

# 3<sup>rd</sup> International Summit on **GMP, GCP & Quality Control**

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## Current directions for process validation according FDA and EMA

EMA published the EU GMP Annex 15 on “Qualification and Validation (Feb 2014) and the revision of its process validation guideline (Feb 2014): Guideline on process validation for finished products-information and data to be provided in regulatory submissions, (effective on Aug 2014), with the objective of integrate modern GMP aspects in the guideline:

- Harmonization with the current FDA Guidance on Process Validation.
- Introduction of a validation lifecycle and continued process verification, thus Integration with the ICH Q8, Q9 and Q10 Guidelines
- Incorporation of Process Analytical Technology (PAT), Quality by Design (QbD) and Real Time Release Testing (RTRT).
- Integration of the Annexes to the current Note for Guidance

Both agencies addressed a new direction in validation: Validation is now a Life Cycle Process. The focus is on process knowledge and process understanding. Both should be a result of development and verified in routine production. Some aspects and the possibilities for implementation are under discussion

- What disciplines are needed to fulfill new requirements?
- New guidelines are good but, let's talk about unmatched needs. Are our Quality systems aligned to the new expectations?
- Is the eCTD good enough to present new data?
- Are inspectors ready to evaluate new data?
- Are our Quality Units experienced enough and trained to oversight operations performing under new standards?
- How to practically start working on Knowledge management?

## Biography

Victor Sanchez, a Chemist, holds an MBA in Industrial Management from the Inter American University of Puerto Rico and a Postgraduate Diploma in Pharmaceutical Validation Technology from the Dublin Institute of Technology, Ireland. Victor is the President of European Operations for Pharma-Bio Serv, a consulting service company which provides on-site support and training to FDA and EMA regulated industries. Sanchez's has comprehensive management experience in Quality Systems, Compliance, Quality Control, Validation and Manufacturing Operations. He holds an outstanding career track record of improving compliance, quality, efficiency, efficacy and maximization of manpower through continuous process improvement. His expertise focuses in the areas of: manufacturing and quality operations, analytical method development and validation, analytical problem solving, process validation, GMP quality systems, and regulatory affairs and compliance. Prior to joining Pharma-Bio Serv in 2011, Victor spent seventeen (17) years in different senior positions. His previous roles includes Director of Operations for OSD, LOCM, and Transdermal patches, at MSD, Madrid, Spain; Manager of Analytical Support Laboratory at the same MSD site. Manager of QC Validations, at Schering-Plough, Puerto Rico where he was responsible to fulfill the QC site commitments during the Schering-Plough Consent Decree. Victor, based in Spain, teaches compliance disciplines, such as process validation, cleaning validation, QRM, and QbD, in different institutions as the CESIF and CEU-San Pablo, Pharmaceutical Industry Master's Programs from recognized Spanish institutions and the University of Barcelona-IL3, a continuous educational program. He also trains groups in technical writing and root cause analysis. Victor is Kepner-Tregoe PSDM Certified and a PR Licensed Chemist. He is a RAPS, PDA and ISPE active member.

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