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Gloveless robotic technologies in aseptic manufacturing for high potent active pharma ingredients

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One of the most problematic issues of the aseptic manufacturing is the involvement of the personnel. Human being is generating every minute million of particles and some of them are biologically active and might generate a product contamination. Now the technology can help us in removing from the aseptic manufacturing equation the human being and the relevant impact in the sterility of the product. Stainless Steel GMP robotic arms have been introduced to handle fill finish operation within a gloveless isolator. The advantage of this solution, apart from sterility improvement, is the possibility to handle High Potent Active Pharmaceutical Ingredients (HPAPI) like cytotoxic drugs. The presentation will go through all the main features of this gloveless robotic solution.

Biography

Sergio Mauri is holding a Chemical Engineering degree and involved in Clean Room technologies since 1980. At present he is in charge of the Integrated Projects Business Unit at Fedegari Group, dealing with the design and the supply of new solutions for the sterile drug manufacturing including GMP robotics. Scientific Technical Association activities: member of the board of the Italian association of contamination control ASCCA (www.ascca.net) since 1986, President of ASCCA 1998-2000, ISPE member since 2001. At present ASCCA vice president. He is also a Promoter and responsible of the training course on "General introduction on Clean Room technology, isolation concepts and critical parameters definition". He is also a Trainer on pharmaceutical HVAC design at La Sapienza University (Roma) for students of chemical and pharmaceutical technology. Author of several papers on clean technologies and experienced giving training lectures to AIFA GMP Italian inspectors.

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