

## Holly Springs Site Fact Sheet

### Location

Holly Springs Business Park  
475 Green Oaks Parkway  
Holly Springs, North Carolina, USA

### Description

The Holly Springs site is a US-based influenza vaccine production facility leveraging novel cell culture-based manufacturing technology as an alternative to traditional egg-based influenza vaccine production<sup>1</sup>. Once completed, the site is designed to provide 150 million adjuvanted doses of pandemic influenza vaccine within six months of declaration of an influenza pandemic.

Commercial output of seasonal flu vaccine and multiple Sandoz products from the fill finish facility is planned after expected licensure. Fifty million dose capacity of commercial production of seasonal flu vaccine from the bulk facility is planned after expected licensure. MF59 adjuvant\* production will be operational to support US and Global pandemic preparedness efforts.

A viral pilot plant addition is currently in start-up to provide process development and clinical manufacturing capability for pipeline products.

### Partnership with HHS

The Holly Springs facility is a result of a joint partnership between Novartis and the US Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS, BARDA), and the Office of the Assistant Secretary for Preparedness and Response. The facility is the first of its kind in the US and highlights an important milestone in efforts to bring new influenza vaccine manufacturing technology to the US.

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In June 2012, HHS awarded Novartis a contract under the HHS Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to aid in the development and manufacturing of medical countermeasures.

The contract underscores the Novartis partnership with the US Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS, BARDA) to protect the public from pandemic influenza and other health threats<sup>2</sup>. The

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contract support from HHS builds on the strategic investment made by Novartis in vaccine innovation, and reinforces the significant financial and technological investments already committed to the Holly Springs facility.

### Site

The Holly Springs site is comprised of six buildings connected by a central corridor, including bulk production, secondary production, viral pilot plant, warehousing, maintenance, quality control testing and office buildings. The manufacturing facility includes more than 475,000 gross square feet (44,130 square meters) of space and the site consists of 185 acres (75 hectare), of which approximately 67 acres (27 hectare) have been cleared for the current phase of construction.

- **The buildings will range in height** from 30 to >90 feet (9 to >30 meters)
- **>6,000 tons of structural steel** was used to build the facility (5,500 metric tons)
- **There are >8,000** total process automation Input/Output points
- **The site has to undergo** >160 validation and commissioning plans
- **There are >85 factory acceptance tests (FATs)**, >165 FAT protocols, >400 commissioning protocols and >650 qualification protocols required to start-up the facility
- **Approximate capital costs** of \$650 million (excluding capitalized expenses)

### Employment/Hiring

The site is projected to provide 550 highly skilled jobs when fully operational. Currently, ~450 full time associates are employed at the site. To date, 75% of associates have been local hires, 21% have relocated to Holly Springs and 4% have transferred from within Novartis. Novartis is a partner with North Carolina State University's Biotechnology Education Center (BTEC) program BioNetwork's community college program, and multiple other university programs across the country to build a source of talent for future positions.

75% of the associates at the Holly Spring site have been local hires.

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## Construction

The original groundbreaking of the site took place in August 2007.

- **Peak construction staff** was >800 craftspeople
- **>20 miles of pipes (32km) and >750 tons of ductwork (680 metric ton)** will have been installed upon completion
- **More than 100 local construction companies**, as well as numerous material and equipment suppliers, have been involved
- **Plant commissioning/qualification, validation, initial runs, FDA approval/licensing** to occur between now through expected licensure

The groundbreaking of the new TD lab and pilot plant to support the viral target vaccines portfolio took place in February 2011.

## References

1. Gregersen, Jens-Peter. "A Quantitative Risk Assessment of Exposure to Adventitious Agents in a Cell Culture-derived Subunit Influenza Vaccine." *Vaccine* 26 (2008): 3332-340.
2. US Department of Health & Human Services. "HHS creates new centers to develop, manufacture medical countermeasures." June 18, 2012. Available at: <http://www.hhs.gov/news/press/2012pres/06/20120618a.html>. Accessed October 3, 2012.