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Process development for pneumococcal protein vaccines based on recombinant pneumococcal surface protein A (PspA) and hybrids of PspA and pneumolysin toxoid

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Pneumococcal proteins have been studied as alternative to polysaccharide based vaccines. PspA is one of the most promising vaccine candidates. Several studies showed protection after immunization with N-terminal fragments of PspA in different animal models and human anti-PspA antibodies were able to protect animals through passive immunization. This protein is present in all pneumococcal isolates and is classified in three families and six clades, according to the homology of amino acid sequences, but some PspAs can induce antibodies that cross react with proteins from all clades. Another protein recognized as important pneumococcal antigen and virulence factor is pneumolysin, an intracellular toxin released during infection, promoting lysis of host cells by cholesterol mediated pore formation. We developed a purification process for a recombinant N-terminal fragment of PspA from clade 4 (PspA4Pro), which was previously reported to induce broadly cross reactive antibodies. PspA4Pro was obtained without any fusion tag in the soluble fraction of *Escherichia coli* and the purification process resulted in good recovery (>35%) and high purity (>95%). It was shown that a genetic fusion between PspA and a genetically detoxified pneumolysin, called PdT, improved the immune response in comparison to the simple mixture of proteins. However, the hybrid without linker was unstable and could not be purified to a high purity due to the cleavage. Therefore, a hybrid was obtained with proteins separated by a molecular linker that forms an alpha helix. This linker improved the molecule stability, allowing purification and further studies are being conducted to optimize the production process.

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.

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