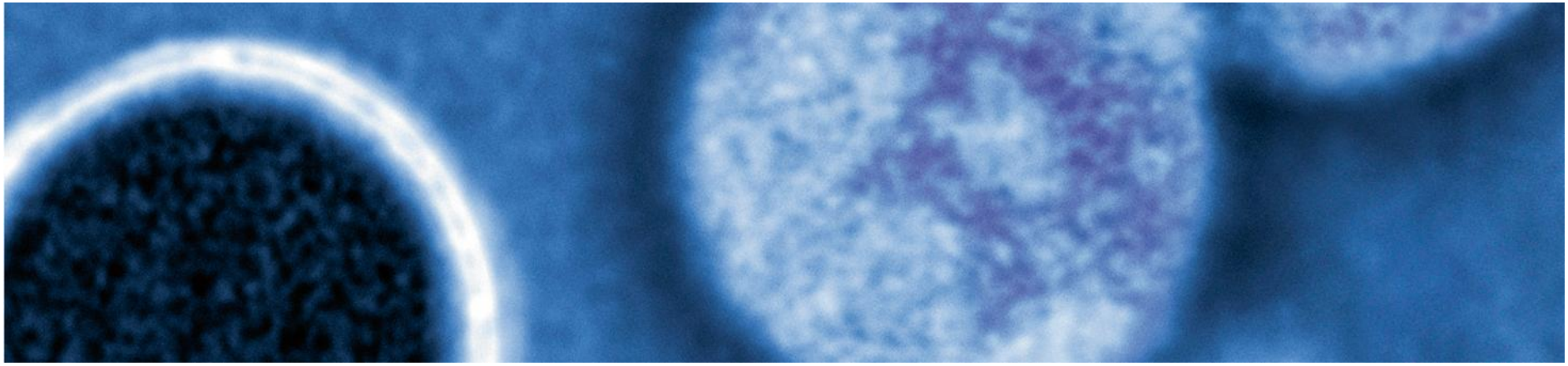


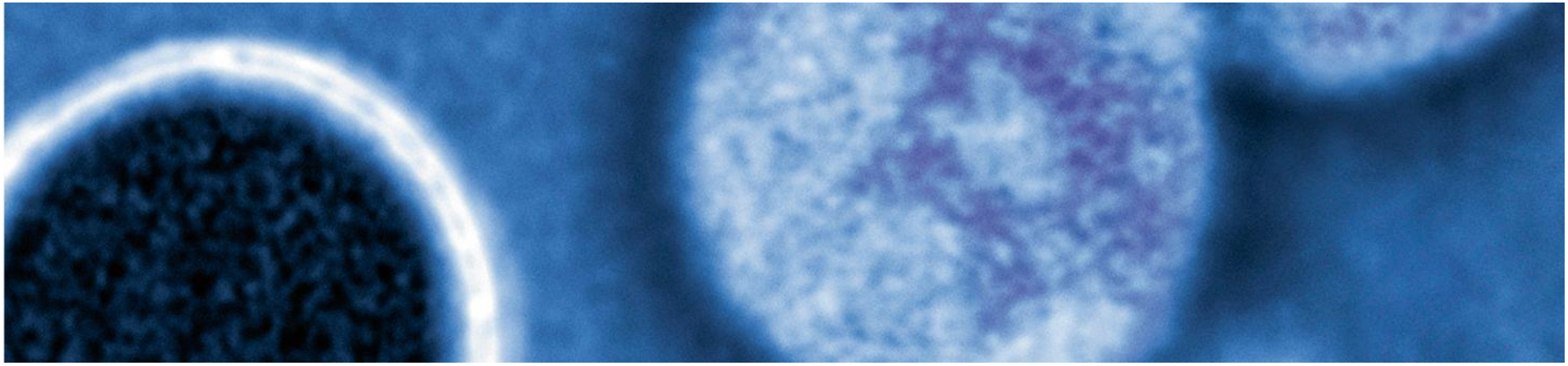
MES Deployment in a Changing Environment

Paudie O’Keeffe

27/03/2014

Agenda

1. Amgen and Introduction
2. Site Changes in 3 Years
3. Infrastructure and Organisation
4. MBR Design challenges
5. Lessons Learned and Future Challenges
6. Voice of Customer



1. Amgen and Introduction

Amgen background

- A biotechnology pioneer founded in 1980
- Amgen was one of the first companies to successfully discover, develop, and make protein-based medicines.
- Amgen seek treatments for patients with diseases for which there are no options or where needs are not fully met
- Amgen focuses on areas of high unmet medical need

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About Amgen Dun Laoghaire (ADL)

- Located on 25-acre site near the coast about 7 miles south of Dublin
- Aseptic operations facility - freeze dry and liquid vial filling; plus syringe filling capabilities
- Purchased by Amgen in May 2011; previously a Pfizer plant
- ADL specializes in secondary manufacturing – formulation, fill and packaging
- The site also includes laboratories and cold chain warehouse

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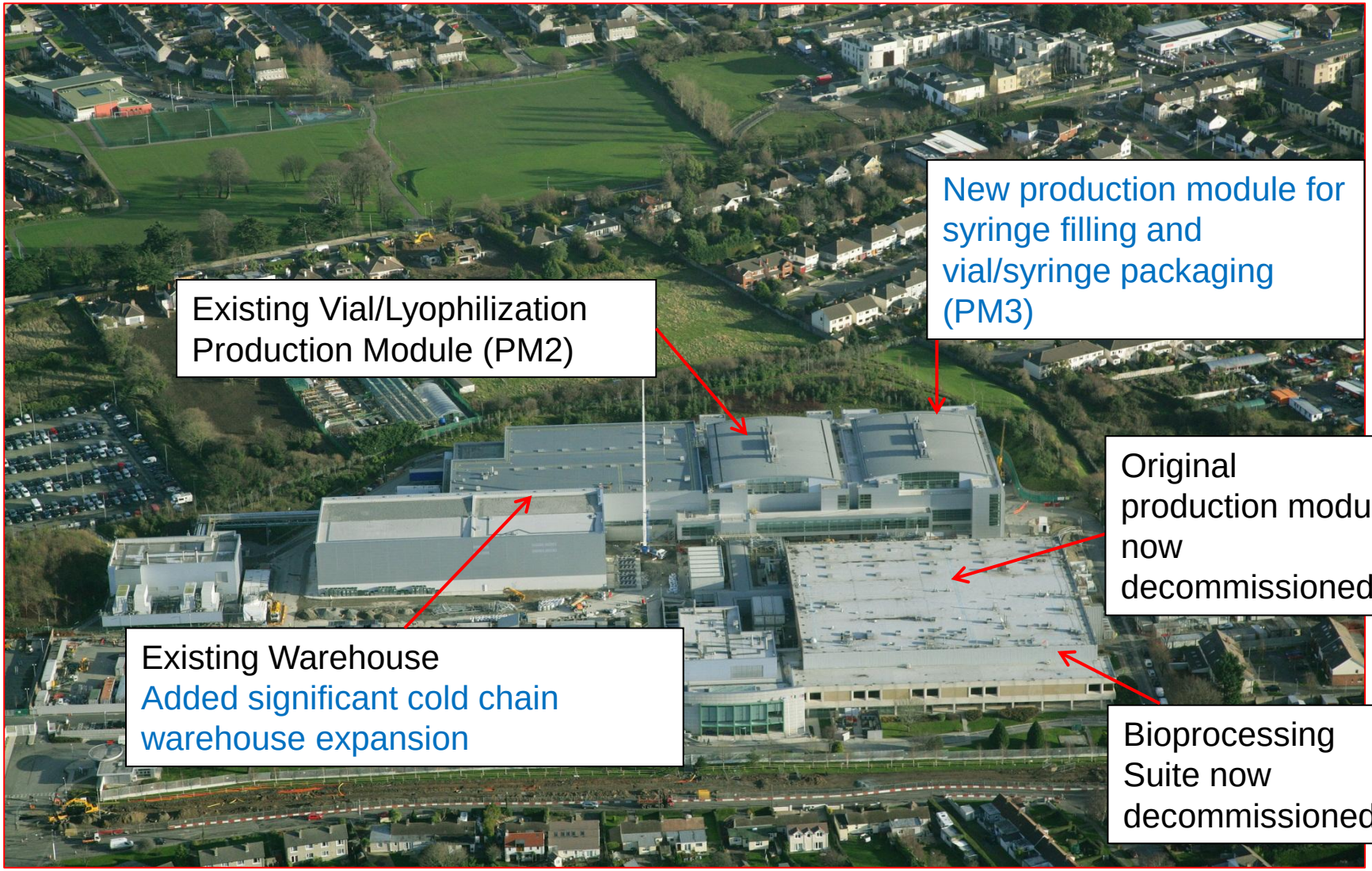
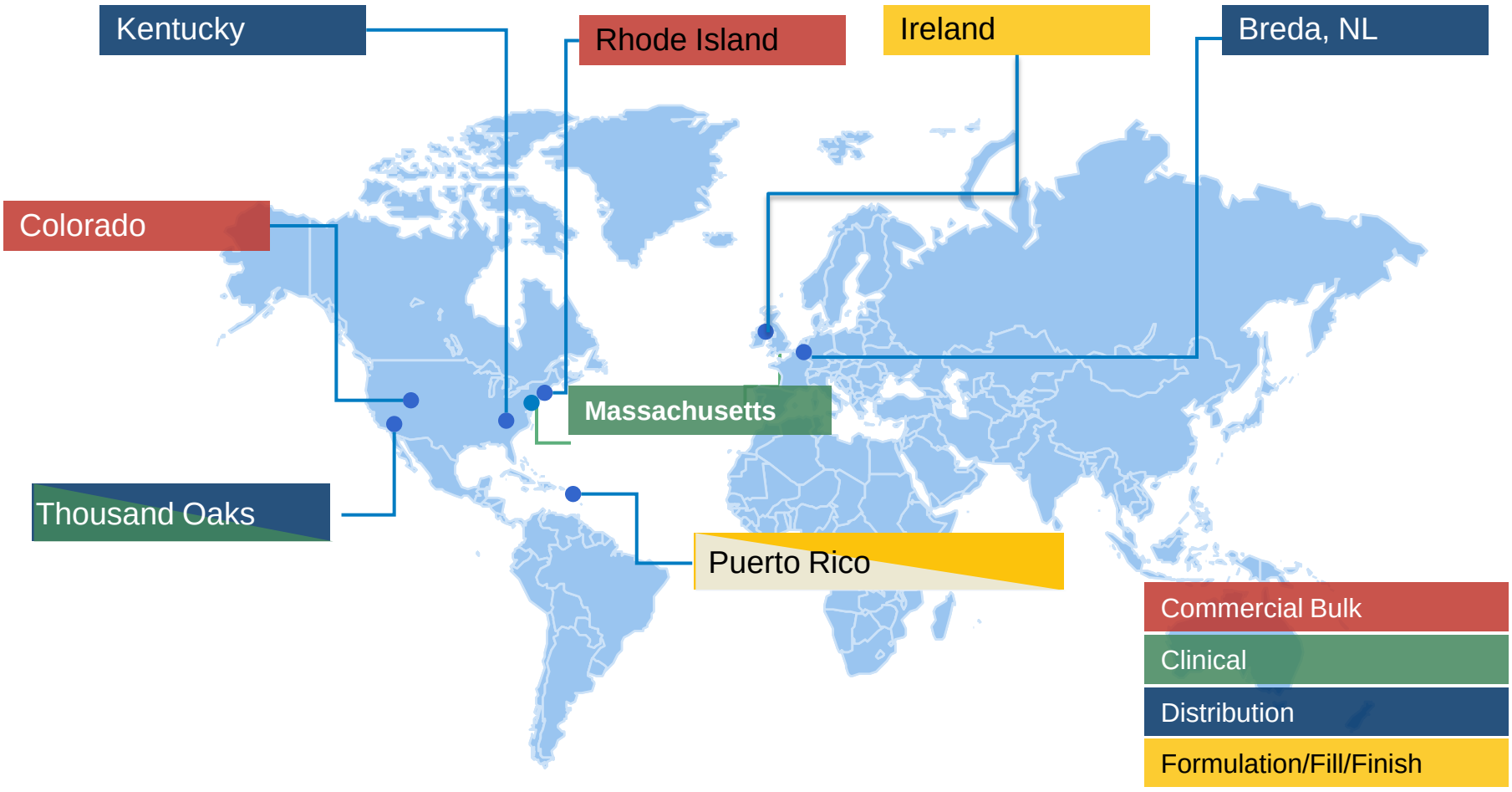
Aerial View Amgen Dun Laoghaire (ADL)



Our Manufacturing Network



Intro

- MES System Owner and Project Manger at Amgen Dun Laoghaire site
- Working on MES at the site since 2006
  - Joined during the MES deployment in Production Module 2
  - 5 years later, deployed Amgen MES System in Production Module 2
  - Currently, introducing MES into Production Module 3 – Packaging & Formulation / Syringe Filling. Plus serialization in the packaging hall.
- Prior to MES, I have worked in the semi conductor and CM industries

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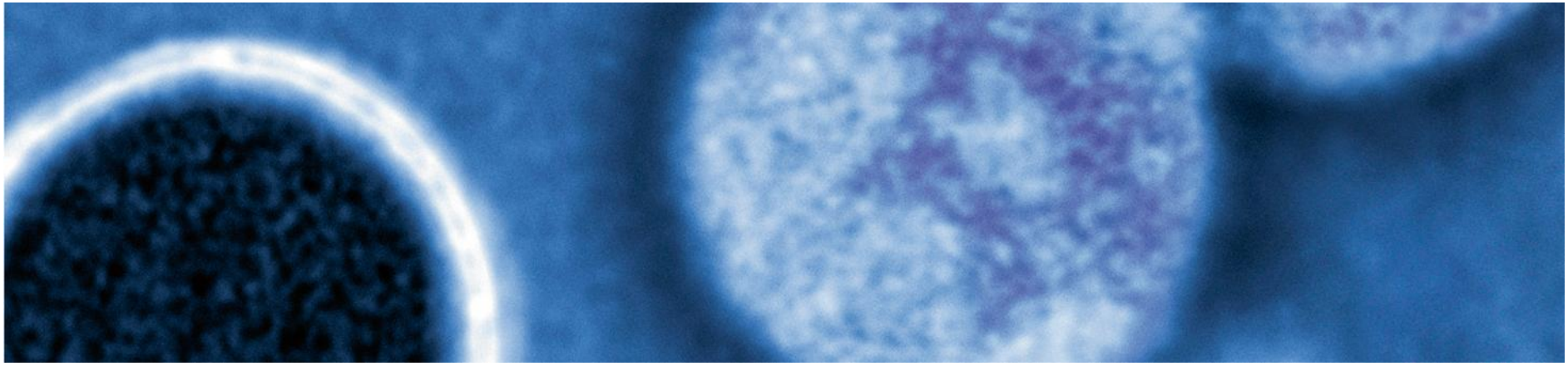

2. Site Changes in 3 Years

An Aerial View of ADL: Q1 2011

2011 - then

Dun Laoghaire site under Pfizer:

- Mature MES system (PMX MES™) as per Pfizer MES CoE
  - In place for 5 years in 1 Production facility (Production Module 2)
- Interfaced to the Pfizer MAPS ERP system
- MBRs had been optimized through:
  - Deployment of Electronic logbooks
  - Deployment of Equipment management module
  - Level 2 integration
- MBRs had been streamlined through Kaizen event

An Aerial View of ADL: December 2013

2014 - now

Dun Laoghaire site under Amgen:

- New MES system (PAS|X) as per Amgen MES CoE
  - In place for 2 Production facilities (Production Modules 2 and 3) and 1 Packaging facility
- Interfaced to Amgen SAP ERP system
- Serialization project also in process in packaging lines

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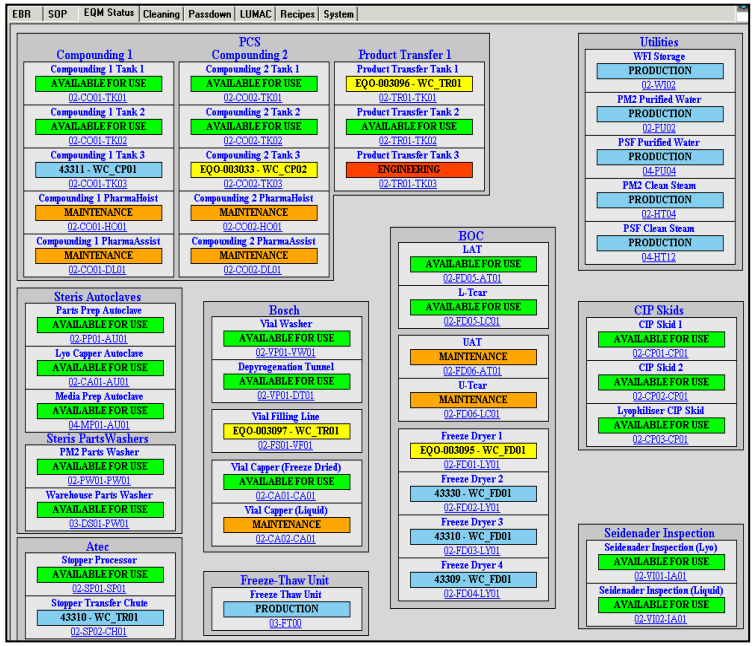
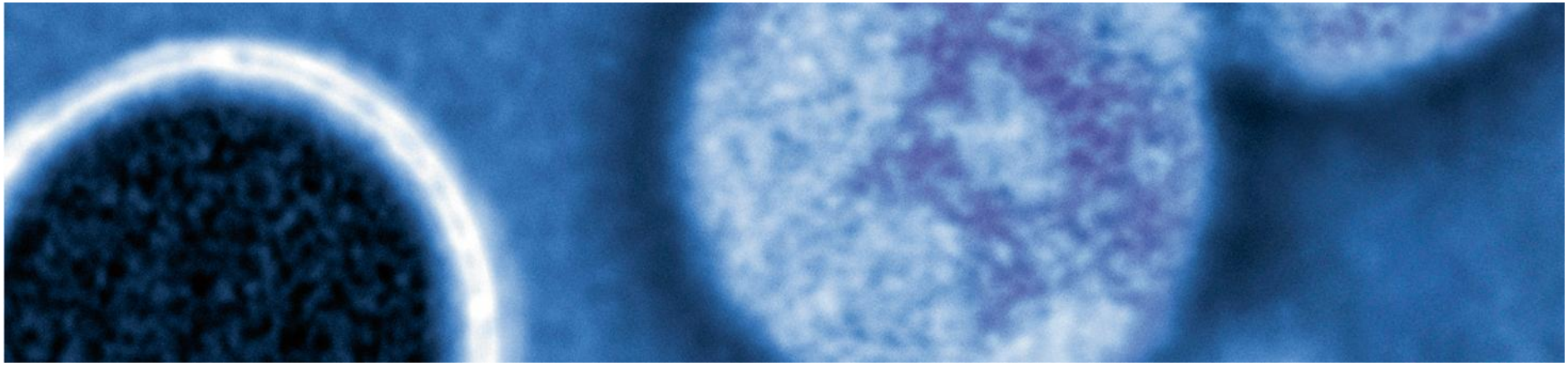
In between (2011 – 2014)

- The site was manufacturing both Pfizer and Amgen products simultaneously
  - While phasing in Amgen processes
- Therefore, there was a need to run 2 MES and ERP systems in parallel for this duration
- Significant effort in managing approaches to:
  - MBR design and content
  - Equipment
  - Level 2 integration
  - Materials management & inventory control
  - User access and training
  - System uptime, integrity & compliance

Charter for Introducing Amgen MES

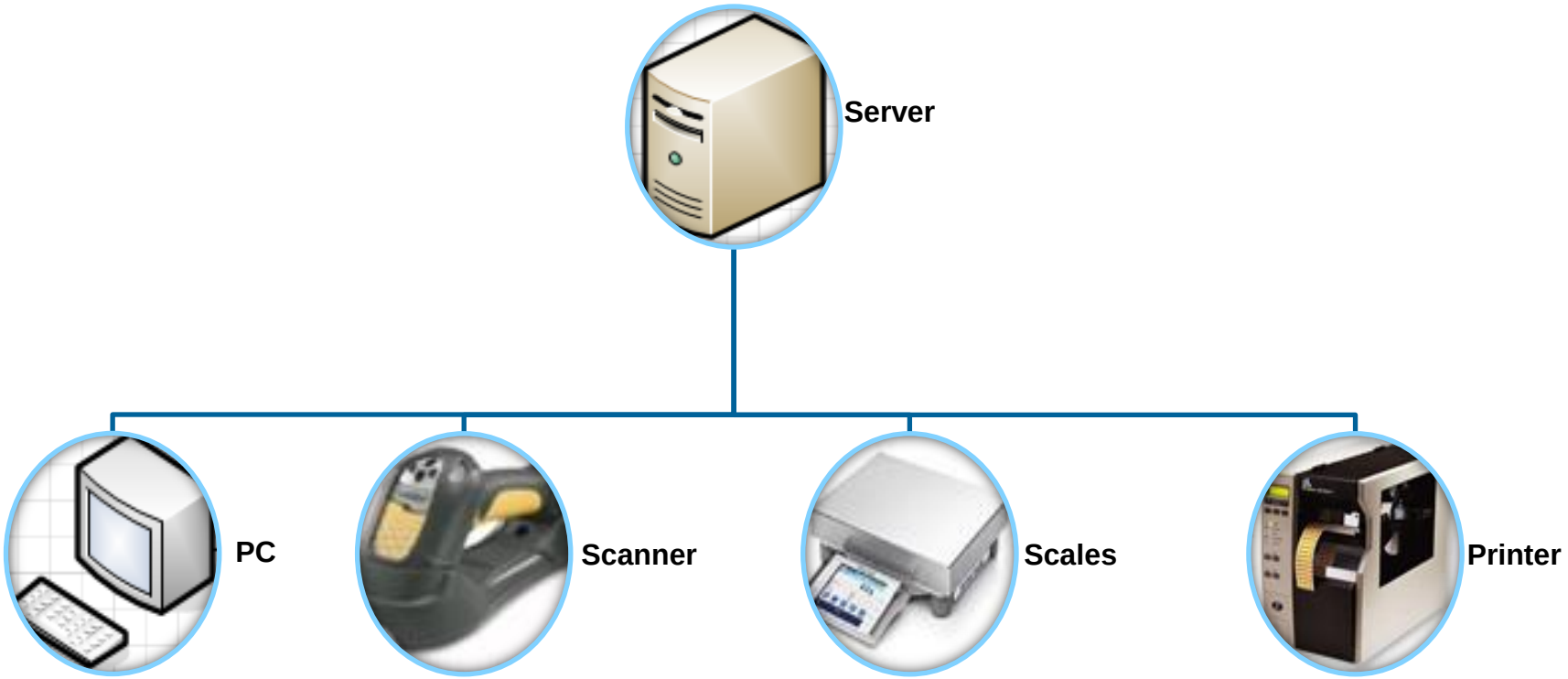
- Maintain legacy MES functionalities
  - Bridge gap with legacy MES RBE and PAS|X capabilities
- Align MBR development process with other Amgen sites
- Maintain MES dashboards of information for equipment and batch record review
- Maintain regulated requirements
  - GHS labels for European market





3. Infrastructure and Organisation

Typical MES Hardware

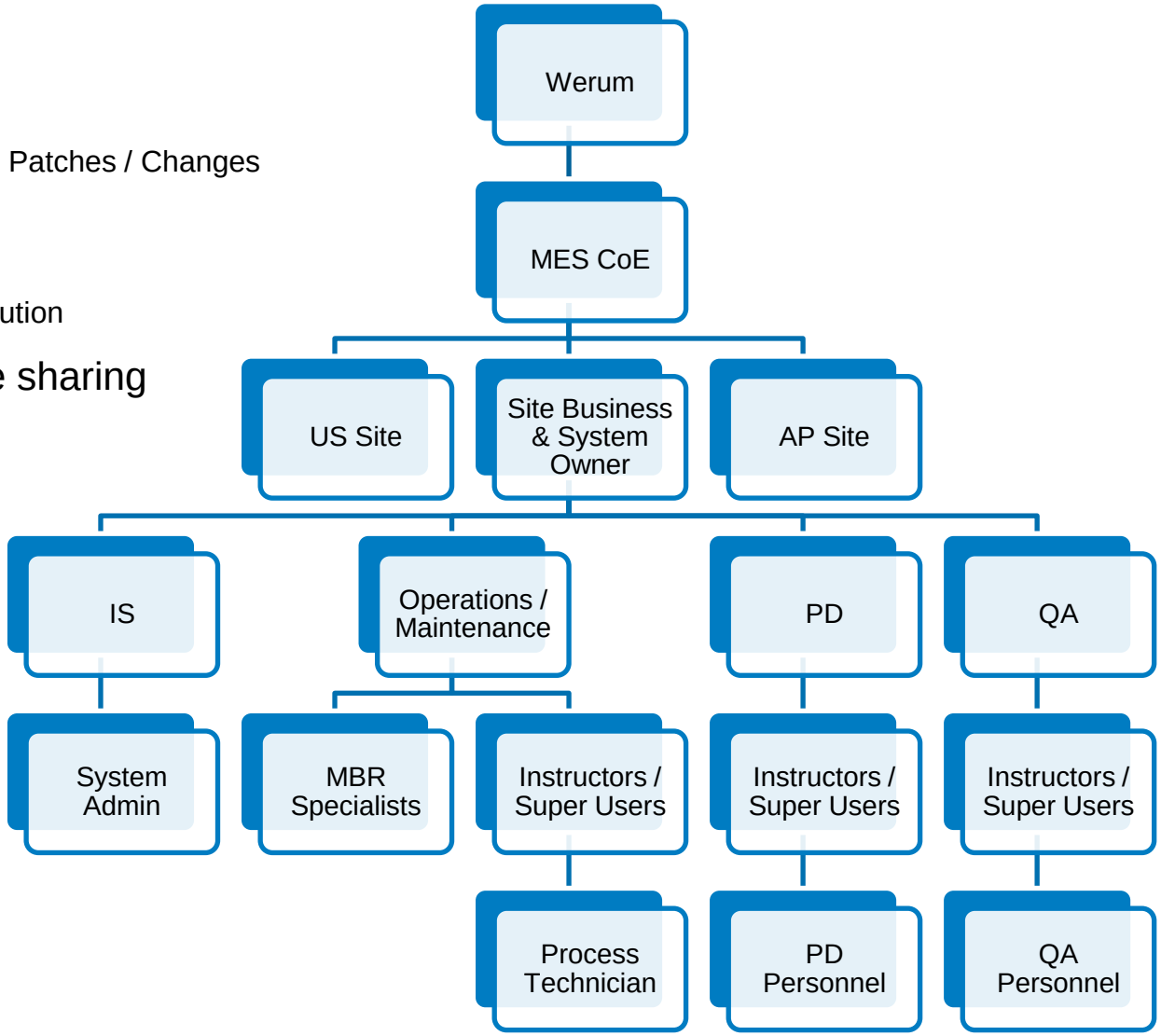


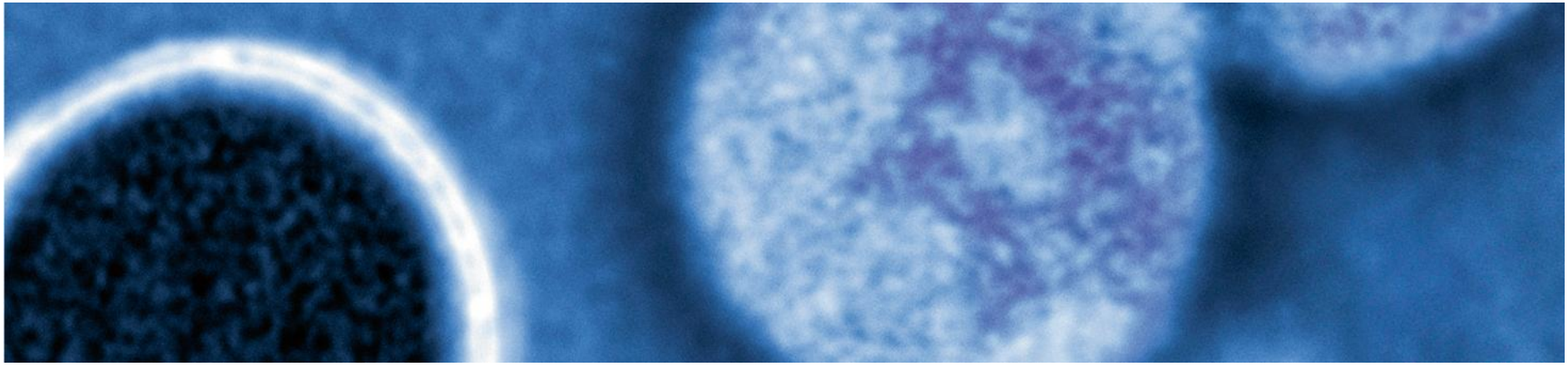
Infrastructure Differences

	Rockwell's PMX	Werum's PAS|X
Scanners	DS3408 tethered / DS3478 cordless Symbol barcode scanner	DS3578 cordless Symbol barcode scanner
Label Printers	Intermec PM4i Printer	Zebra 110Xi4 300 DPI
Scales	RS-232	Ethernet
Infrastructure	Deployed on Manufacturing Network	Deployed on Business Network
Platform	MS Server 2003 SP2	Red Hat Linux v. 5
Clients	Thin Client XP	Citrix Client Vista
MBR Design	End-to-end MBR	MBR segmented by process
ERP Interface	MAPS	SAP

Global Org Structure

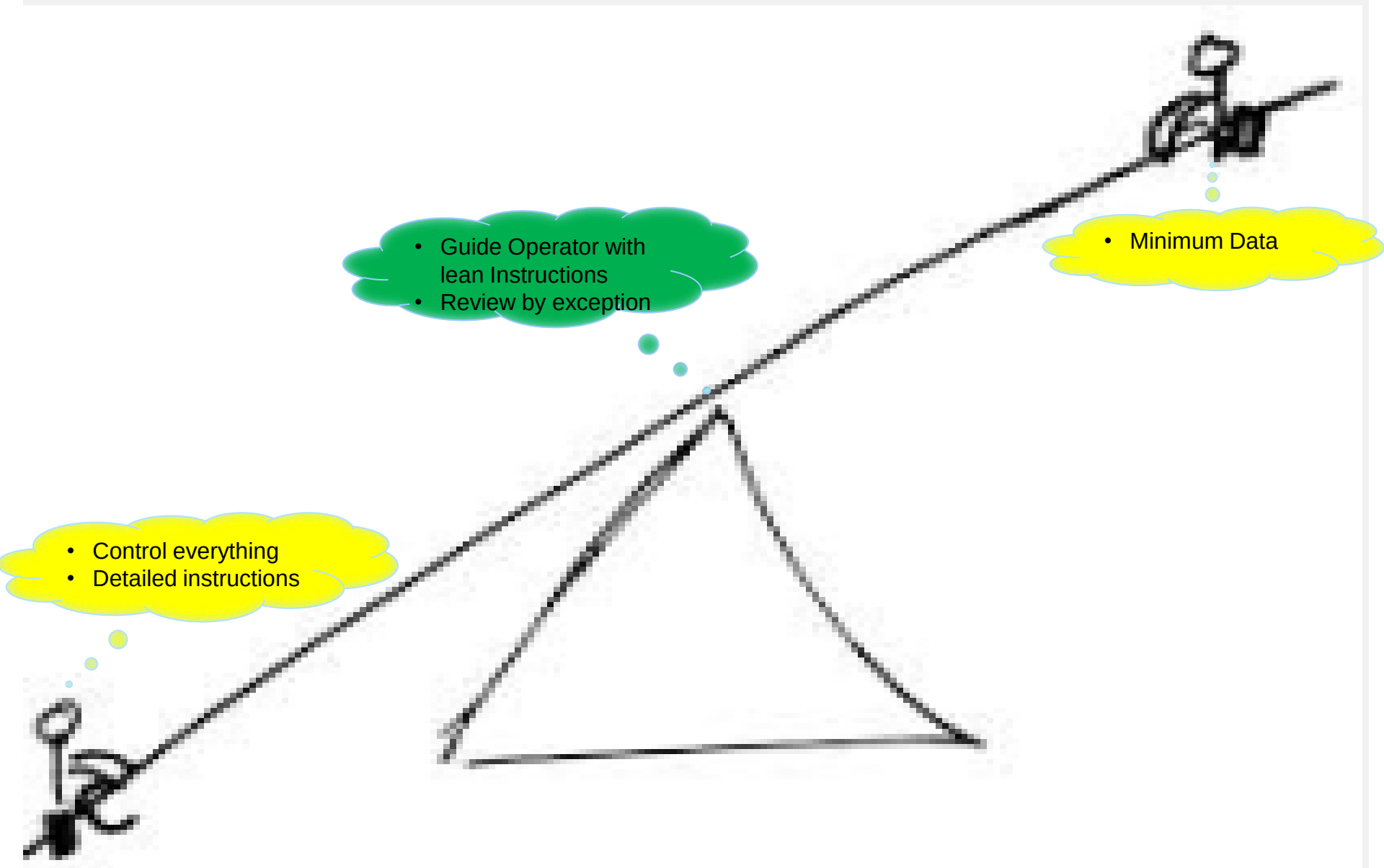
- Top down
  - Training
  - Upgrades / Patches / Changes
- Bottom up
  - Support
  - Issue resolution
- Best practice sharing





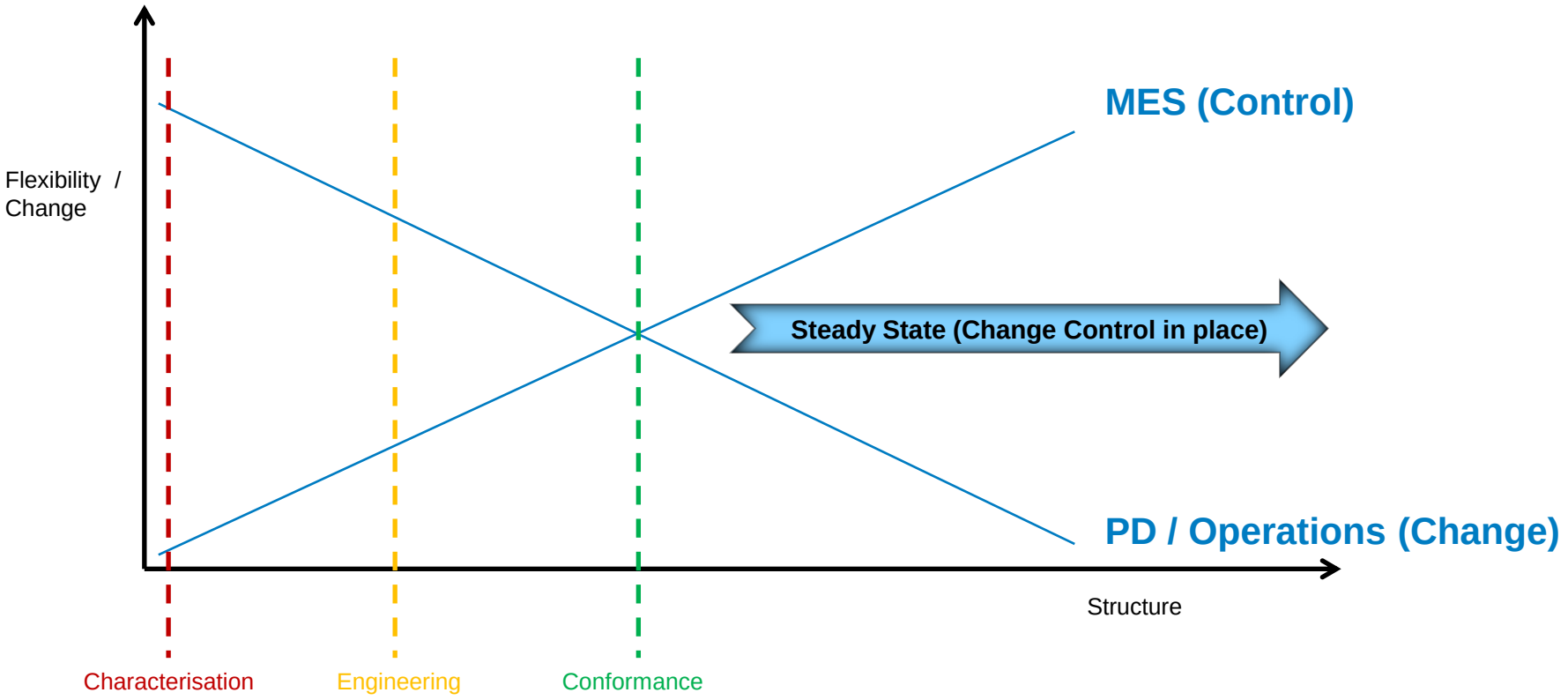
4. MBR Design Challenges

Lean Principles Applied to MBR Design



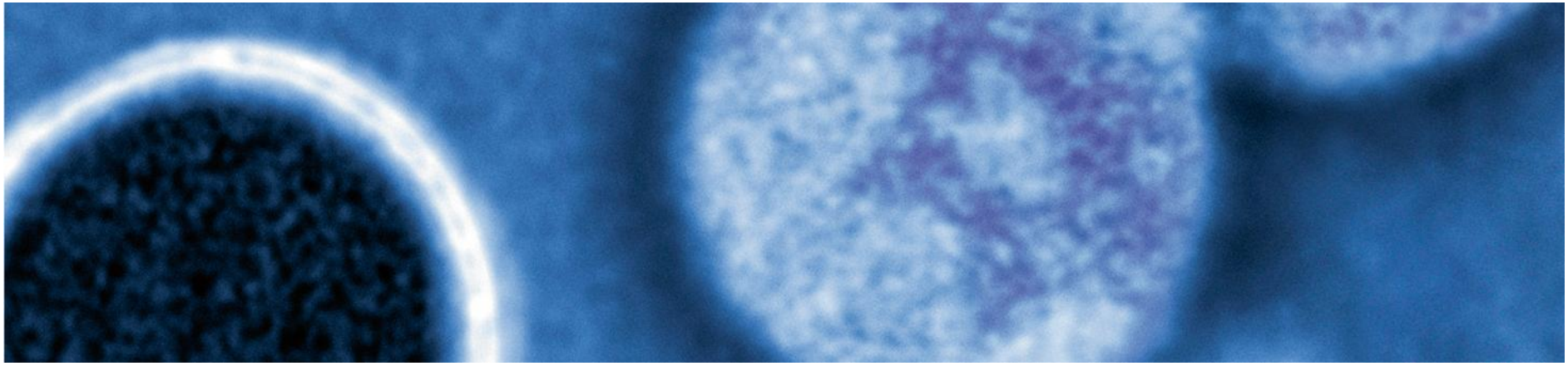
When to introduce MBRs during a project?

- MBRs require rigor and structure
- PD / Ops require flexibility as the process is defined – still in experimental mode
- Iterative process with design reviews, workshops, dry runs



Guiding Principles in MBR Design

- Operating standards for MBR development team
  - Style guides for MBR development team – consistent conventions, libraries etc
- Consistency, alignment and re-usability in -
  - approach to requirements gathering and process mapping
  - participation and accountability across departments
  - batch record content – CQAs, CPPs, instructions etc
- Consistent approach makes for better project planning, communication and results
- As a global company flexibility in your supply chain and being able to deliver different products in different jurisdictions in a timely manner is crucial
  - Products can be moved and manufactured across sites, quicker NPI, contingency across sites



5. Lessons Learned and Future Challenges

Lessons Learned

- Senior management buy in
  - Map out and communicate the MBR development lifecycle and process flow with the stakeholders
  - Time defined development process and prerequisites in place
- Not just an IS project – business need to take ownership of application to understand and reap the benefits
- Need to involve resources early - “Super Users”, QA, PD, Supply Chain
- Get access to systems early
- MES can do a lot - Don’t bite off more than you can chew
- Leverage other sites and CoE documents
- Change Management & Communications

Future Challenges and Considerations

- MES CoE goal to consolidate sites on one standard platform
  - Local, Regional & Global Considerations on -
    - Deployment – upgrades and patching windows
    - Support
- Guiding principles for development of system interfaces – can lead to improved data integrity across the organization
  - Training
  - Laboratory
  - Quality
  - Level 2
  - Engineering
  - ERP
- Distribution of MES data
  - Using MES data to track KPI s; as an OEE tool
  - Optimize reports and investigations
  - Drive decision making and planning

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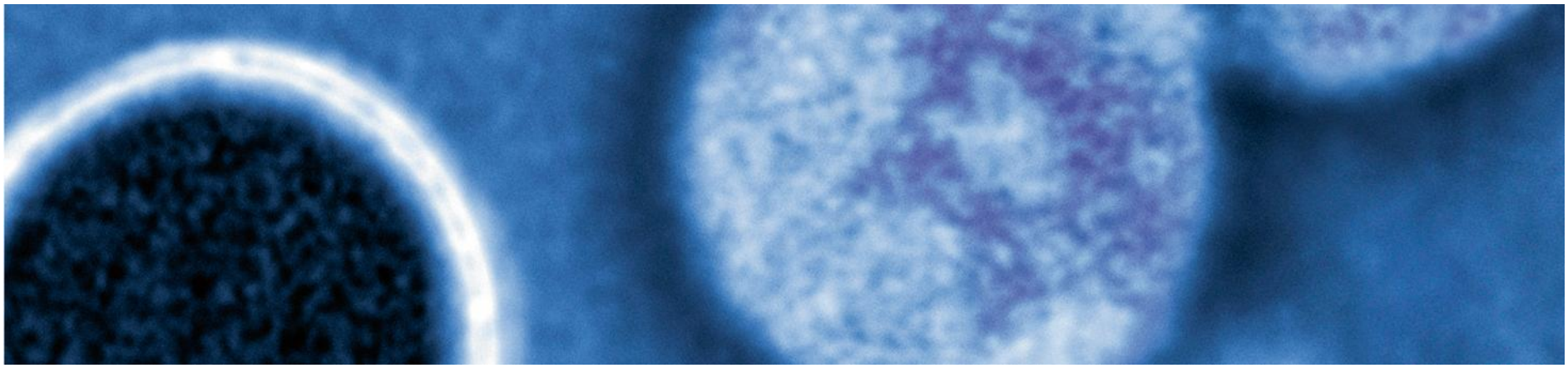

6. Voice of Customer

Going from paper to MES

PROs

- Automated system, better control, review by exception possible
- Increased compliance
- Improved sequence of operations
- Automation of calculations
- More control by defined EBR workflow, material consumption, equipment status checks
- Added controls around user input
- Centralized administration and execution of critical manufacturing data

CONs

- Review by exception not set up properly at start (most likely due to lack of understanding/fear of change), some reports not integrated so still require manual review and attachment
- More complex review/approval process
- Validation activities
- Training activities
- Increased effort to update MBRs
- Ongoing platform challenges and resource expenditures to meet evolving business requirements

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Without MES we wouldn’t be able to…..

- Review by exception
- Be paperless
- Easily share shop floor information to a wider audience, review batches by exception and easily trend information for audits/inspections
- Quickly and easily access much of the manufacturing order info
- Confidently drive all execution and informational aspects of the end-to-end manufacturing processes.

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Next for MES, wouldn't it be great if MES....

- Had full integration of all systems
- Easier systems integration for us non IT heads
- Was a strategic priority for senior management to ensure full engagement across the business
- Pushed intelligent notifications
- Platform upgrades could be performed without business downtime
- And the ERP system were one or if MES was used in more industries (I want to work in a chocolate factory…..)

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