Overview of BCHT and Update to LAIV Project

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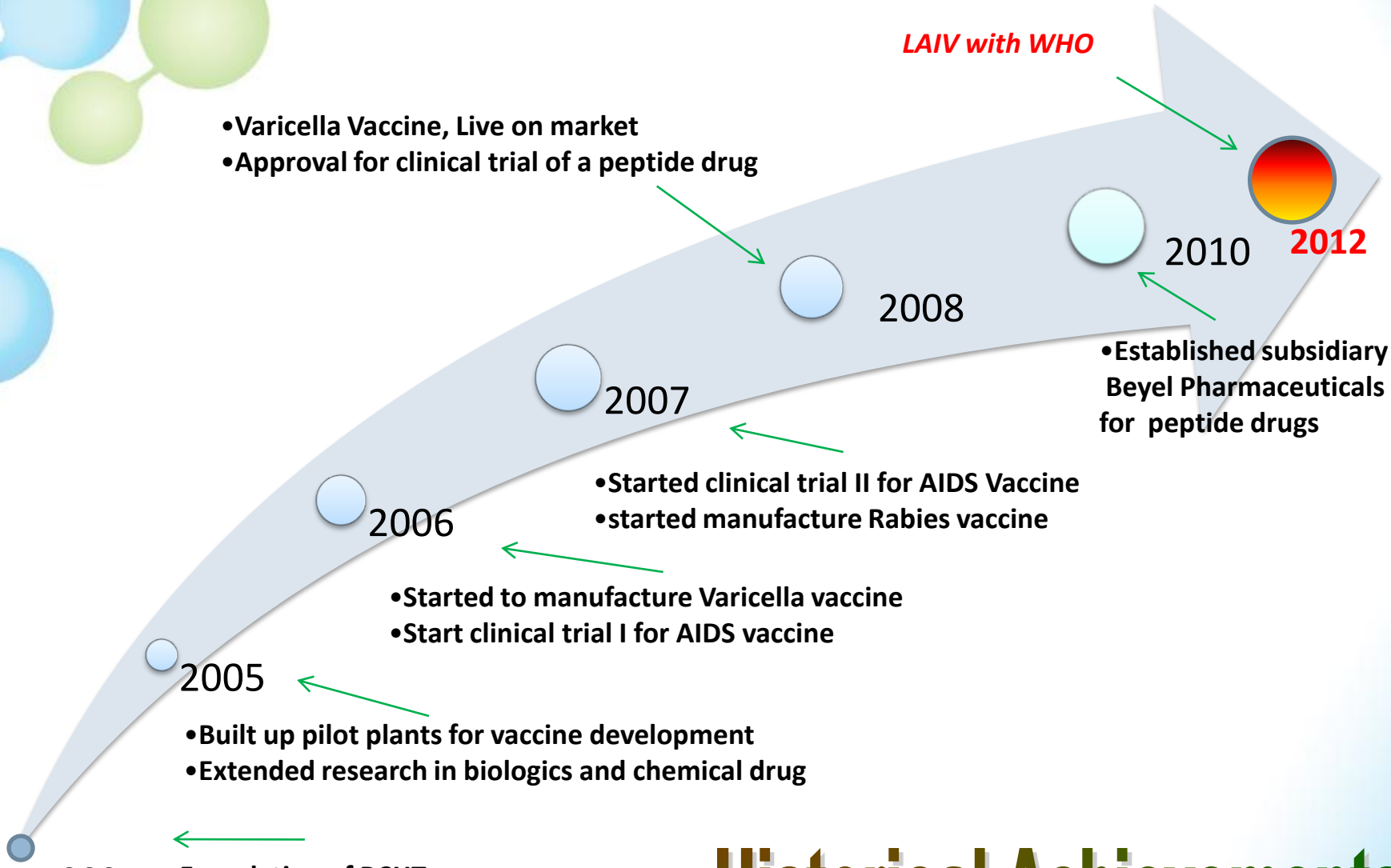
Changchun BCHT Overviews

- Established in March 2004 at Changchun High-tech Zone, Jilin Province, Northeast China
- Research, development, production and marketing of vaccines, biologics and peptide & chemical drugs
- More than 600 scientists, technicians and supporting staffs
- Three manufacturing plants and advanced R&D facilities
- Two vaccines on the market
- One peptide drug in clinical trial and with strong product pipeline
- Full domestic marketing organization and international cooperation

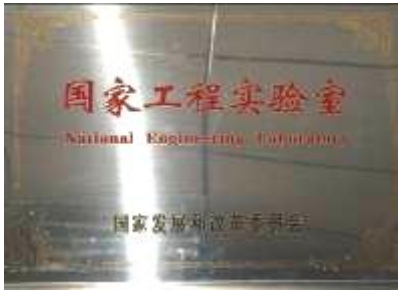
Historical Achievements

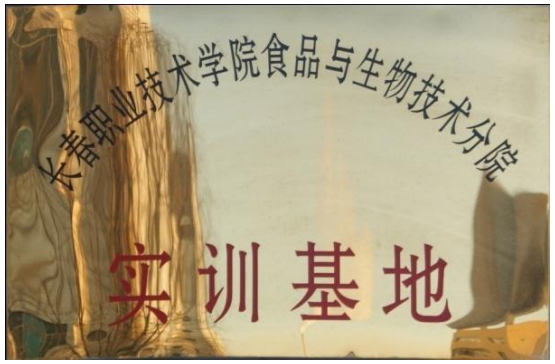


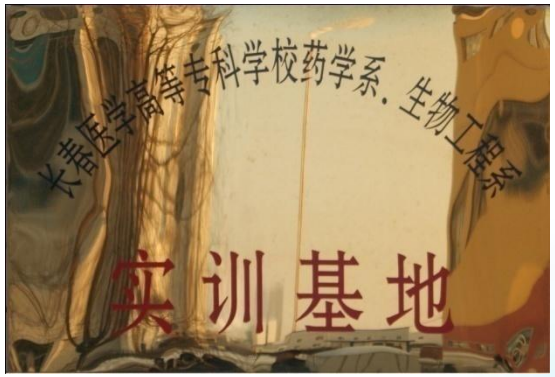
Joint Research Programs with University & Institutes

State Engineering Laboratory for AIDS Vaccine

BCHT and Jilin University







Product Quality Assurance and Control

Audit all suppliers and verified and certificated by QC all materials before use

Bacterium and virus seeds are strictly carried out by three tiers seeds batch administration and the same as for cell bank

Monitor environment and water for production at regular intervals

Verify the equipments, factory facilities and production process at regular intervals

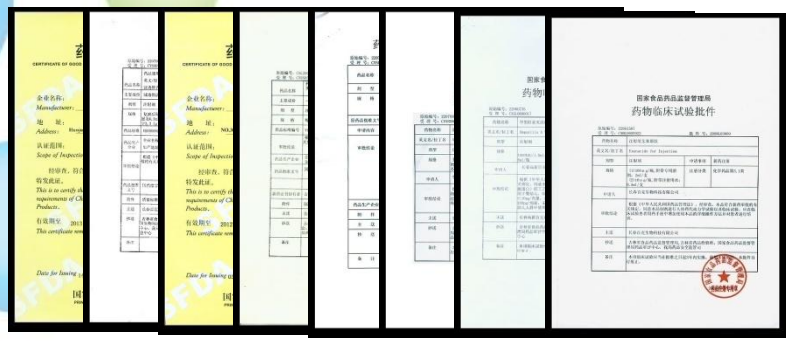
Manufacture products strictly under GMP compliance and control the whole production process on three levels

Equip the most advanced analytical, test product quality by verified methods to guarantee accurate data from the test, follow SFDA regular for batch certificate.

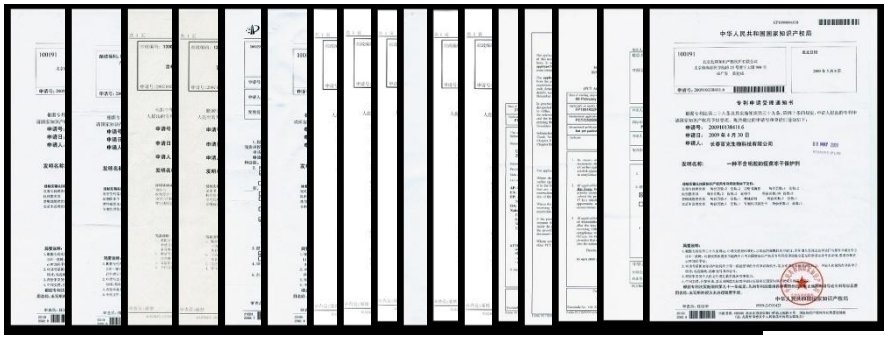
Follow strictly state's regular to provide all the detailed data in the cold chain in transport from factory to the delivery terminal, ensuring quality control of the product in logistic.

Establish the completed and efficient system for warning and handling adverse reaction events. An emergency committee headed by President and consist of assigned staffs has been set.

Approvals of Clinical Trail and Production

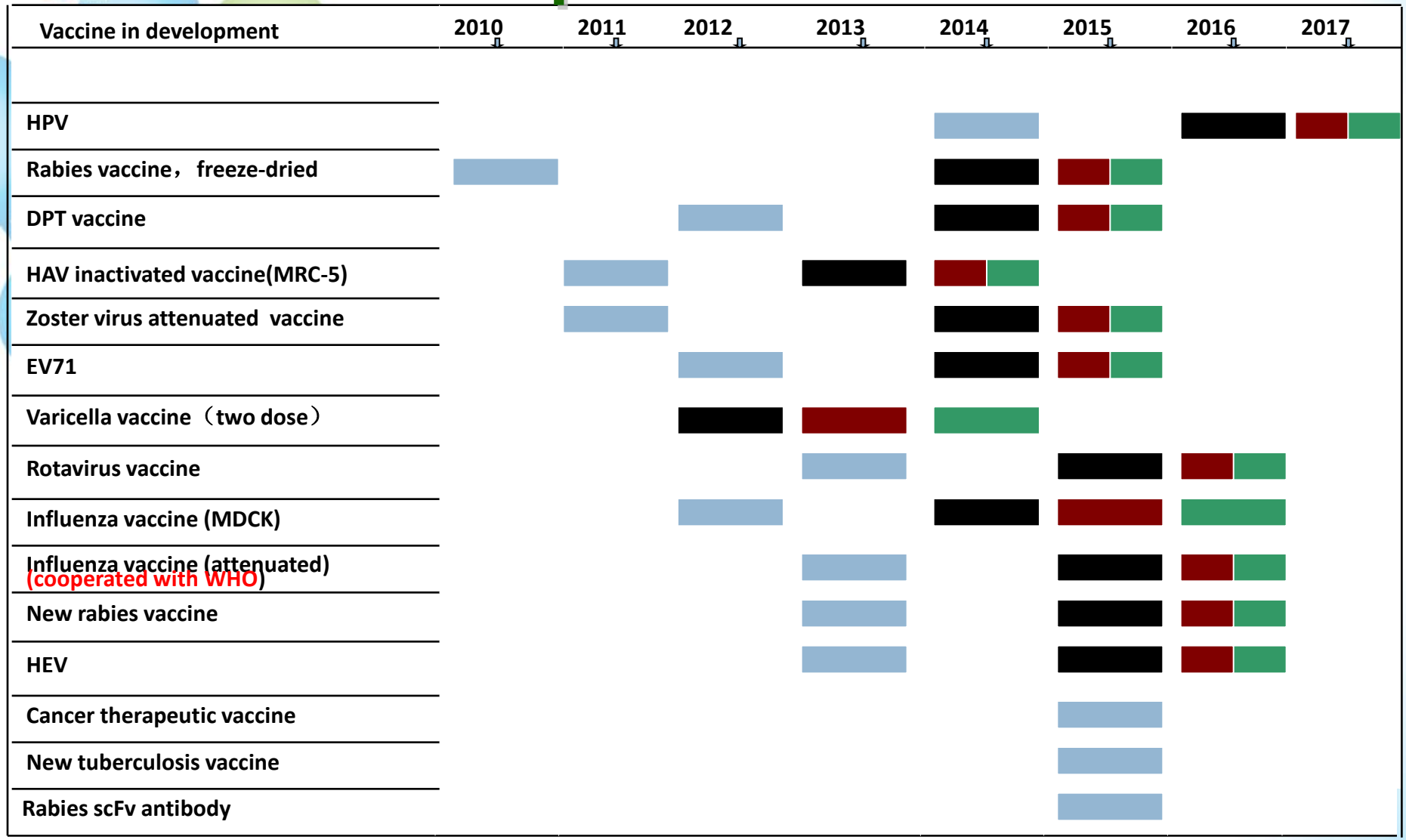


Patents



Certificate of state and province projects

Pipeline of R&D



Why Influenza Vaccine LAIV

- **Social benefits**

  In China, only a very small portion of population vaccinated (<5%)
- **Market potentiality**
- **LAIV features with lower production cost and shorter time for mass production in pandemic outbreak**
- **Unique inoculation via Intranasal procedure**
- **BCHT is in a fast-growing phase**

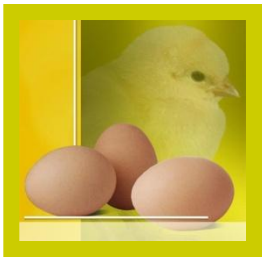
Accomplished Tasks

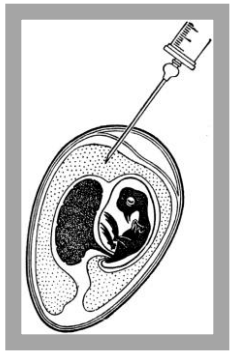
- Tech-transfer from IEM, Russia
- Master and Working Seed virus built up
- Production process optimized
- Analytical methods established
- IND samples prepared
- IND application documents in finalizing
- Facility design (CD and BoD completed and DD under review)
- Facility construction

Production Process

H1N1 / H3N2 / B strain

innoculation





harvest

AF

UF/DF

Monovalent

Pooling

Trivalent

Lyophilization

Final product

Key development:

- Egg disinfection
- Sterile operation
- Phenotypical study
- ID test
- Infection titer testing
- Exogenous factor detection
- Liquid formulation development

Infection Titer Testing of Monovalent and Trivalent

Samples	Antiserum	Infection titer $LogEID_{50}/0.5ml$
H1N1	-	7.1
H1N1	Anti H3+B	7
Trivalent	Anti H3+B	7
H3N2	-	6.7
H3N2	Anti H1+B	5.9
Trivalent	Anti H1+B	6.3
B	-	6.9
B	Anti H1+H3	7
Trivalent	Anti H1+H3	7

Short Term and Long Term Development Plan

- IND filing (April, 2013)
- Site inspection by local SFDA (June, 2013)
- Production process optimization (end 2013)
- Finish pre-clinical (Ferret) studies (mid 2013)
- Complete facility construction (end 2013)
- Purchase and install of production equipments (end 2013)
- Market the vaccine by the end of 2016

Lessons and Challenges

- Import of strains
- Titer of virus test
- Egg supply
- Stabilizer and freeze drying cycle
- Spray device
- Preclinical study (efficacy and toxicity studies)
- Clinical trial (HAI, MN, IgG , IgA , CD4+ and CD8+)
- SFDA approval with non-correlated data of immunological markers for efficacy and limited subjects in the trial
- GMP compliance by SFDA and pre-qualification by WHO


BCHT

Thank you !
谢谢！

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