Andrea Simonetti

Indipendent Pharmaceutical Advisor

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Biography:

Andrea Simonetti received the MS degree and the PhD degree in electronic engineering from the University of Ferrara, Italy. In his career he has successfully led large scale commissioning, validation and quality projects for worldwide major pharmaceutical regulated companies. Standards, risk management, EU and FDA regulatory compliance are significant interests and responsibilities.

He has directed top-performing sales and marketing global teams, implemented strategies driving revenues and profits, growth and competitive market positioning plan; he has organized dynamic business units and international cross-functional project teams, dealt with quality assurance, validation, product R&D, standardization of several equipment and systems by fostering design best practices and operational excellence focus. He has been also responsible for the strategic direction of global pharma machinery suppliers.

In 2010 Andrea has started providing stable educational support to US Food and Drug Administration Office of Pharmaceutical Science and Office of Generic Drugs.

He is a frequent speaker at conferences and seminars including ISPE, PDA, BFS IOA as well as a frequent contributor to leading pharmaceutical and engineering associations. His insights have been drawn on for topics ranging from conferences to scientific publications and regulatory dossiers. Most recent publications involve developing Process Analytical Technology strategies for pharmaceutical systems, innovative Container Closure Integrity Testing methods for parenteral drugs and PDA Technical Report No. 86 (TR 86) "Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing".

Andrea is currently working with PDA Prefilled Syringes, Visual Inspection and Blow Fill Seal Association task force teams. He has also been part of the workgroups who have revised USP <1207> and EU GMP Annex 1.

He has taught many pharmaceutical engineering and industrial technology master courses at several worldwide Universities for the past ten years and lastly he has a long track record as a member of PDA Italy Chapter steering committee with volunteering activities such as workshops, conferences and webinars.