Computer System Validation:
Building Quality into Automated Processes

Frans Leijse
ITC Validation Consultants BV
Zaanenlaan 129

NL-2023SL Haarlem
The Netherlands – EU

www.itcvc.com

Computer technology is all pervasive. It is hidden in domestic appliances, built into smart cards and security devices, mobile phones, PC's, Notebooks, process plants, aeroplanes, automobiles. Computerized systems are everywhere. The inexorable rise of computerized systems is seen in corporate strategies of Industrial, Pharmaceutical and Healthcare companies calling for investment in new technology to improve business efficiency and competitive edge. When such technology is associated with financial reporting, high-risk public safety projects, the production of life-saving medicines or medical devices, it falls under the scrutiny of regulators. The regulators need to know that automated operations are reliable, quality assured and validated. In other words companies need to demonstrate structural integrity of data.

Global pharmaceutical companies are bound by US Federal regulations and European Union (EU) regulations. These regulations impose Good Practices on manufacturing of medicine, medical devices, clinical investigation and laboratories. Pharmaceutical companies must show compliance by presenting documented evidence that a given system or process does what it purports to do. Hence such companies must validate their processes in order to show fitness for purpose.

A few years ago the US-FDA introduced a new initiative called PAT (Process Analytical Technology). The goal of PAT is to understand and control the manufacturing process, which is consistent with the FDA drug quality system: "*quality cannot be tested into products; it should be built-in or should be by design*".

The Dr. W.E. Deming philosophy, the US 21 Code of Federal Regulation
(21 CFR), EU-Eudralex Annex 11 & 15 and Sarbanes Oxley (SOX section 404) share similarity in that the aim is to build quality into processes.

This presentation discusses the current thinking in assuring fitness for purpose of automated systems; i.e. embedding quality into the automated process.