



From Colour Photographic Paper to Biologics.
FUJIFILM Diosynth's journey to Bio Manufacturing Excellence.

Gary Cockerill, Reliability Engineer

Partners for Life

Advancing tomorrow's medicines

#### Who we are



# 80:20 Joint Venture between FUJIFILM and Mitsubishi Since 2011



Bringing the best of Japanese Business Management

Excellence in Management

#### **FUJ!FILM**

80 years of successfully combining Technology and Manufacturing

FUJIFILM Corporation

#### Mitsubishi Corporation

Deep Partnership Expertise Global Presence and Experience

> Mitsubishi Corporation



US / UK People
Technical
Knowhow Assets
Ways of Working
Track Record

Excellence in Action





# One Global Company

3

**SITES** 

Billingham, UK College Station, TX RTP, North Carolina 6 LICENSES

For commercial manufacturing

1,100

**EMPLOYEES** 

World Wide

20+

**YEARS** 

Of Biologics CDMO experience.

280+

**MOLECULES** 

In process development and/or manufacturing



## If you search for us....

FUJIFILM Diosynth Biotechnologies awarded IChemE Award

**GE Healthcare installs purification tech at FujiFilm Diosynth site** 



FUJIFILM Diosynth Biotechnologies

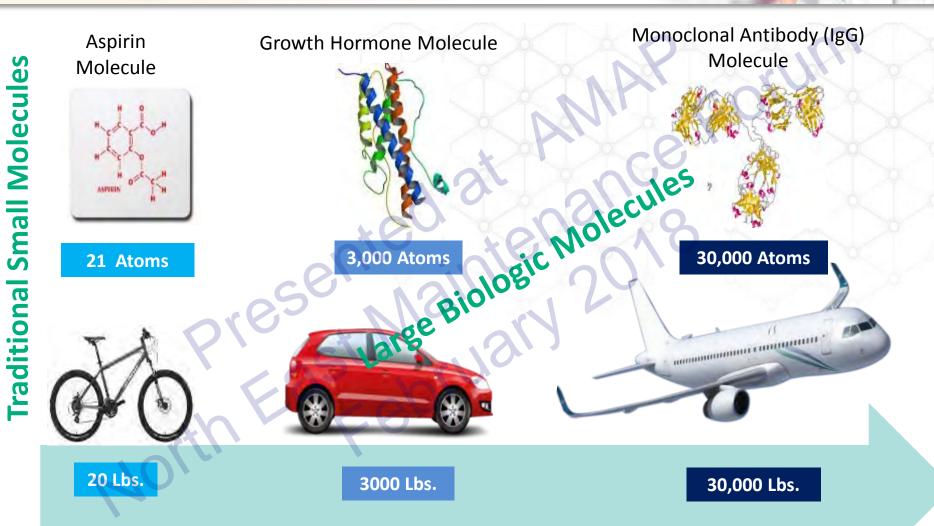


Fujifilm Diosynth builds new Billingham manufacturing plant

New case study shows how MHRA helps Fujifilm future-proof manufacturing facility



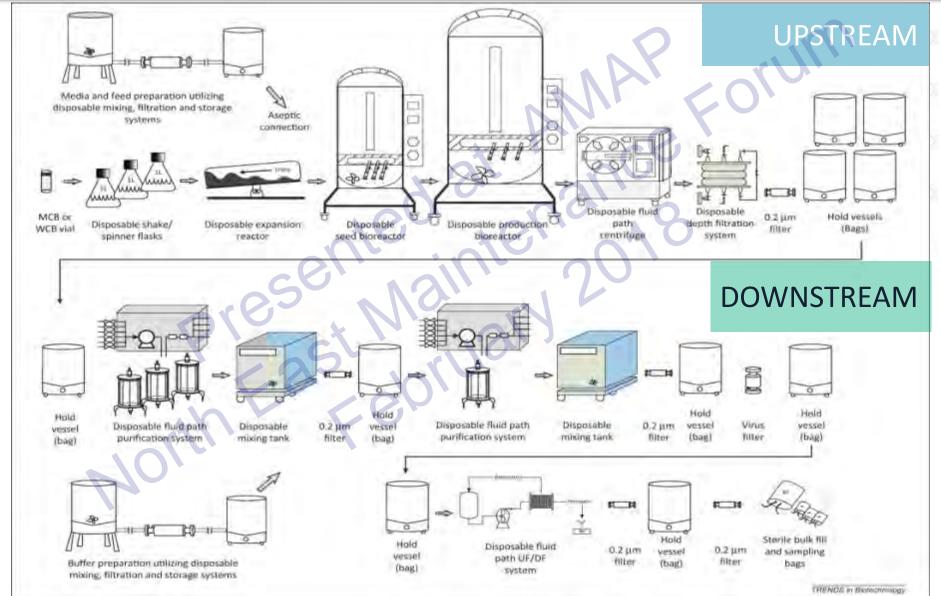
# What is a Biologic?





# Complete Biopharmaceutical Manufacturing Process





#### 2013 Position



- FUJIFILM ownership encouraging strong investment into the Billingham site.
- Awareness of a legacy engineering and maintenance problem.
- Business was booming and our assets were being asked to do more.
- FUJIFILM were sceptical of our manufacturing ability.



#### 2014 Position



In 2014 our chronic problem became an acute one....
 ....despite having...

6,000

PM Routines

Executed

2,100

Unplanned
Maintenance Tasks
Executed

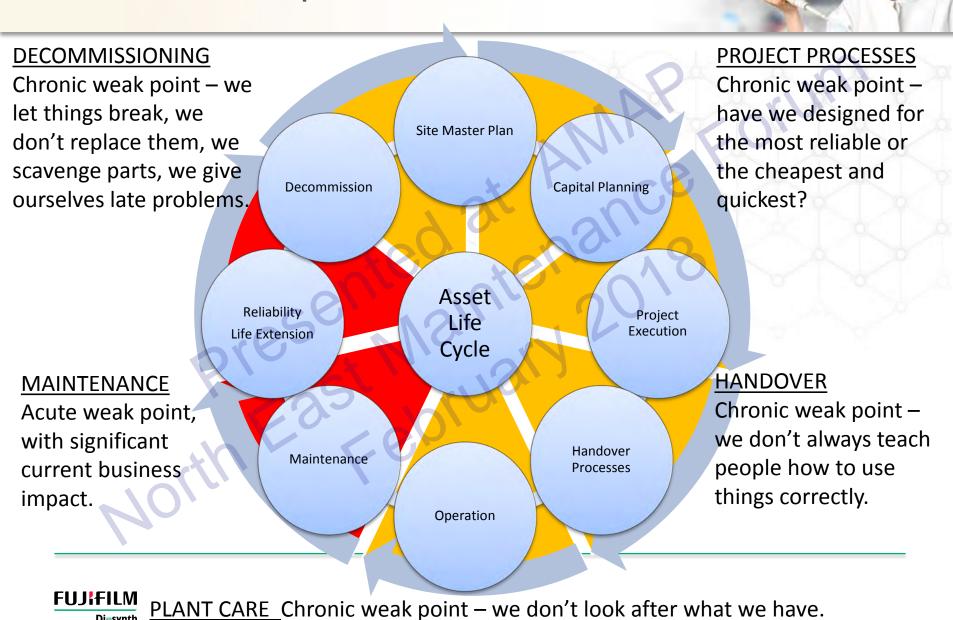
.... we experienced

10

Batch losses due to equipment failure



## Where was the problem?



# Tilburg – Fujifilm Paper plant



• In 2014, visit to FUJIFILM's Fine Paper Factory Europe





# **FUJIFILM's Factory Europe (EF)**



- Imagine a continuously operating complex plant....
- ....with a product you cannot test....
- ...which operates in the dark...
- .....but which very rarely has the type of failures we've experienced.

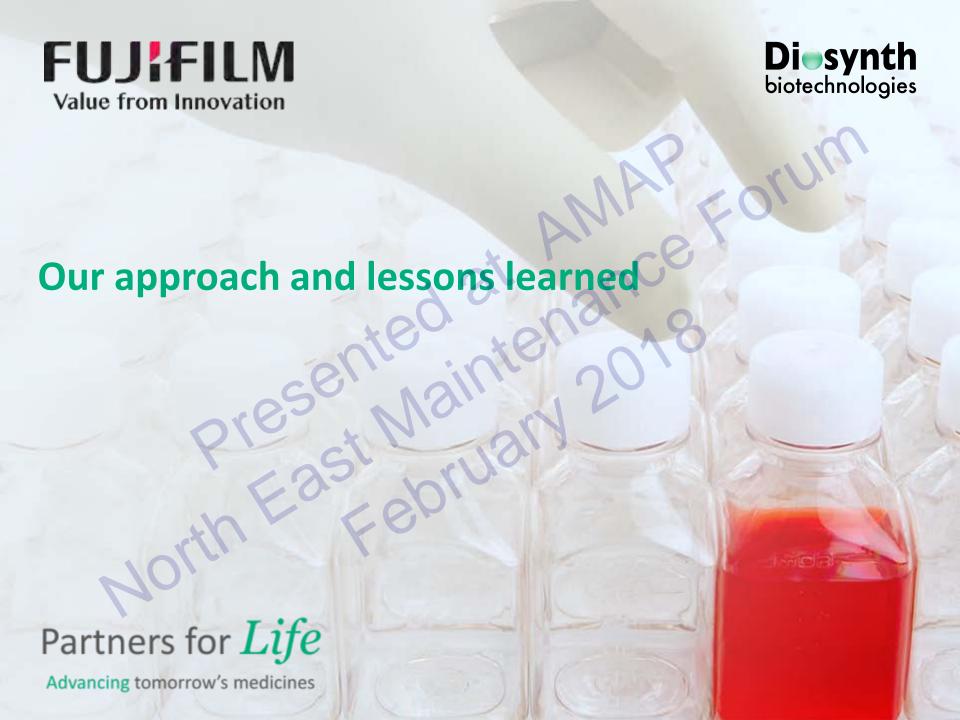


# FUJIFILM's approach to quality



- More than just film or paper, each photograph is a memory of a special time.
- This foundation created a Fujifilm mindset of manufacturing excellence.
- Since 2014 we have been working to create "Bio Manufacturing Excellence."





#### Benchmark



- Be critical of yourselves.
- Find friends who will tell you.
- Look across industries.

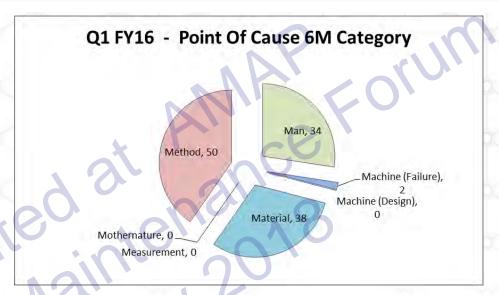
We have encouraged our teams to "go see". GEMBA



# Measure what's happening



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To begin with, we didn't have the data we needed.



# Don't overcomplicate it



FMECA, RCM, TPM etc. etc. etc.

- What's hurting you today?
- What keeps you awake at night?
- Fix those before getting too complicated.

This was the "top down" part of our project.



# Don't overcomplicate it



 Regularly send your maintenance technicians to the equipment and get them to assess it and if possible fix it right away.



This was the "bottom up" part of our project.



# Consider the people



- What are your team telling you?
- Remember that the change and the day job need to run in parallel.
  - A dedicated change leader brings focus.
- Who might be resisting?
- Does everyone understand what the goal is?



# Spend wisely



External consultants have a role

There is much to learn.

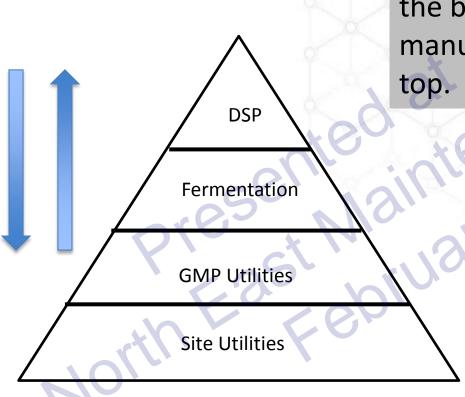
- External voices sometimes have more impact.
- But remember don't overcomplicate it!

We probably didn't get value for money.



### **Prioritise**





While maintenance focussed at the bottom of the pyramid, manufacturing began at the top.

Priority is given to the systems at the bottom of the pyramid.



# Focus your efforts





#### Focus On GMP Assets

 Reliability Improvement and Compliance

# **Engineering Support**

Focus On Capital Programme Delivery

Project
 Management
 Excellence
 and Value



Focus On The Non-GMP Facilities

 Service quality, Delivery, Cost Reduction.



# Get your maintenance data in shape



- We initially thought SAP a weakness.
- Actually it was the lack of data, or incorrect data.
- We didn't have the skills to put this right, or understand what was possible.
- This year we've reviewed and updated 2000 maintenance routines held within SAP.



#### Think about the Vision



A facility which never lets us down.



