Presentation Contents

- Background
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- Generating sponsorship
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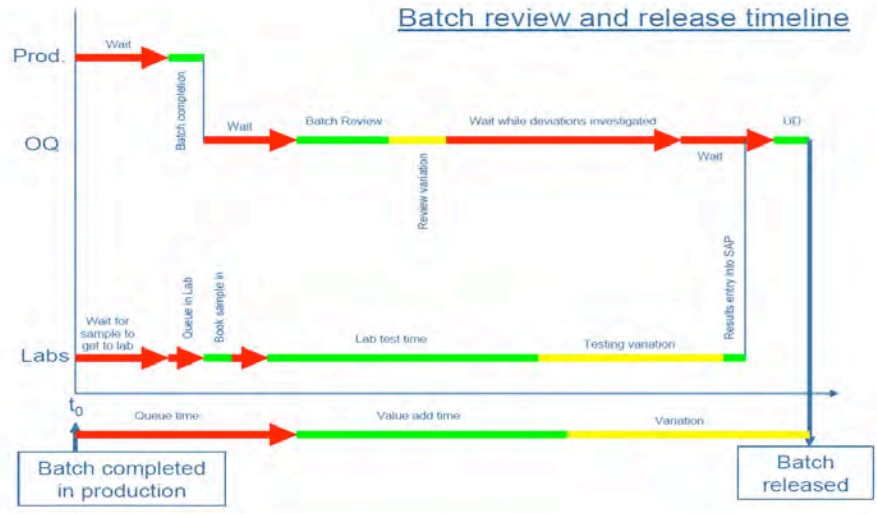
- Creating critical mass – the 'Tipping Point"

Boronia Quality Department

Understanding Business Needs & Stakeholder Expectation

Findings from Batch Review & Release Functional Baseline Feb 2007



Understanding Business Needs & Stakeholder Expectation

Undesirable Effects

- Jan 07 Boronia *Internal Delivery Performance 84%*
- Batch release & laboratory *testing lead times not linked to real customer requirements nor pace of production*
- Chemistry Laboratory lead time 18 day Steriles, 16 day TM
- Microbiology Laboratory lead time conformance 66%
- OQ batch release lead time conformance 69% to 81%
- Large *variation of waiting time & cycle time*
- No consistent WOW, *constant re-prioritisation & expediting*

Understanding Business Needs & Stakeholder Expectation

Corporate Initiatives

- Vision Factory
- Pharmaceutical Operations Benchmarking of Solids (POBOS) Nov 06 to July 07
- GMS Network Review

Stakeholders

- Internal: Planning, Production, OQ, other laboratories, Site Leadership Team
- External: Australian commercial customers, other GSK customers, GMS Executive Team, Core OE, GMS Network Review Team

Understanding Business Needs & Stakeholder Expectation

Expectations

- Secure supply – never miss an order
- Reduced batch release & testing lead times
- Batch release & laboratory testing at pace of Production
- Productivity improvement
- Minimal co-ordination & expediting
- Reduced process variation
- Method capability

Identifying Improvement Opportunities & Approach

Boronia Future State 1 Flow Test & Sentencing System

Goal: Enable achievement of Vision Factory Future State 1 for Boronia by completing flow test & sentencing system activities for Future State 1.

Definition of FS1 for Flow Test & Sentencing:
- Testing/ sentencing at manufacture pace (short resid., high RFT &prod.)
- Bxs flow FIFO thru' Quality, no routine planning/scheduling/expediting.

Future State 1 for Flow Test & Sentencing:
- Demand analysis, testing requirements analysis & product grouping has been used to define the appropriate cell structure
- High attention to cell layout & detailed line design to minimise motion & transport waste
- 5S in terms of equipment & consumables layout
- Kanban control of material & equipment consumables
- High equipment uptime
- There is no sample planning or planner, as fixed repeating test schedules are used to control the pace of testing & sentencing
- FIFO is strictly adopted & sample receipt & storage is organised to facilitate this
- Heijunka operates to ensure that the flow of different sample types through common test stations is smoothed in line with the ratio of customer demand
- Analysts & sentencers are allocated to each cell, & can perform any role to permit rotation
- Testing time, sentencing time & laboratory RFT are collected & reviewed to plan improvement
- Standard work in place & in use
- Documented evidence of use of Sigma tools MSA/ DOE

Business Case:
- No laboratory & OQ batch release scheduling
- Progression of samples & batch doc's at same pace that they are created

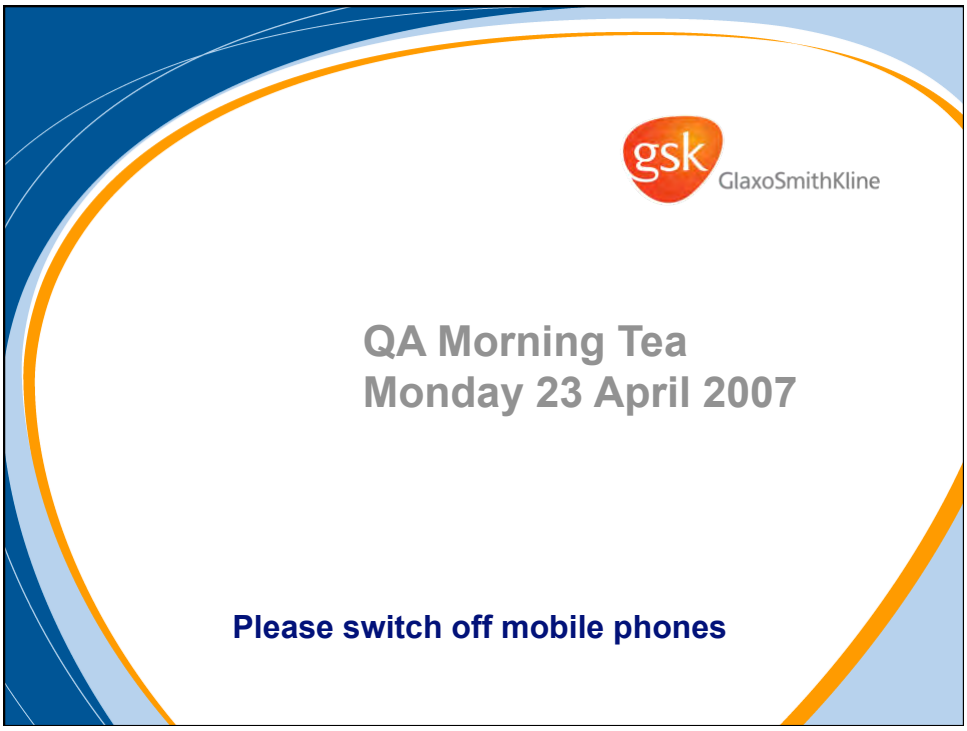
Boronia's Progress Towards FS1 Flow Test & Sentencing – completed:
- Micro Lab works FIFO & at the pace of manufacture.
- Demand/ testing requirements analysis performed for I. G. Lab.
- Cell structure exists in all labs.
- 5S, Kanban & Heijunka in place & in use in Chem Lab.
- Analysts/ sentencers allocated to each cell, job rotate in Chem/ Micro cells.
- Testing/ sentencing time & Lab testing RFT reviewed in Chem & I. G. Labs to plan improvement. Data collected in Micro Lab & OQ but not reviewed.
- Standard work is partly introduced in the Labs & OQ.
- Documented evidence of MSA exists in the Chem & I. G. Labs.

Work to be completed to claim FS1 for Flow Test & Sentencing:
- Physical layout/ 5S/ Green & Red Lanes/ Heijunka OQ Offices (Q3 07)
- OQ Standard Work for FP/ Zofran Plastic Amps/ Hand Packing (Q2 07)
- 5S I. G. & Micro Labs (Q2 07)
- Retro. MSA in Chem Lab for parameters with PPK < 1.33 (Q2 07)
- Kanban & Heijunka in I. G. Lab (Q2 07)
- Changes to mindset, culture, r & r and organisation (Q2 07)

FS1 for Flow Test & Sentencing is also dependent on the following out of scope deliverables:
- Planning standardised Ways of Working – Planning to quantify
- Notifications (Oct 07)
- Batch Documents NRFT (Q2 07)

FS1 Flow Testing & Sentencing KPIs:
Test & Sentence time reduction and door to door time reduction
Improved material availability for despatch
Supply performance improvement
Inventory reduction
Analyst productivity improvement

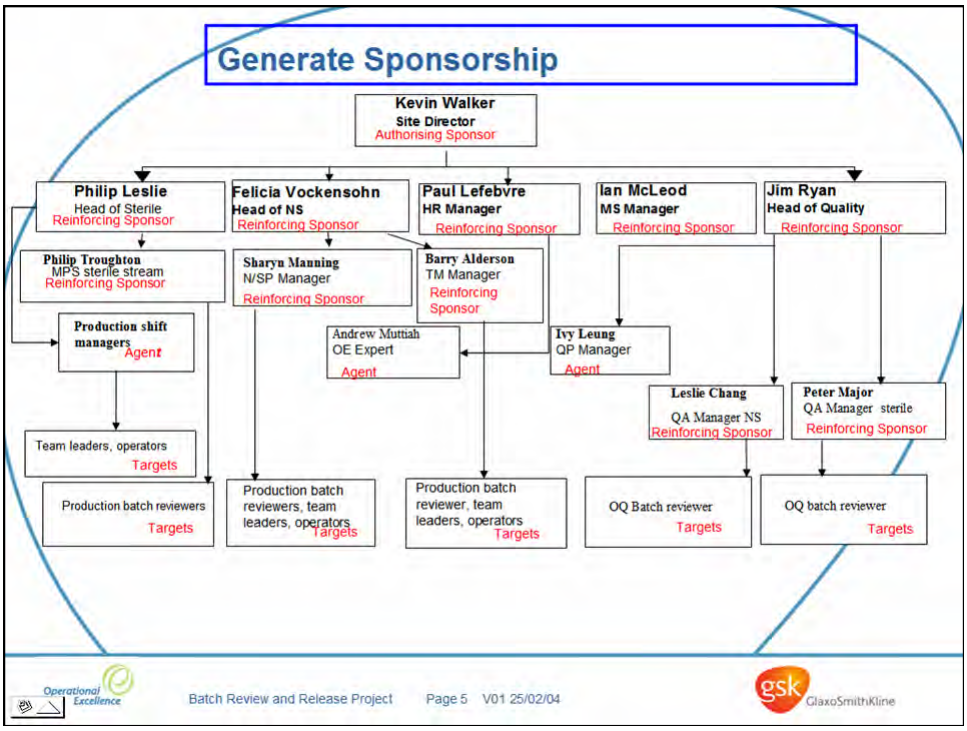
Boronia Flow Test & Sentencing KPI Progress
Reduce Chem test lead time from Av. 18d Steriles/ 16d TM to sustainable at 10d
Reduce OQ Batch Review/ Release lead time by Av. 11d Steriles & 5d TM
Reduce OQ Batch Review/ Release lead time variation from 14d – 76d to 14d – 30d for Steriles & 6d – 36d to 5d – 18d for TM
Develop productivity measure for analysts & microbiologists



Identifying Improvement Opportunities & Approach

Vision Factory Flow Test & Sentencing Kick Off Meeting Agenda

- Vision Factory & Future State 1 definitions
- Changes to mindset & culture
- Flow Test & Sentencing
  - -- Definition
  - -- Timeline
  - -- Benefits
  - -- KPIs
  - -- Projects


Generate Sponsorship
Kevin Walker
Site Director
Authorising Sponsor
Philip Leslie
Head of Sterile
Reinforcing Sponsor
Felicia Vockensohn
Head of NS
Reinforcing Sponsor
Paul Lefebvre
HR Manager
Reinforcing Sponsor
Ian McLeod
MS Manager
Reinforcing Sponsor
Jim Ryan
Head of Quality
Reinforcing Sponsor
Philip Troughton
MPS sterile stream
Reinforcing Sponsor
Sharyn Manning
N/SP Manager
Reinforcing Sponsor
Barry Alderson
TM Manager
Reinforcing Sponsor
Production shift managers
Agent
Andrew Muttiah
OE Expert
Agent
Ivy Leung
QP Manager
Agent
Leslie Chang
QA Manager NS
Reinforcing Sponsor
Peter Major
QA Manager sterile
Reinforcing Sponsor
Team leaders, operators
Targets
Production batch reviewers
Targets
Production batch reviewers, team leaders, operators
Targets
Production batch reviewer, team leaders, operators
Targets
OQ Batch reviewer
Targets
OQ batch reviewer
Targets
Operational Excellence
Batch Review and Release Project
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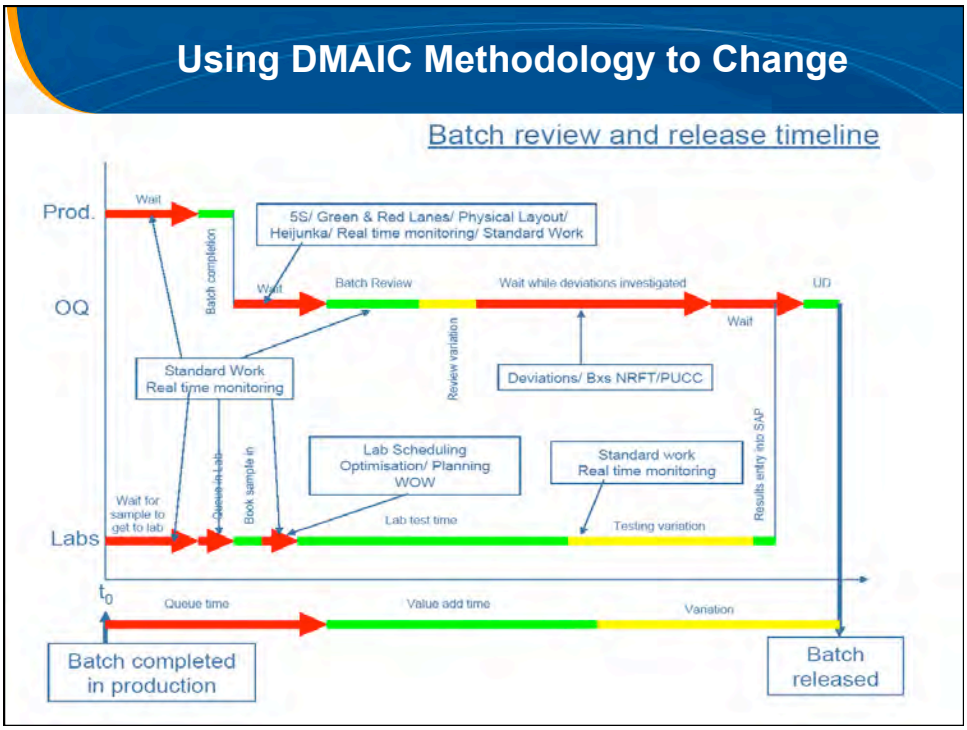
GlaxoSmithKline

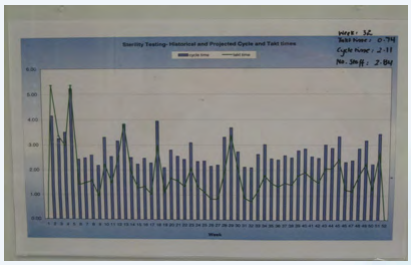

Using DMAIC Methodology to Change
Batch review and release timeline
Prod.
OQ
Labs
Wait
Batch completion
5S/ Green & Red Lanes/ Physical Layout/ Heijunka/ Real time monitoring/ Standard Work
Wait
Batch Review
Wait while deviations investigated
UD
Wait
Review variation
Standard Work Real time monitoring
Deviations/ Bxs NRFT/PUCC
Lab Scheduling Optimisation/ Planning WOW
Standard work Real time monitoring
Results entry into SAP
Wait for sample to get to lab
Queue in Lab
Book sample in
Lab test time
Testing variation
t0
Queue time
Value add time
Variation
Batch completed in production
Batch released

Using DMAIC Methodology to Change

- Physical layout review & 5S
- Process mapping
- UDEs
- Cycle & lead times
- Demand analysis
- Takt time & staff no.
- Load levelling

Micro Process Flow Maps

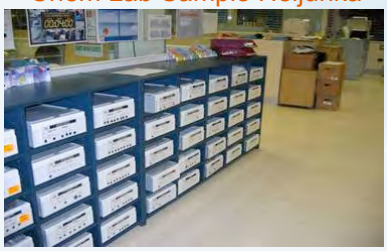
Sterility Testing Takt & Cycle time



Using DMAIC Methodology to Change

- Heijunka systems
- Visual planning
- FIFO testing
- Standard work
- Required equipment time
- Cross-functional Kaizens

Chem Lab Sample Heijunka



Micro “Qantas” Planning Board

Making Real Difference to the Bottom Line
QA Productivity Improvement 2007 – 2009

Goal: To be the Best in Class QA function in GMS & pharmaceutical industry

Background:
- 84% Site IDP in Jan 07
- Chemistry Lab lead time 18 day Steriles, 16 day TM
- Microbiology Lab lead time conformance 66%
- OQ batch release lead time conformance 69% to 81%

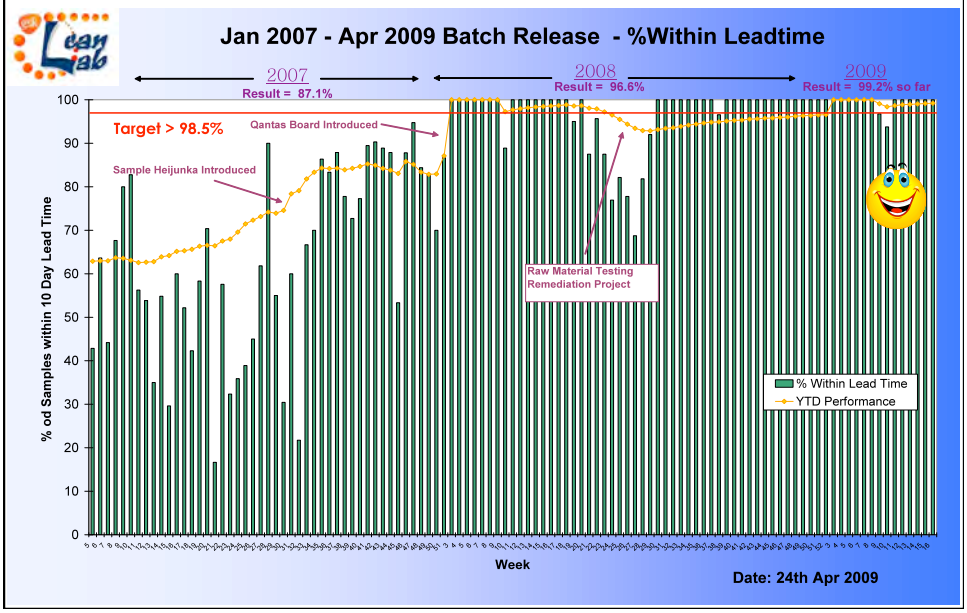
Improvement Approach:
- Demand analysis, Calculation of Takt time, Cycle time & theoretical staff #
- Visual management & 5S in QC & OQ including Heijunka, planning board using "Perfect flight path",
- Green & Red Lanes
- Daily accountability meeting
- Management Standard Work
- Completion of mergers in OQ & QC

Current Status:
- 98.8% Site IDP
- Chemistry Lab testing lead time 6d
- Microbiology lab testing lead time conformance > 98%
- OQ batch release MA Dates conformance 99.5% %
- Certified as "Class A" QC Labs

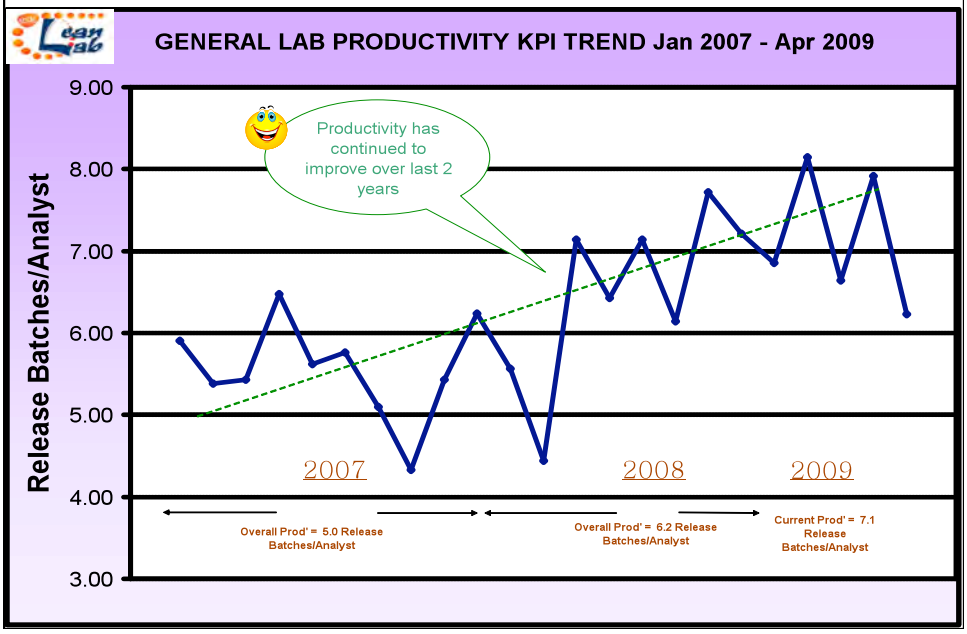
Future Steps:
- Completion of QA slimming
- Control Charting (in progress)
- SMED" of HPLC (in progress)
- Rationalisation of raw material testing
- Method capability improvement

Benefits Realised:
- Site IDP of 98.8%.
- 67% Reduction in release testing lead time variation
- 62% Reduction in stability testing lead time
- 59.4% OQ batch release productivity improvement
- 38.5% Microbiology Lab release testing productivity improvement
- 42% Chemistry Lab release testing productivity improvement
- Increase Chemist HPLC productivity from 3 runs/week to 4.5 runs/week
- FIFO testing & batch review

Making Real Difference to the Bottom Line
Chemistry Laboratory



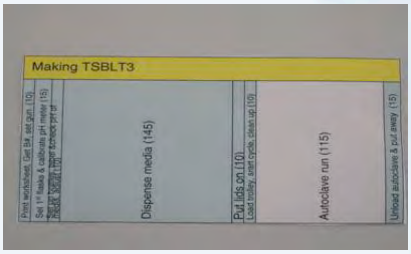
Making Real Difference to the Bottom Line
Chemistry Laboratory



Building Success Upon Success

Micro Lab "Perfect Flight Path" V1

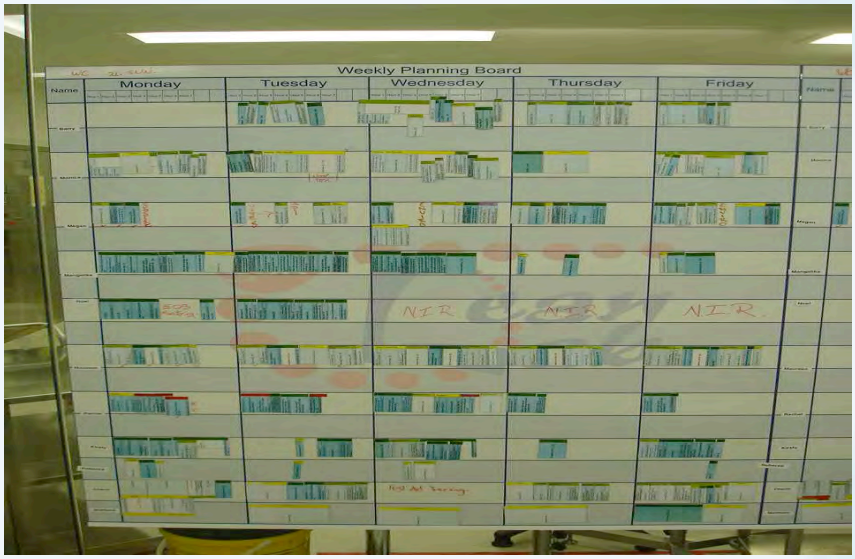
Micro Media Preparation Strip



Chem Lab "Perfect Flight Path" V1

Building Success Upon Success

Micro Lab "Perfect Flight Path" V2



Building Success Upon Success

Micro Lab Heijunka

Chem Lab Heijunka

Chem Lab Sample Label

SAMPLE LABELS – COLOUR CODES				
BATCH STATUS	<50% LEAD TIME (GREEN)	50-75% LEAD TIME (YELLOW)	75-100% LEAD TIME (ORANGE)	>100% LEAD TIME (OVERDUE) (RED)
TEST STATUS	TEST NOT COMMENCED (Blank)	UNDER TEST (BLACK)	TESTING COMPLETED (SILVER)	CHECKED (GOLD)
TECHNIQUE CELLS	Dissolution Disintegration UV	HPLC	INHALED	TOC TLC NIR Titrations

Building Success Upon Success

Operational Quality Planning Board – "Perfect Flight Path"

Operational Quality Batch Document Heijunka system

Creating Critical Mass – the "Tipping Point"

The Tipping Point" by Malcolm Gladwell

- Three Rules of social epidemics

(i) Agents of Change – Law of the Few
- -- Connectors, Mavens (knowledge accumulators) & Salesmen

(ii) The Stickiness Factor
- -- Memorable ideas (practical & personal advice) that move us to action

(iii) The Power of the Context
- -- Create community where new beliefs can be practised, expressed & nurtured
- -- Small close knit groups magnify epidemic potential of a message or idea
- -- Peer pressure: Knowing people well enough that what they think of us matters

Thank You !