



PARTNER:



Pfizer

Grange Castle

MID-TERM REVIEW MEETING

Torino, 31 October 2013





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Grange Castle: 2000-Today



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



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Grange Castle – Site Statistics



Site Footprint 90-acre site; 1.1 million sq.ft. buildings:

Manufacturing Suites – 352,000 square feet
Drug Substance – 241,000 square feet
QA/QC/Admin – 186,000 square feet
Warehouse – 130,000 square feet
CUB – 119,806 square feet
Development – 74,000 square feet

14 Quality Control Laboratories Covering:

- Microbiology incl Grade D sterility test lab
- Microbial Identifications
- Chemistry/Biochemistry/Raw Materials
- Virology /Mycoplasma
- Cell Culture/Immunology/Bioassay/Potency
- TOC/Water Testing Lab
- Stability Storage
- Analytical Technologies
- Sample management lab

Markets and Geographic Areas Served:

Most major markets served including US, EU, Australia / NZ, Canada, Latin America, Middle East, Asia Pacific, Japan. China pending regulatory approval.



Major Technologies, Equipment and Capabilities:

Cell Culture Purification
Conjugation (vaccines)
Formulation
Lyophilisation
Aseptic Processing (Sterile syringe filling)

~ 1,000 Full-Time, Highly Committed and Flexible Colleagues

University/third-level educated: 95%
Masters and PhD: 20%
19 different nationalities





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**Drug
Substance
(ENBREL DS)**

**Utilities
Building**

Warehouse

Development

**Suite 3:
Syringe Fill/ Finish
PREVENAR 13
MnB**

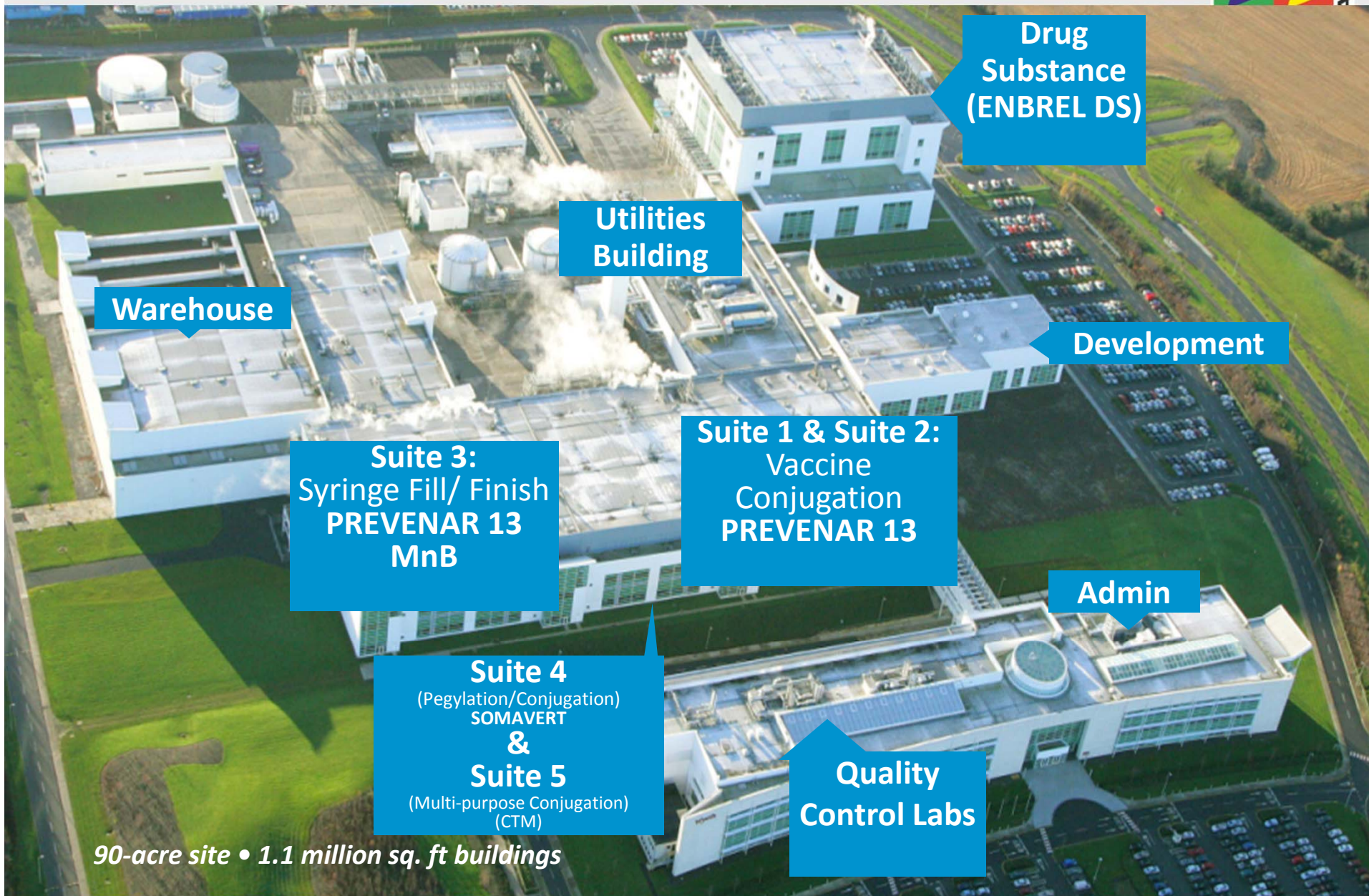
**Suite 1 & Suite 2:
Vaccine
Conjugation
PREVENAR 13**

Admin

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

**Quality
Control Labs**

90-acre site • 1.1 million sq. ft buildings





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People & Environmental Excellence



- A positive attitude, pride in our products and people engaged at all levels.
- Approximately 1,000 full-time colleagues.
- Male 55% • Female 45%
- University/ 3rd level educated: 95%
- Masters & PhD: 20%
- 19 different nationalities

Strong environmental performance year after year.

- 100% compliance: permits and licenses
- 84% non-hazardous waste recycling rate
- 55% reduction in hazardous waste
- 9.4% decrease in CO2 emissions
- 20% reduction in water usage



In 2012, Grange Castle won the prestigious Chemical & Pharmaceutical Manufacturers Safety Award.

This safety award celebrates excellence in occupational health & safety management practices & encourages best practice amongst organizations & individuals.



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GC Vision Statement:

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

At Pfizer we care about:

- High Quality Products (Patient Safety)
- Safe systems of Work (Employee and Environmental Safety)
- Cost Effective Manufacturing:
 - High Equipment Availability - OEE
 - Maximising batch yield
 - Right first time – no deviations, no rework
- We are a **highly regulated** operation, mistakes lead to lost output, additional cost, adverse regulatory attention – and if undetected, **potential patient harm**.





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Research Team:

ER: Doytchin Doytchev Mar 2013 -

ESR: Darren McDonnell May 2013 -

Supervisors:

Peter Mulvey (Eng Manager)

Dermot O'Rourke (OE Lead)

James Cullen (Site EHS Lead)

Gene Russell (Site Reliability Lead)





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- Training and Research Opportunities
 - Reliability Engineering:
 - Predictive Maintenance
 - Quantitative determination of plant condition.
 - Impact of HOF on plant availability.
 - Organisational Design and Optimisation
 - Driving Culture Change – IIF
 - Communications Analysis
 - Impact of HOF on Product Quality
 - Analysis of QA event data
 - Assessment of CAPA effectiveness.





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- **Benefits**

- Develop and utilise HF expertise to further improve safety performance and productivity through improved risk assessment and management.
- Integrate HOF into organisational design, process design, production operations, quality management and maintenance management systems.

