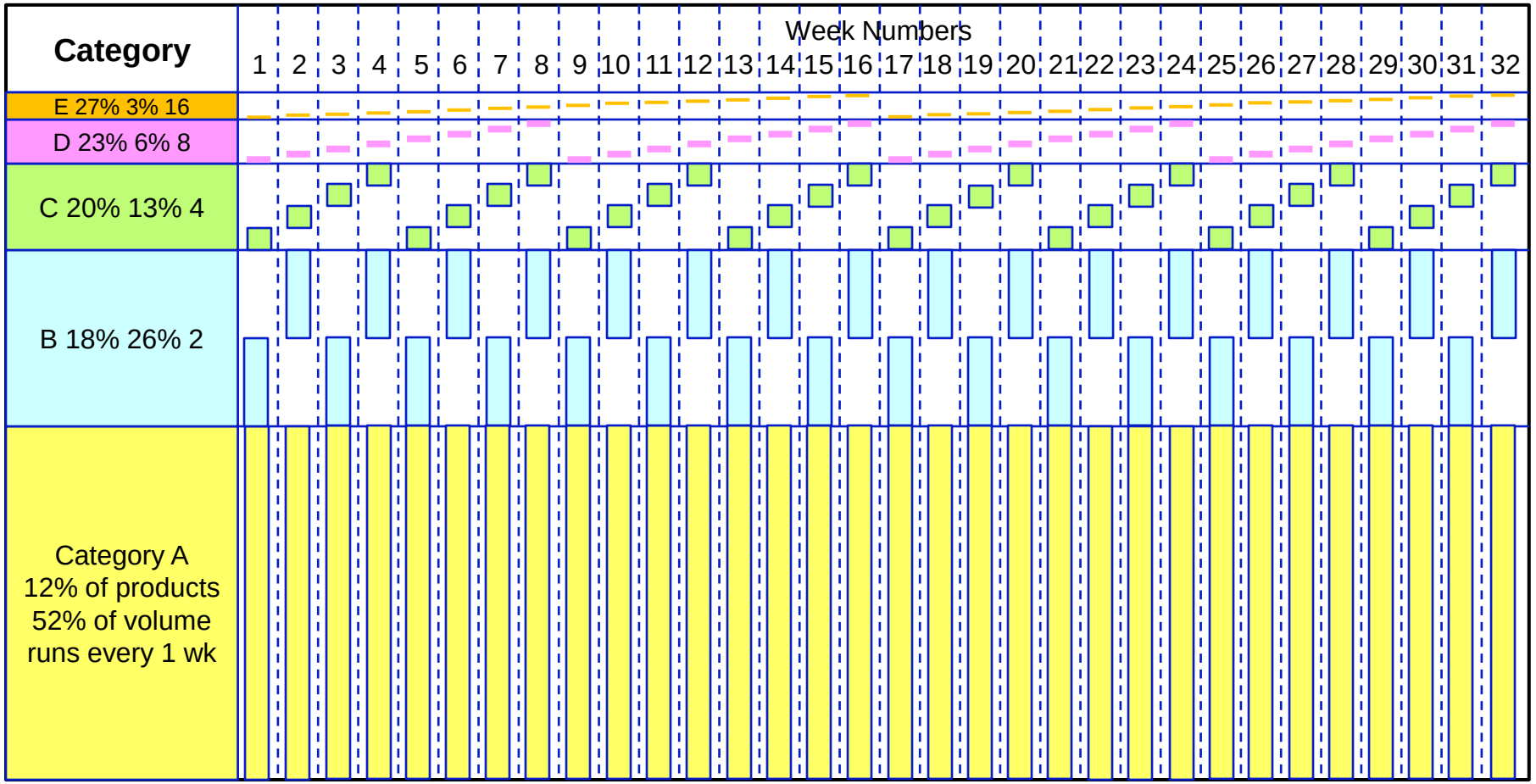
Planning & Scheduling – Bulk Current – ACD 20mg



Planning & Scheduling – Bulk TYM – ACD 20mg



Planning & Scheduling – Packaging Rhythm Wheels (Typical)



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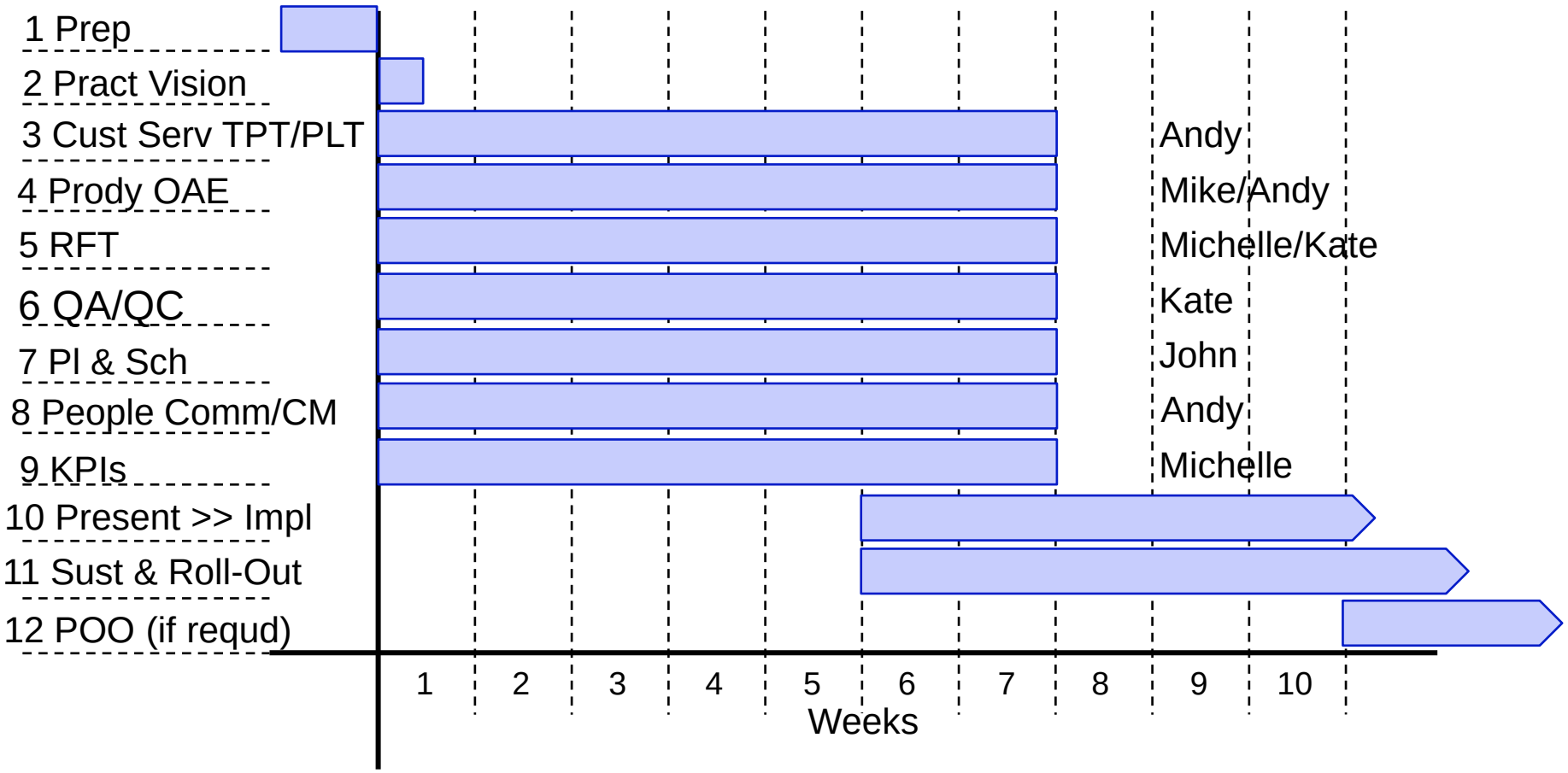
Milestone Plan



Milestone 4. OAE – Briefing Document

SCOPE: To achieve OAE targets for Tableting and packaging of ACD

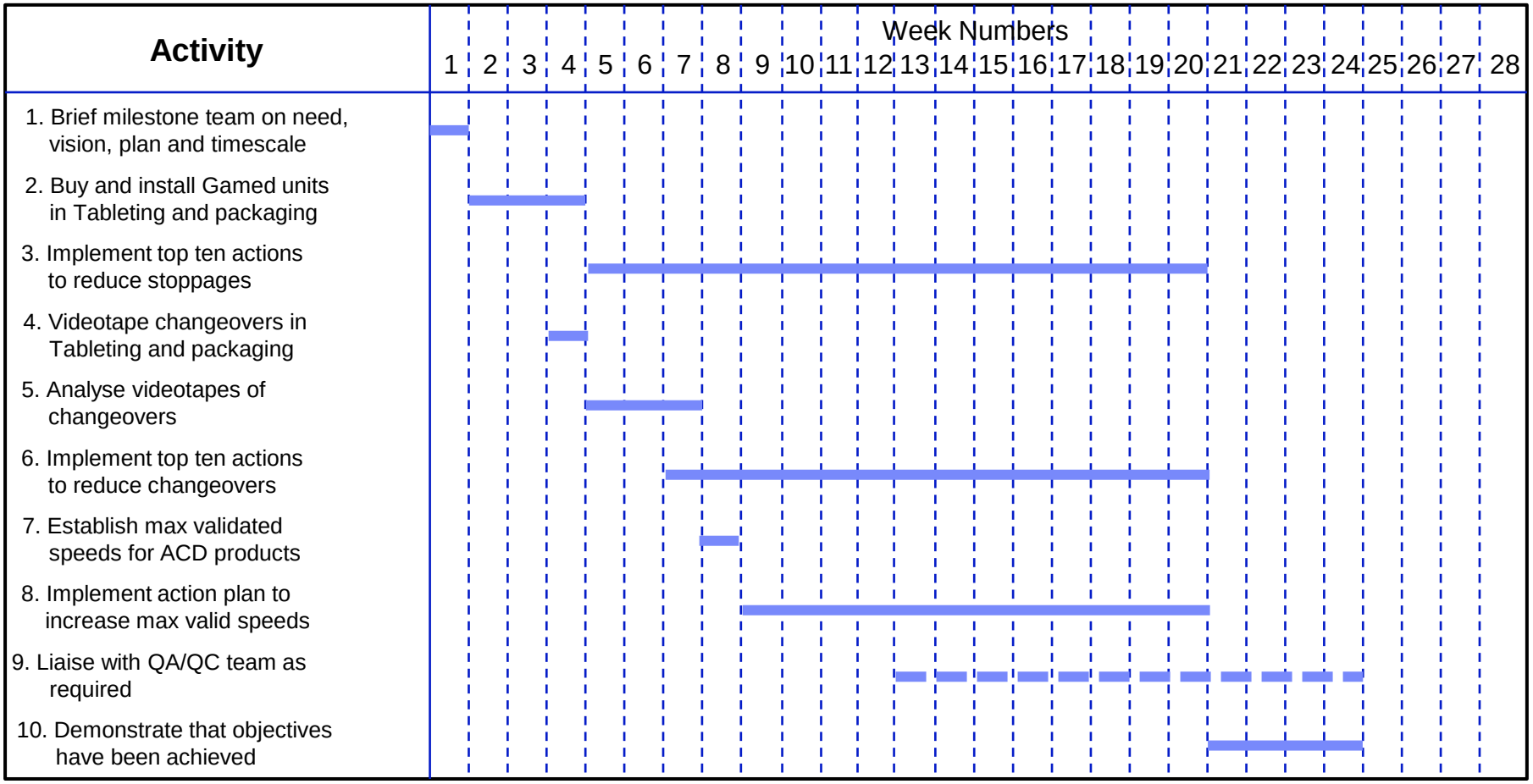
KEY CHANGE ISSUES:

- Reduce changeover times
- Reduce stoppage times
- Run consistently at max validated speed

CRITERIA FOR SUCCESS:

- Tableting 70% and Packaging 40% by month 6
- Sustained for two weeks

Milestone 4. OAE – Activity Plan



Milestone Teams

Milestone	Depts Involved	Team Members	Leader/Facilitator
Steering Group	SMG; TYM	Ken C; Peter W; Martin F; Brian J; Ian A; Andy S	Ken C (L) Andy S (F)
3. TPT/PLT	TYM; Sales; Finance	Andy S; Lean Core Team; Anne F; Phil S, Focus Gr	Andy S (L)
4.OAE	Manufacturing; Packaging; Engineering; IT	Mike T; Kevin S; Andy S; Steve W; Ed J; Norman F Peter T; Frank J, Focus Gr	Mike T (L) Manufacturing Andy S (L) Packaging
5. RFT	Engineering; Production; QA; QC;	Michelle D; Bob W; Dave B; Annabelle J; Betty W	Michelle D (L) Annabelle J (F)
6. QA/QC	QA; QC; Manufacturing; Packaging; Planning	Fred S; Kate B; Betty W; Kevin S; Steve W; Joe C	Kate B (L) Fred S (F)
7. Pl & Sch	Planning; Sales; Production; Purchasing; Quality; IT	John W; Anne F; Carlos R; Sam Y; Kate B; Charles S	John W (L)
8. People & Org	TYM; Communications; HR: Production; Quality; Sales	Andy S: Sharon B; Jan T; Bob W; Margaret N; Jean D	Andy S (L); Sharon B (F)
9. KPIs	Engineering; Production; Finance; Planning; IT;	Michelle D; Alan F; Phil S; Joe C; Frank J;	Michelle D (L)

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Inventory Benefits – from reduced TPT

	Current inv in $k		Potential savings		Savings ACD in $k		Savings all products in $k	
	ACD	All products	% min	% max	min	max	min	max
RM	860	4150	25	40	215	344	1038	1660
Pack	520	2230	25	40	130	208	558	892
WIP	720	2950	50	75	360	540	1480	2213
FG plant	2060	10750	35	50	721	1030	3763	5375
FG cust	240	1030	35	50	84	120	361	515
Total					**1510**	**2242**	**7200**	**10655**

Productivity Benefits (applied company-wide)

- Before TYM: output budget for 2010: 57.6m units
  site budget for 2010: $67.3m
  35% variable costs - $23.6m
  65% fixed costs - $43.7m

Avge Unit Cost – $1.17

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Avge Unit Cost – $1.17

- After TYM: + 10% increase in productivity
  increase output to: 63.4m units
  site budget would be: $69.7m
  35% variable costs - $26.0m
  fixed cost remain - $43.7m

Avge Unit Cost – $1.10
6% reduction

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  site budget would be: $69.7m
  35% variable costs - $26.0m
  fixed cost remain - $43.7m

Avge Unit Cost – $1.10
6% reduction

- Without TYM: +10% increase in output – 63.4m units
  site budget would be: $74.0m

Thus Saving from TYM
$4.3m

Benefits Summary from TYM

- Improved flexibility (shorter set up times, reduction of stoppages)
- Improved customer service (more consistent supply, to build trust)
- Increased capacity (up by 50% to >80m units by 2012 with same resources)
- Lower unit costs (down by >20% by 2012 on today's values)
- Improved profitability (up by >$20m by 2012 compared with no TYM)
- Released working capital (up to $10m by 2012 on today's output)
  (up to $15m by 2012 on higher output)

Note: Assumed that 50% capacity increase filled with additional products at same price / volume mix

Investments Summary

Investment	$k
Washing equipment and storing for tooling	155
Equipment modifications for fast changeover	32
Gamed or equivalent system	16
Kanban and signalling system	12
NIR or equivalent for QC	45
Air tube transfer of samples to QC	60
Total – Pilot Phase this year	**320**
Additional fast changeover parts and equipment	85
Additional Gamed or equivalent system	42
Additional NIR or equivalent for QC	45
QC layout optimisation	180
Additional Total - Roll Out Phase next year	**352**

Conclusions

- TYM can provide –
  - Fast, flexible, compliant production operations
  - Significant operational, financial and business benefits
  - Firm foundation for future improvements
  - Improved competitiveness for the Sydney facility
  - At minimal capital cost
- Therefore, we would like your approval to begin implementation

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Back-up Slides

(Briefing Docs and Activity Plans
for all Milestones – plus these)

Milestone Team Rules

- Meetings must be held weekly and total no more than 4 hours per week
- All team members must attend meetings and advise their manager accordingly
- Milestone teams must create and maintain team logs of activities
- All findings, conclusions, recommendations and actions must be recorded in the team log
- Milestone teams must follow the Activity Plan as set out in their individual Milestone Plan
- Criteria for Success as stated in the Milestone Briefing Document are not negotiable
- Allocated tasks must be carried out between meetings while maintaining normal duties
- Any proposed changes to the Activity Plan must be agreed with the TYM Core Team leader
- Milestone team leaders must ensure sufficient preparation for Steering Group meetings

Steering Group Meetings

Date	Pres A: 15.00	Pres B: 15.30
02 Feb	MS 3	MS 4
16 Feb	MS 5	MS 6
02 Mar	MS 3	MS 7
16 Mar	MS 8	MS 9
30 Mar	MS 3	MS 4
13 Apr	MS 5	MS 6
27 Apr	MS 3	MS 7
11 May	MS 8	MS 9
01 Jun	MS 3	MS 4
22 Jun	MS 5	MS 6
13 Jul	MS 7	MS 8
03 Aug	Summary Meeting	Review of Project