



Best Practices: Implementing Computer System Validation

Why is CSV important for the Life Science industry? For starters, CSV prevents software malfunction, but more importantly, it's the law!

As the pharmaceutical and life sciences industries continue to modernise and implement more technology, there is an increasing need to be sure these technologies are safe and accurate for patients and end users. Computer system validation (CSV) is a documented process for assuring that a computer system does what it is designed to do. Both the European Medicines Agency (EMA) and the Food & Drug Administration (FDA) have produced guidelines for CSV practices.

There are two important reasons for performing CSV with life science technologies and software:

- (1) CSV can prevent software problems before reaching the usage environment. In particular in the clinical trial field, malfunctioning computer systems can cause serious adverse consequences to the patient. This could in turn lead to lawsuits, fines or eventual shutdown.
- (2) Not performing certain computer system validations in accordance with Best Practices could be against the law. Both the EMA and FDA have rules and regulations in effect for GMP (Good Manufacturing Practices), GLP (Good Laboratory Practices) and GCP (Good Clinical Practices).

FDA

The FDA is aiming to strengthen its CSV standards by aligning them with International standards like ISO 9000:2000. GAMP (Good Automated Manufacturing Processes) focuses on applying GxP (Good Practice Quality Guidelines) to the IT environment. FDA regulations depend on the type of software being validated, off-the-shelf, configurable or customisable software, "retrospective" validation for older systems that have never been validated and business and compliance risks.

EMA

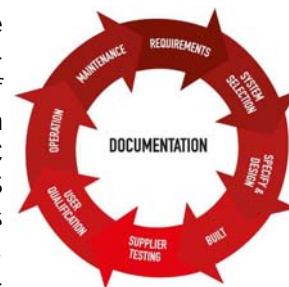
The EMA recently revised its CSV guidelines in January 2011 with an adoption date of 30 June 2011. Topics include requirements for spreadsheets, data security of databases, risk management, retrospective validation, storage time of electronic data and documents and validation for small devices. The EMA's website, <http://www.ema.europa.eu> offers the latest CSV regulations and validation.

21 CFR Part 11 Compliance

21 CFR Part 11 compliance is required for electronic records and electronic signatures. CSV becomes important as the FDA requires all computerized systems with GxP electronic records to be validated. The life science industry is proactive in validating systems in compliance with 21 CFR Part 11 which means the ability to generate accurate and protected records and time-stamped audit trails.

ARITHMOS and CSV

ARITHMOS has extensive experience in the computer system validation of GCP applications, in particular Oracle OC/RDC and AERS. ARITHMOS can support customers in planning, conducting, reviewing and maintaining the validation status of their applications through GxP assessment, validation planning, user requirement analysis and authoring as well as IQ/OQ/PQ authoring and execution including validation reports. ARITHMOS can also provide CSV training and support customers in developing internal SOPs for CSV. ARITHMOS has an ISO 9001 certification for its Quality Management System.





Mobile "Apps" and Tablets in Clinical Trials



Market Overview

The mobile and "apps" market has been growing rapidly and steadily for the past few years. With the introduction of the iPad in 2010, the tablet market is gaining attention as product value soars in many industries. Health and pharmaceuticals is one of those industries openly accepting the mobile and tablet takeover as these devices and their "apps" bring added benefit and new innovative solutions.

A snapshot of the overall market emphasizes the importance of embracing these technologies. In 2010, there were over 250 million smartphones sold worldwide. To clarify, a smartphone combines the capabilities of a mobile phone with PDA (personal digital assistant). Many of these smartphones include "apps". The Apple store alone has over 500,000 "apps" which can be easily created by consumers. The tablet market has the fastest market growth rate, with the Apple iPad owning about 90 percent market share. Apple recently reported that about 65 percent of Fortune 100 companies are using or

testing the iPad for use within the company.

The pharmaceutical industry has been embracing these markets for several reasons. One of the biggest reasons is patient compliance. Patients want the "WOW Factor" - the digital and personalized experience.

Devices such as tablets and smartphones can cut clinical trial costs as well. Setting up desktops or laptops, or even printing paper, can be more expensive than simply downloading information on a device. Using these devices also allows patients to just send information via a click or an IM/sms. With the installation of "apps" medical information can be downloaded instantly by doctors or Investigators.

Investment by the pharma industry in wireless devices has grown 78 percent in the past year. Reference "apps" like WebMD are most popular, and "apps" are used for compliance, consent and even diagnosis.

Devices in Clinical Trials

What are some of the most noteworthy mobiles, tablets and "apps" in use today in clinical trials?

1. BlackBerry (BB)

The BB allows users to be identified via PIN which helps confirm patient compliance. Data can be transmitted via SMS, BlackBerry Messenger (BBM) or Bluetooth technology. The BB allows for instant data transmission and instant communication between patient and Investigator. For clinical trials in diabetes (the fastest growing therapeutic area in pharma), a glucometer can connect via Bluetooth to a BB Curve model to transmit data.



2. iPad and iPhone

These devices garner attention in the patient compliance area. The touch screens and "apps" make these Apple devices popular and easy to use. Patients are identified via username and password and bluetooth technology is enabled.

3. Top Pharma "Apps"

- ◆ WebMD
- ◆ Novartis' GIST calculator
- ◆ Roche's Nursing ACE
- ◆ Merck's iChemoDiary
- ◆ Sanofi-Aventis GoMeals (Diabetes)



ARITHMOS to Sponsor Spanish ePharma Day in Barcelona

ARITHMOS will be a co-sponsor with CROS NT of Spanish ePharma Day, to be held on 27 October 2011 in Barcelona, Spain. The theme of the event is "Optimizing Value and Quality in Clinical Data with Standards and Data Integration" and is intended to engage the Spanish and Portuguese pharmaceutical, CRO and biotech market in this discussion. Official languages for the event are Spanish and English. CROS NT CEO, **Paolo Morelli**, will be attending.

ARITHMOS was also a sponsor of Italian ePharma Day in April in Milan, Italy and German ePharma Day in May held in Munich, Germany. The goal of these events is to localize emerging topics in the biopharmaceutical industry and invite local country experts to present on these issues.

Oracle Health Sciences will also be a sponsor of the event and will co-host an exclusive VIP dinner with the CROS NT Group for those who register. Registration for the event is now open and an early bird rate applies until 30 September.

Event Details	
	When: Thursday, 27 October 2011 from 10.00– 17.00 VIP Dinner 26 October 2011 at 21.30
	Where: Grand Hotel Central Calle Laietana, 30—08003 Barcelona
	Registration: € 300.00 on or before 30 September 2011 € 350.00 on or after 1 October 2011
	Website: https://www.epharmaday.org/ePharmaDay2011

ARITHMOS to Present and Exhibit at OHSUG 2011 in Canada

This year, ARITHMOS has started attending major events as a co-exhibitor. In March, ARITHMOS exhibited in the Oracle Partners Network booth and in June went to DIA Chicago as a co-exhibitor with CROS NT. But, the Oracle Health Science Users Group (OHSUG) Conference is ARITHMOS' main event. The OHSUG Conference 2011 will take place 16-19 October in Toronto, Canada.



ARITHMOS will be exhibiting and presenting at this year's conference. Attending from ARITHMOS will be Chief Operating Officer, **Stefano Piccoli**, and conference veterans, **Silvia Gabanti** and **Gianluigi Albertini**. Gianluigi will be giving two presentations: "Accessing Study Data With Oracle Business Intelligence on iPad and iPhone" and "Management of a Study with Device Integration in Oracle RDC". Silvia, Head of Unit for Health Science Services, will present "Oracle AERS Integration with Oracle Business Intelligence".

Visit **ARITHMOS** in the Exhibitors Hall for your chance to win an Apple iPod Touch! Contact us at info@arithmos.it for more info.

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About the ARITHMOS Newsletter

The ARITHMOS newsletter is published bi-monthly alternatively with the CROS NT newsletter. The goal of the newsletter is to share relevant news and events from the biotechnology sector and showcase work ARITHMOS has been doing in industry. Content is produced in-house by ARITHMOS staff. For more information, contact ARITHMOS Marketing Officer, Mary Wieder: mary.wieder@crosnt.com

About ARITHMOS

Founded in 2010, ARITHMOS is the technology branch of the CROS NT Group. Based in Verona, Italy, ARITHMOS offers IT solutions such as hosting, data integration, computer system validation and software development to "fill the gap" where a technological need exists for our clients or in the marketplace.