

# CREATING A LEAN COST-EFFECTIVE QMS



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Clerk to Lab assistant to Lab Technologist

Scientist MMed Science/ PhD -

Director of Lab - 11 sites

36 000 samples per year

Test profiles (all types, HPLC/MS; NGS) Clinical pathology etc etc

Trainer Registrars /Medical Technologists

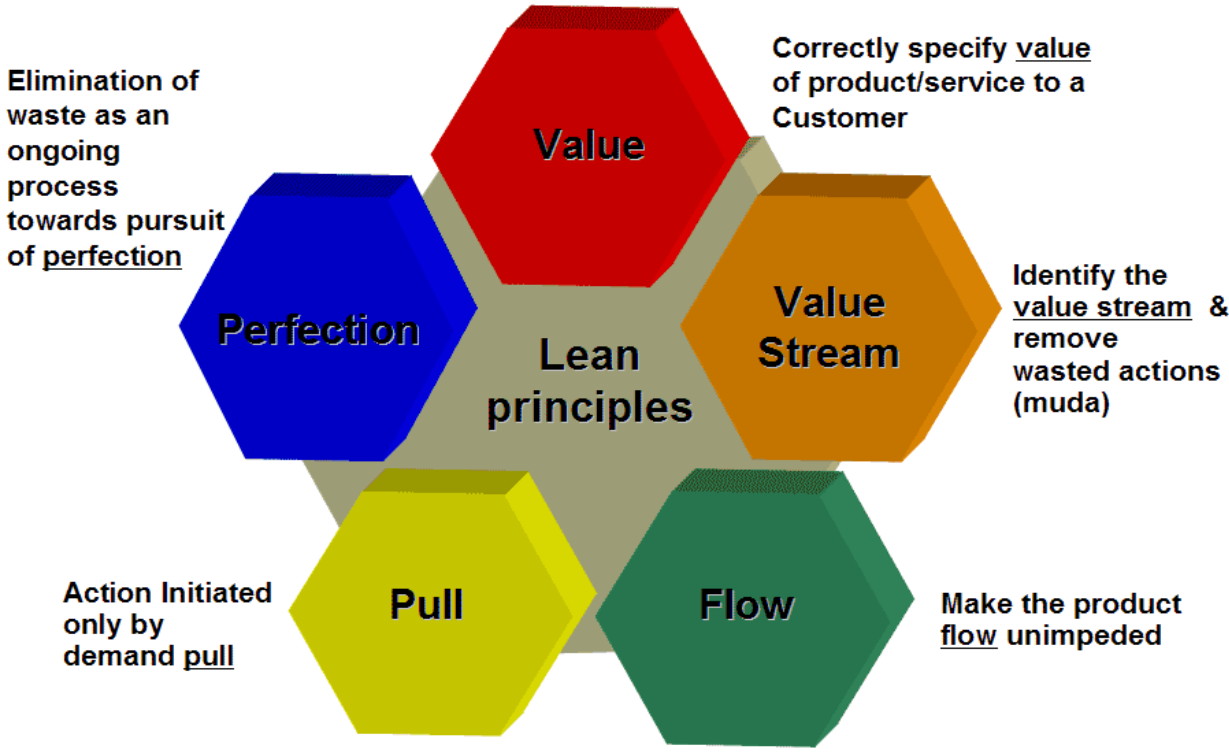
Auditor Sanas and HPCSA

# BACKGROUND

- NHLS/ State Labs – 25 years - Large personnel – 5000 samples a day – always short of money
- MRC / Clinical Research – FDA Drug studies - GREAT we get USA Funded - Dollars
- Private/ Academic Lab - 392 Staff complement – Madly competitive/ Hectic deliverables

(Lowest cost/ Highest Quality) – You can get taken out of the market very quickly

# WE ALL KNOW THIS



# HOW DO WE IMPLEMENT , these are my own experiences

- **PERFECTION** (training, monitoring, evaluation, giving levels of responsibility based on Trust/ Trust must be assessed – eg if You assigned a task to Person A and B who will you Trust and Why) Benchmark, Eventually with increasing Morale, people aim to become Trust worthy .....more and more quality is achieved

(Training – No end to this process. Not even the highest level manager cannot learn from the most junior staff ) – I interact with all levels – Because I really believe this is key

**Please Expose Hands on persons ;** Why do just Supervisors and Managers attend training, conference trips , workshops – **THIS IS REALLY NOT PROGRESSIVE** (eg Roche Diagnostics has an annual End of Year Scientific Gratitude event/ included is a prestigious speaker eg from Mayo Clinic USA, the rest is a gratitude event –really exclusive event- **I SEND MY LAB SCIENTISTS** who are users of the Roche system– am the only lab that does this)

# PERFECTION AS A HIGHLY COST EFFECTIVE TOOL

- Planning comes before Perfection

**(Every Protocol is Planned with the Entire Team)** - its not just presented ; It's a joint INPUT/EFFORT – gosh if anything works – JOINT TEAM EFFORT is the KEY

Eg if the Data capturer suggests a way to save time – which is money – Listen, assess, correct in a way using the 9 Pros and 1 cons approach ; sometimes you want to reverse this but its very simple to change the cons to appear like it is Pros) – BELIEVE ME if the IDEA COMES FROM THE PERSON, they WILL MAKE IT WORK , this is boosting confidence

Again The Team tasks out the Protocol , You as the upper management/Director are here to ensure that the Key components are adhered to; give them the opportunity to tease out

# PERFECTION is KEY TO COST SAVING

- Usually first time correct, occasionally concern noted
- Less and Less Repeat testing
- WASTE – due to Pre-analytical errors; Analytical errors and Post Analytical errors

**Implement DISCREET QC checks to cover all 3 aspects AT ALL 3 PHASES**

# DEFINE A LABORATORY

- IS A COURIER ON WHEELS

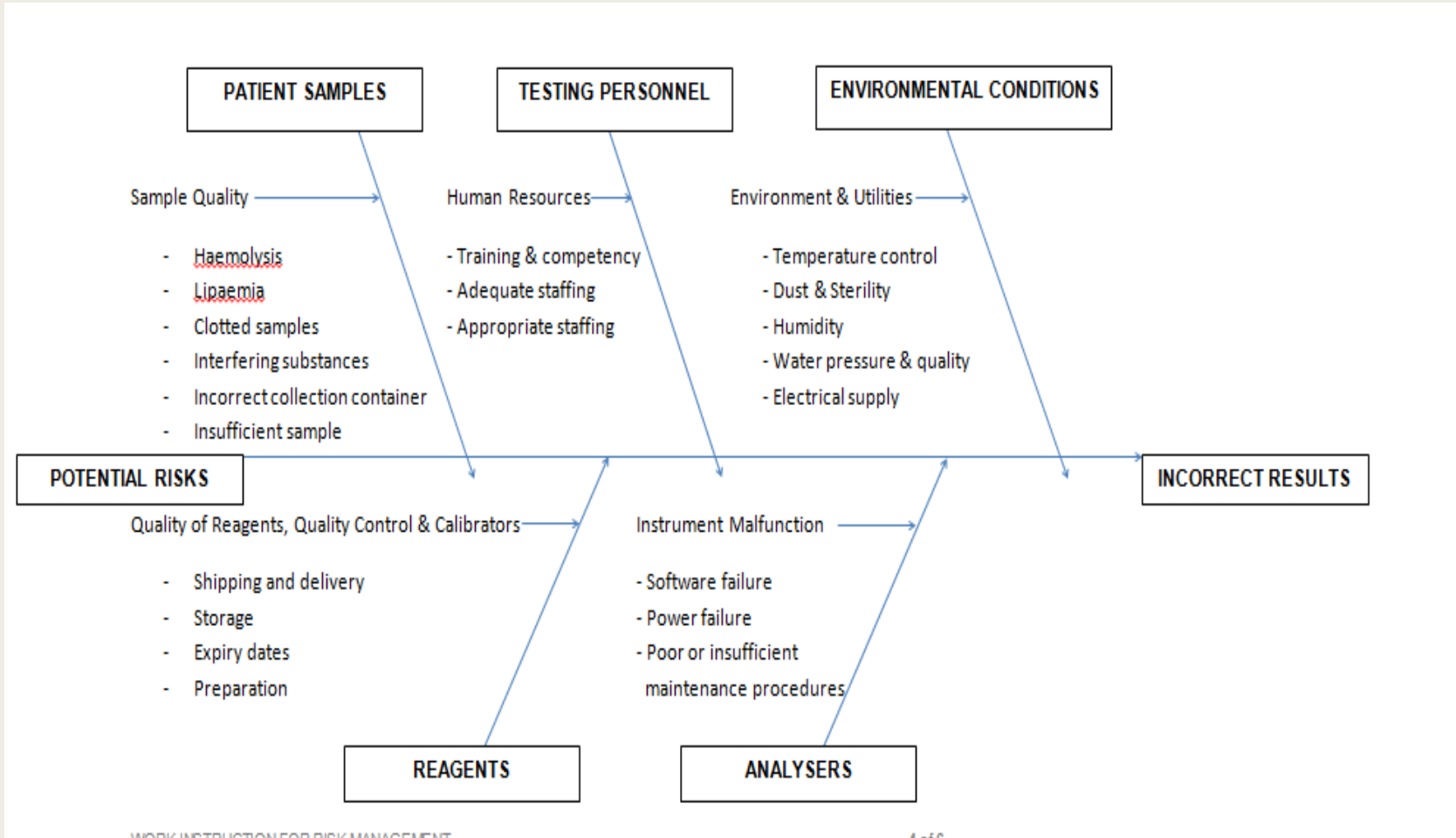
Hence Where DOES QUALITY START

**Don't NOT** TAKE RESPONSIBILITY OF THE PREANALYTICAL PROCESSES

(You don't have to be accountable BUT take responsibility)



# \* RISK ASSESSMENT



# PREANALYTICAL PROBLEMS

- (incorrect sample; inaccurate sample labelling; poor sample collection, inadequate sample tracking ; inappropriate sample transport)
- POOR CHAIN OF CUSTODY / INADEQUATE MONITORING PROCESSES)

Answer Use Technology to support eg Electronic Temp Monitoring; Electronic tracking etc)

Initial cost – ultimate MASSIVE COST SAVING

# ANALYTICAL PROBLEMS

- Simple not followed SOPS – catch it and sort it – weekly training in the lab on SOPs; hadoc Witnessing – the QA team will perform this – looking at those on shift (Minimum of once in 6 months on all assays performed by the tech – We run 120 assays in the lab)
- Review of Raw data – ongoing adhoc –
- Review of IQC **real time** – Analyser trends on frequency of reruns and Who is the common Lab tech – who reruns – TRAIN AND RETRAIN -and Take action if you fail Take note IQC is the MOST EXPENSIVE Component of a lab ( frequency of running IQCs cannot be compromised but you also have to contain costs –eg in a 24 hour lab All levels of IQCs must be run minimum 8 hourly – volume of patient sample dependent – DONOT COMPROMISE THIS – SAVES you ultimately

# ANALYTICAL PROBLEMS- Our labs experiences

- How long does it take to solve /identify IQC failures / and how expensive is it – VERY EXPENSIVE –eg Biorad used in our Lab

(How often do we fail Westgard Rules )? – WESTGAURD IS OUR GURU

Please do-not trouble shoot for ever ; and coincidently when you get it right after 5 times then you accept the Results – because you will FAIL THE NEXT RUN – if the problem is NOT LAB TECH incompetency related –

(Set very stringent Failure rules in YOUR LAB – this saves money/ time/ effort)

How often to we consult and talk to the Service providers or Reagent suppliers

(Eg after we wasted Folic acid calibrators/controls/ rerun rerun rerun –weeks later to be told by the supplier –other users have complained , we have a Batch No ... is problematic) – too late to reverse wastage -,LAB TECHS MUST BE smartly taught

# ANALYTICAL COST SAVING

- Stringent IQC process
- Real time action

- OWN INTERNAL /ADDITIONAL / INCREASE YOUR CONFIDENCE IQC

( Do we realise VIRAL LOAD testing Analytical QC is based Only on the Reagents and Apparatus ) –

What about Sample (pre-analytical IQCs – create your own processes – Please – Run at least 2 levels of Your own validated IQC samples with every batch- This reduces query repeats/ increases your confidence/improves quality at all levels – LONG TERM saves

# ANALYTICAL COSTS

- Other **Major cost** in a lab – MANPOWER

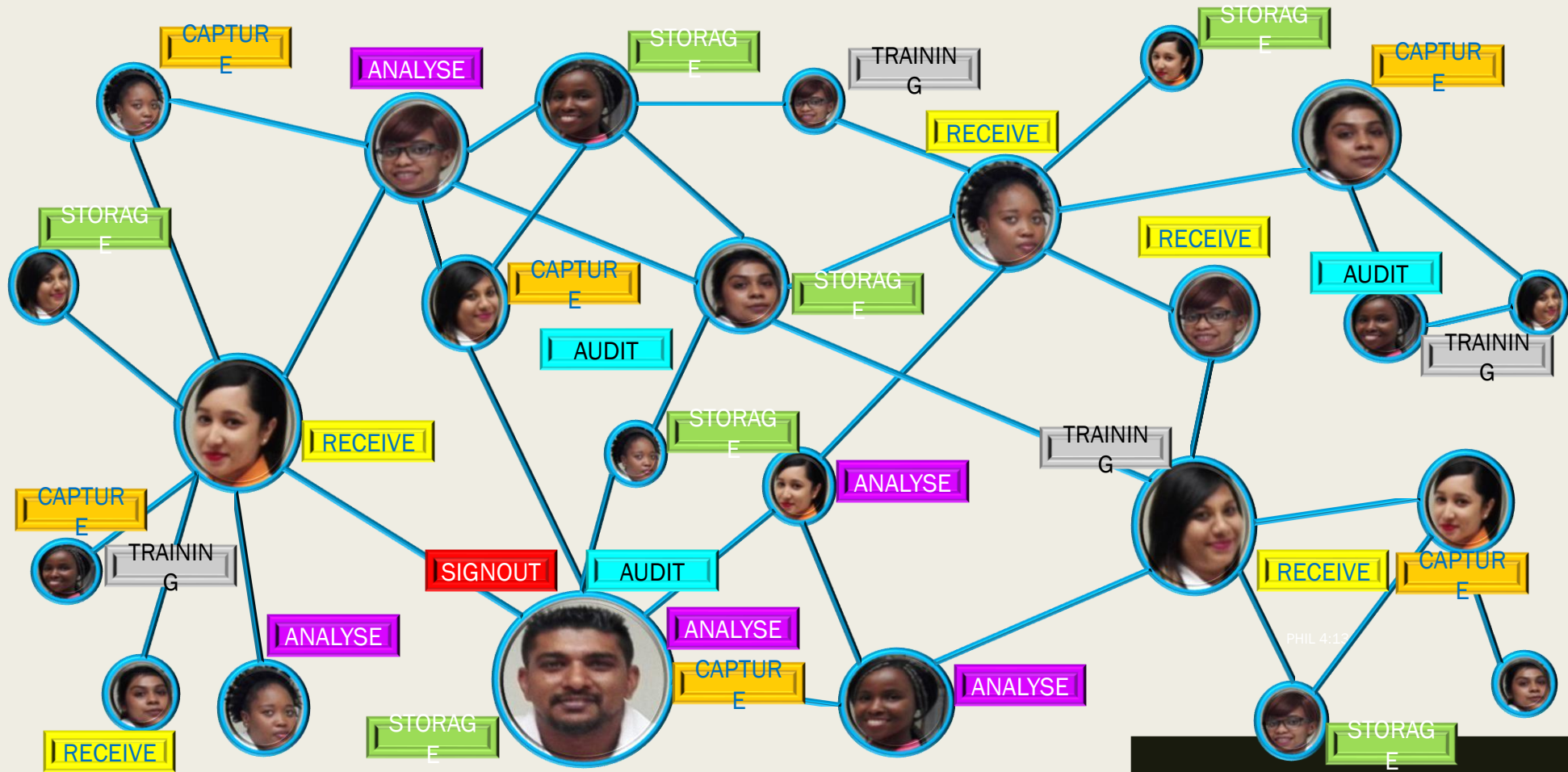
(Please teach people to be Multi skilled – Not beyond their scope though)

Eg In the Viral load lab – THEY must KNOW how to spot DBS cards, Extract / Test etc etc

(I worked at facilities where one will fold their arms whilst the other is preparing the samples ) – WHY – I encourage end to end processing – 2 FACTORS – cost saving PLUS full accountability

(I employ staff and I take full accountability for the training – making me accountable for what I produce- all aspects)

# Department Overview



# AUDITS – a tool to save Costs

- Internal audits –(staff with technical knowledge from a completely unrelated department to cross audit) PLEASE do-not schedule because ISO requires proof of twice a year – USE THIS AUDIT to identify Problems/ failures/ etc – AND WORK ON IT REAL TIME, it will ultimately save you money, time, IMPROVES QUALITY

(Highlight problems /resolve – Monitor/ recurrence will be less and Less)

PLEASE do-not put things under the carpet – MY STAFF are taught ‘Get it out, and FIX it)

**(Frequently Please – Decide on your staff no and sample no)**



# AUDITS to Save Costs

- External Audits/ External Eyes - Eg Our Lab – Audits by

1. Every Research org that works with us – If we have 5 Orgs – all 5 will audit / by our request
2. Frequency – monthly plus quarterly – minimum

Our Lab has the ffl audits

1. Monthly – Caprisa
2. Quarterly HSRC
3. Twice a Year HPP
4. Twice a year HPP
5. Annual Sanas
6. Annual PPD (You would hate working in my Lab)- But after a while it becomes a lifestyle because audits can be done today for today –??? Extreme cases – But at least announced a week in advance

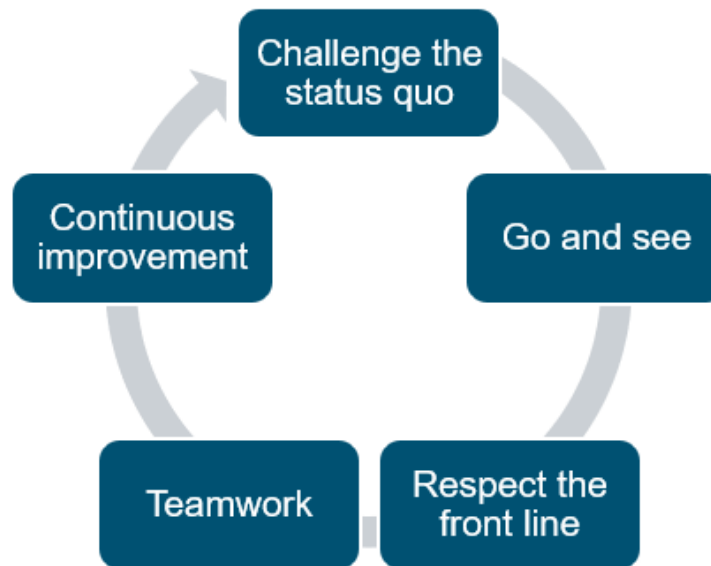
# INTERNAL AUDITS

- 27 were scheduled and were completed, 2 scheduled for December



# WE ALL KNOW THIS

## *5 Leadership Principles for Lean*



# NON-CONFORMANCE CONTI



16016	02-03-2016	CHEMISTRY	A SIVLAL/	B R PILLAY/	S	17-03-2016	31-05-2016
16017	11-03-2016	STORES	M REDDY	S PATHER		05-04-2016	05-06-16
16018	11-03-2016	STORES	M REDDY	S PATHER		05-04-2016	07-06-2016
16019	11-03-2016	STORES	M REDDY	S PATHER		01-06-2016	01-09-2016
16020	23-03-2016	LOGISTICS	EARL/GAVIN	S PATHER		05-04-2016	03-06-2016
16021	23-02-2016	LOGISTICS	JOHN D	S PATHER		28-03-2016	01-06-2016
16022	30-03-2016	CHEMISTRY	A SIVLAL	S PATHER		26-04-2016	19-05-2016
16023	30-03-2016	CHEMISTRY	A SIVLAL	S PATHER		01-04-2016	02-06-2016
16024	28-04-2016	HAEMATOLOGY	UGEN/SOHANA	S PATHER		30-04-2016	28-07-2016
16025	28-04-2016	HAEMATOLOGY	UGEN/SOHANA	S PATHER		04-04-2016	28-07-2016
16026	28-04-2016	HAEMATOLOGY	UGEN/SOHANA	S PATHER		03-05-2016	28-07-2016
16027	28-04-2016	SEROLOGY	PRISHEN	S PATHER		05-05-2016	28-07-2016
16028	28-04-2016	HAEMATOLOGY	UGEN	S PATHER		30-04-2016	28-07-2016
16029	28-04-2016	MICRO	MEGAN/VERONICA	S PATHER		29-04-2016	30-07-2016
16030	28-04-2016	MICRO	MEGAN/VERONICA	S PATHER		28-04-2016	30-07-2016
16031	28-04-2016	MICRO	MEGAN/VERONICA	S PATHER		29-04-2016	29-07-2016
16032	29-04-2016	TB	RHONA/THOMBISA	S PATHER		27-05-2016	27-07-2016
16033	29-04-2016	TB	RHONA/THOMBISA	S PATHER		27-05-2016	27-07-2016
MP-1	09-06-2016	QA	DIPAK/SUSHIE	M.POO		26-06-2016	26-09-2016
MP-2	09-06-2016	QA	DIPAK/SUSHIE	M.POO		25-06-2016	25-09-2016
MP-3	09-06-2016	LOGISTICS	DIPAK/SUSHIE	M.POO		10-07-2016	10-10-2016
MP-4	09-06-2016	QA	DIPAK/SUSHIE	M.POO		26-06-2016	26-09-2016
MP-5	09-06-2016	LAB	DIPAK/R PILLAY	M.POO		25-06-2016	25-09-2016
MP-6	09-06-2016	QA	DIPAK/SUSHIE/ROX	M.POO		26-06-2016	26-09-2016
MP-7	09-06-2016	LAB	DIPAK/ROX	M.POO		26-06-2016	26-09-2016
MP-8	9/6/2016	QA	DIPAK/ROX/ROWANNE	M.POO		26-06-2016	26-09-2016

# PLEASE FOLLOW THIS PRINCIPLE TEAM WORK

- BE - FIRST
- DO - BE A DOER, get the knowledge , run the tests yourself, calculate the results
- SEE -
- THEN ONLY TELL - ie give out your Expectations
  
- HOW CAN A SUPERVISOR /MANAGER DICTATE BUT NOT LEAD BY EXAMPLE

# CASE SCENARIO

- FIRST VIRAL LOAD OF 26 COPIES /ML
- (SADGURU – DR WESTGAURD)
- (IMPORTANT , MOST IMPORTANT GURU – A MISTAKE – LEARN NEVER TO MAKE IT AGAIN) -how, Empower, BY TRUST

# Department Overview - Staff



# WORKING TOGETHER IMPROVES QUALITY AND SAVES MONEY

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# THE ONLY WAY

Power of working in Team, Team Work !  
The power of teamwork, make the  
impossible possible!

