

Step-Auto 2015: Speaker Proposal

Title	Agile Testing in a Regulated Medical Device product
Category of Topic	<input type="checkbox"/> Wit and Wisdom: "Perfecting Your Practices" Note: Select One Bulleted item and Delete All Others from the above list.
Author(s)	Mahantesh Maganur, Project Manager, Philips India Ltd, Bangalore
Abstract (Provide Details of the Topic and limit to 150 words)	<p>In a highly regulated environment such as Healthcare, product safety is the highest priority and it will have direct impact on the patient life. For most medical devices, release readiness is not just the completion of structured development and testing, but also a need to systematically comply with various regulatory standards for different countries (FDA, IEC, CE) that should be met to enable deployment in those countries.</p> <p>On the other hand, majority of the R&D organizations are rapidly embracing Agile methodology where Software testing tools expected to be flexible to adapt to this methodology.</p> <p>Following are the most important success factors for medical devices:</p> <ul style="list-style-type: none"> • Quality: With an uncompromising focus on product safety, we just can't release product which has any safety critical defects in it. This has a large impact to business and the reputation of the organization. • Time to market is critical. Late discovery of defects and related testing delays subsequently delay regulatory approval and product release. This will have direct impact on the business plans and market share. <p>This paper/presentation covers innovative approaches in the QA team in different phases of the Agile product development that can positively impact quality/timelines and ensure regulatory compliance for successful and timely delivery of products in medical devices.</p>
Terms of Reference <Specify Technical Terms Used in the abstract>	Agile FDA, IEC 13485 Quality
Authors Details <Provide Details of the topic and limit to 150 words>	Mahantesh is a senior test manager in Philips.

PS: Please enclose High Resolution Photograph of Each Author, and send them along with the Speaker Submission form by email to submissions@isqtinternational.com