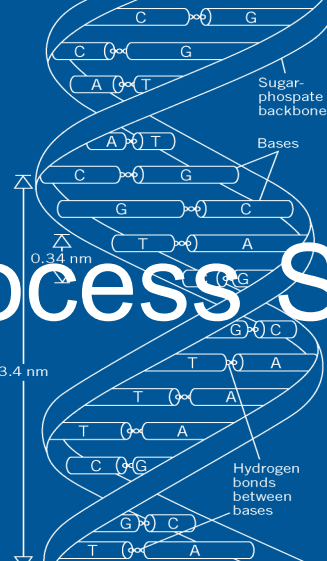




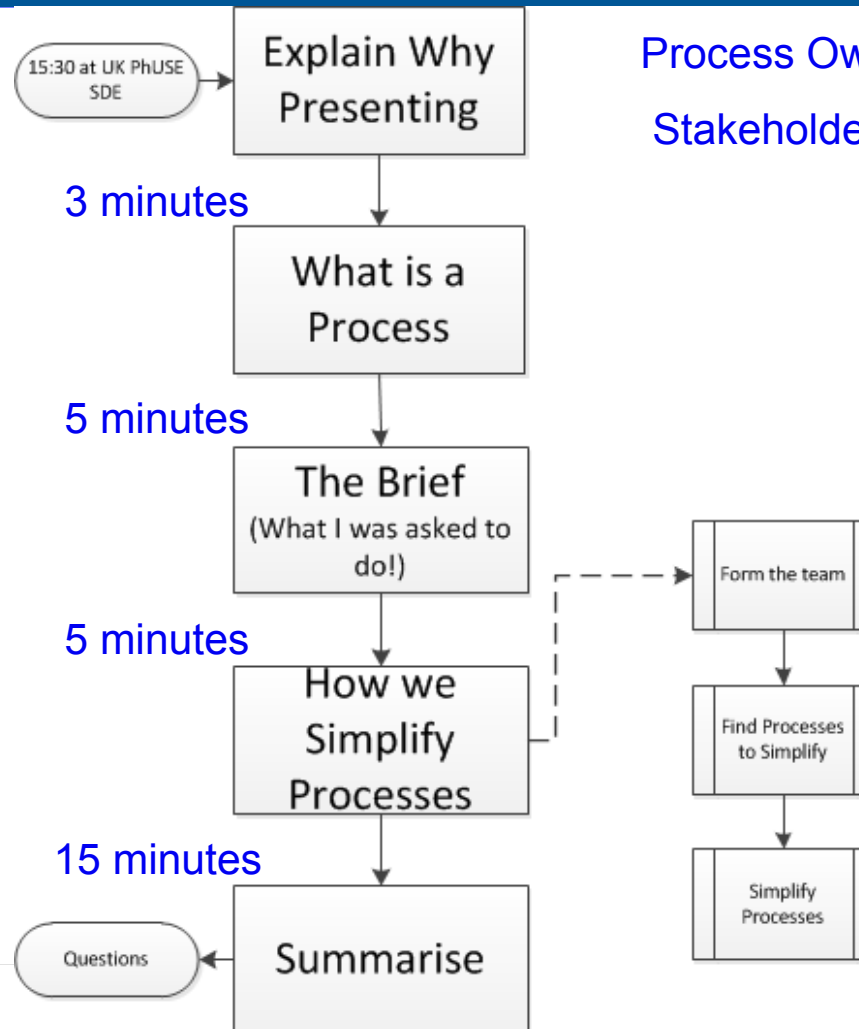
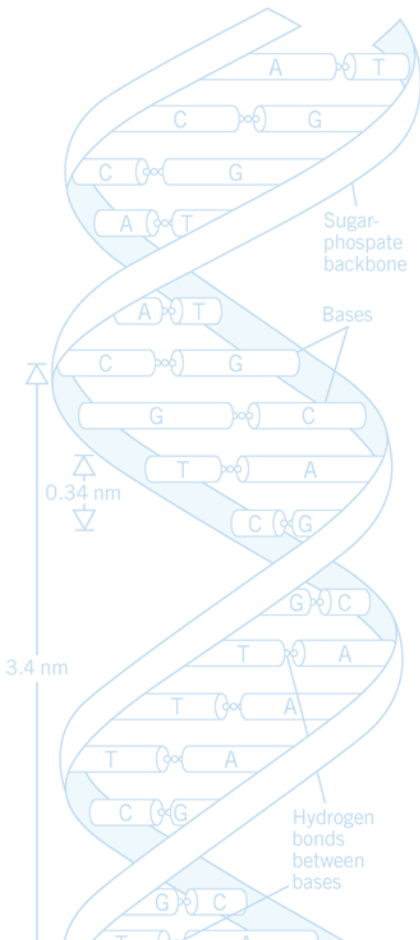
Process Simplification – *An Approach*

June 2012

“If you can't describe what you are doing as a process, you don't know what you're doing.”

W. Edwards Deming

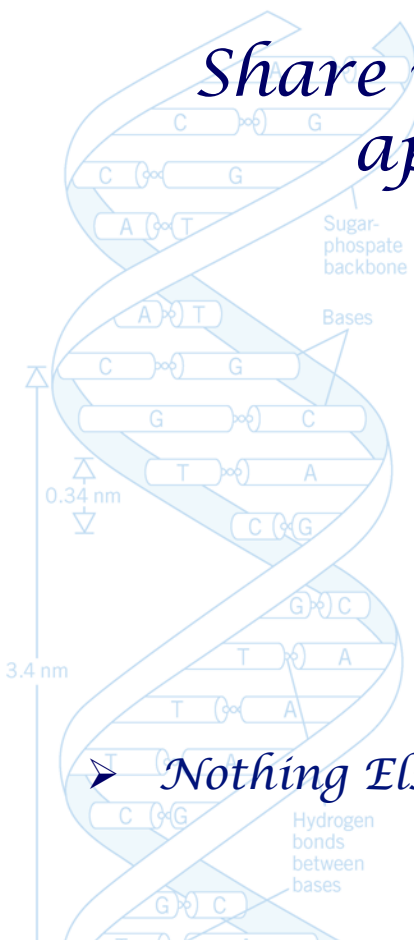
Content



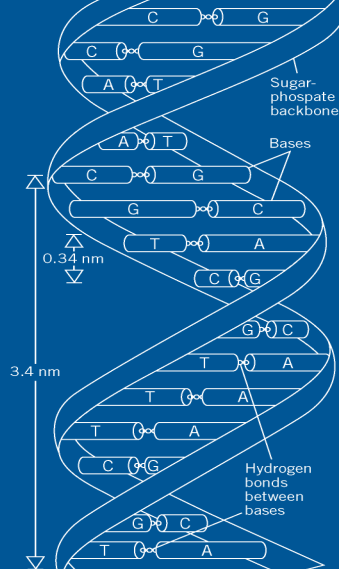
Process Owner – Neeraj Malhotra
Stakeholders – PhUSE UK SDE
Delegates

Purpose of the Presentation

Share with you a Statistical Programmer's approach to Simplifying Processes



➤ *Nothing Else.....lessons will be at the main conference!*



What is a Process?

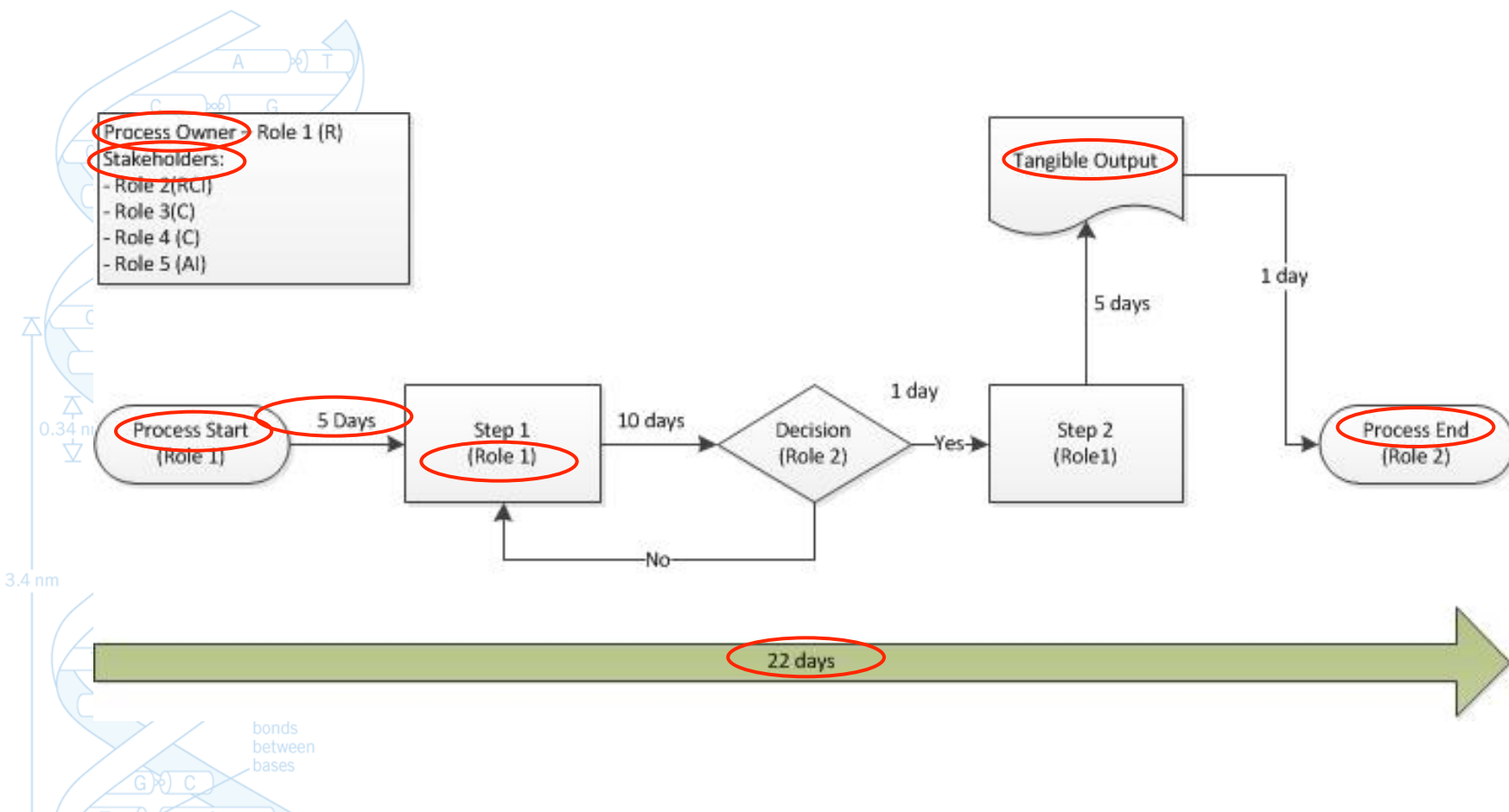
What is a Process?

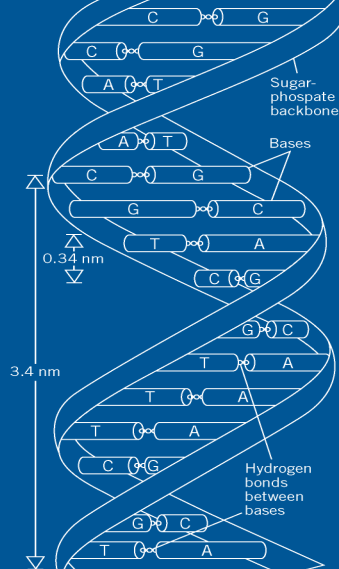
- Steps that take you from A to B
- Process $\neq$ Documentation
- Should be Simple (11 year old test!)

- Why we need processes?

- ✓ Help us find out **WHO, WHAT & WHEN** for any given PoW
- ✓ Drive efficiencies through standardisation

Simplest Process!





The Brief

Continuous

*No
External
Consultant*

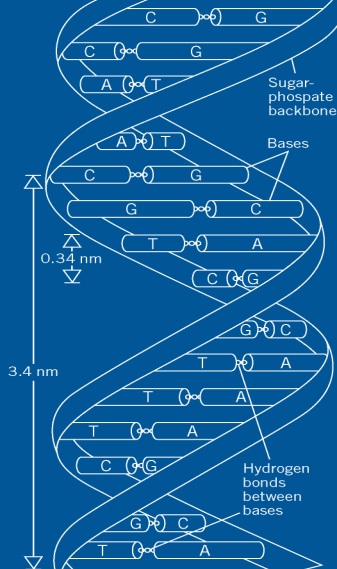


*Be
Innovative*

CHALLENGE ACCEPTED

*Highest
Priority
Goal*

*Dedicated
Group*



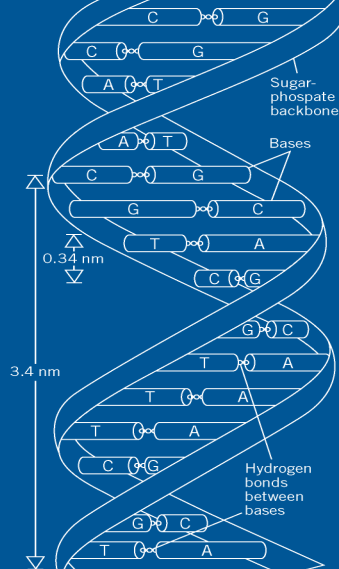
Hmmm
????

What is Process Simplification?

Justification - *Thought Process!*

Process Start	Process End	Process Start	Process End
Protocol	Analysis Plan	Protocol	Completion
Analysis Plan	Requirements (LoPO)		
LoPO	Delivery		
PoW Trigger			
**Document			
Outsource			Complete
Vendor Selection			Test
Decision to Offshore			Implement
Analysis Plan	PV	New Starter begins work	
		iDMC Trigger	iDMC Activities Complete

~20 processes
 Happening ~2 times in a year
 5 sites
 EVEN IF WE CAN SHAVE ~3 HOURS OFF EACH ONE.....
 $20 \times 2 \times 5 \times 3\text{hrs} = \underline{\underline{600 \text{ hours savings}}}$



Team Structure

Team Structure

Engaging the community

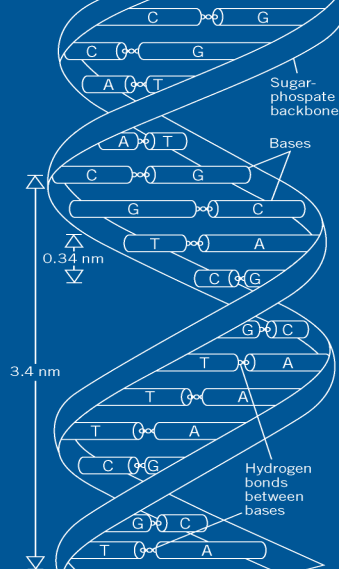
PST #4
(Focus on Improvements)

Core Team
(Focus on the problems)

PST #4
(Focus on Improvements)

PST #4
(Focus on Improvements)

PST #4
(Focus on Improvements)



Finding The Problem(s)

Prioritising Processes

➤ Based on:



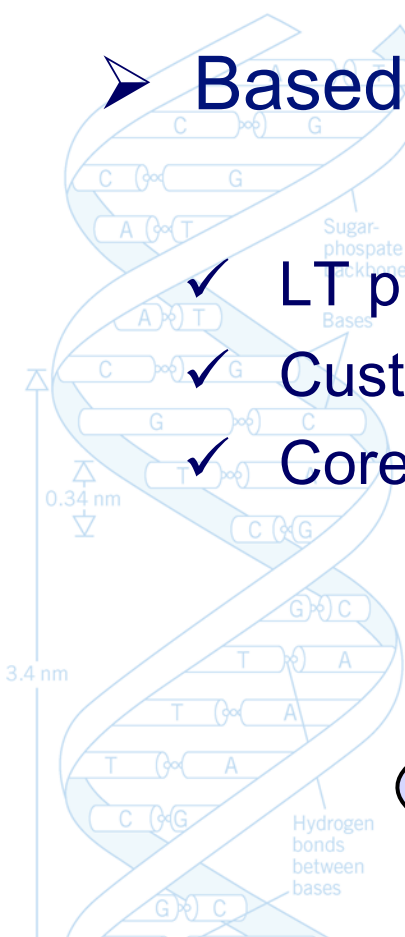
LT preference



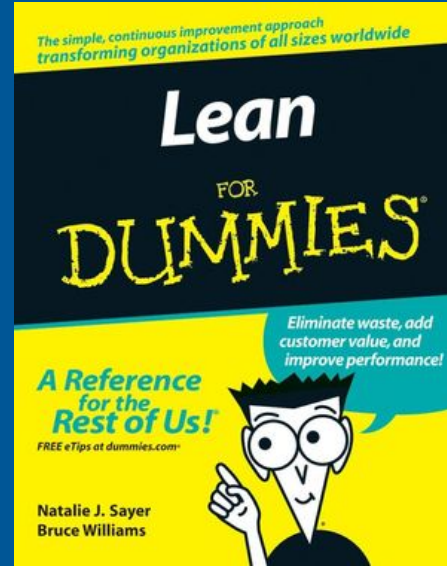
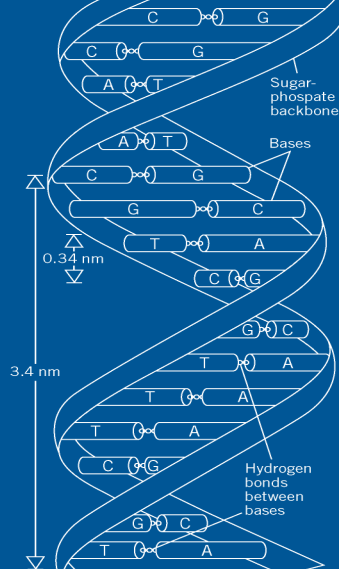
Customer Feedback - Crowdsourcing



Core Team's Perceptions & Gut feeling!



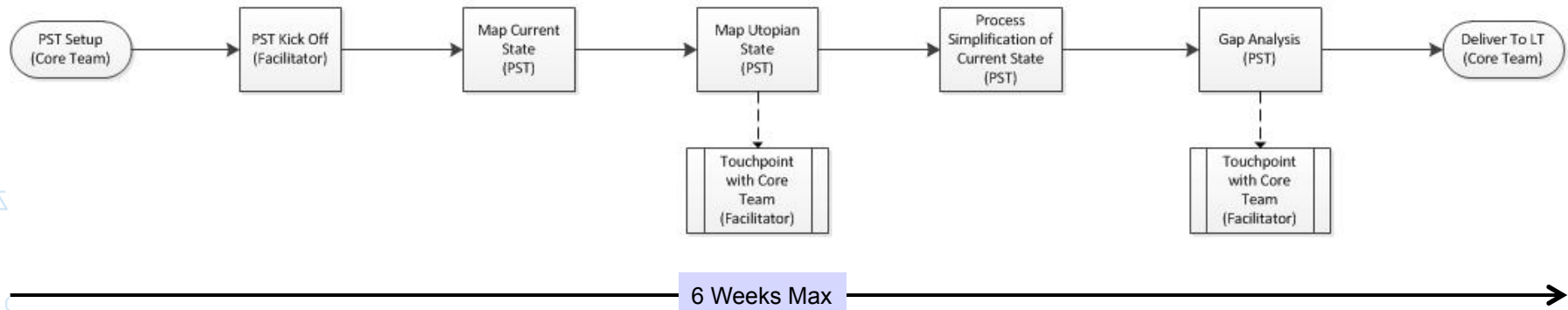
Innovative Solutions
begin with finding the
right problem to fix



Simplifying the Processes

The Process

SPA Process for Process Simplification



Simple
Enough?



The Lean Way

Create/Use the current state process

Assess the current state process

Create the future state process

- Ensure **time values** are assigned to each task
- Identify **Value and Non-Value** Adding Tasks

- Listen to **customer complaints**
- Assess process for any of the **7 types of waste**
- Assess Process Steps for **Quality/Risk**

- Start with **Utopian State** (Value added tasks only)
- **Add tasks** based on what they add to the end deliverable

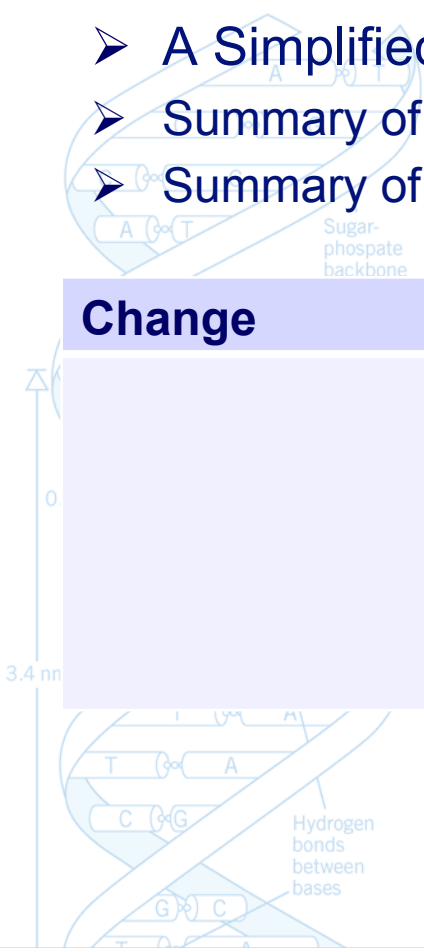
What part(s) of a process can be simplified/improved?

- 
- Documentation (including access)
 - R&R's
 - Process Steps
 - Milestones
 - Review/Approval Cycles
 - Timings
 - Communication Flow
 - Quality Steps
 - *Perceptions!!*

7
*Types
of
Waste!*

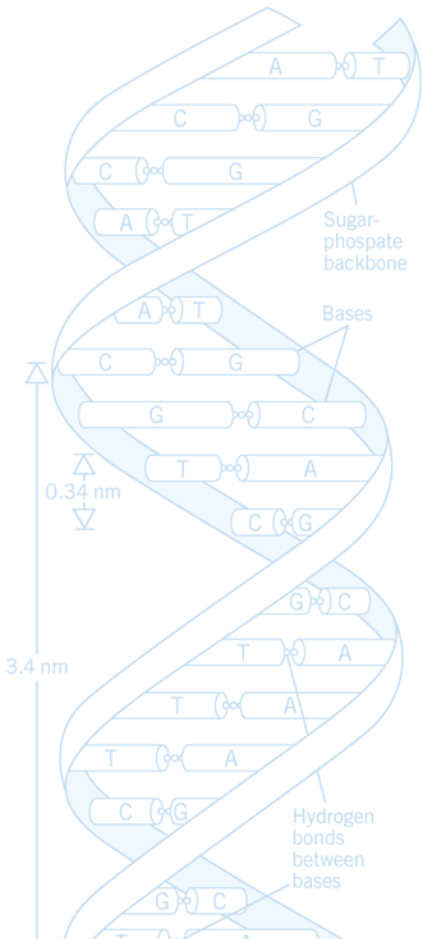
Goal Deliverables

- A Simplified Process Map
- Summary of Documentation and Governance
- Summary of changes with benefits and risk (see table below)

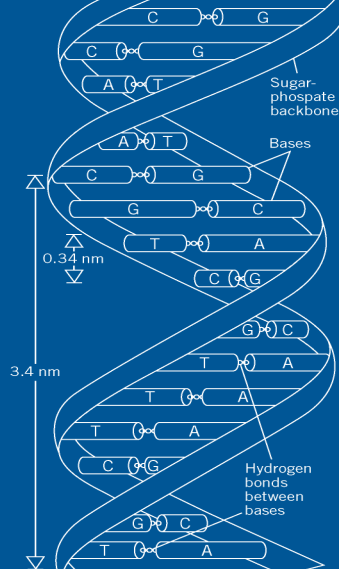


Change	Benefit	Risk
	Time -	Time -
	Resource -	Resource -
	Quality -	Quality -

The Magical Checklist



Microsoft Excel
97-2003 Worksheet



Summary

Summary

➤ This is the plan

✓ Does it work? – Don't Know!

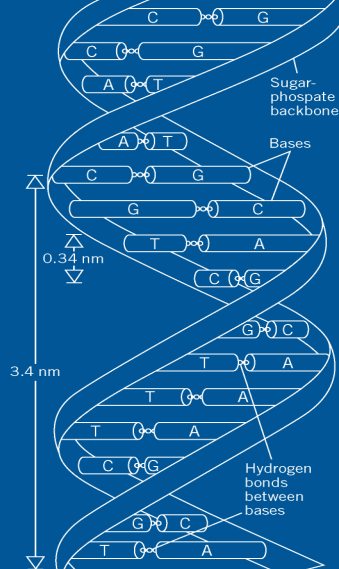
➤ Other Functions have Expressed an Interest

✓ Admin

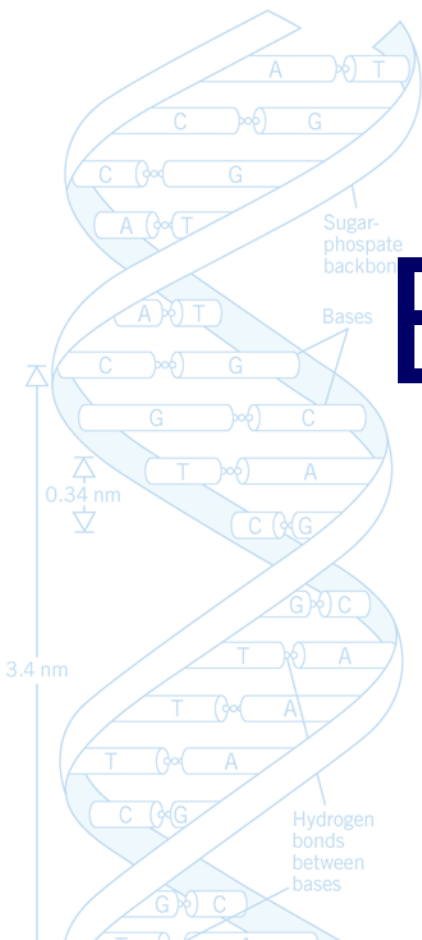
✓ Drug Safety

✓ At Home????

Feedback Welcome 😊



Questions?

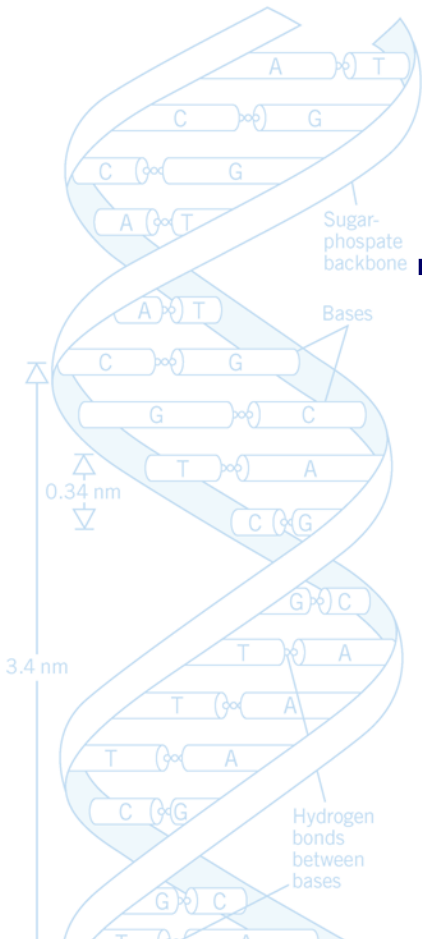


Backup Slides

Learning's So Far....

- 
- Prioritisation was tough!
 - Gap between legacy organisations
 - ✓ Legacy SOP's not decommissioned.
 - Gap between different sites
 - ✓ Cultural Differences
 - RESOURCE!!!
 - Correct Type of Resource!
 - Metrics – *You need them!*
 - Stick to the plan – *team profile, process, timelines.*

Process Simplification Process



The 'Lean' Way

Define Value

Value Added Activities

The business must be willing to pay for the activity

The activity must transform the product or service in some way

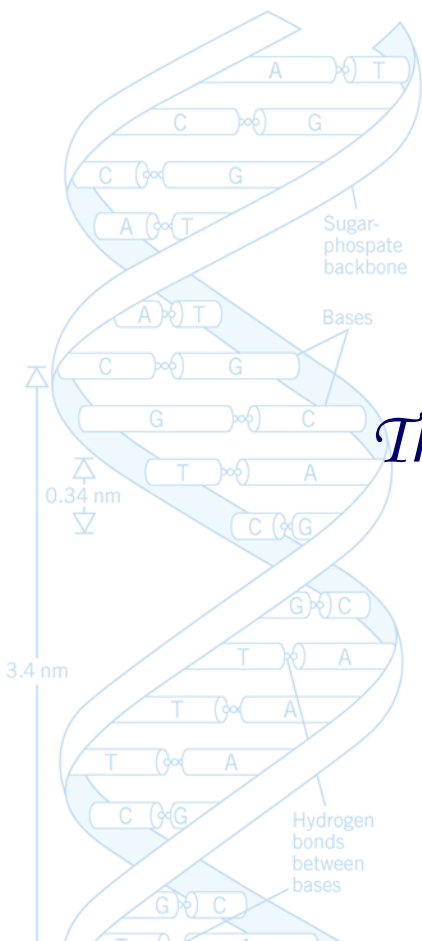
The activity must be done correctly the first time

Non Value Adding Activities

(*Muda*)

Muda (waste) –consumes resources without creating value (7 types of waste) –

- 1.Transport
- 2.Waiting**
- 3.Overproduction**
- 4.Defect**
- 5.Inventory
- 6.Motion
- 7.Extra Processing**



*I KEEP six honest serving-men
(They taught me all I knew);
Their names are What and Why and When
And How and Where and Who.*

Rudyard Kipling

2) Value Stream Mapping (VMS)

Analyse the Current State – 3 hours

a) Listen to the customer

- Dissect each complaint – 5 why's!

b) Search for Muda (waste)

- Seven Types of Waste

c) Examine Value Added Tasks for Quality

d) Examine the information flow in the VSM

2) Value Stream Mapping (VMS)

Future State– 2 hours

Low
Tech

a) Apply changes to the Current State VMS?

- a) Utopian State – Only Value Added Tasks
- b) Grounded future state – reduced waste and non-value adding steps

b) Key questions to ask during this stage:

- a) What is the bottleneck operation?
- b) Where can continuous flow happen?

This is where I get
confused about
applying the lean
principles!

➤ A mind-set

✓ From top to bottom...everyone adopts!

➤ Requires you to have standards

✓ Standard Systems

✓ Standard Processes

✓ Standard Work Instructions/Documentation

➤ Focus you on eliminating waste from VSM

Muda Muda Muda

➤ Muda (waste) – consumes resources without creating value

- ✓ Type 1 Muda – doesn't add value, but deemed necessary
- ✓ Type 2 Muda – doesn't add value and unnecessary

➤ Two Cousins of Muda:

- ✓ **Mura (unevenness)** – waste caused when activities don't go smoothly (e.g. rework, returns)
- ✓ **Muri (overdoing)** – unnecessary or unreasonable burdening of people, equipment or systems by demand exceeding capacity

