From paper to digital records in Life Sciences Manufacturing – a journey

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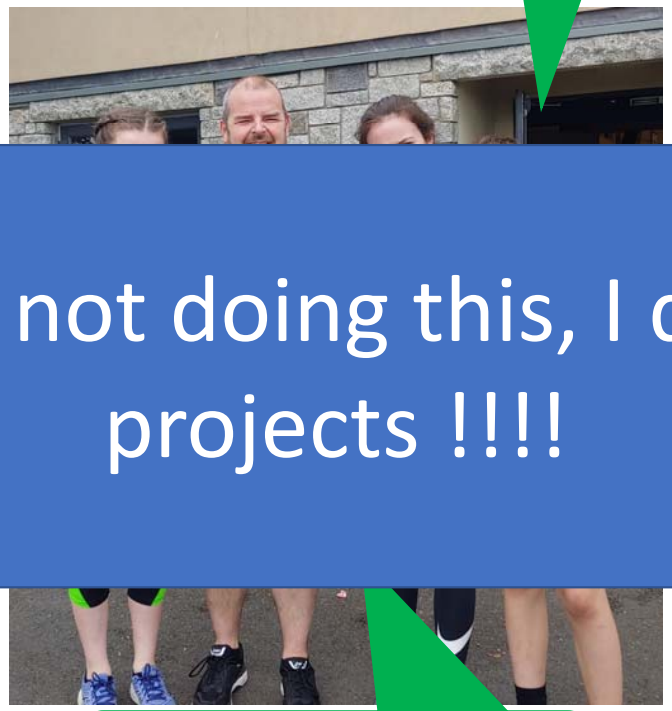
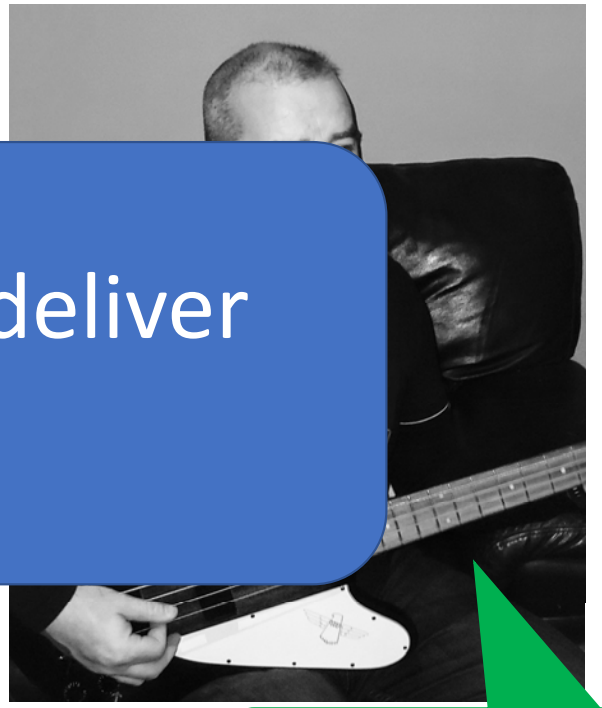
About Me

From Dublin, Ireland

Live in Carlow – 100 km South of Dublin

Run 5k and 10k





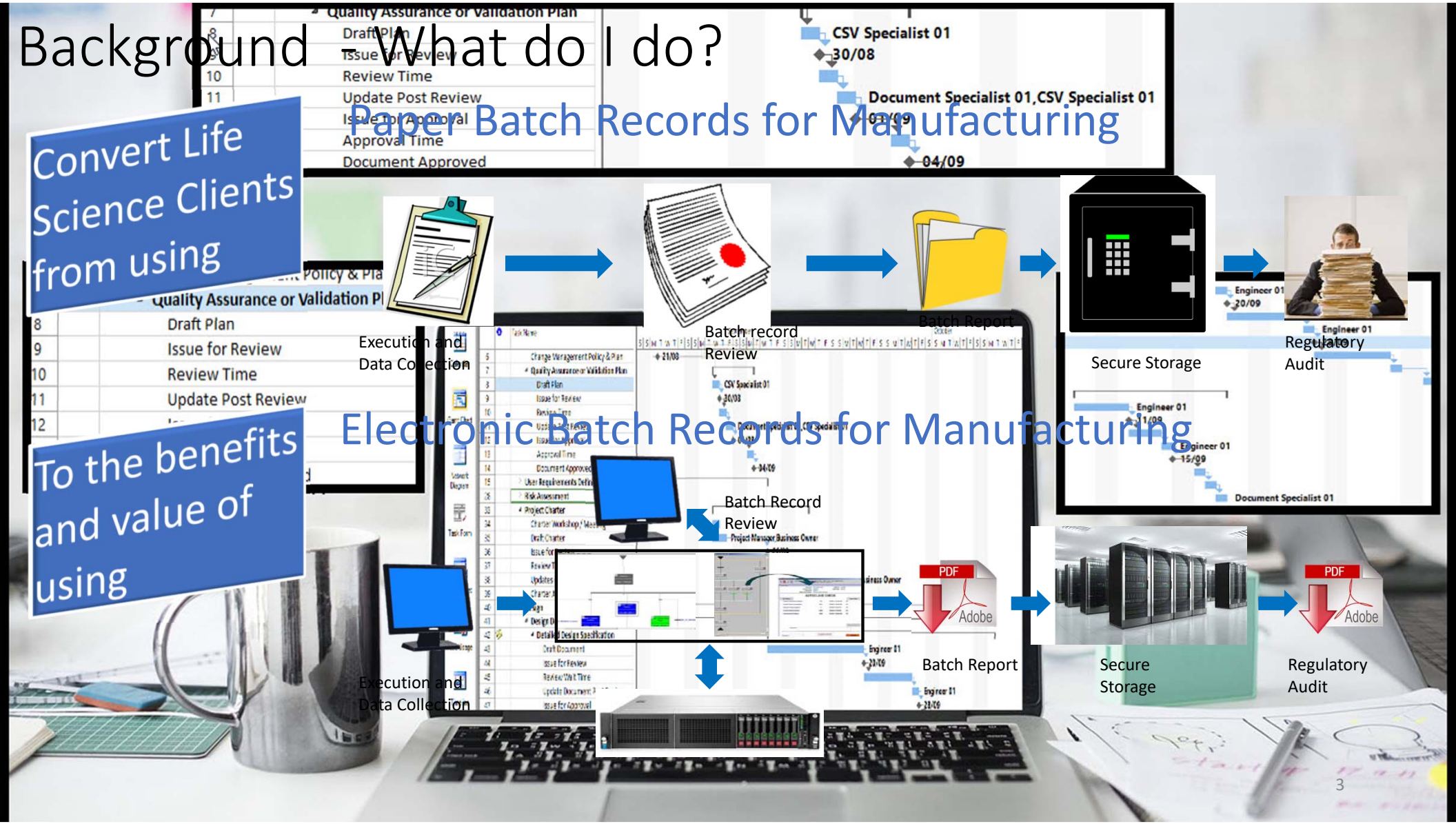
When not doing this, I deliver projects !!!!

I walk the Blackstairs Mountains

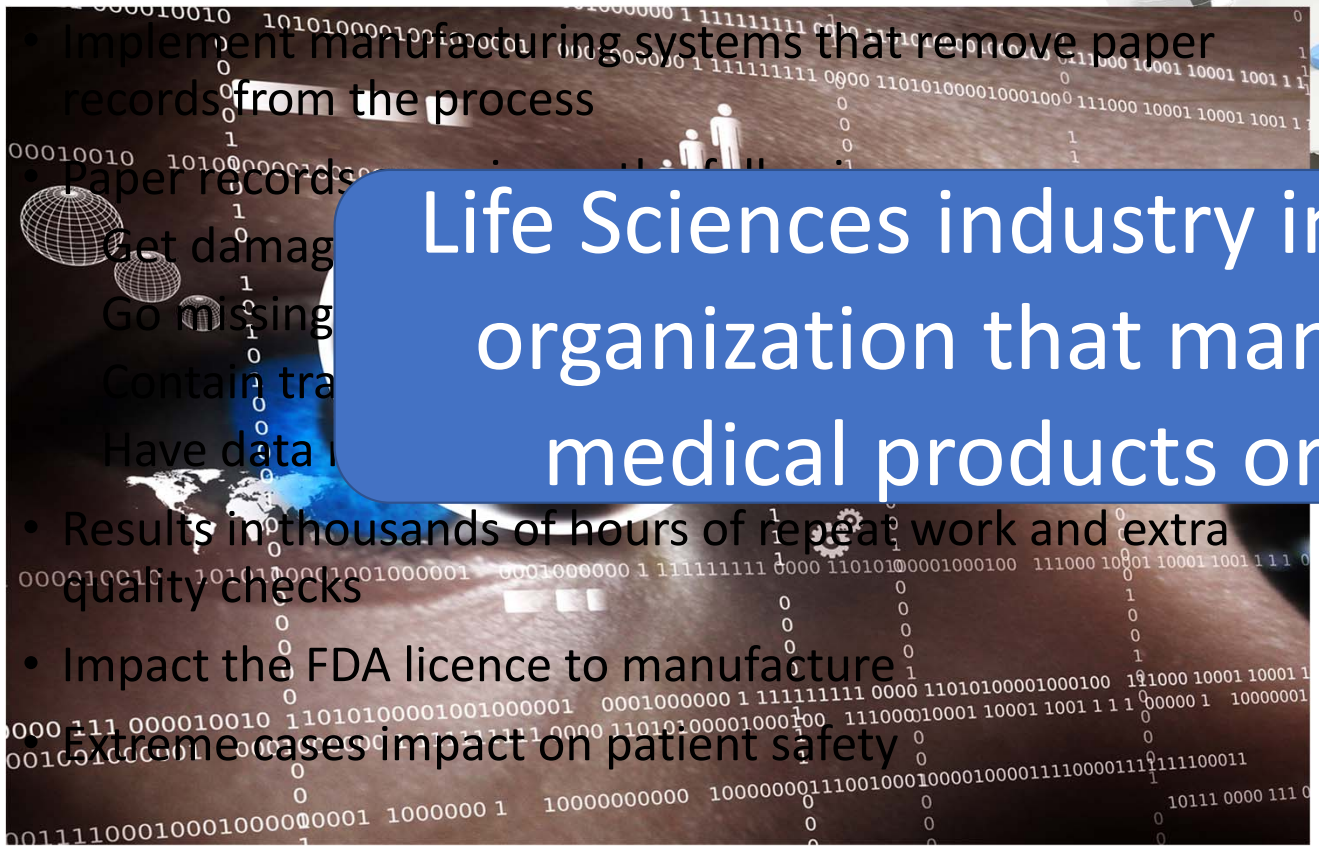
Father of 3 children

Play the bass guitar

Background - What do I do?



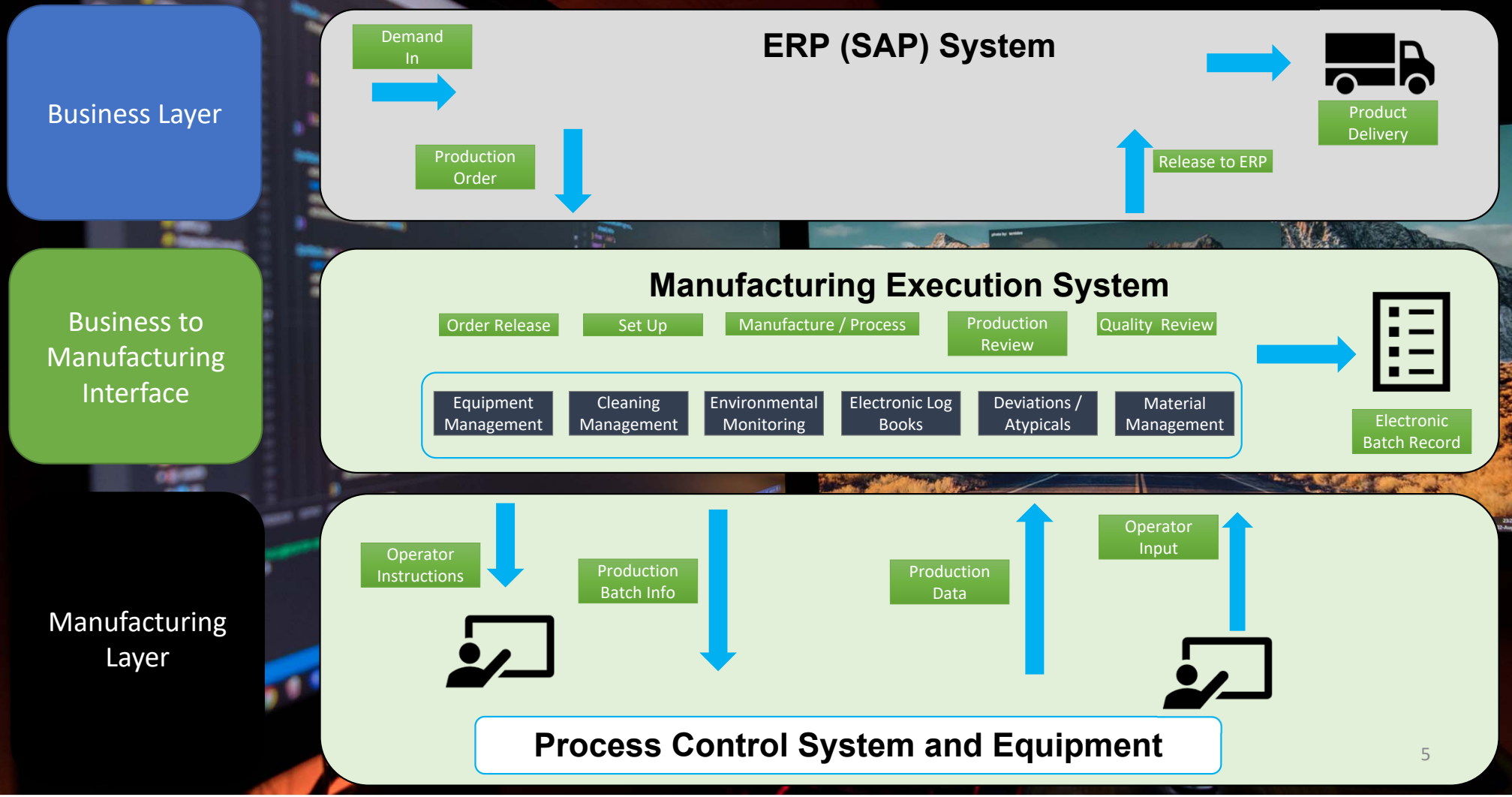
Background – paper records in manufacturing



- Implement manufacturing systems that remove paper records from the process
- Paper records
  - Get damag
  - Go missing
  - Contain tra
  - Have data
- Results in thousands of hours of repeat work and extra quality checks
- Impact the FDA licence to manufacture
- Extreme cases impact on patient safety

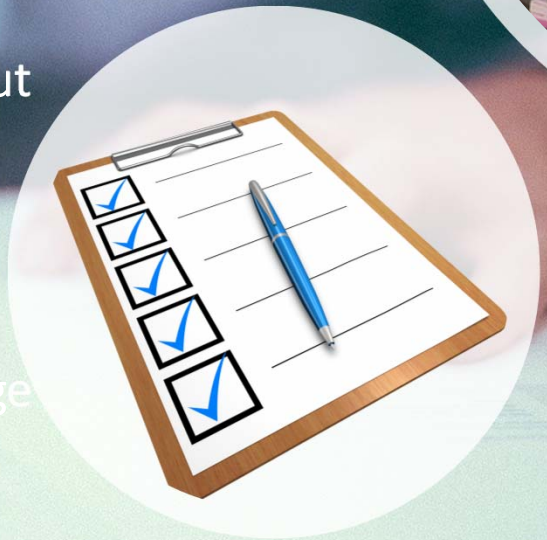
Life Sciences industry includes any organization that manufactures medical products or devices

Background – [illegible] – Scop



The Challenge of Change

- System implementation involves the removal of paper records
- When removing paper from a largely manual process, the impact is massive
- This is not a difficult challenge – it is all about the detail
- There are no short cuts
- We need to understand the impact of change
- The implementation needs to happen and maintain compliance with the Life Sciences regulations



Life Sciences Software Waterfall Approach

Very difficult to estimate scope, effort and cost accurately at the beginning of 12 month complex software project

Background – Life Sciences Manufacturing

- Must maintain compliance with FDA regulations
- Regulations in place for electronic records since 1997
- Must guarantee the integrity of all data associated with manufacturing
- Use paper widely, paper is very flexible but that comes with great risk
- Life Science companies are increasingly being issued with citations from the FDA as a result of issues related to paper records
- The reason for regulations is to ensure patient safety

ckground – Benefits of digital (e

1. Enforced Workflows – Operators
2. Quality Review made easy
3. Reduction of paper usage – resulting in elimination of documentation errors – reduced “non right first time”
4. Improved Batch reporting – retrieval of Data
5. Makes investigations and product recalls (😨)easier
6. Increased Data Integrity
7. Improved quality of product into the supply chain

The challenge

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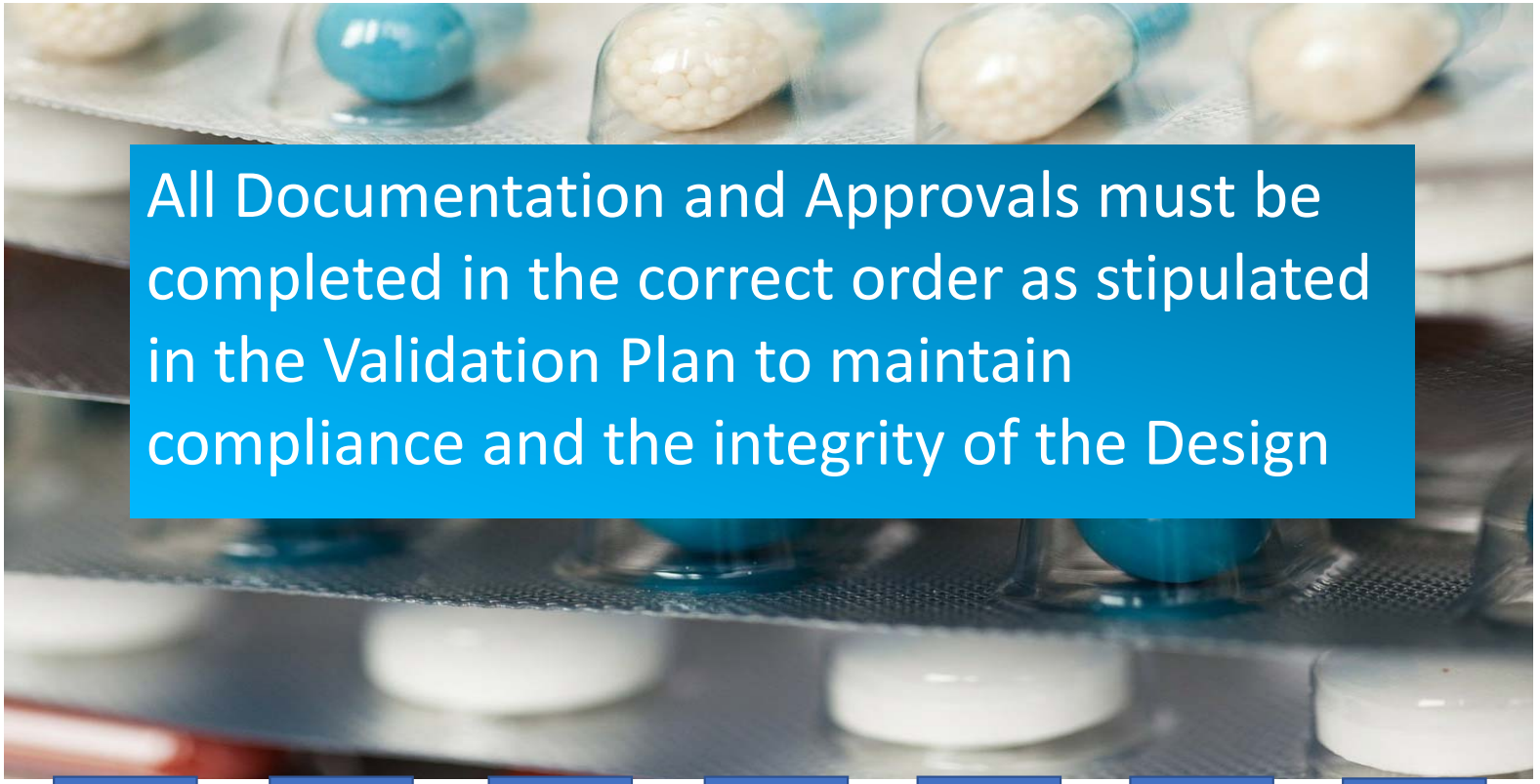
hange associated with system

Compliance and Regulations

- Life Sciences - All design documents must be created from an approved set of user requirements
- All Test Case Documents must be based on an approved Design
- Life Sciences n an approved design
- All requirem for use
- Typically hav
  - Developme
  - Test – Valid
  - Production – Validated and Controlled

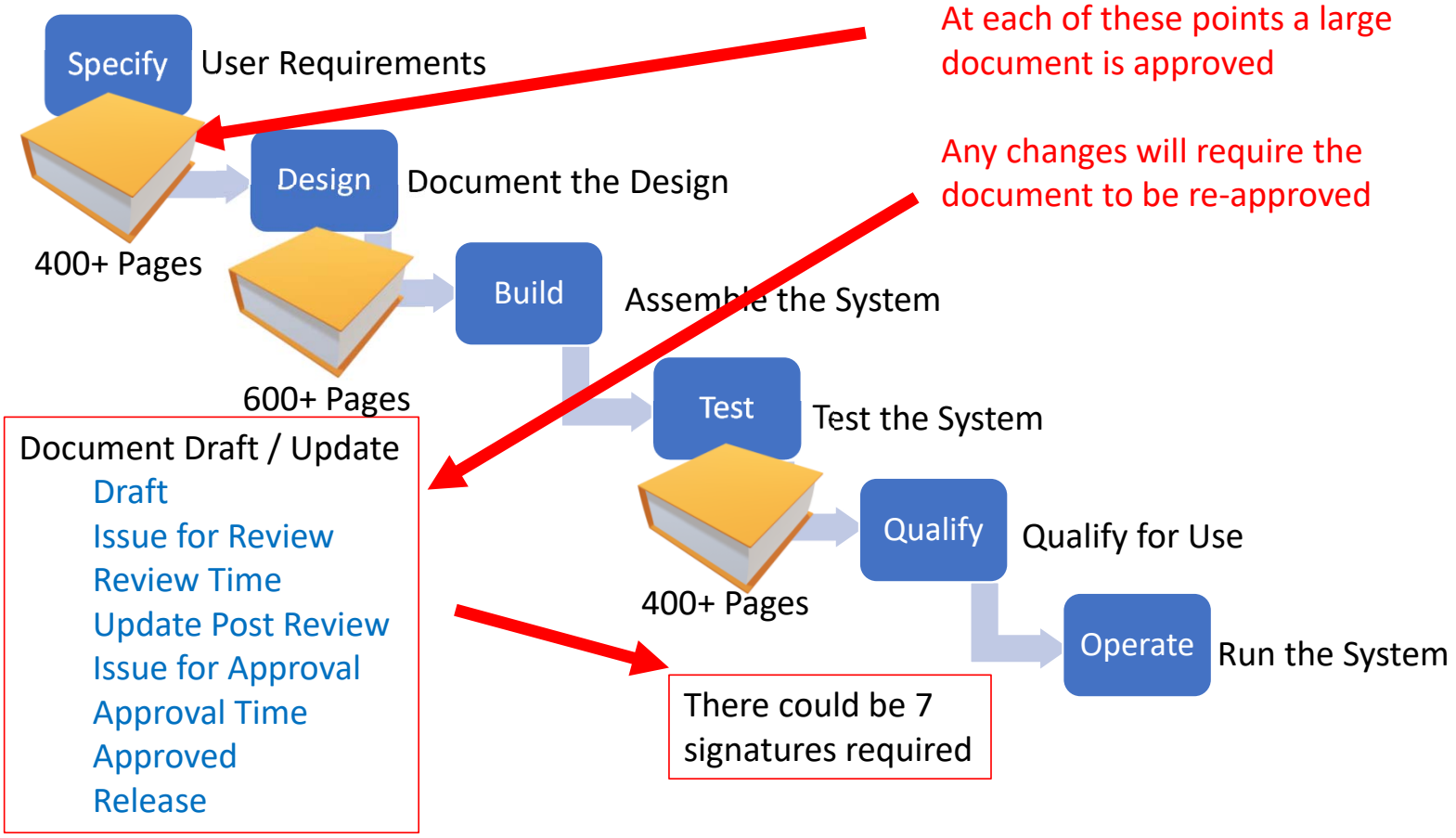
The problem with this approach is that it is not always possible to understand your requirements fully until the users have used the system

Life Science Regulations



Life Sciences Software Project Life Cycle

This is the general approach in Life Sciences as outlined in the project validation plan.



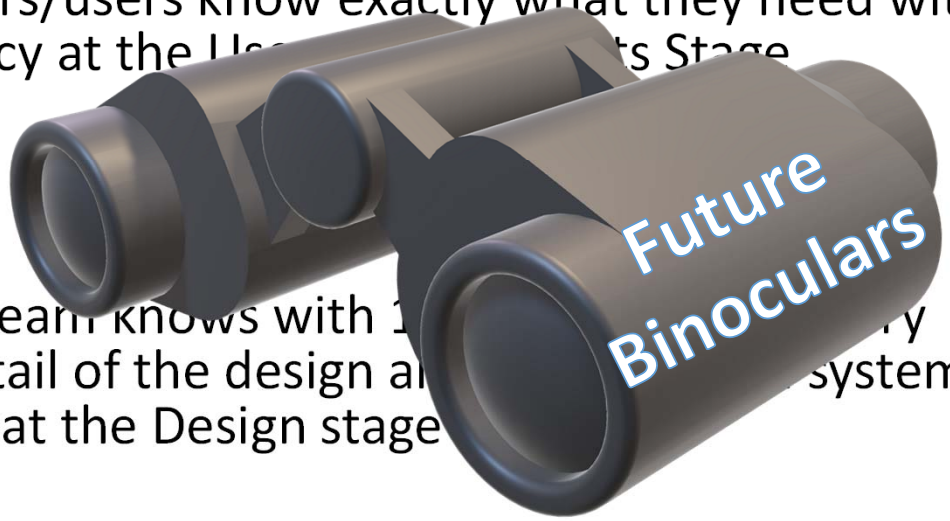
Life Science Software Projects – Waterfall

- Well known and well followed process
- Dependable
- Supports Compliance with regulatory requirements
- Predictable
- Comfortable
- Expensive
- Inflexible
- Changes are cumbersome
- Rarely delivered on time or on budget

Life Science Software Projects - Waterfall

Based on the assumptions that

The customers/users know exactly what they need with 100% accuracy at the Us ts Stage

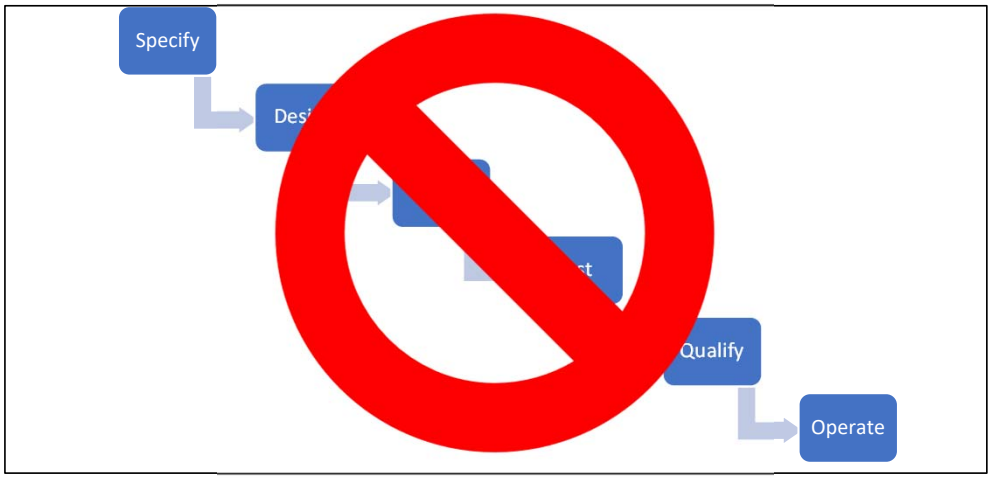


The project team knows with 1 y facet and detail of the design al system will function at the Design stage

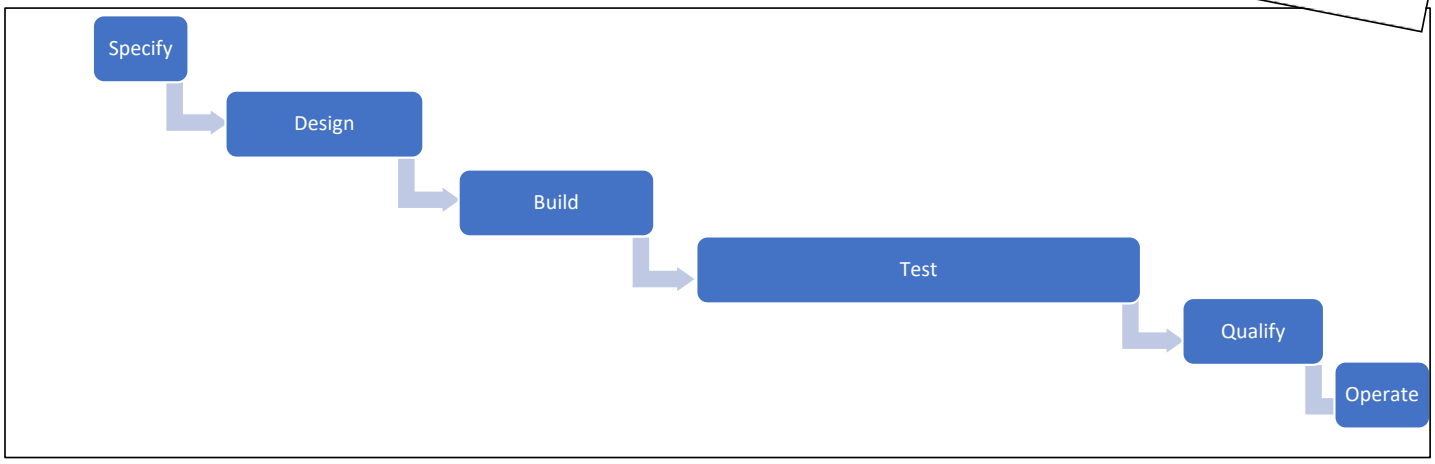
Nothing will change along the way from Specification to Operation

Life Science Waterfall Approach

The Intention

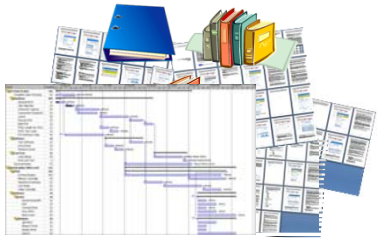


The Reality

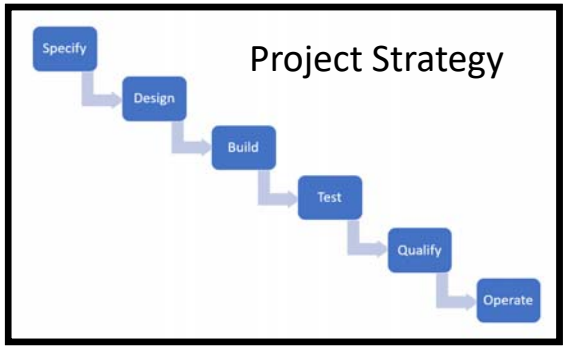


Waterfall Approach to Projects

Project Team



Project Plan and Scope



Project Completion

Life Sciences Software Waterfall Approach

Fixed time,

1. The s
2. The s
3. The b
4. Peopl … cking and screa

Requirements definition

Solution Requirements

Regulatory Requirements

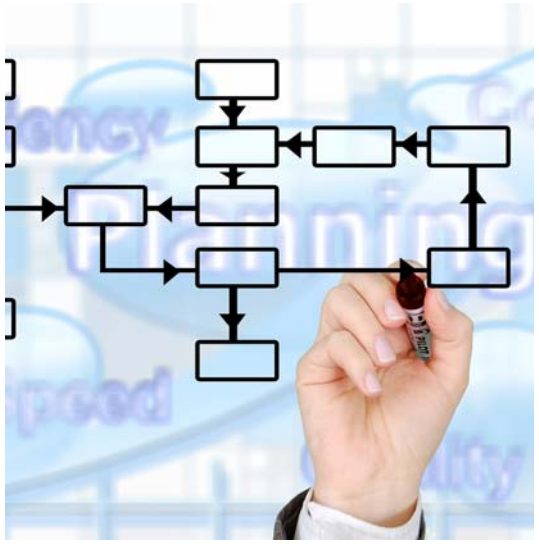
Quality & Business Requirements

Removal of paper

Enforce Workflow Digitally

Satisfy user needs

Improved Data Access and Reports



Requirements definition

- A Subject matter Expert from each department is needed – Quality, manufacturing, technical, Logistics
  - Gather raw user input on every step of the process
  - Many, many Workshops
  - Lots of Process Mapping
  - Lots of post it labels
  - Plenty of arguments (constructive)
  - This is not for the faint hearted

Process Mapping

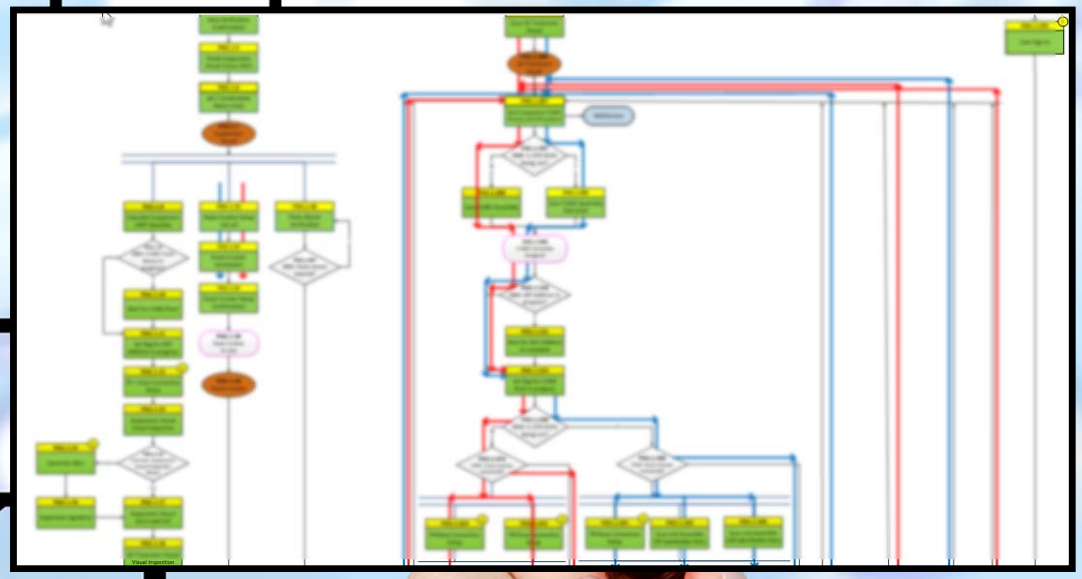



- The existing business process as known must be mapped in every detail
- Every step, data record, decision, transaction, resource, equipment, outcome needs to be documented in the process flow
- This is a time consuming process – detail, detail, detail
- The time invested here will pay dividends. If this stage is rushed or poorly attended, the system implementation will suffer
- Format is irrelevant, content and detail are key – generally post its, brown paper charts – but whatever works for the project

Process Mapping

Once the existing process has been mapped, the future state process needs to be mapped with the following in mind:

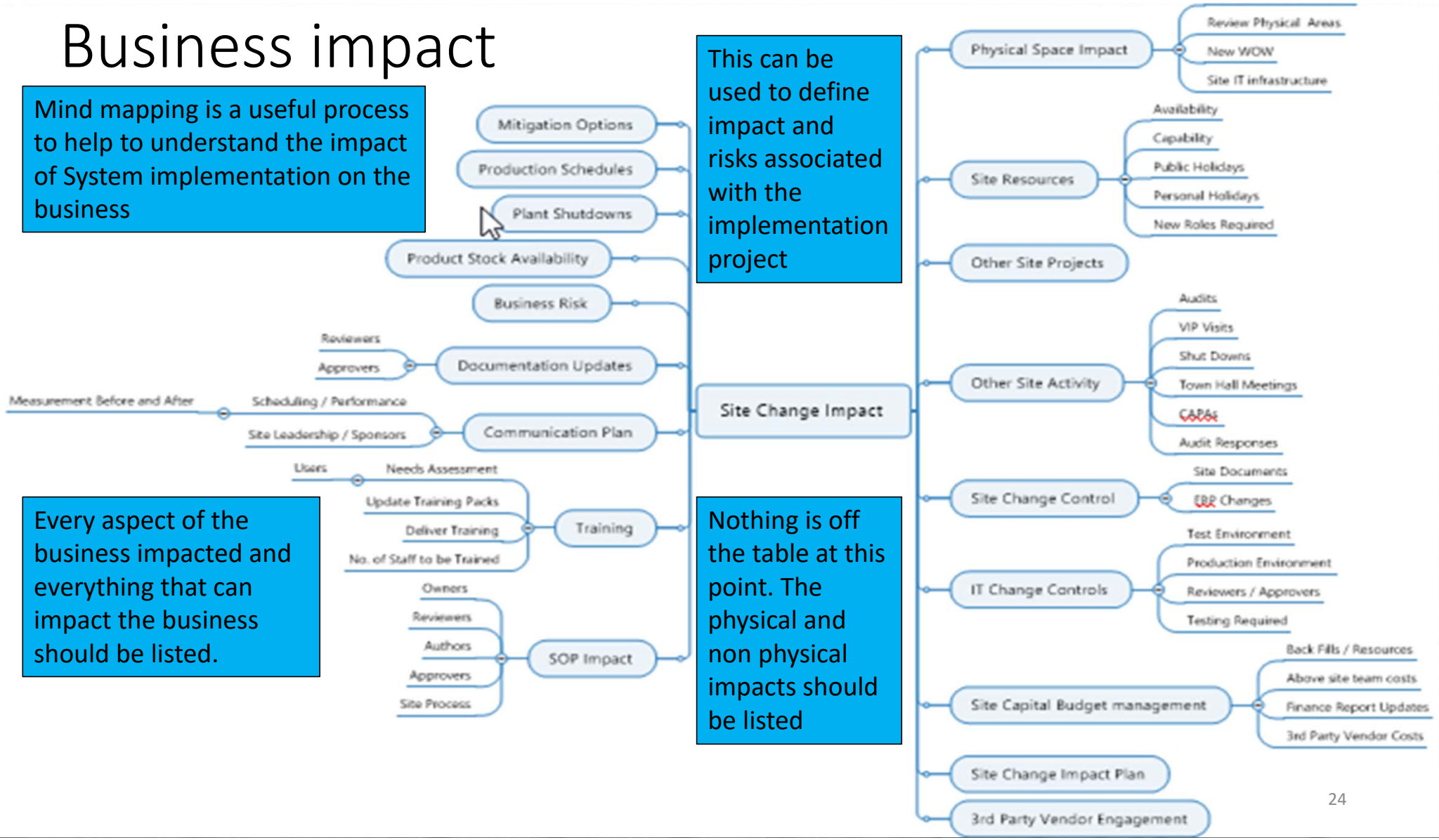
- What are the opportunities to remove / reduce paper?
- What are the opportunities for efficiencies / improvements?
- What steps/stages are non value add?
- Map the same level of detail in the new process – indicating what is now digital/electronic



- Depending on complexity, there may be numerous flow charts required.
- Rather than creating documents initially, use these charts to document the scope and requirements
- Note: you will not get this 100% at the first attempt

Business impact

Mind mapping is a useful process to help to understand the impact of System implementation on the business



This can be used to define impact and risks associated with the implementation project

Every aspect of the business impacted and everything that can impact the business should be listed.

Nothing is off the table at this point. The physical and non physical impacts should be listed

How can we estimate benefits in numbers?

Typical Manufacturing Batch Record for a production line contains 110 pages.

Average manual transcription data entry points per page is 20, i.e. 2200 manual entries on paper per batch (110 x 220 = 2200)

1 production line – 200 product batches per year (200 x 2200 = 440,000)

440,000 data entries per production line per year

The companies measures a 28% rate of non right first time errors - (28% of 440,000 = 123,200)

123,200 data entry errors that need to be reviewed/clarified / corrected – if each of these takes 5 minutes to resolve on average

616,000 minutes or 10,266 working hours per year spent reviewing data errors

How can we estimate benefits in numbers?

10,266 working hours per year spent on non value add activity

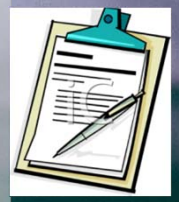
Based on the technical solution to be applied – it is possible to reduce the paper batch record from 110 pages to 7 pages (old equipment, major site wide impact to upgrade)

7 pages – 20 entries per page - 200 batches per year = 28,000 data entries – even with a non right first time rate of 28% this gives 7840 data entry errors – 653 hours per year spent correcting documentation errors.

How can we estimate benefits in numbers?

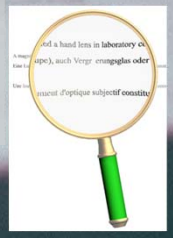
Pre System Implementation 10,266 hours spent on document errors

Post System Implementation 653 hours spent on document errors



Net hours saved 9,613 that can be invested in more value add activity

As an added benefit, the thorough review of the process often leads to improvements in data entry quality and general efficiencies.



SOPs Standard Operating Procedures

The Life Science Industry thrives on SOPs,

SOPs can be ignored during large projects

SOPs must be included in the impact assessment, planning, testing and qualification as a key element of project success.

The drafting, updating, testing and verification (and retiring)of SOPs is needs substantial resources

Good SOPs are key to the new system being deemed a success

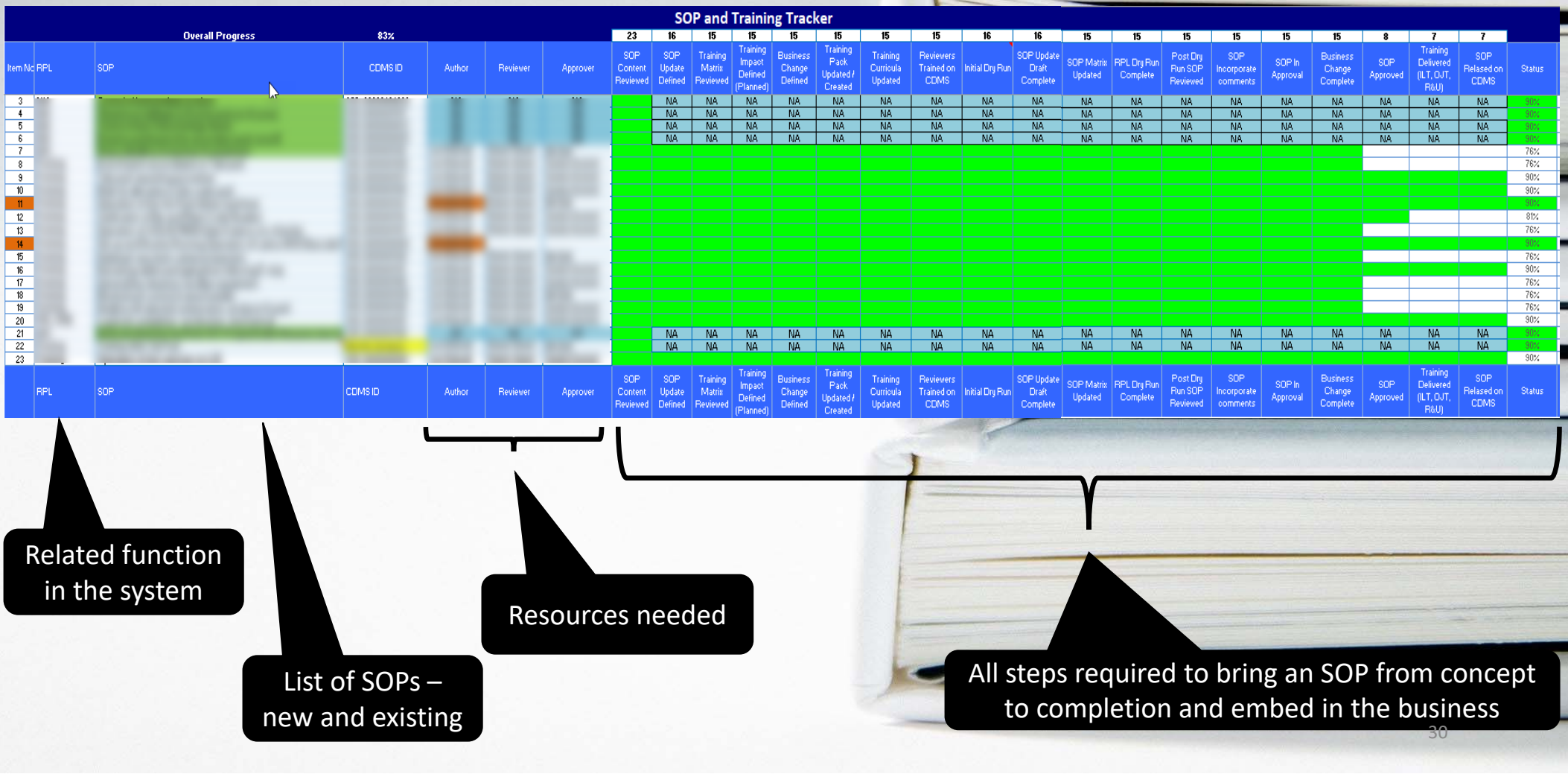
SOPs Standard Operating Procedures

What is also often over looked is the amount of effort and number of stages required to update existing SOPs , create new SOPs and retire old SOPs.

Such stages include:

- Assess If Impacted
- Draft Update (or Retire)
- Review
- Test and Verify
- Approve
- Release
- Train Users

SOPs - sample progress tracker



SOP and Training Tracker

Overall Progress 83%

Item No	RPL	SOP	CDMS ID	Author	Reviewer	Approver	SOP Content Reviewed (23)	SOP Update Defined (16)	Training Matrix Reviewed (15)	Training Impact Defined (Planned) (15)	Business Change Defined (15)	Training Pack Updated / Created (15)	Training Curricula Updated (15)	Reviewers Trained on CDMS (15)	Initial Dry Run (16)	SOP Update Draft Complete (16)	SOP Matrix Updated (15)	RPL Dry Run Complete (15)	Post Dry Run SOP Reviewed (15)	SOP Incorporate comments (15)	SOP In Approval (15)	Business Change Complete (15)	SOP Approved (8)	Training Delivered (ILT, OJT, Rl&U) (7)	SOP Relased on CDMS (7)	Status
3								NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%
4								NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%
5								NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%
6								NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%
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22								NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	90%
23																										90%

Related function in the system

List of SOPs – new and existing

Resources needed

All steps required to bring an SOP from concept to completion and embed in the business

Case Study

Life Sciences - Manufacturing System implementation

Budget was spiralling out of control

Schedule was a year late – eternal test time

They needed help – (understatement)

They had to do something different

The project strategy was not working

A new approach

Initial review to understand the full scope or work

Stopped the current tests as they were failing chronically

Back to review the requirements gathering stage

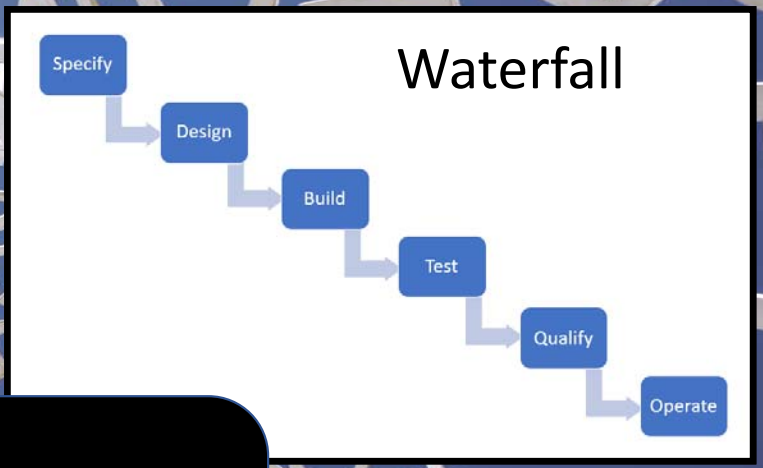
For the project – we broke the scope of work down into functions – usable software modules based on their functionality

These functions would then be pieced together to create the system

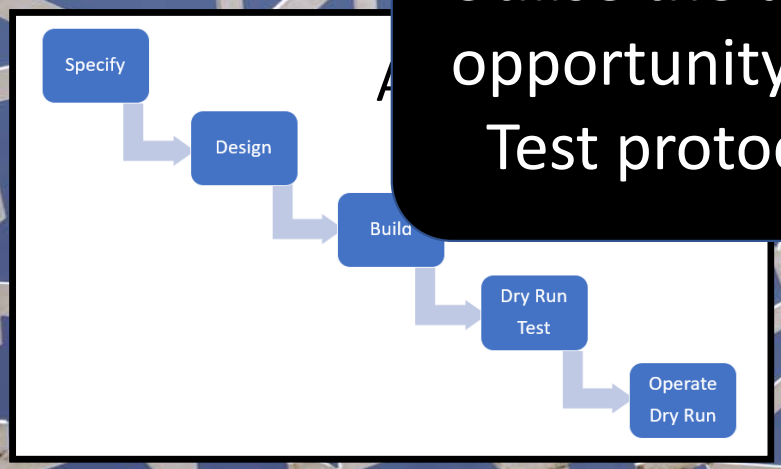
Treated each of these functions/modules like a mini deliverable

Project Approach

Instead of the entire project being governed by this strategy



Utilise the dry run testing as an opportunity to verify the SOPs, Test protocols and train user

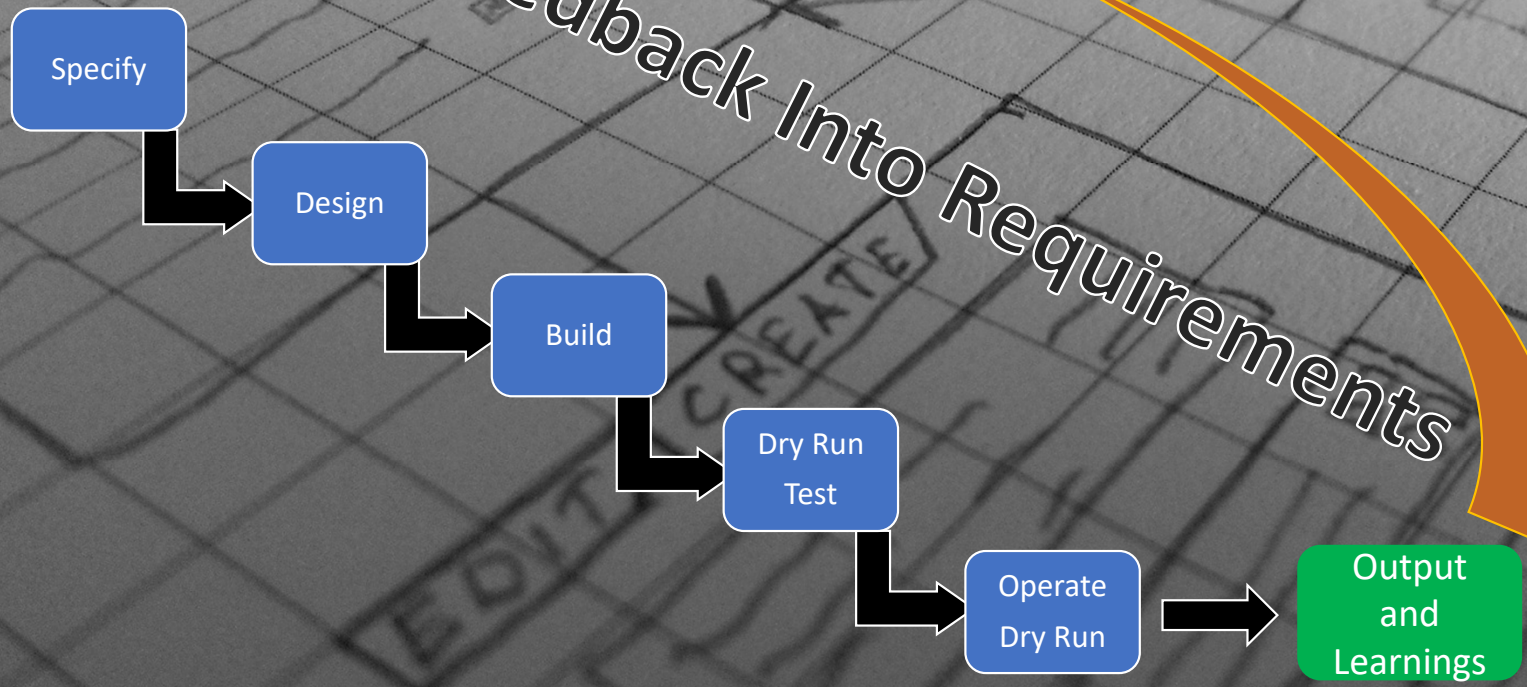


he project
ons into smaller
bodies of work
and run each of them like this

Breakdown the Solution

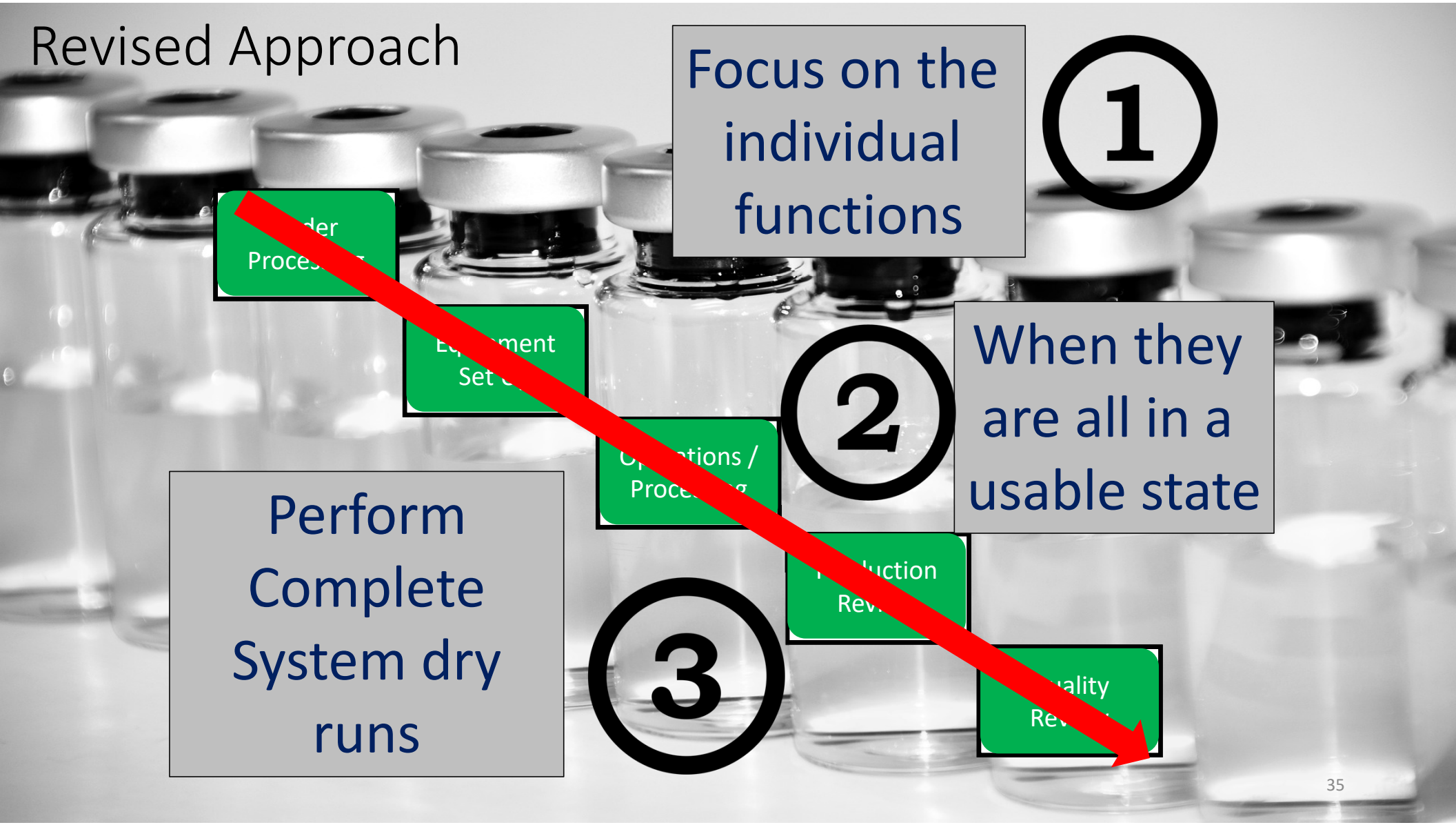
For Each Software Function
or Module or Grouping

Repeat the Process
Until the Solution
is complete



Update SOPs
Update Requirements
Update Test Protocols

Revised Approach



Key Points to Note

Only when the team has complete confidence in the solution outputs, should the design be closed. The SMEs and users on the team decide by consensus that the design is complete.

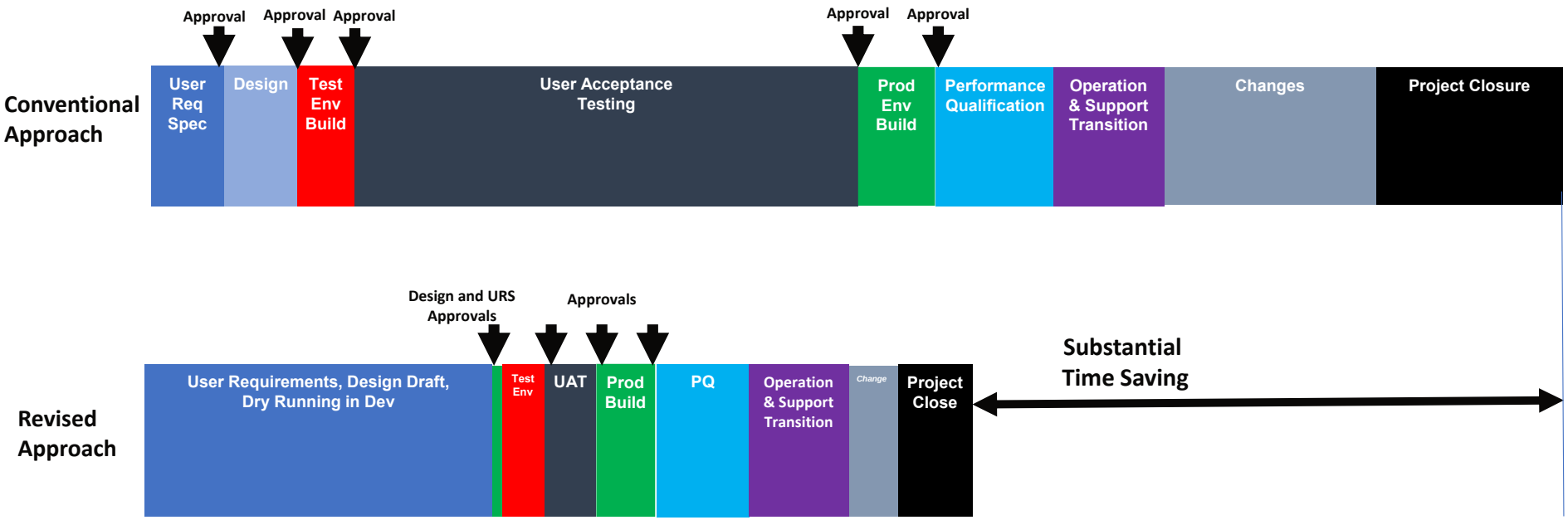
This is a team effort, continued input from all departments in the business is needed to make this type of project a success. This is key to ensuring that the users from all departments will adopt the new system seamlessly.

As the testing has been performed multiple times in the development environment, the official testing is successful first time. This also serves to train users

Only when the team are confident that the user requirements are complete, have been road tested and are fit for purpose should the first documents be sent for approval.

Conventional Approach v Revised Approach

Timelines



This approach saves time and reduces test failures!!!!

It can be difficult to resist the corporate pressure to complete the design and start testing ASAP – this will end in tears

Review – Are we Compliant with regulations?

- Life Sciences - All software builds must be refer to an approved design
- Life Sciences - All design documents must be created from an approved set of user requirements
- All Test Case Documents must be based on an approved Design
- All requirements must be traceable to qualification for use
- 3 Computer System Environments
  - Development or Sandbox
  - Test – Validated and Controlled
  - Production – Validated and Controlled
- Compliant with the Validation Plan – follows Life Science Regulations

Results

- The paper patch record was reduced from 110 pages to 7
- Data entry errors dropped from 28% non right first time to les than 10% in the first 6 months
- Other improvements measured included batch throughput and line turnaround times
- Batch release times from quality also decreased
- Users were engaged and supported as each team had a “ready made” Subject Matter Expert
- SOPs were proven to be accurate
- The system was expanded for use across the manufacturing site due to the success of the implementation

Lessons Learned

- Breaking the software system functions down into usable modules is key to the approach
- Multiple instances of Development Sandbox can facilitate concurrent effort and shorten the time to completion
- Develop a prototype early
- Each Dry Run is an opportunity to learn and hone the User Requirements
- The more time spent dry running – less errors during acceptance testing
- Daily meetings are the lifeblood of success
- Involving users in every stage of the design is key to success
- Assemble the large documents piece by piece, not as one big volume

Time to Hit the Road

- Thank you for your attention

Mail: barry@systeme.ie

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- Go raibh mile maith agaibh !!!!!

(Irish for Thank you all so much)

- Any Questions?

Agile Model Explained