

A Comprehensive Look at Governance Across R&D Systems

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Organizations are faced with the issue of data overload and rely heavily on the accuracy and availability of their regulatory information to get and keep products on the market. Poorly classified and governed data is a growing issue across organizations and there is a need to remediate and govern this information.

Often, information is missing, or includes poor metadata, redundant or duplicate information making it hard to find the right information. Human nature seems to be to rush through filling out information, providing the least amount of “Required metadata” as possible. Rushing to save off information often in places it is hard to find when you need it again. Organizations, although they try to implement structured systems to store their information, often find themselves weeding through information that is poorly organized and categorized.

Governance by definition is the act or process of [governing](#) or overseeing the control and direction of something. Within Life Sciences, adhering to policies and regulations is a must in order to satisfy the requirements set forth by agencies such as the FDA Food and Drug Administration. In fact, there are dozens of Standards and guidances that have been issued to help with this very thing. So why is it that organizations are struggling to implement or enforce governance?

Governance is usually an afterthought and often times this is the reason why organizations struggle to keep their information consistent and controlled. Governance is more than just governing systems, it is governing people, processes and technology and can be overwhelming to manage. We recommend including governance early on as part of your road map and strategy and to include governance during your implementation when configuring and integrating your systems. Don't let governance fall by the wayside. Governance should be defined early on and included in your procedures, training and communication. A governance control board should also be defined to help manage change and ensure compliance with your overall plan.

Choosing a document management system that includes functionality to help govern data is important, however, including cross integrations to share data is even more important. Coming up with a strategic plan for your R&D systems early on will help you to think through and implement your systems with a plan geared toward governance. Having master data disseminated throughout your systems may seem like a challenging task, however spending the time up front choosing the right systems and integration paths will save time and money in the future.

Don't do it alone! Choosing a skilled business partner like CrO Biosciences, to help with things like defining a roadmap and strategy, choosing the right technology and integration points, optimizing information to remediate data issues and streamline processes that align to your plan will help you to visualize and carry out your plan in a way that meets your organizational needs. Business partner organizations offer unique skills that can help you to align your technical and business needs across your entire platform by providing skilled resources well versed in industry best practices that have dealt with and overcome many of the same challenges you may be facing.