

**Danilo Baltodano,**

Quality Systems and Regulatory Affairs Specialist

Mr. Baltodano is specialized in Electro-mechanic for Automated Systems. He is an auditor and technical expert in Quality management systems and International Regulatory Affairs. He also acquired deep knowledge of IPC standards. Since 1994 he is been working in the quality field as a Manager of Quality Assurance. His domain of expertise is the creation, implementation and maintenance of Quality Systems, based on ISO 9000 and ISO13485 in the industrial and manufacturing field, such as Electronic Security Systems, Hardware and Software Simulation Systems and Medical Devices Systems. Since 1999 he's been helping medical devices designers and manufacturers enterprises to comply with ISO9000, ISO13485 and other regulations applicable to medical devices. He has been also assisting companies in improving their manufacturing process by dynamic approach. He has helped many companies to develop a quality control system to cope with the different aspects of incoming inspection, in-process and final inspection. Through practical experience in the quality field, Mr. Baltodano has developed tremendous experience in training capabilities. For him education is a capital aspect of quality within any area of activity. Some of the topics he teaches with passion are: General requirements of ISO9000;ISO13485, FDA 21 CFR and TPD CGMPs; Documentation and Data Control; Design Control; Process Control and Process Validation; Incoming, in-process and final inspection and many others.

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