



Manufacturing Flu vaccine in Mexico:

a major Public Health & Technology Transfer challenge



Roger Vinas - Vaccine Technology III - June 2010

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Agenda



1. Flu vaccine, made in Mexico:
 - 1.1 The Mexican Public Health stakes
 - 1.2 The Technology Transfer challenge
 - 1.3 Project status

2. Vaccine Technology Transfer to Mexico; Key points to consider:
 - 2.1 Methodology & Guidelines
 - 2.2 Administrative procedures / steps
 - 2.3 Partnering for Engineering & Construction
 - 2.4 Staffing Project & future Manufacturing operations

3. Conclusion / Headlights

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1. Flu vaccine, made in Mexico:



■ 1.1 The Mexican Public Health stakes:



Producing Flu Vaccine on its own territory will lead Mexico to be part of the few auto-sufficient countries worldwide, for seasonal Flu, as well as in case of Pandemic outbreak



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1. Flu vaccine, made in Mexico:



■ 1.2 The Technology Transfer challenge:

Starting grass-roots , to build a Vaccine plant to produce Influenza antigens in Ocoyoacac, Mexico state.

Seasonal Flu Vaccine should be available for Mexican population on 2012

■ Technology Transfer from France to Mexico:

- 100 M€ Capital Expenditures
- 5,000 m2 floor area on a 5ha. land (cornfield)
- 100 new positions created (direct jobs)

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1. Flu vaccine, made in Mexico:



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1. Flu vaccine, made in Mexico:



■ 1.3 Project status:



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2. Vaccine Technology Transfer: Key points to consider



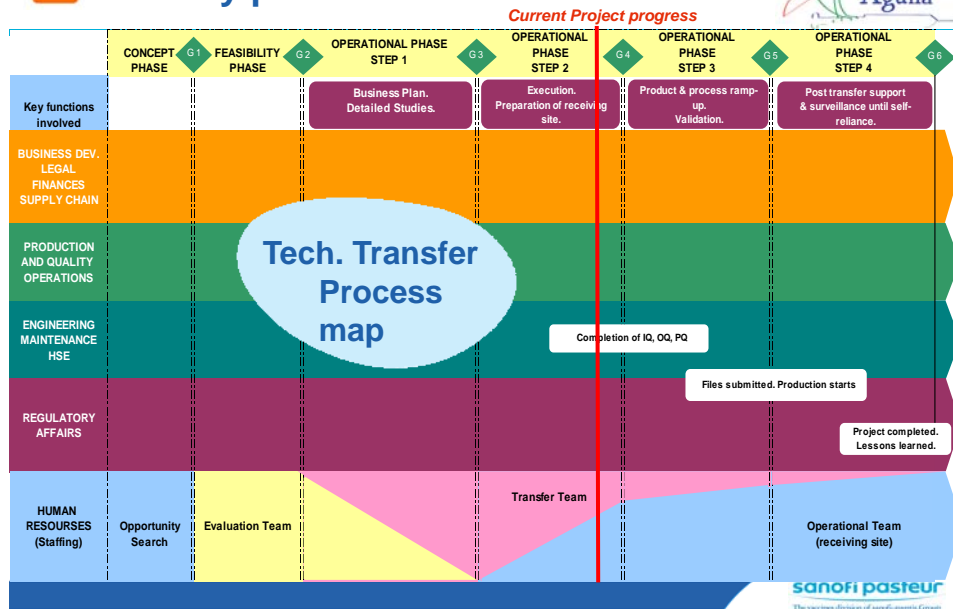
2.1 Methodology & Guidelines:

2.1.1 Technology Transfer Definition

- A Technology Transfer manufacturing process of a product from the transferring site to the receiving site. This includes all the associated knowledge, information and skills to be able to manufacture the product at the receiving site in compliance with approved dossiers and with same or better safety and potency than the sending unit
- Technology transfer embodies both the transfer of documentation and the demonstrated ability of a Receiving Site to effectively perform the critical elements of transferred technology, to the satisfaction of all parties and any, or all, applicable regulatory bodies.



2. Vaccine Technology Transfer: Key points to consider





2. Vaccine Technology Transfer to Mexico: Key points to consider



■ 2.2 Administrative procedures/steps:

- In order to get all permits, legal & Regulatory authorizations, access to energies, ..., in due time, the country specificities & administrations organizations should be known & relations should be managed accordingly.

- A good address book is a key success factor/leverage

- As an example, for a building permit in Mexico, one should follow thoroughly the entire pathway, considering 3 steps:
 - Municipality
 - State
 - Federal authorities

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2. Vaccine Technology Transfer: Key points to consider



■ 2.3 Partnering for Engineering & Construction:

- To assess which Engineering companies have enough background & experience, with respect to the activity to be created; in this case, Bio-pharmaceutical Industry.

- To check if the potential Engineering partners have experienced implementation of "big projects" while working with local contractors, in this case, Mexican / Latin America companies

- To check, as well, the robustness of Safety Policy, Program & Tools proposed by the Engineering companies

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2. Vaccine Technology Transfer: Key points to consider



■ 2.4 Staffing Project & Future Manufacturing Operations:

- To involve, from start, all contributive functions:
 - At Sending & Receiving Sites
 - Global Supportive functions: Business Development, Supply Chain, Finance, Legal, Quality, Regulatory,

- To build, from start, a long-term staffing plan, including Transfer Team & Operational Team, considering overlaps between both

- To anticipate on recruitments and always consider teamwork skills & behavior as a discriminating criteria

- To ensure that key people from the Transfer Team will stay until receiving Site self-reliance

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3. Conclusion / Headlights (1/2)



■ ***“As Health partner of Mexican Public authorities initiative, Sanofi Pasteur is committed to build a Flu Vaccine Site, on Mexican soil, in order for this country to be self-sufficient, for seasonal vaccination campaigns, as well as in case of Flu Pandemic event”***

- **Commitment & enthusiasm from receiving Country, Authorities and People is a key leverage to fulfill and respect Project objective**

- **Another Key Success Factor is to comprehend the specificities, culture, behaviors of the host Country and to adapt accordingly**

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3. Conclusion / Headlights (2/2)

- Overall, the Key Success Factor is:

Partnership, Partnership, Partnership, ...



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L'essentiel c'est la santé.

**Mexican Health
Authorities
+ Birmex**

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