ADJUVANT MANUFACTURING SCALE-UP AND TECHNOLOGY TRANSFER

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Strategies to increase the availability of cGMP adjuvant formulations for emerging and re-emerging infectious diseases comprise an essential component of global pandemic preparedness. We have focused on two approaches to increase global adjuvant supply and build local capacity: (1) scale-up of our cGMP adjuvant manufacturing capacity through equipment and process improvements, and (2) technology transfer of adjuvant manufacturing know-how to developing countries. Regarding manufacturing scale-up, we have increased our cGMP oil-in-water emulsion adjuvant manufacturing capacity from 2K doses/batch to 5M doses/batch by upgrading processing equipment and implementing innovative process efficiency improvements. We demonstrate this new capacity by manufacturing proof-of-concept batches of emulsion at the 5M dose scale and demonstrating acceptable particle size, emulsion component concentrations, pH, osmolality, and visual appearance. Regarding technology transfer, we highlight our local capacity building efforts in India, Romania, and South Africa, resulting in successful local production of adjuvant formulations and, in the case of India, Phase 1 clinical testing of the manufactured material as a component of a malaria vaccine [1-3]. Together, these efforts have enabled enhanced global adjuvant manufacturing capability, facilitating local capacity building and increased pandemic preparedness.

References

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