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Paper

24 Hour Challenge

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ABSTRACT

Governance of Regulatory Information and Knowledge across R&D and Operations in AstraZeneca.

This paper will give a high level understanding of the programme that has focused the Astrazeneca organisation on the importance of Regulatory information and Knowledge in submission to the regulatory authorities and in defense of product information. The paper will discuss the creation of governance model and functional teams, Communications and behavioral changes, Audit and Metrics and Stakeholder Management and buy-in.

Introduction

The way in which AstraZeneca creates stores and retrieves regulatory information has a significant impact on its reputation, efficiency and ability to keep products on the market. That's why the 24 Hour Challenge project is trying to make AstraZeneca the best it can be in responding to regulatory requests.

SUMMARY

The 24 Hour Challenge is all about optimizing the way AstraZeneca responds to requests for regulatory information and is a major behavioural change taking place across R&D and operations. The term '24 Hours' may be an aspiration, rather than a defined objective, but the challenge is clear - to be as efficient and as effective as possible in responding to questions from regulatory authorities.

This means that every root cause to the problems outlined are being addressed to achieve the goals. This isn't about putting the right system in place to manage the information but about behaviours, governance and measures that need to be addressed. Additionally knowing how information flows across and within functions is important to gain a true understanding of what information is in place to support the label of a product and the speed and accuracy at which it can be accessed.

One of the main theme's to the project in AstraZeneca has outlined the theme of Create, Store and Retrieve. This is building an awareness that the information that is created today needs to be stored and documented in the right way to achieve effective retrieval in the future. Information and knowledge generated needs to be traced back to the raw data in an efficient and effective timeframe.

When you think about the label that is submitted for approval, what we are basically saying is that we, as a company, have proved that the product is safe; effective in the use defined, is manufactured to an acceptable quality and intended for use in a certain population. There is a vast amount of information that goes into a submission that includes the clinical, research and pre-clinical areas, chemistry, manufacturing & controls and of course the regulatory area. In fact the majority of our regulatory knowledge is generated outside of the regulatory affairs function.

This means that everyone has a role to play. Many employees may not even be aware that a routine task or function constitutes regulatory information or knowledge. That's why the 24 Hour Challenge team has embarked on a high profile behavioral change campaign to raise awareness of the importance of regulatory information, as well as identifying and tackling the issues that impact response times.

The IS (Information Services) organization has a role to play in this, not from a technical and system point of view but from an information management and process point of view. The IS community, has played a major role in the work, including the Challenge's 'Diagnosis and Prescription' phase – helping functions to identify issues, problems and blockages that may impact the regulatory process. This initial project has delivered a capability to measure success in responding to regulatory authorities by monitoring relevant activities and base lining responses to key questions. Monitoring the impact of an International Procedure for Defining Regulatory Knowledge has delivered a unique cross-functional visibility for monitoring progress and identifying opportunities for synergies and standards that will benefit all functions. The project will also influence the wider aspects of change that needs to happen to be fully effective in its mission.
A new governance organization is also now in place to take up the challenge and lead the continuing improvements in AstraZeneca's ability to respond to regulatory questions. Chaired by the Regulatory Affairs VP, the cross-functional team includes an IS VP as well as functional leads. A new Regulatory Knowledge IS Community Leadership Team, has also been set up to represent IS functions and build bridges between IS and business communities. The group will help identify projects that can help achieve the 24 Hour Challenge and similar 'Information Communities' are expected to be launched soon.

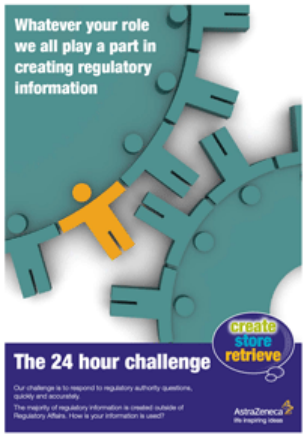
Many of the major issues behind the 24 Hour Challenge are related to the way we manage our regulatory Information. These are mainly behavioral, process and information related rather than just IT related, which is why the 24 Challenge is much more than just an IT/IS (Information Technology/Information Services) response. It involves a partnership between IS and key business areas and they have worked hard to align all the IS functions that support the regulatory process with this approach.

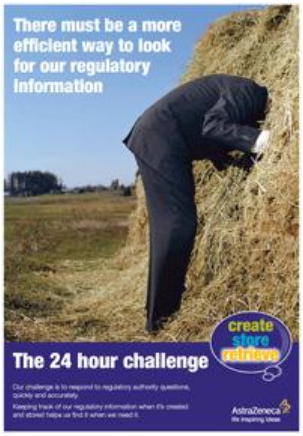
Governance

The importance of the Intellectual Property that is generated in support of a product can become increasingly more complicated if it's not managed effectively. The generation and accessibility of the data, information, knowledge and wisdom needs to be governed from the top and that's why the senior executive team in AstraZeneca have given accountability to the VP's in the organization to ensure traceability so that IP is not compromised. During a products lifecycle many different people inside and outside the organization are generating information that contribute to the approval of the product. That is why it is important that a governance team is in place to oversee the compliance to policy relating to regulatory knowledge within and across the functions. Alongside the day to day adherence to the definitions for regulatory knowledge they also need to ensure the cross functional understanding and delivery of business and external drivers.

Functional teams are also important in the delivery and support of the governance organization. Tactical and strategic projects are in place within the functions to be able to deliver the vision of the project. The real power in what has been achieved is the cross functional collaboration that will drive better information flows and efficiencies across the functions. The main focus of this project is the creation, storage and retrieval of information which is common to all areas.

Communication and Behavioral changes





Behavioral changes across large organizations can be daunting. The 24 hour challenge project embarked on a communication plan that involved people right from the top of the organization and included a customized approach for specific audiences. The CEO of the organization, David Brennan along with several functional heads participated in video campaigns which underlined the importance of Regulatory information to the organization. The poster campaign delivered through to individuals an effective message about how the Creation, Storage and Retrieval of information is important from day 1 through to the end of the products life. This campaign has brought about discussion over a six month period and will deliver a powerful behavioral change that will last for many years. In addition there are many training and

awareness sessions giving everyone a chance to contribute, discuss and act on how their own behaviors could make improvements to the benefit of the AstraZeneca products.

Audit and Metrics

There are many areas where AstraZeneca are already improving their processes and technology to speed up the submission of a product to regulatory authorities. The emphasis here though is not just on submission but on the approval of a product. Understanding the needs of the regulatory reviewers in submission is important to be able to deliver the right information in the first instance. Learning from previous submissions is important, from competitor's submissions, from collaborating and contributing to industry standards and from acting on the requests to regulators needs. Through looking at our root causes of the problems we have been able to understand the true picture of what needs to improve, what needs to be prioritised and what we can do as an organization not just a function. This blue print forms part of the capability of measuring our success in achieving our goal.

The true measure of success is to be able to understand the organizational effect this approach will have in the future. By base lining where we are now, it gives us another capability to measure our improvement and success in the future. How long does it take us now? How good is the quality, how can it be improved and what benefit will this give us in the long run. What seems to be savings at the submission time may affect the final time and label approved by a regulatory authority.

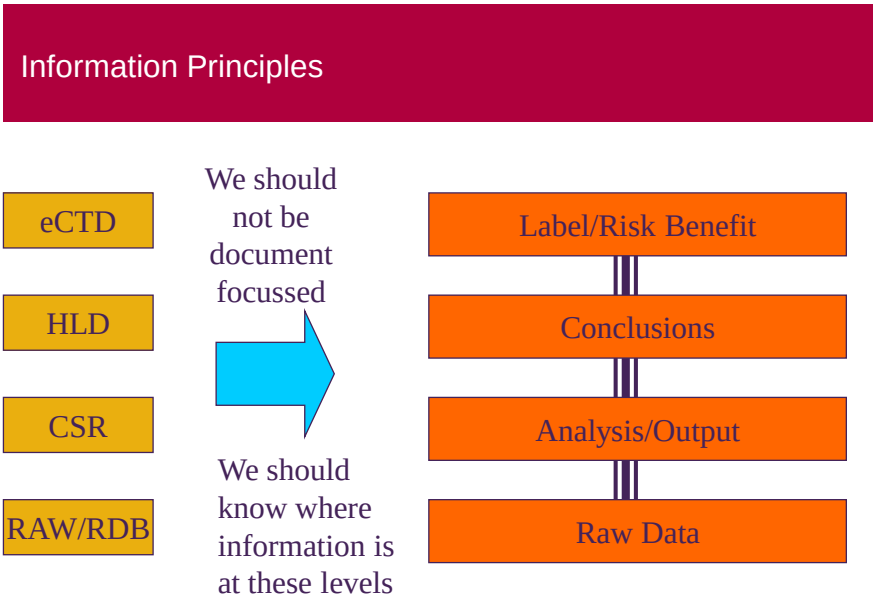
Stakeholder Management and buy-in

It is important in any project to have the right stakeholder management and buy-in from the very start. Everyone in this project in R&D and operations at AstraZeneca is a stakeholder as everyone at some point in the lifecycle of a product will come into contact with Regulatory Information. Making this work effectively required the documentation of the influencers, decision makers and blockers. The relationships made during the project between the project team and people in the business needed to be visible and continuously managed to gain effective understanding and support. The communication teams at AstraZeneca play a big part in making this happen and the effective management of stakeholders can be the make or break of the success of a campaign on such a large scale.

Information Principles

When working across functions it becomes more apparent that no matter what part of the research and development process that you are in, 'information' is 'information'. And what do we mean by information. In terms of definitions we use the words information, data and knowledge interchangeably. In my mind there are 4 different levels of information that contribute to the label

1. There is the Raw Data that is collected during the trials that are conducted.
2. This is then summarized and reported, the derived data then becomes the information
3. Then expertise is applied to that information then this becomes the knowledge/conclusions
4. Decisions then are made on conclusions that then become the Label



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It is at these levels that information should be gathered. The documents in a submission should not be the creation and storage of our information but **the users of the information** that has been stored and tracked through metadata. Any statements used in a document can then be traced right back to the raw data.

To get to the label it is obvious that it is important to track this back right to the raw data in support of the label. The label needs to be supported in terms of 4 main factors.

1. Safety
2. Efficacy
3. Quality
4. Patient population

In effect, every statement that is stated in the label needs to be supported by evidence through the wisdom, knowledge, information back to the raw data. It is the traceability to this raw data that needs to documented and tracked to enable the faster response times to regulatory authorities.

CONCLUSION

To be more effective in our management of regulatory knowledge and information it is important to think in terms of the governance, behaviors, information maturity and basic principles of how all our data, information, knowledge and wisdom is generated and how this can traced throughout its lifecycle. This brings us back to how we create and store our regulatory information in the first place so we can retrieve it when required. Then how do we keep track of all this over a long period of time. How does this relate to the questions that get asked during the approval process? Well our ultimate metrics around how good we are in terms of the submission relate to the approval timeframe and the quality of the submission. In essence if we don't get asked the question in the first place then our response times are kept to a minimum and this is a true measure of the quality of information supporting the statements in the label.

CONTACT INFORMATION

(In case a reader wants to get in touch with you, please put your contact information at the end of the paper.)
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