

Creating capacity: Innovative solutions for the future of bioproduction

June 2017

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Vaccine market and technology **Evolution**

Vaccine market trends

Emerging markets taking the lead for established EPI vaccines. Developed markets focusing on vaccines for unmet clinical needs.



Single-use technologies and automated solutions gaining traction.

Influenza vaccine evolving from egg based to cell based (e.g. Flucelvax[®]/mammalian cell, Flublok[®]/insect cell).

Viral vector platforms emerging at the cross roads of immunotherapy in oncology and vaccines.

Reverse vaccinology in the design of next-generation vaccines will allow development of personalized vaccines.

Self-amplifying messenger RNA platform investigated by major pharma players: Merck, Sanofi and GSK.



Emergence of higher value therapeutic vaccines based on new technologies

Prophylactic vaccines

- Bacterial disease:
 - Diphtheria, pertussis, tetanus, pneumoccocal, Hib, meningoccocal, tuberculosis, clostridium difficile...
- Viral disease:

Measles, mumps, rubella, polio, influenza A&B, hepatitis A&B, rotavirus, HPV, JE, rabies...

- Parasitical disease: Malaria, leishmaniosis...
 - + combination

Therapeutic vaccines

- Cancer: breast, cervical, colorectal, lung,
- melanoma, prostate...
- Physiological disease (diabetes)
- Allergies (rhjnitis, food peanut, gluten...)
- Drug addiction (nicotine, cocaine)
- Cardiovascular diseases (hypertension...)
- Chronic infectious diseases: Hepatitis B and C,
- HIV, tuberculosis, clostridium difficile...
- Alzheimer
- Orphan diseases/autoimmune (sclerosis)

HIGHER PRICES / LOWER VOLUMES



Evolution of vaccine technology and pricing



Biomanufacturing Transformed

Why single-use technologies

Single-use technology enables regulatory/quality advances from facility design through validation and operations





Evolution of flexible capacity









Transformed **Flexibility**

Connected configurable biomanufacturing platform

- Process environment easily replicated (equipment and automation)
- Reduction in tech transfer requirements
- Multi-product flexibility
- Consistent liquid connections
- Uniform automation and control
- Remote monitoring and control
- Increased batch release efficiency
- Ease of validation
- Simplified training
- Streamlined operation





Automation

An integrated, centralized monitoring and control system enables you to optimize the performance of your bioprocessing equipment in real-time.





End-to-end vaccine manufacturing solutions



Single-Use Vaccine Manufacturing Case Studies

Product	Purpose	Cell Line	Bioreactor Scale/type	Registration
West Nile subunit vaccine	GMP Mfg. for client partner	S2 Insect cells	XDR-200 mammalian	IND filed
Yellow Fever Inactivated Virus vaccine	GMP Mfg. for Xcellerex product	Vero cells microcarriers	XDR-50 mammalian	IND filed
recombinant Protective Antigen (rPA)	DoD Accelerated Mfg. Contract	Pfenex pseudomonas bacteria	XDR-50 microbial	
Swine flu H1	DoD Accelerated Mfg. Contract	Pfenex pseudomonas bacteria	XDR-50 microbial	
Swine flu H1N1 VLP	GMP CMO contract	SF-9 Insect cells	XDR-1000	
Dengue soluble antigen 4 serotypes	GMP mfg. for clinical trials	Insect cells	XDR-200	IND filed



Transformed **Timelines**

KUBio[™] for mAbs - and coming soon: for vaccines!

A complete solution with cost and timeline defined upfront

KUBio video





Time to market compression

With a modular approach, facility and processing equipment can be developed concurrently saving significant time





Mitigating risk by delaying capital investment



~1.5 - 2 years to build... start as late as post Phase 3 when clinical development is guaranteed and efficacy is known

KUBio[™] is a turnkey cGMP-compliant process and facility solution for bioproduction that dramatically reduces time to market.

A complete solution for biomanufacturing with cost and timeline defined upfront

Configurable, pre-engineered solution.

Assembled, qualified and cGMP-ready within 18 months for mAbs (24 months envisaged for vaccines)

Prefabricated units constructed off site, transported and assembled on site

Site expansion or greenfield

Automation-integrated FlexFactory[™] processing platform

Project management, commissioning, qualification and training included





Customers Transformed

Enabling flexible, financially sound global biomanufacturing capacity





GE Enterprise solution: CMO

NEED	SOLUTION	GE ADVANTAGE
A fast-growing biotech startup needed a complete solution for biosimilars production in China, with multiproduct processing, rapid start up and financial consultation to help fund the investment.	GE addressed this need with a 4 x 2000 L KUBio™, Fast Trak services, and financing recommendations.	KUBio was (and is) the only offering in the marketplace that delivers fully functional cGMP biomanufacturing capacity worldwide in just 18 months.





§ Financial consultation





GE Enterprise solution: big biopharma

(ge)

NEED	SOLUTION	WHY GE
A top-five biopharma company is looking to enhance global capacity with a transplantable biologics production in China, for China.	GE 4 x 2000 L KUBio [™] , FlexFactory [™] production platform with integrated automation, Fast Trak services, and support in China with identical processes in other locations to improve tech transfer and development.	In addition to KUBio's unique concept and GE's deep process knowledge, GE also has a strong footprint and proven track record in China. Production environments can be replicated across the globe. The manufacturing facility in China will be operational in 18 months, well ahead of other buildings on the campus.
Speed to market	Q Local expertise: China	buildings on the cumpus.
Process development	Operator training	Complete biomanufacturing solution
Creating capacity: Innovative solutions for bioproduction Jul	y 11, 2017	23

GE Enterprise solution: innovator

NEED	SOLUTION	WHY GE
An emerging innovator in Asia has a mission to make healthcare more affordable in the region.	GE is addressing this need with a 4 x 2000 L KUBio™, FlexFactory™ production platform, Fast Trak services, and financial consultation. HIGHLIGHTS Complete biomanufacturing solution Process development O Local expertise: China Operator training	In addition to KUBio's unique nature The manufacturing facility in China will be operational in 18 months, well ahead of other buildings on the campus.



Coming soon...

KUBio™ for Vaccines

- BSL-2
- tailored for vaccine production requirements
- pre-engineered, configurable solution

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