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Identification of bacteria in a Vaccine production

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Production of vaccines requires an intense program of testing. In the microbiological field testing is done by analyzing raw material samples, production water samples, in-process samples, final product samples and testing of the environment where the production takes places, e.g. environmental monitoring.

The requirements for all these testing are found in pharmacopeias (e.g. the European Pharmacopeia, the United States Pharmacopeia and the Japanese Pharmacopeia), and in guidelines (e.g. EU-GMP, Annex 1, USP <1116>, FDA Guideline for Aseptic Processing) and standards (ISO 14644 and ISO 14968).

The limits for allowed microbiological contamination in all the production steps are strictly regulated and when microbiological isolates are found the identification is necessary to find the root cause and if needed, "to track" isolates found in different parts of the production cycle.

The presentation will give an introduction to how identification of bacteria in a vaccine production can be performed for this purpose.

Biography

Lene Blicher Olesen was educated engineer of chemistry in 1996. Since 1997 she has worked in the field of microbiology, as manager and latest as director (since 2009) for the Quality Control department responsible for the analysis of Raw Materials, WFI, Packaging Materials, Microbiology and Clean rooms associated to the vaccine production at Statens Serum Institut in Copenhagen, Denmark. She is also expert in 3 working groups under ISO TC 209, concerning microbiological and particulate testing of clean rooms.

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