ONLINE BUSINESS APPLICATIONS, INC

INSIDE ONLINE

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IRMS workshop 2005

This past March in San Diego, Online had its most successful user work-shop to date, and that's not us telling you, you told us.

Our latest half yearly work-shop broke new ground in terms of the number of par-ticipants (our highest ever) and also the most positive responses we have ever received, a tribute to the organizational skills of Lind-say Oles, who not only had to deal with the no show of some of our shirts (the real reason anybody even bothers to at-tend), but also the fact that this was our first two-day event.

Dennis, Joe and Dianne gave their normal impressive dis-plays ably assisted by Rod, and a special thanks must also to our guest speakers Victoria, Yvelise, Jane and Mike. This year's discussions on global medical information, validation and the initiation of the IRMS User Group were timely and relevant and we appreciate our speakers time and effort.

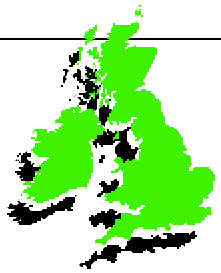
The slide presentations are available on our website http://www.irmsonline.com. There is also some additional information in this edition of the newsletter which discusses validation and our IRMS User Group.

Validation

Is IRMS validated? Is IRMS CFR Part 11 compli-ant? Does my system need to be validated? These are questions being asked in Medical Information depart-ments around the country today.

CFR Part 11 is an FDA guideline that addresses the use of electronic sys-tems for record keeping. Before electronic systems, sheets of paper were literally signed by the person modifying or submitting information. With an electronic system, obvi-ously, trying to sign the infor-mation in the same way only leaves hard-to-remove marks on your monitor. CFR Part 11 discusses how a system needs to have 'electronic signatures'. These are used in order to en-sure the data within the system has integrity

CFR Part 11 details out some specific required features of electronic systems. Some ex-amples are unique user IDs and passwords, audit trails, process documentation, and of course, validation.



Welcome David!!!

On Monday 25th April 2005 whilst trying to divert attention away from a mind numbingly boring British general election campaign the BBC announced, in a moment of jocularity for which it is not generally noted, "a U.S. survey has uncovered that 1 in every 3400 Americans is an Elvis impersonator".

Now just think of it from a foreigners perspective, that means there are in the United States alone nearly 100,000 Elvis impersonators making my chances of meeting The King far better than those of meeting the Queen!

Of course it is unlikely that Joe, Dianne, Rod and Dennis (or any of the Online gang) spend their Friday evenings crooning "The Great Pretender" Las Vegas style at a local gin joint, but hey, who knows!

My reason for mentioning this fact in my first newsletter column is that I believe understanding the little cultural quirks that exist in people and societies, particularly your own, and acknowledging them, is often the key to a successful business at home and abroad.

So! Wherever you are in the USA or the world and whichever organization you're with I look forward to talking with you about your business its needs and, if invited, attending your next performance.

Oh, by the way, I'm David Hayward, the newest team member, having joined OBA from Oxford England as Accounts Manager with special responsibility for existing clients.

Validation

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Now whether a Medical Information system *needs* to be validated per CFR Part 11 is a whole 'nuther question, and determined mostly by a companies own internal Quality Assurance department. CFR Part 11 is for systems that directly report information to the FDA. Since Medical Information systems generally do not do this, they would not fall under CFR Part 11. The situation gets considerably murkier however, if the Medical Information group is taking the initial information for Adverse Events or Product Complaints.

If the initiation of an AE or PC record is in IRMS for example, and data is transferred electronically to an AE or PC system, then IRMS, or at least some components, would need to be validated. Even if there is simply a printed report being passed, some companies may feel validation needs to take place. The impact on validation requirements due to integration of IRMS with AE or PC systems is not clearly defined by the FDA; therefore, it is ultimately the decision of the internal QA department.

Online Business Applications has built IRMS to be completely CFR Part 11 compliant and capable of being validated. There is no computer system that is 'pre-validated'. Validation occurs at the client site, before, during and after the software has been implemented. We have formed a good working relationship with a company who specializes in validating off-the-shelf software packages. We have provided them training and documentation, and they have experience in validating IRMS.

Our clients can leverage pre-existing documentation, specification and test scripts to make the validation process more efficient and less costly, as well as work with us and our partner to determine the specific validation needs as required by the FDA. If your company is investigating validation of IRMS, or you would like to learn more, please contact Joe Pierce at extension 209.

User Group

One of the responsibilities of the position of Account Manager is to try and ensure that our clients get what they need from IRMS and of course by extension OBA.

Since our main workshop in San Diego, prior to the annual DIA conference, I have been actively engaged with some of our clients and several of our staff in trying to get the IRMS User Group off the ground, as there was clear and unequivocal support for a forum in which to discuss IRMS issues and uses, not only with Online but also with each other.

As I saw it, my first task was to revamp an under-used resource here at Online Business Applications, namely, the Message Board. To that end I employed the creativity of Adam Oles and Stewart Hartz from Client Services and support and picked the brains of a few interested parties, particularly Mike Schur from P&G, whom I know is known to many of you.

And behold! We have altered the message board, to be found on our website www.irmsonline.com

Whilst I feel the format of the new message board as it stands is embryonic and requires input from forum members, it could be said that this also applies to the User Group itself. As the user group grows, I'm sure many great ideas will emanate from YOU the user.

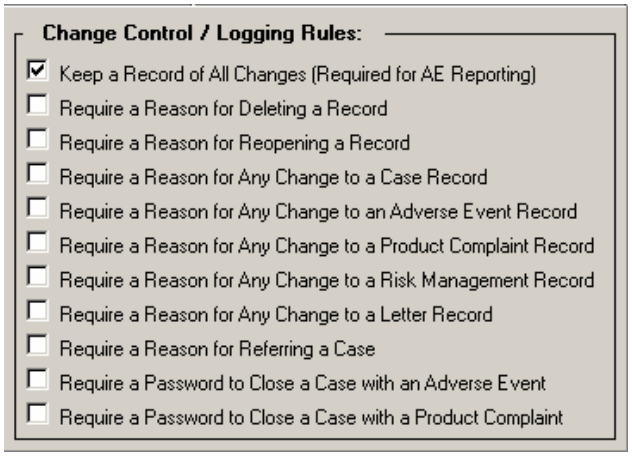
It is the intention of Online Business Applications and some of its key clients to have regular teleconferences with members of the User Group. We hope to meet many of you at our twice-yearly workshops, the next one to be held provisionally in New Orleans in late September/early October, and to attach the Annual Meeting of the User Group with our main workshop which will coincide with the main DIA conference (next year in Orlando)

We will soon be emailing everybody we know that has expressed an interest in the group, plus those we feel may find it useful for themselves and their organization, that the board and the group is open for business.

However the one small fly in the ointment is all those who have signed in previously will have to do so again. A small price for the effort of trying to make the message board and user group work for the benefit of us all.

Did you know? A tip from our trainer

By default in IRMS, if a case is deleted there is no history or log of contact information kept in the system. Once deleted, it's gone! However, there is a setting in Division Parameters (Version 5) that allows you to keep a record of any case information, even if the case was deleted.
To keep a record of case information, check the "Keep a Record of All Changes" setting in Division Parameters (System Menu). This information is then available under View Data (System Menu). The tables, RequestContactLg, RequestLg, and ResponseLg contain the data for the deleted case.



Webex

One of the hardest things about being part of a tech support team is trying to correctly interpret issues our clients may be having with IRMS. Most of the requests we receive can usually be resolved with the client on the phone or through email correspondence. There are some however, that we cannot replicate. When that happens we need to see the activity for ourselves as it happens. The most cost efficient method to accomplish this is through remote assistance.

About a year ago, one of our clients introduced us to a new remote assistance tool for viewing their environment over the internet. This new tool is called Webex, and recently, it has greatly increased our ability to assist our clients in resolving IRMS issues. You can learn more about Webex at www.webex.com, but I want to cover it's benefits and how we can use it to benefit our clients.

Webex Meeting Center gives us the ability to virtually visit our client and stand over their shoulder as we try to resolve a problem an IRMS user may be having. We can also ask the user to allow us to control the mouse/keyboard so that we can maximize the time used in these sessions. When the problem is resolved (or we're at a point where we need to take the information back to the development team), we can resume control of the Webex Meeting Center and close the Webex session for everyone.

Webex is a great solution for Online Business Applications in that it covers the trifecta:

(1) Availability - Webex is available anytime of the day (provided both parties have internet access)

(2) Reliability - Webex is highly reliable in that it is as close to real-time remote assistance as we've seen (besides RDP/Citrix access)

(3) Security - When using Webex, each session is secured with Advanced Encryption Standard (AES) as well as providing the option for securing all content through Secure Sockets Layer (SSL). Additionally, nothing can be done at the client environment that the client doesn't explicitly allow. Once a meeting is ended, there is no access to the client's machine.

For more information about getting the benefits of remote assistance with Webex, please contact Joe at joe.pierce@irmsonline.com or by phone at 630-243-9810 x209.

Training

Are your Division Parameters set appropriately? Are you utilizing all that IRMS has to offer?
We have training and consulting services available at our new training facility in Lemont, Illinois. Each course includes hands on learning with practical exercises.

Contact Dianne Pullman for information dianne.pullman@irmsonline.com. See our website for the latest schedule of courses available at OBA's Education Center. Including Basic User Training, Advanced User Training, Report & Query, Documents in Depth and more.

If you have specific training needs not currently offered by OBA, please send your request to Dianne!

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