



Marcela Rodríguez

Laboratorios SFC, Colombia

Technics validation of microbiological quality control in pharmaceutical industries: Study of Colombian challenge

Statement of the Problem: As happened in the entire world, Colombia's pharmaceutical industries had been one of the most regulated economic sectors, which has been good because of the development in the industries giving more dynamics and reaching important levels in quality control. One year ago, INVIMA, the government entity in charge of food and drug regulation, published a legal requirement in which all quality control laboratory has to implement GLPs, (good laboratory practices). With this requirement, laboratories began to define processes that assure the quality of their results. GLPs established necessity to study and formalize the microbiologist quality control, this is the opportunity to validate techniques and show the media the real role of microbiologist in the pharmaceutical industries.

Findings: The first step was to understand the principal techniques to validate, with the difference that we are talking about organisms; the approach was to physiochemical analysis and those not given all the answer to begin the validation process. We understood that is very important to validate techniques, that the microbiologist should know the pharmaceutical product since its manufacturing development and even the most important raw materials characteristics; it has been critic to eliminate possible interferences. Another important point (for me the most) is the inoculum standardization; in this process is very important to know the microorganism and its life cycle, if you do not know how it works, it is possible that you say it is an inhibition because you do not recover the exact quantity of inoculum.

Conclusion: The inoculum standardization is the base of techniques validation and giving key information to show the robustness, uncertainty and others important attributes, when you give a result in a microbiological test, like microbiologists, we have a challenge to show how all of this is critical in the pharmaceutical quality.

Biography

Marcela Rodríguez is an Industrial Microbiologist, specialist in Quality Management. She has her expertise in Quality Control in pharmaceutical industries, specifically in microbiology lab. Early, she has investigated in Bioremediation of oily sludge, one of the most important environment problems in oil and gas industries in Colombia. Currently, she has worked like consultant of different pharmaceutical enterprises in Colombia, supporting the implementation of good laboratory practices and accreditation of microbiological analysis techniques as well as in the training of auditors of regulatory entities of the pharmaceutical sector in Colombia. She has worked for more than 15 years in the Colombian pharmaceutical industries.

domarva@hotmail.com