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Single use digitization and information management: enabling agile and sustainable systems

Shane Kelly

Cian Gibbons

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SU Digitization and Information Management

Enabling Agile Systems

Sep 2023

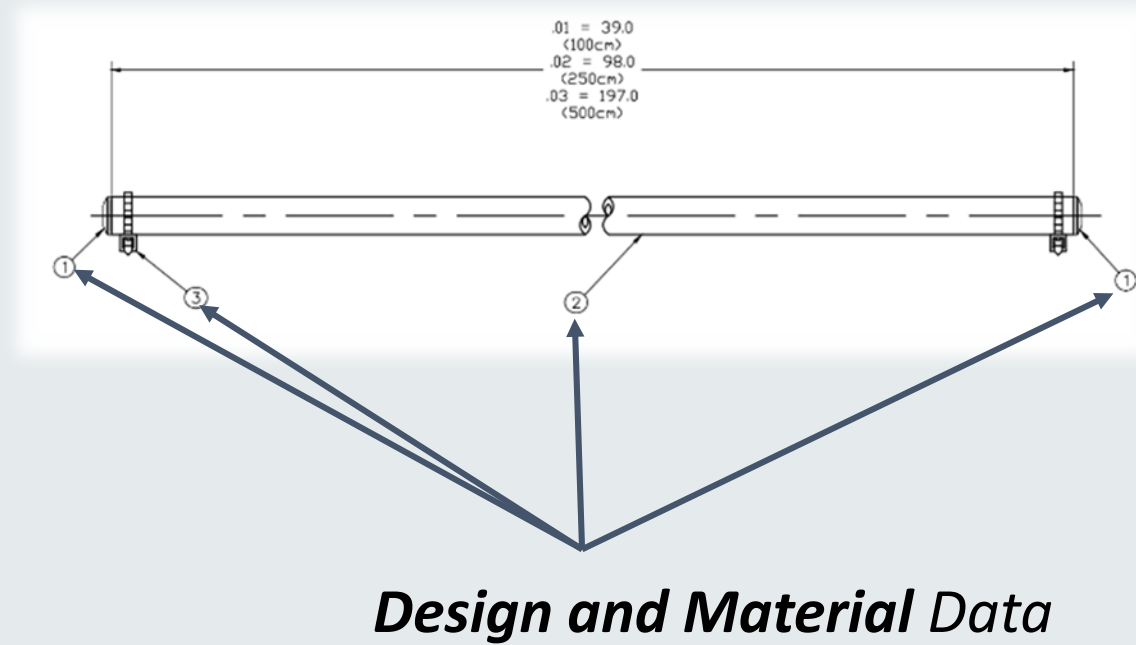Shane Kelly, Fastnet Biopharma

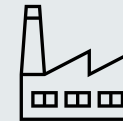Cian Gibbons, Fastnet Biopharma

Dan O'Regan, Fastnet Biopharma

FAST NET

"How you gather, manage, and use information will determine whether you win or lose"

Data in Single Use

Example: *A simple transfer assembly*

Design and Material *Data*

Quality *Data*

Supply *Data*

Operational *Data*

Problem Statement

Our existing systems and understanding does not deliver the agility our industry expects.

Do these questions resonate with you?

- What information is important?
- How to best communicate our requirements?
- How to manage it all the documents?
- How can I stay ahead of my supplier notifications of change?
- Is there a way to really use the data to great effect?

Industry Trends that contribute to the **problem**:

Externalized manufacturing equipment.

Multiplied process contacting materials.

Increased the number of products

Digitization and Information Management Challenge

Agility in SU Digitization

SU Digitization is fundamental to enabling **Agility** in GMP Facilities.

Agility defined as:

Faster
SU E&L qualification duration cut by 90%
Sub-120 day SU program for NPI[1]

Reduced Resources
7,000 person-hours saved for NPI[1]

Reduced Cost
Cut global inventory costs by over 70%

Adaptable and Scalable
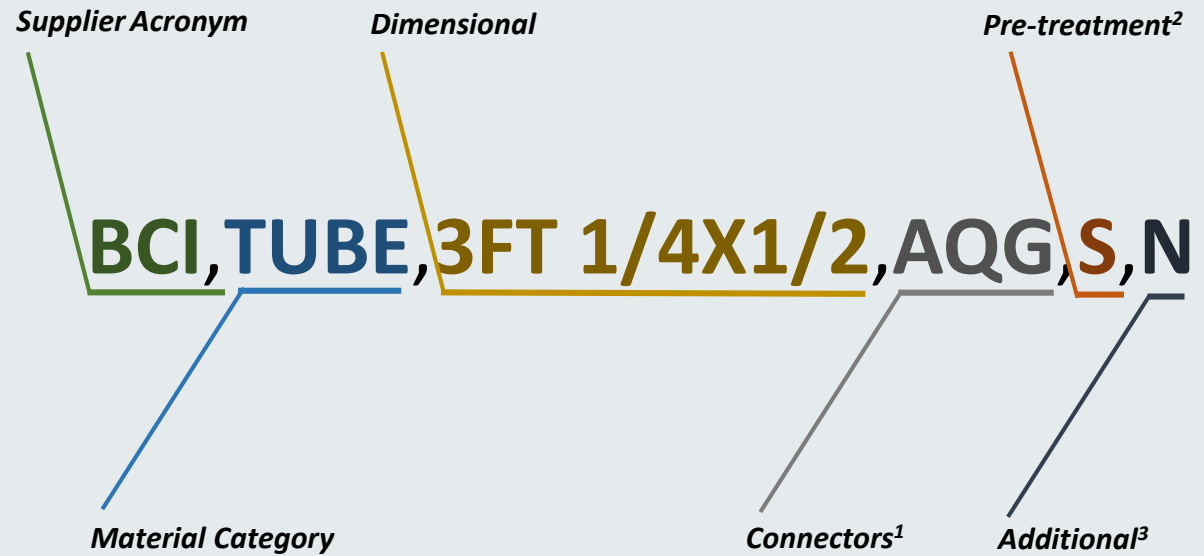Ensure 0 SU items on critical path
Cut global SU designs by 85%

[1]New Product Introduction

Practical examples

5x simple concepts to achieve significant benefits

Example 1
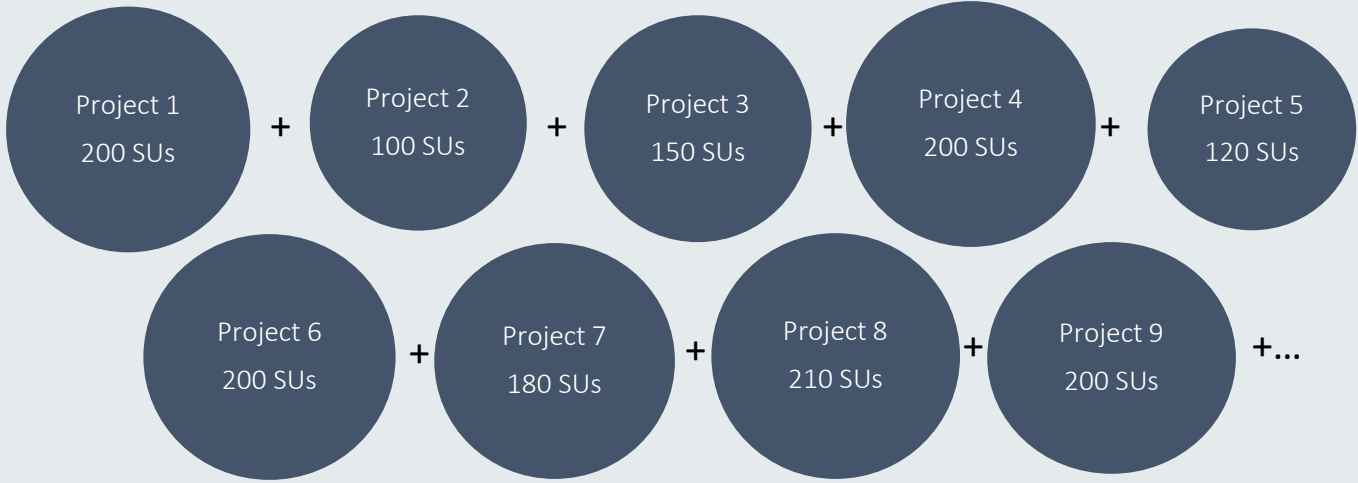
Supply Chain *Naming Convention: Power in Simplicity*

Supplier Acronym

Dimensional

Pre-treatment[2]

BCI,TUBE,3FT 1/4X1/2,AQG,S,N

Material Category

Connectors[1]

Additional[3]

[1]*Aseptiquik G*
[2]*Sterile SAL 10⁻⁶*
[3]*N = no additional information*

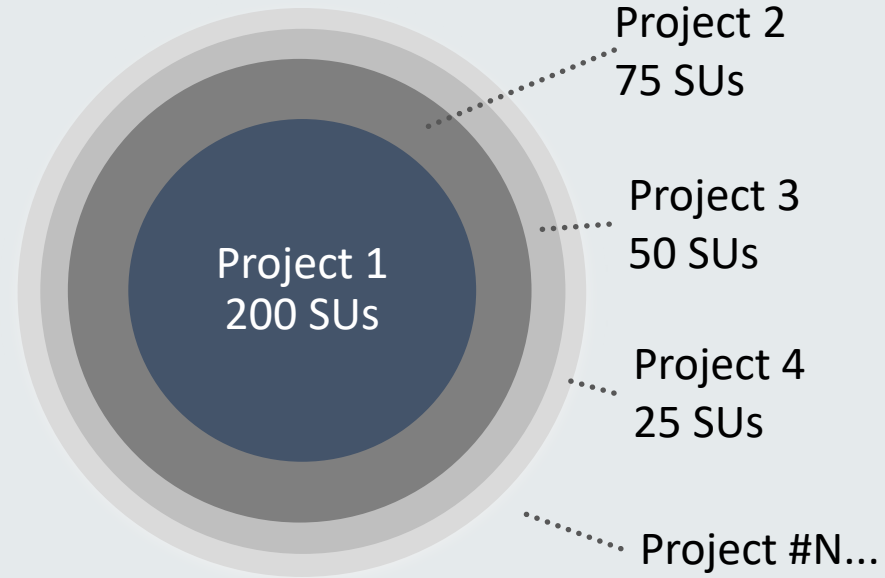| Library of SUTs |
| --- |
| BCI,TUBE,3FT 1/4X1/2,TPE,AQG,S,X |
| BCI,TUBE,5FT 1/4X1/2,TPE,AQG,S,X |
| BCI,TUBE,10FT 1/4X1/2,TPE,AQG,S,X |
| BCI,TUBE,3FT 1/4X1/2,PCS,AQG,S,X |
| BCI,TUBE,3FT 1/4X1/2,PCS,TC-TC,S,WYE |
| BCI,TUBE,3FT 1/4X1/2,PCS,TC-TC,S,X |
| BCI,TUBE,3FT 1/2X1,PCS,TC-TC,S,X |
| BCI,TUBE,5FT 1/2X1,PCS,TC-TC,S,X |
| BCI,TUBE,10FT 1/2X1,PCS,TC-TC,S,X |
| BCI,TUBE,3FT 1/4X1/2,TPE,AQG-TC,S,X |
| BCI,TUBE,3FT 1/4X1/2,TPE,AQG-TC,S,X |
| TYU,SUB,200L,LDPE,AQG,S,pH, Cond |
| TYU,SUB,500L,LDPE,AQG,S,pH, Cond |
| TYU,SUB,1000L,LDPE,AQG,S,pH, Cond |
| BCI,FILTER,500CM2,PES,AQG,N,0.2UM |
| BCI,FILTER,1000CM2,PES,AQG,N,0.2UM |
| BCI,FILTER,2500CM2,PES,AQG,N,0.2UM |
| BCI,FILTER,2500CM2,PES,TC-TC,S,0.2UM |
| TYU,SUM,200L,LDPE,AQG,S,pH, Cond |
| TYU,SUM,500L,LDPE,AQG,S,pH, Cond |
| TYU,SUM,1000L,LDPE,AQG,S,pH, Cond |

FAST𝖭ET

Example 2

Supply Chain
Visualizing the benefits of an SU library

FASTNET

When design teams don't have the tools to communicate

Project 1
200 SUs

+

Project 2
100 SUs

+

Project 3
150 SUs

+

Project 4
200 SUs

+

Project 5
120 SUs

Project 6
200 SUs

+

Project 7
180 SUs

+

Project 8
210 SUs

+

Project 9
200 SUs

+...

Total **4500** SUs

Consolidation enabled through SUT digitization

Project 1
200 SUs

Project 2
75 SUs

Project 3
50 SUs

Project 4
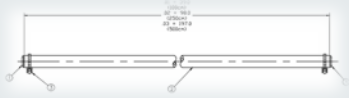25 SUs

Project #N...

Total **550** SUs

Example 3

Qualification *Process-Agnostic Qualification*

'Brute force' qualification:

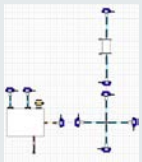*Data gathered haphazardly and rolled into a qualification package*

This design,

With these quality claims,
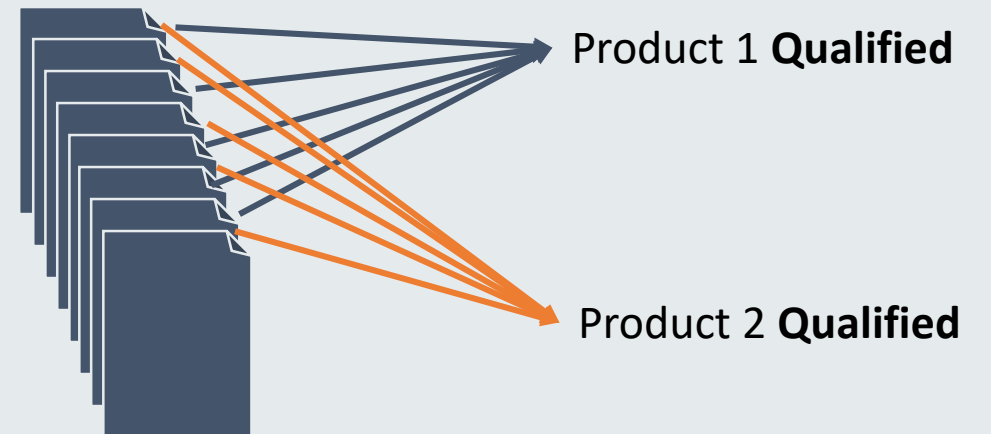
From this supplier,

Used in this application,

Under these conditions,

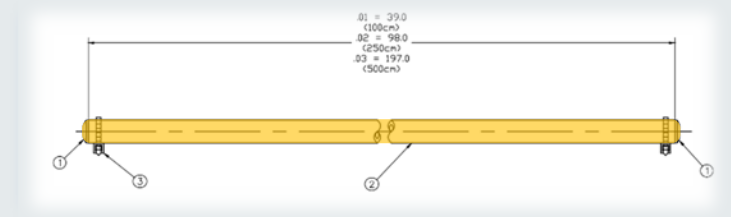Qualified one assembly for one application

Lean data handling:

Material data gathered upon material introduction and reused for multi-product site

Product 1 **Qualified**

Product 2 **Qualified**

Example 4

Qualification *Change Controls – How can we limit the impact?*

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Supplier: Due to an issue in our supply chain, we're **changing** all tubing from Brand A to Brand B
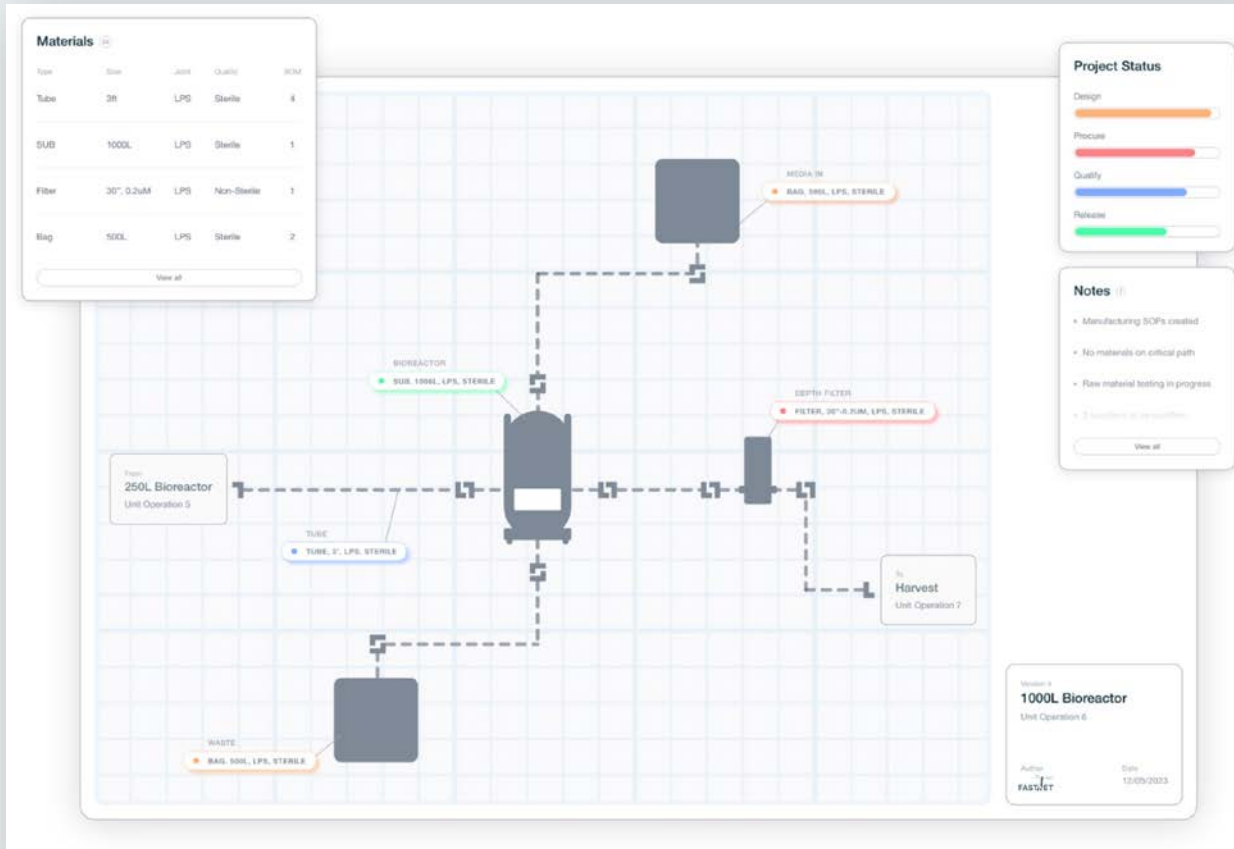
End-User: We use this tubing everywhere.. We need to **Impact Assess** and **Update** all our documentation..

...

End-User: If only I had a **centralized** documentation approach…

Example 5
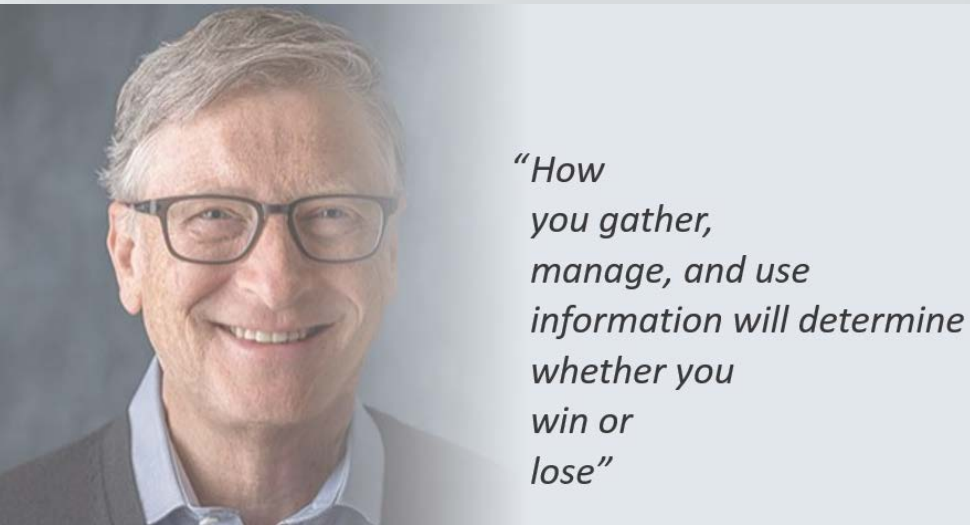
Design *Clarity and Traceability in Process Design*

SU diagram enables:

✓ Accelerated chemical compatibility review

✓ Confidence in BOM Creation

✓ Comprehensive Connectability Review

✓ Operational Clarity

✓ Aseptic boundary assessment

And much more..

Digital Tools & Future Look

*"How
you gather,
manage, and use
information will determine
whether you
win or
lose"*

All this was achieved '**manually**'.
Using Microsoft Office, Adobe and client EDMS

- Open to human error
- Slow
- Only do what is absolutely necessary

What could be achieved using **advanced software**?
Using a bespoke PDF scraper, AI data categorizer and retrieval

- No error
- Instant
- No limit to scope

Final note on Industry 4.0 & AI:
These revolutions are coming – do we have the data fundamentals right?

Any Questions?