RIMS WEBINAR TRANSCRIPT:

How to Optimize the ROI on your RIMS Solution -

Webinar with Jonathan Sandford

celegence

celegence.com

Jonathan Sanford

Jonathan has worked in the field of Regulatory Operationsfor the past 18 years and has over 30 years of pharmaceutical experience. He has managed a team of Regulatory Operation professionalsresponsible for publishing regulatory dossiers across Europe, Asia, and Latin America. He has been the business lead on several Global Document Management Systems, Regulatory Publishing Systems, and RIMS implementations.

During today's presentation, I'd just like to take you through some of the lessons I've learned, as far as deploying RIM systems are concerned. To give you some ideas around what the best questions you may want to consider asking to be able to get the best out of your current or new system.

Approach for selecting the right solution for your organization

How easy is it to get data into the system and how easy is it to report out that data?

It is very easy to get caught up in flashy presentations from vendors, but it is important that the system is as user-friendly as possible. As with all I.T. system information implementation these days, they (vendors) need to come up with a robust business case to demonstrate the value of the system to the organization. It is well worth speaking to the vendor to see if they have any business cases that can help you in preparing one for your own organization.

Level of automation - RIM systems contain a lot of repetitive information. So, it is important that any system you choose has a level of automation and workflow that allows for information to be reused as much as possible - reducing the need to enter the same information multiple times.

Total cost of ownership - You need to look at your total cost of ownership from direct and indirect costs. You need to be able to consider things like the need to backfill your current resources in your organization to allow them the bandwidth to implement the project on time, as well as configuration, training, and migration costs.

Conference room pilots are key for getting your users on board with the system as early as possible. I would highly recommend performing conference room pilots. This allows users to get actual hands-on experience with the tools rather than relying on screenshots and demos run by the vendors themselves. It is the only real way that the users can get hands-on experience within the system and be able to truly find out the usability of the system for themselves.

Vendor Experience and Maturity

Does the vendor have a road map detailing system updates and what new functionalities they are working on?

Do they have migration capabilities? - It is likely that you will be migrating data from an existing system or even excel. So, it is important to understand what migration capabilities the vendor has, or whether you will need to outsource that to another organization.

Look at how the vendor delivery system updates - Are the updates delivered on a yearly or biannual basis? Will they require large amounts of resources? Or, are they delivered on a more frequent basis - reducing the revalidation and training effort required.

What level of validation can the vendor provide you with? - These days, validation packages are usually already available, and they have been written by the vendor. They, after all, know their system the best.

What level of training support can they provide? - Do they already have pre written or e-learning training materials that you can leverage to build your own training programs? If so, they should be utilized and this should be kept in mind.

Support Systems after installment

And finally, looking at postcode live support, would they be able to assist you in helping users during those critical six months of system launch and are they able to assist you in change management? A successful change management program will be critical for the project. Speak to your vendor and see what experience they have in delivering systems to other customers and how you can leverage that information within your own organization.

The Challenges – Operational Challenges facing RA Teams

Now that you have chosen your new system, you will need to consider how you are going to enter your legacy data into your new system.

Legacy Systems

Things to consider regarding the data integrity from your legacy systems - Are there any gaps in the data required for your new system that are not currently in your old system? Think about how accurate your data is within your current system and whether you need to correct that data before migrating it into your new system. Form a cleanup of your data prior to migration - there is nothing that will stall the adoption of a new system quicker than having incorrect data from the very beginning.

Data Governance

Pharmaceutical companies tend to be a little bit behind the curve these days when it comes to data governance. Many large organizations have chief data officers, and they are responsible for the data integrity and quality within their organization. As far as data governance is concerned, I would come up with a policy looking at who the owners of the data are and make sure those owners have been identified. Look at the data as a commercial asset and this will help with buy-in from stakeholders if that data is available.

Managing Data Quality

Data quality is one of the key reasons for failure in the adoption of RIM systems, and it comes from a lack of stakeholder buy-in. It is also unfortunate that RIM systems are defined as regulatory information management systems. However, a vast amount of the data needed for these systems actually comes from across your whole organization. It is very important before you go ahead and look at implementing a RIM system that you buy in across the whole organization, both during the execution and maintenance phase.

The next thing to consider is to look at how you are going to enter the data into the system. I have experience in both centralized and decentralized data entry. I do not think there is any perfect solution, but I think it is worth just going through a couple of the pros and cons.

Pros of Centralized Data Input Model

You may find that you will be able to get a reduction in license costs because most vendors will have different costs, depending on whether you are a contributor or whether you are a consumer to the system. Centralized data input models also reduce the number of resources needed from experienced regulatory staff. You have got to consider - do you really want highly paid regulatory executives performing what is in essence a data entry role, or, would it be better to outsource this data to an offshore company. I believe you get a higher level of quality when using a centralized team on the basis that they will be using the system day in and day out and will not need to relearn the processes every time they want to put in some data. Obviously, there will be a reduced training burden as you will not need to train as many people on the system.

Cons of Centralized Data Input Model

There could be a delay in getting the data from the regulatory executives to the centralized data input team. There is a lack of ownership of the data if you are not responsible for entering that data into the system. I find that a lot of the time it never gets to the top of people's to do lists. So, you are going to have another delay in entering the data into the RIM system.

Decentralized Pros and Cons

As far as the pros for decentralized data input model - if you give that ownership to the regulatory executives and they are accountable for it, they are more likely to make sure the data is entered in a timely manner. With a decentralized model, again, it is likely that you will have a high training burden. You will get data quality issues when the regulatory executives enter the data they must relearn the processes. Regulatory professionals are spending time on data entry, and is that really their skill set? Also, you could have higher license costs.

Maintaining Data Quality – Setting up KPIs

It is important when defining your KPIs, you make sure that it is useful for your organization and you are not just collecting them for collecting's sake. I have had experiences where we defined hundreds of KPIs just for the very fact that it looks good - that we have got hundreds of KPIs - but all we did is collect them and they were never actually used. So, make sure you know what you are going to use those KPIs for, and make sure they are fit for your purposes.

KPIs should be defined to maintain a level of quality within your systems. You will have both internal as well as external metrics and KPIs. The external KPIs will be driven by the health authority timelines and the internal ones should be driven by your process improvements.

Collection of KPIs - it can take a long time to collect the KPIs, so consider whether or not you can collect them and automate that collection, or whether you have to collect them manually.

How do you present the KPIs to your organization? - I find that senior members of organizations prefer nice dashboards rather than just lists within Excel reports. Really think about why you are collecting them. Make sure they stay current within the organization and that you annually assess them to make sure they are delivering what you need.

Potential Integrations

Information within your RIM system will come from several different sources. It is worth considering what integrations you have and how you are going to connect them within your RIM system. You can look at direct integrations with things like - your drug safety or quality systems - or maybe look at a data warehouse integration. The advantages of data warehouse integrations are that they allow you to translate the data into your remaining convention before entering it into your system, as well as aligning with those external vocabularies.

As health authorities require more and more data from us, it is important that we can seamlessly pass information from our internal system into the RIM system and then to our health authorities' systems as

well. Make sure that with any system integrations you have, they will also work for the health authority systems. Obviously, this is very important, especially considering the SPOR initiatives and the upcoming IDMP regulations.

When you are looking at system integrations, the key questions you need to answer are - identify what systems you would like to integrate with, what data do you need from those systems, and where is the single source of the truth? It is likely a lot of your systems will contain multiple copies of the same piece of data. It is very important to work out where that single source of the truth is located.

Adoption and Maintenance – Change Management

As with most I.T. systems, change management is a key to success. You need to look at your user base and assess whether there are any reasons for resistance to change in using the new system. It is much easier to try and address these resistances prior to going live with the system rather than once you have already gone live. I find you get much better adoption of the system if you manage to address any reluctance to use the system prior to going live.

Once the system has gone live, obviously that is only the start of the journey. You want to look at user issues in the aid of continuous business improvement, and make sure all your users are being listened to. It really does turn users off to using a system if they come up with ideas about how to improve it and they are not listened to employ those system champions; those system champions will be key in helping you be able to deliver change within your organization and look at evaluating new technologies as they come along. Natural language processing can turn structured, unstructured data into structured data, which then you can import into your RIM system. That is going to be a key for the future in trying to improve data quality by automating that data entry process.

Conclusions

- **Stakeholder buy-in** is absolutely critical, and that stakeholder buy-in is not just from regulatory, it goes all the way through the entire organization.
- **Assess the current quality of your data and identify any potential gaps** in that data before looking at importing or migrating data into the system.
- **Define where "your single source of the truth"** is - If there is a piece of data that comes from a different system and that is the source of the truth, then make sure that that is documented.
- **Use the right resources for data input** - I am a big believer in a centralized data model. It really does help with data quality, in my experience.
- Keep looking at **new technologies, automate, automate, automate** - it is quite old fashioned, if you think about it, that we are still entering data manually by using a keyboard into a computer system. I think the real future will come from handing these kinds of processes over to artificial intelligence and things like structured content authoring to be able to migrate the data directly from the source documents into the system.

Helping You With Regulatory Operations

We can help improve your Regulatory Operations with Learning Management.

For more information, reach out to us at

info@celegence.com

or contact us online at

celegence.com

celegence