

MBR Development Using Offsite MBR Team

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Pfizer in Ireland

Prevenar 13
Pneumococcal Saccharide Conjugated Vaccine Adsorbed, 13-valent

SOMAVERT[®]
(pegvisomant for injection)

Enbrel[™]
etanercept



Over 3,200 people employed.

Six locations around Ireland.

\$7 billion in Ireland over the past decade.



Grange Castle: 2000-Today.

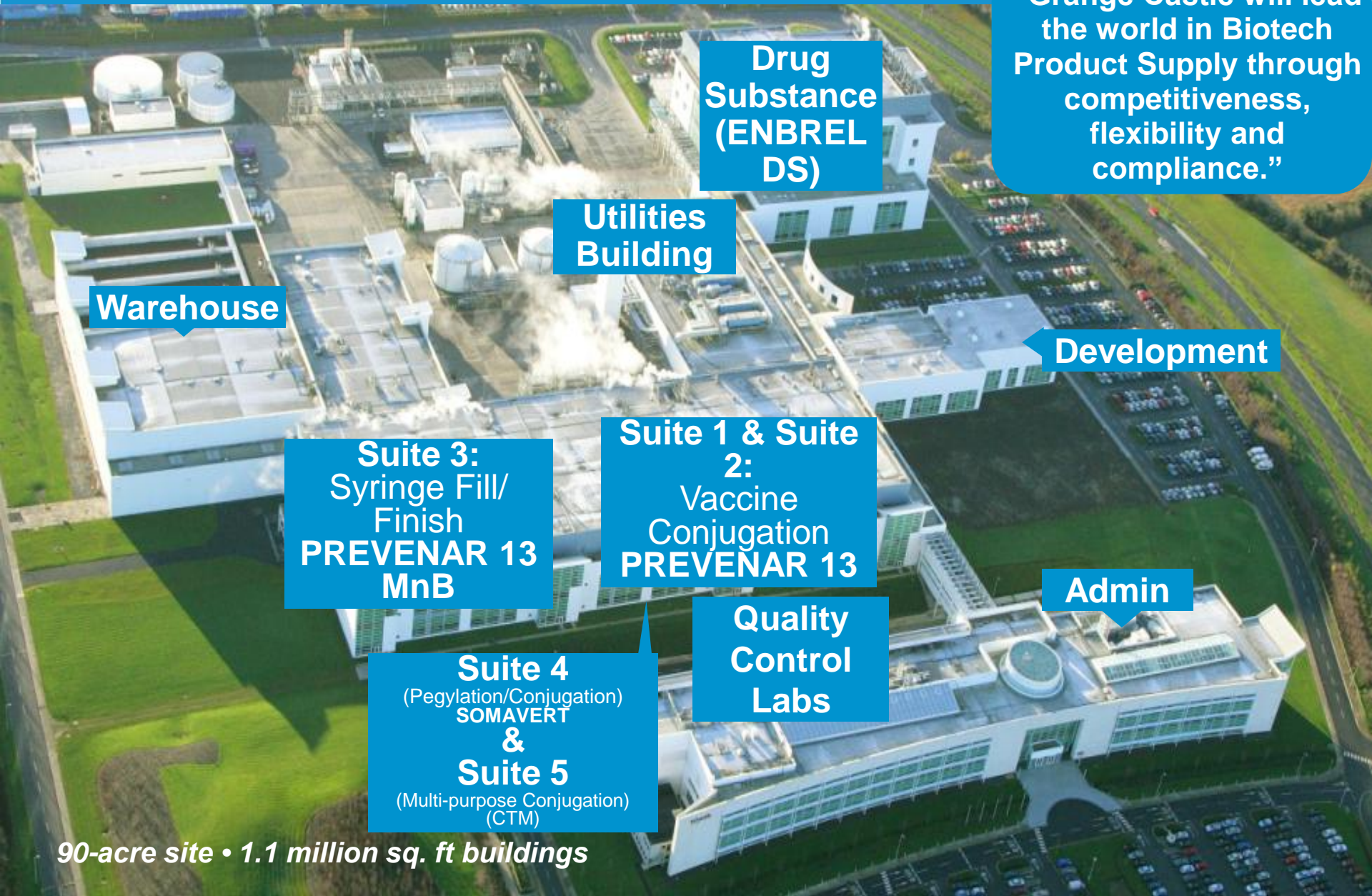


- 1999-2003:** Engineering and building construction
- 2003:** Pfizer Grange Castle opened to colleagues
- 2005:** Grange Castle's official opening
- 2009:** Grange Castle joins Pfizer

Site Overview

GC Vision

“Grange Castle will lead the world in Biotech Product Supply through competitiveness, flexibility and compliance.”



Drug Substance (ENBREL DS)

Utilities Building

Warehouse

Development

Suite 3:
Syringe Fill/
Finish
PREVENAR 13
MnB

Suite 1 & Suite 2:
Vaccine
Conjugation
PREVENAR 13

Admin

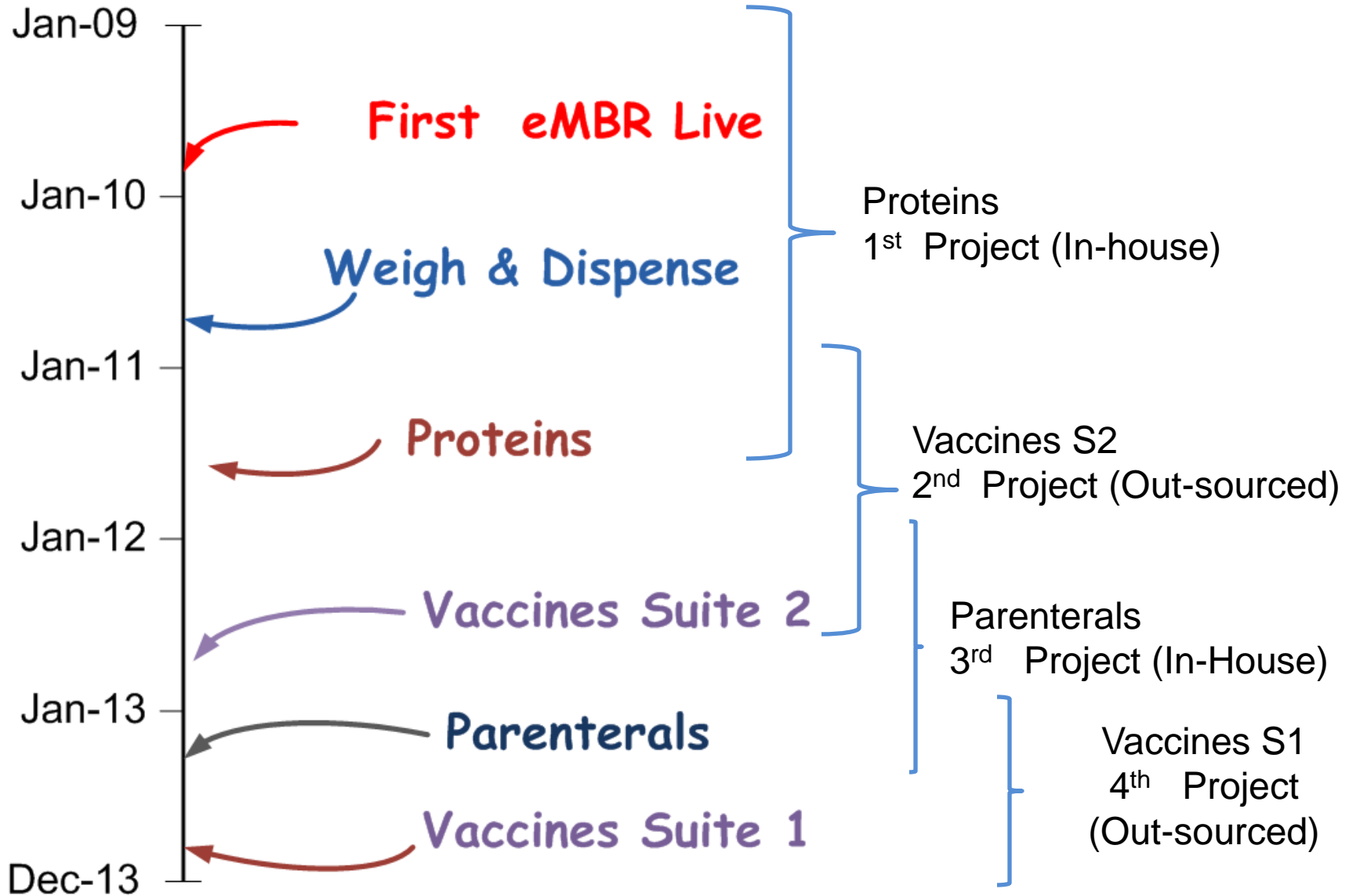
Quality Control Labs

Suite 4
(Pegylation/Conjugation)
SOMAVERT
&
Suite 5
(Multi-purpose Conjugation)
(CTM)

90-acre site • 1.1 million sq. ft buildings

- Scope of MES implementation at GC
 - Objective was to implement fully **paperless** batch recording and **Review by Exception**.
 - **Integration** with other systems:
 - **SAP** for Order Recipes, BOMs, material consumption etc.
 - **MCS** and **SCADA** controlled Equipment for batch load, GMP alarm recording & OPC Reads.
 - **LIMS** for recording of QC test results in eBR.
 - **bench top equipment** e.g. Scales, pH meters for reading of analytical results.
 - **PDOCS** – hyperlinks to SOP's.

Timeline of MES at G.C.

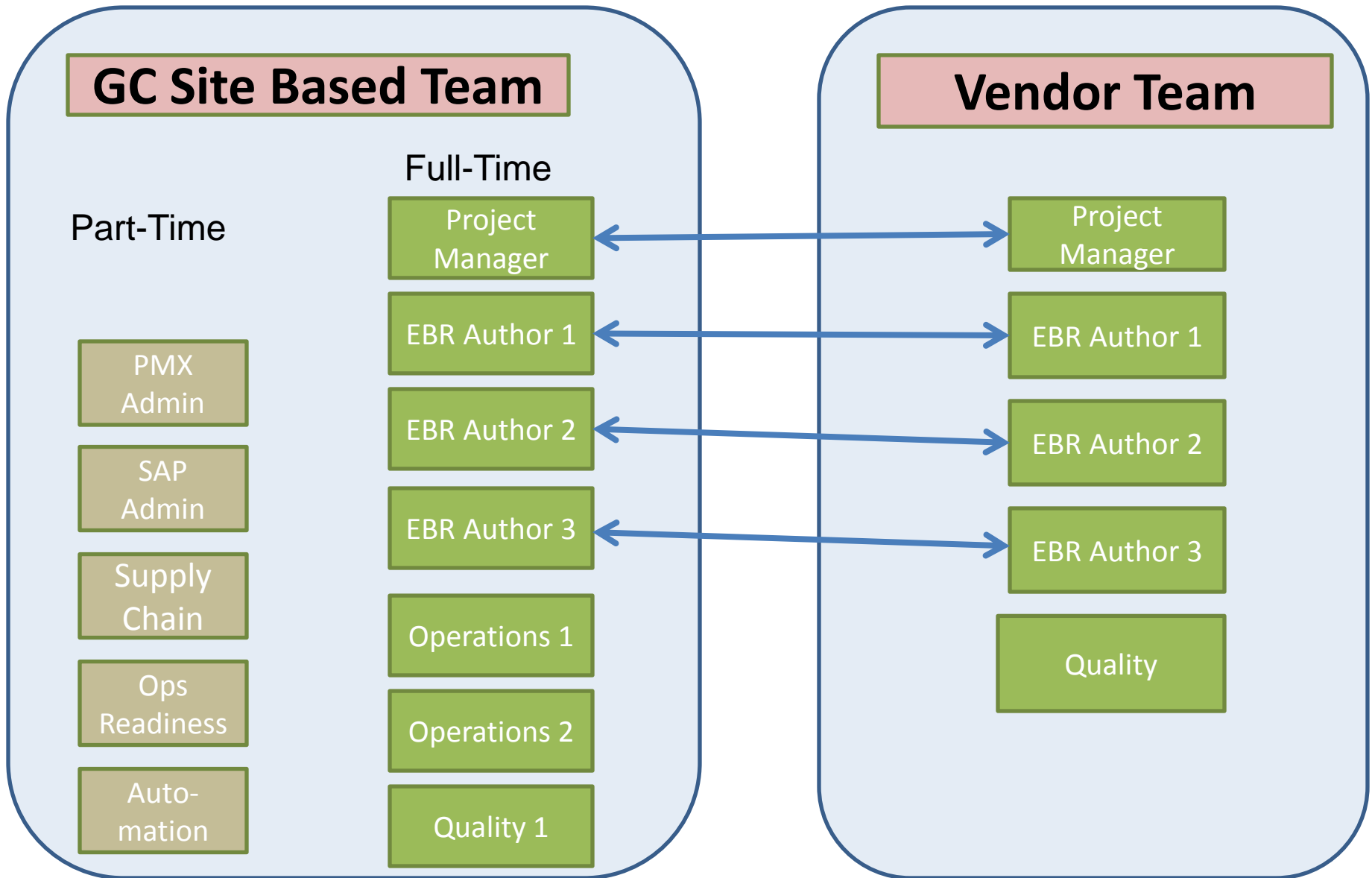


- **MES: PMX at GC.**
 - Wyeth/Pfizer Corporate MES solution
- **Scope of first project:**
 - Infrastructure and Application deployed and qualified.
 - pBRs replaced with eMBRs.
 - EQO's to replace primary equipment logbooks.
- **Large Project - completed in-house:**
 - Made use of MES Contract resources from automation companies.
 - Basis for further collaboration.

- In 2010 Pfizer committed \$200m investment to GC to expand Manufacturing Capacity at the Site.
 - Included construction of a new Vaccines Manufacturing Suite.
 - Transfer of processes from the USA to GC.
 - Decision was made to bring the Suite up on MES.

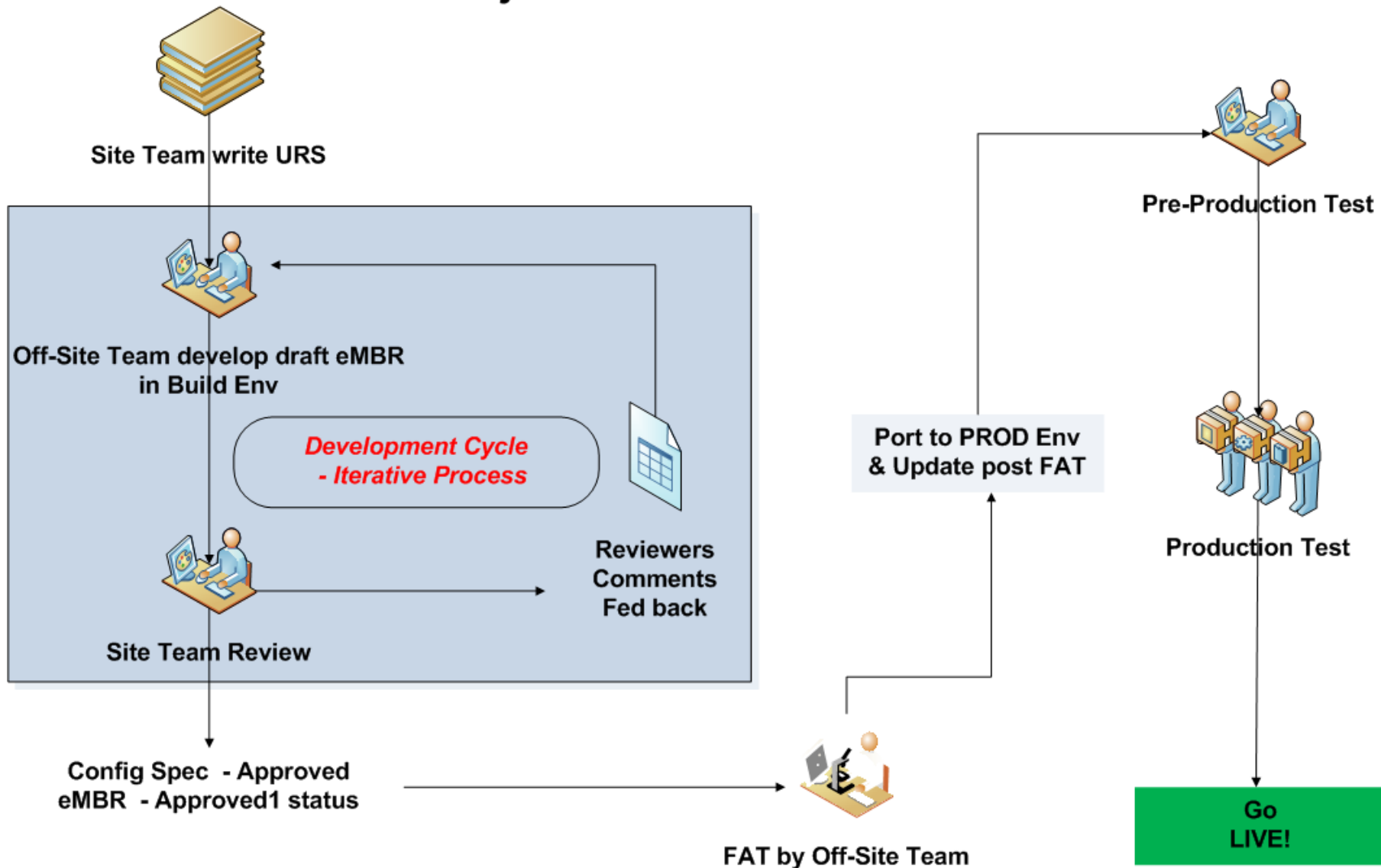
- Three Automation houses were requested to quote for a Fixed Price contract.
 - Requirements based on paper Batch Records
 - Bid based on their assessment of the work involved.
 - A preferred bidder was selected. Detailed negotiations led to an award of a contract.
 - Selection of bidder based on:
 - A good working relationship existed
 - Price
 - Location

Project Organisation



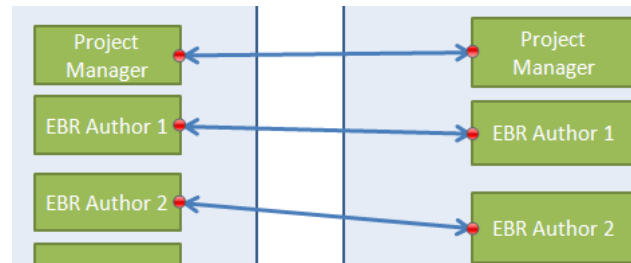
MBR Build Process

Project eMBR Build Process



- eMBRs went live in 2012
- Overall a successful project:
 - On time
 - Within budget
 - eMBRs were used for PV Batches for FDA Filing
 - Suite underwent a successful IMB Inspection in January.
- Provided valuable lessons to the Site on the outsourced model.

- GC did not provide Vendor with sufficient guidelines on Build requirements:
- Managing the iterative Build/Review process:



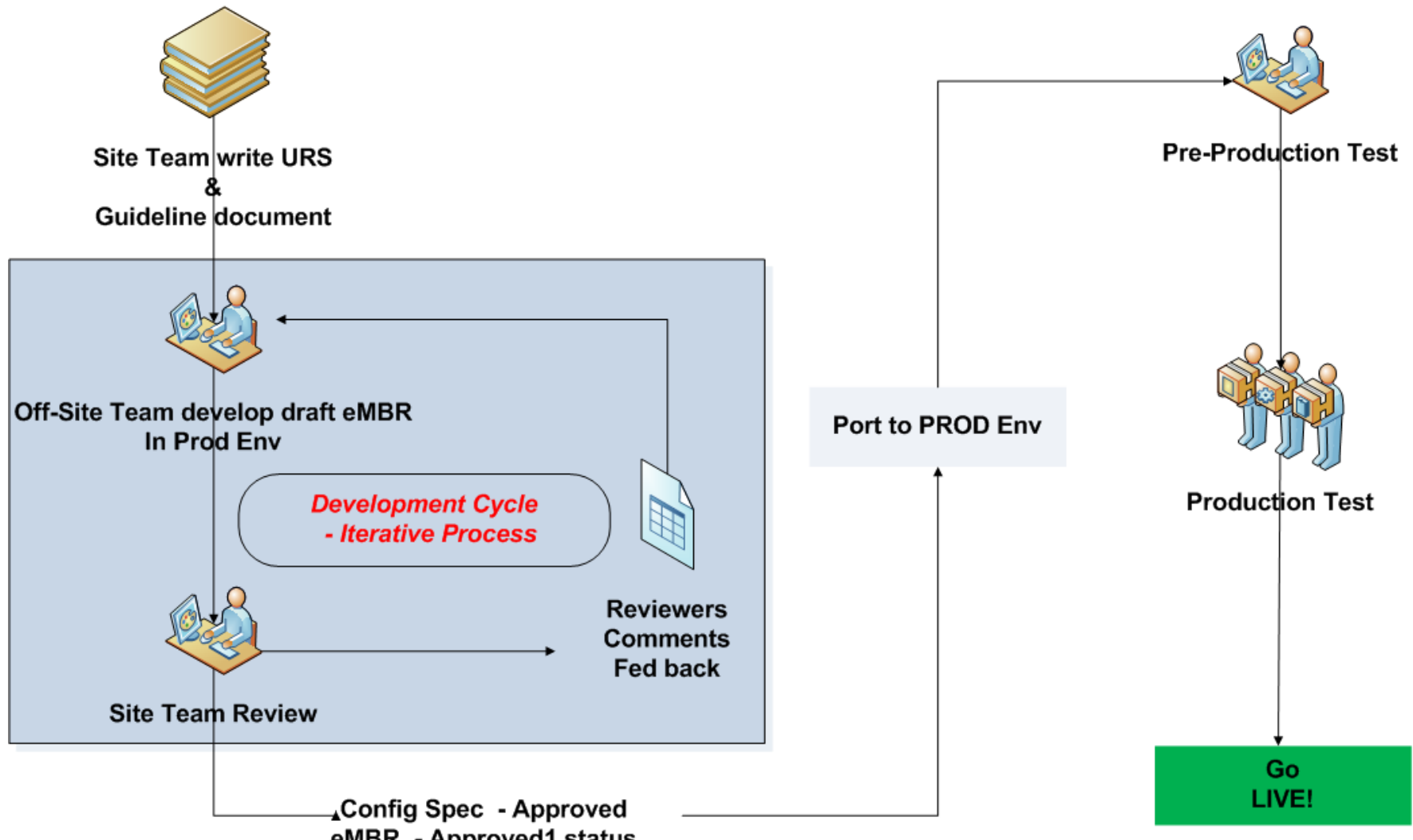
- Managing Scope Creep.
- Build Environment did not work well.

- In 2011 decision made to replace pBRs in existing Vaccines Suite with eMBRs.
- Same Vendor was asked to price this work:
 - Similar processes to first project.
 - First project was successful.
 - Possibility to leverage some of the First Build.
 - Relationship with Vendor had grown stronger.

- Changes to process made based on lessons learned from S2 implementation:
 - URS + Guideline Document.
 - Vendor given remote access to Prod Env.
 - Vendor eMBR Authors trained in Site Procedures.
 - Agreed the Vendor Authors who would do the Builds.
 - Used same team who had worked on first project.

Improved MBR Build Process

Streamlined Project eMBR Build Process



- eMBRs went Live in December 2013.
 - Completed in 12 months.
 - Most efficient deployment to date.
 - Excellent Project.
 - Feedback from End Users has been very positive.

- Using an Off-Site Team worked well for G.C.
- The Model improved over time:
 - Relationship with the Vendor is important.
 - Requires trust and co-operation on both sides.
 - Significant amount of work still done in-house:
 - Review and approval of designs
 - Updates post FAT/PPT.
 - Final testing (P.T.) and the Go-Live process.
- Further improvements possible.

Thank You.

THANK YOU!

QUESTIONS

