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## Pneumococcal inactivated whole cell vaccine: Development of the production process

Viviane Maimoni Goncalves  
Instituto Butantan, Brazil

Current pneumococcal vaccines are based on the protection offered by capsular polysaccharides (PS). However, there are more than 90 pneumococcal serotypes described, each one corresponding to a chemically and immunologically distinct PS. While 23-valent PS vaccine confers broader coverage for serotypes related to invasive diseases but it is not effective in children, 10 or 13-valent conjugate vaccines are highly effective in children, but offer limited coverage of serotypes, which led to serotype replacement in the population. The pneumococcal whole cell vaccine is a low cost strategy based on non capsular antigens common to all strains, which induce serotype independent immunity. Therefore, we developed the production process for this cellular inactivated vaccine. Initially, cultivation was performed in 60-L bioreactors and the consistency of the production process was demonstrated, as evaluated by growth curves, glucose consumption and lactate and acetate formation. Cells were recovered by tangential filtration and the conditions for inactivation with beta propiolactone (BPL) were optimized. BPL was hydrolyzed after pneumococci inactivation by heating. The criteria and methods for quality control were defined. Vaccine lots displayed high potency, inducing between 80 and 90% survival in immunized mice when challenged with virulent pneumococci and were stable for up to 18 months based upon survival assays following I.P. challenge. As a whole, our results demonstrate the feasibility of production of this vaccine, which would represent an economical alternative for developing countries and should provide serotype independent protection.

### Biography

Viviane Maimoni Goncalves has completed her PhD in Biochemical Pharmaceutical Technology at University of São Paulo in 2001 and Postdoctoral studies at Pasteur Institute, Paris, France, in 2005. Since 1993, she has been working as a Scientific Researcher at Centro de Biotecnologia of Instituto Butantan, a public organization that is one of the main vaccine producers in Brazil. She has published more than 25 papers in reputed journals and supervised 7 graduate and PhD students. She has expertise in process development of vaccines and biopharmaceutical products.

[viviane.goncalves@butantan.gov.br](mailto:viviane.goncalves@butantan.gov.br)

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