

Optimization of R&D Operations

Industry Thought Leadership

By Subject Matter Experts at Daiichi Sankyo

# ***A winning strategy for a global EDMS Implementation***



***...in less than 9 months!***

**Insights from Industry Experts and Executive Thought Leaders**

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## Overview

Daiichi Sankyo, headquartered in Japan is a global pharmaceutical company with over 15,000 employees and operations in Japan, US and EU. Daiichi Sankyo faced a common industry challenge in balancing the rapid rate of change in technology, with increasing regulatory requirements and the need for improved end user efficiency in the use of information systems to meet the demands of global health authorities.

*Sobe Good (Senior Director, Head R&D Informatics), Cheryl Ressler (Executive Director, Regulatory Operations) and Don Costello (Senior Director, Medical Writing) of Daiichi Sankyo partnered to drive a complex but successful EDMS (Veeva Submissions Archive Vault) implementation in less than 9 months!*

The company therefore set out to optimize its operations to gain efficiencies in its regulatory submissions globally. A critical component of that optimization was the implementation of a single "global" Information System, a single "source of truth". Sobe Good, who heads Daiichi Sankyo's R&D Informatics team was assigned as the Project Leader and served on the Global Project Management team along with two business leads, Cheryl Ressler and Don Costello (Business System Owners); this solid team of three led the Daiichi Sankyo organization through this complex change.

To make the project more "interesting", the system had to support all phases of Regulatory Document production, including CMC, Nonclinical, Clinical, Labelling, study-level trial support, and CTD submissions and submissions support. It also had to support documents for both English and Japanese-language submissions in the US, the EU, and Japan, as well as in local markets. Processes

for the production of these documents in both Japan and the US had to be aligned, and the system designed to support those processes.

This Industry Thought Leadership Paper is provided to share Sobe, Cheryl and Don's experience in leading this complex global Information system implementation with other leaders in the pharmaceutical industry.

*"Systems come and go but the business process remains at the core"*

## A Framework for Success

As project leader, Sobe led the technology implementation with a two pronged focus (1) Organizational Change Management (OCM) and (2) Business Process Engineering / Optimization (BPE). Sobe explained that you can't implement a new system without impacting the business processes.

*Companies need to look at optimizing their current business processes in conjunction with helping the organization learn to shift and adopt these dramatic changes, as part of the holistic approach to the system implementation - Sobe*

Having implemented several global and regional systems, Sobe saw that end users and business and IT executives did not realize the systems' full operational value or economic value when the organization or the business leaders were not fully engaged in both OCM and BPE. Without this dual focus, the implementation results in suboptimal configuration, adoption and use, and the full benefits of the system are not realized.

Based on extensive hands-on real world experience, Sobe mapped a solid plan to lead this project with a comprehensive approach that

would reinvent, refresh, and reimagine the approach to a global system implementation.

Cheryl Ressler stated “Systems come and go but the business process remains at the core of how we work. Without a defined business process, it doesn’t matter what system you select, as you will never reach your full potential; once the business processes are in place, the system just becomes the mechanics for execution”.

As a Regulatory Executive, Cheryl’s approach to this project comes from managing teams who have had to work with systems that didn’t meet their business needs. This led to significant inefficiencies in business operations coupled with the inability of the system to fully address the unmet needs of the business.

Don further elaborated on the necessity of a framework centered on business process excellence, “Business processes are translated into the way we use the system. Technology is simply an enabler of those processes, not an enforcer. If we want to harmonize how we are going to use the system, then we must first harmonize our business processes”.

As a leader in the R&D organization, Don and his team have been end user

stakeholders of systems that contributed to some operational inefficiencies. Simple tasks, such as finding or uploading documents were challenging as the systems were not configured appropriately. Furthermore, their use was not communicated to the users in a manner that enabled streamlined use and adoption.

With the framework established, the team set out to establish a robust business process that laid the foundation for a solid Information System implementation.

*“A system is more than just software that needs to be deployed, it is an enabler of business processes”*

As project leader, Sobe approached the project with an innovative mindset. Sobe explained, “Pharma needs to stop thinking of IT as system deployers and more as system implementers”. She continued to explain the difference: “what we mean by a system is more than just software that needs to be deployed, rather we need to think of systems as enablers of business processes”.



## *“A Specialized Bridge Between Business and IT”*

“A framework centered on the premise of business transformation as the core of a successful system implementation is a lot easier said than done”, explained Sobe. “For that approach to be successful, both IT and business functions need to understand this concept holistically and embrace what it actually means. The complication arises from the fact that the two groups essentially speak different languages, and ‘someone’ must be able to translate between these two groups. That ‘someone’ must be in the IT organization but have subject matter expertise and comprehend business processes. That ‘someone’ is the Informatics function within the IT organization who must serve as the specialized bridge between business and IT. Without this role, a system implementation framework centered on business process will not be viable”.

Sobe continued to explain that business processes must be facilitated by a Business Process Engineer. This is a specialized skill set that is ideally driven from within Informatics as the central ‘translator’ between the business and IT. The Business Process Engineer/s must work tightly with the business to gather their business requirements, facilitate the optimization and re-thinking of these requirements to improve operations, then translate those business requirements to the technical team for system configuration.

Equally critical, Sobe continued to explain, is a solid management of organizational change. With any system optimization or implementation comes process changes. These changes need to be explained to the Organization in a manner that allows the business to understand them and their value so that adoption is proactively embraced and not forced.

## *Informatics: Non-Traditional IT*

Sobe explained that there is a difference between a system implementation led by a traditional IT function and one led by an Informatics function. “Traditional IT may or may not work directly and closely with the business to gather requirements. Typically, they only involve the business at the early stages to provide a list of system requirements, or when they think the business needs to be involved. In contrast, a strategic Informatics function starts with the business needs upfront, and those needs are then translated from business talk to IT talk. That translation occurs smoothly when done by Informatics, who understands both the business talk and the IT talk”.

Sobe stated, “that for this approach to be successful, the Business and Informatics must have ‘the handshake’ right up front, with both functions acknowledging the importance of the other function's role in the project. Specifically, the system configurations must be driven by Business as ‘the providers of business needs’ and by Informatics as the ‘optimization facilitator’ and as the “translator of business processes to technical requirements”.

## *Informatics: The Business Perspective*

Cheryl stressed the importance of a healthy business and IT relationship and how critical it is for the success of a system implementation. She highly recommends ensuring that a very strong Informatics Lead is in place to help drive the process and infrastructure of the solution with the business and also that there is an IT Application Lead to ensure the system performance delivers as required.

Don explained that business and IT look at things from two different perspectives, therefore keeping the two perspectives constantly in sight is important to ensure all checks and balances are provided throughout the engagement. Don stated “It’s critical to

ensure the business drives the technology decisions hand-in-hand with IT. This includes involving the business in the evaluation, configuration, testing and migration”. He stated that the business processes were much more complicated than the IT systems; therefore, they needed to be well defined in advance of any configurations.

### *A Dynamic Tag-Team Partnership*

While a healthy relationship between business and IT, fostered through Informatics who served as the central glue to Business and IT by providing leadership in Business Process Engineering and Organizational Change Management, was an essential component of the program, the dynamic between the two business co-leads was also a critical contributor to hitting a home run with the project.

Although, both served as business co-leads, Cheryl and Don lead two different R&D sub-functions (Regulatory Operations and Clinical Medical Writing, respectively). They naturally fell into a trusted partnership that worked incredibly well in supporting all key stakeholders (cross-functionally and globally) in the implementation of the new Information Management system.

Their compatible business leadership roles had Cheryl driving the strategic components of the project, and Don focusing on the operational level details of how the system needed to work to support all functions. In both capacities, the business co-leads worked hand-in-hand with Informatics to achieve the desired technical end state.

As Don summarized “this dynamic ‘tag-team’ approach instilled a quick but critical decision-making process that allowed the team to move quickly throughout the various stages of the project”.

### *Strategic: Structure and Engagement*

The strategic components of the project included stakeholder management, organizational change management, training and communications, hyper-care, and innovative solutions (which are explained further within this document).

Cheryl explained that consistent team engagement was a fundamental component of success and several factors fed into this, including:

#### *Stakeholder Management:*

- Executive Management: Meaningful communications to senior management.
- Core Leadership Team: Having involvement and tight communication between the Informatics lead and the business co-leads, as well as members of the Business Process Team, Change Management Team, Global Representatives and Training Services, etc.). *Managed through weekly team meetings.*
- Project Team: Consistent communication and alignment on deliverables. *Managed routinely through weekly team meetings and through cross-functional workshops for critical decision-making and alignment of processes.*
- Vendor Management: Working closely with Informatics to ensure the system vendor stayed the course for delivery of defined business processes.

#### *Organizational Awareness and Engagement:*

- Organizational Change Management strategy and framework was present at the onset of this project and provided proven methodology, tools and interventions throughout the project.



- Frequent and consistent communications of the project outside of the project team, to instill awareness and implementation readiness.
- Active “Change Management”, preparing all functions globally within the organization for the upcoming changes.
- Active management of resistance; proactively working with all key stakeholders to bring them along willingly, this cannot be forced. Therefore working closely with those resisting change in order to turn them around and know that they are behind the project makes a huge difference.

### *Operational: Global and Cross-Functional Business Requirements*

The operational components of the project included defining data standards, process details and security requirements that laid the foundation for system configuration and migration.

Don’s role in the project was indispensable and came with its challenges. Don explains most systems span 1-2 functions and may be used by a limited number of countries; in the case of a global platform for Submissions Management, it is utilized by 10-12 functions and spans every region worldwide. Therefore, to ensure success of such of this global implementation the business team across all regions and functions were required to align on the business requirements.

Don emphasized the explicit needs of such an engagement, including:

- Looking at the full picture. Don explained that in his case this required him to step out of his Medical Writing role and ensure that the requirements of

all the key stakeholders involved in the process were adequately addressed. Don further explained that mapping the current state processes was an



### *Designing for the Masses*

The team worked collaboratively to design a system that delivered for the masses. Cheryl stated “the 10% requirement outliers, can be managed with smaller focus groups after the initial “big” implementation is successfully rolled out; ensure you plan to design for the masses as a priority”

Along those same lines, Cheryl continues to explain that it’s important to design a “global” system, one that can serve as the basis and foundation for all regions, so that affiliate rollout at a later time is streamlined. To be successful at this, the business must ensure they define a “global business process” that accommodates regional differences to serve as the foundation for the system requirements. Cheryl gave the following example to illustrate this point. Different regions may call the same role different things and the responsibilities of that role may vary slightly, to make this a truly “global” application, the regions must agree and align on terminology, regional differences may continue, however a “global” reference would be required.

important activity as it highlighted to the team the range of the “to-be” processes within the organization. Everyone can relate to their component of the process, but to design the system effectively, they needed to get an up front appreciation of the broad reach of the end-to-end processes that a system of this kind entailed.

- Connecting all the critical deliverables of the program, ensuring that silos were not created during any part of the project, and certainly not in the defined processes or system usage.
- Being careful with what you set in motion before you put a stake in the ground.
- Being prepared to “negotiate”, to get all the pieces to connect. Don provided an example to explain this point: “Simply deciding whether a set of documents should be kept together or stored separately can start a heated discussion; so everyone needs to come to the table ready to negotiate”.
- Empowering the employees to come up with creative uses of the new system capabilities and to share prior experiences. This will ensure that different perspectives are incorporated into the requirements.
- Allowing for innovative perspectives: enabling our employees to bring business workarounds to a system that didn’t have a defined function but had a great deal of flexibility allowed us to implement a system that had more capability than the out-of-the box design would have allowed.
- Exploiting lessons learned to avoid prior pitfalls.

- Leveraging prior bad experiences to encourage employee participation and buy-in, empowering them through authority to drive and develop their own “optimized” state.
- Allotting enough time for all key team members to contribute. This led to great engagement and ensured dedication to the project. This may be especially true in a multi-cultural project like this, where differences in the cultural styles of Japanese and Westerners may make it easy to ignore subtle but important differences. For the leaders it is important to “listen hard” to all of the contributors.
- Setting standards throughout the project to help drive consistency throughout the process. This will require definition of rules and managing controversial discussions around those rules.

Don explained, a lot of people from a lot of different functions were included in the project; contributions across the board were incredibly valuable, as it ensured all the details were checked, the process worked for all functions globally, and a proactive drive of adoption was considered across the board.

Don added, “Surprisingly, engagement is easy when the team is doing a great job. Others see that and are eager to join”.

## *Essential Elements for Success*

Besides the framework and structure that was established to run the project, this leadership team of three defined several other essential elements for success.

(1) Having the **Company’s leadership support**, with the highest corporate officer endorsing and referencing the project provided the foundational support needed to get global and cross-functional participation.

(2) Ensuring **cross-functional and global teams were established and engaged** throughout the project, both to provide their input but also to ensure all their concerns were addressed and the broader functions remained aware of the project and its continued progress.

(3) Ensuring **business processes were well mapped out and applicable globally for the masses.**

(4) Ensuring a **robust organizational change management strategy, strong communication plan and tight collaboration between OCM, Business Process Engineering and Project Management** was in place, as you develop a new process or optimize existing processes, you will have a continuous theme of change that needs to be managed globally and cross-functionally. Adoption is key and will be impacted by engagement during development, training and after system go-live.

*The business as an organization needs to be led through this significant change – Sobe*

*Clear communication of the Value of the project will go a long way to ensuring adoption – Don*

(5) Establishing an approach for continued improvement and enhancement with the ability to field questions and gain awareness for several months after deployment.

*Instituting critical and newly defined roles and responsibilities -*

*Cheryl stated that the consideration and development of new strategic roles to support the system were required. The establishment of 'Cross-Functional Business Administrators' and Super Users that represent all critical functions globally within a well-defined governance structure is crucial for long-term success.*

## *“Pitfalls to Avoid”*

Having lived through several system implementations, Sobe provides guidance on what pitfalls to avoid in such a large complex system implementation, these include:

- **Do not allow the “Age Old Scope Creep”:** There will always be a need to optimize further or define more requirements; hence the project needs to be tightly managed with a concrete “lock” date. The system should be rolled out accordingly, with a mindset of future incremental optimizations when needed
- **Educate Early - Do not “Postpone Demos”:** Waiting until the end to show the business how the defined business requirements have been translated into the system will result in significant rework. Demo the system to the business on an iterative and rolling basis to share progress with them along the way so that any misalignments can be quickly corrected.
- **Do not “Think of Change Management as Communication”:** Change management is much broader and deeper than just communications, it includes proactively engaging all key stakeholders, raising awareness, training all users and ensuring system adoption. Thinking about change management (inclusive of training) from the start of the project is critical.

## *Other Critical Considerations*

### *Budget: Robust Planning in Advance*

Cheryl stated that Sobe managed a tight budget for the project, both across the IT organization



as well as working closely with the two business leads, ensuring that every aspect of the project was given the attention and funds it required. This included ensuring that efforts for business processes, system configuration, migration, training, SOP alignment and change management were considered upfront as part of the project plan and budget analysis.

### *Comprehensive Deliverables*

Sobe explained the importance of approaching the project with robust planning upfront. Identifying all required deliverables and understanding who is responsible for them, what each deliverable will entail, when the deliverables are due, and what their interdependencies are. These deliverables include but are not limited to:

- Process Maps / Descriptions
- File Guide (Standards, Properties and Metadata definitions)
- Security Matrix (Permissions and Access controls)
- SOPs
- Change Management Plan and Execution
- User Requirements Specifications
- User Acceptance Testing Plan, Scripts and Execution
- Configuration Plan and Execution
- Validation Plan / Execution
- Migration Plan / Execution
- Training Material / Plan and Deployment
- Hyper-Care and Maintenance plan

Sobe explained that there are a lot of moving parts with a project of this kind and its important to tightly manage all of these in parallel with transparency across the broader team.

### *Migration*

Don expressed the importance of migration planning upfront and in conjunction

with the business. He advises (if possible) to approach migration with a unified set of methodology and rules, meaning define these in prep for migration, and ensure the business and the technical team work off of the same set of rules. He also stated that establishing master data is critical to ensuring you have something of value to which to map.

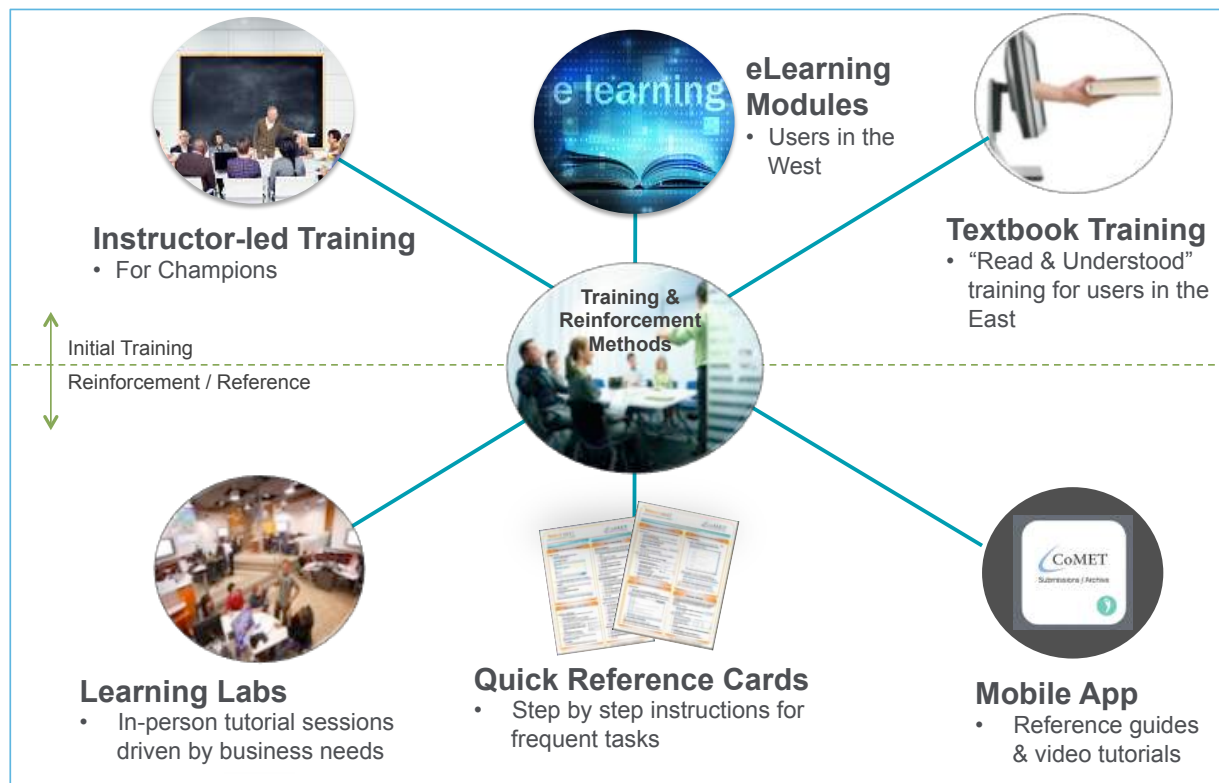
### *Training*

Cheryl advises, “training is a critical component of the overall program and shouldn’t be left to the end. The business leads should always have an eye on how the defined processes, business requirements and system will translate to the End User from the beginning”. Don, Cheryl and Sobe all explained the importance of taking the business processes and using them as the starting point for training materials. They emphasized that without this approach, the critical details will be lost and training will offer limited value. Don stressed, “Training is where the rubber hits the road and it plays a key factor into system adoption. If training isn’t well received people are less likely to want to use the system”.

Cheryl continues, “There are other considerations to keep in mind when considering a robust training program. For large complex system implementations, don’t get stuck in a One-Size-Fits-All approach. Your program should be comprehensive enough to accommodate regional differences, varying learning styles and different levels of expertise. Some examples to be considered in a comprehensive training program include, but is not limited to (1) Instructor Led Training (ILT) (ensure the instructor is a subject matter expert (SME) and fluent in the business process and system use for cross-functional use) (2) e-Learning (ensure the team developing the materials develops them off of the business process and the materials are detailed enough to provide sufficient value) (3) Static “textbook” (which is a detailed booklet that explains every aspect of the process and use of the system.

This tends to work well for individuals and/or cultures that require in-depth detail for a solid understanding of “how-to” complete specific tasks”.

- Establishing a new and/or optimized process in conjunction with the implementation will require continuous



## Hyper-Care and Innovative Solutions

Sobe instituted a period of Hyper-Care within the scope of the project. She explains, Hyper-Care is the period of support comprised of business process, change management and technical support. This critical period ensure that everything (people, process, technology (BPE+OCM) + Tech) runs smoothly immediately after go-live. Sobe explained that organizational change management doesn’t end when the project ends, but rather reinforcement becomes equally critical in immediately post implementation to enable the organization to leverage the system optimally.

Cheryl explained the importance of Hyper-Care and innovative solutions in support of a global System implementation:

support with an extensive Hyper-Care plan.

- A hyper-care plan needs to be defined early in the project (well before go-live) and carry the project well beyond system go-live.
- The hyper-care plan needs to consider each and every function as well as global and regional needs. It needs to consider expertise with the process and utility of the system.
- The plan needs to go beyond basic training; it should include establishing new roles and governance committees to support all functions and regions with the process and system moving forward

as well as establishing a framework to maintain the newly implemented system.

- Cheryl confirmed that the “Typical training solutions were not enough to support the organization through such an extensive change, and that hyper-care required innovative solutions that addressed the organization’s needs. Therefore as part of the hyper-care plan:
  - A Help Hotline was established to address both technical and business process related inquiries
  - A mobile app incorporating Quick Tips was developed to provide “in the moment support” for stakeholders who need it.”

Cheryl explains, “Users get frustrated if they can’t get an answer to their question quickly. The Help Hotline was part of the Change Management strategy which provided a quick and simple way for all sorts of questions on both the process and the system to be answered. The technical team can address the technical questions but the business questions must be triaged to a process expert and system Super User. The Quick Tips mobile app supported an integrated work environment, despite people working in different places (home / office) and different locations (from their home town or in a different state or country), they always have their phone with them, therefore providing support through a mobile app, ensures the user will have access to critical processes and job aids to help them use the system in the moment of need.”

An additional critical component was the implementation of “Functional Champions”. These were users in the various functional areas who were intensively trained before the system went live. These Functional Champions served two critical roles: 1) they kept the functions informed on the progress of the system

implementation and the benefits of the system, and 2) they could either answer simple user questions or direct the users to the Help Hotline for support.

### *“A Transition without a Start or Stop”*

In Summary Sobe explains that sustainability is an essential part of the implementation. That Process Optimizations and Organizational Change practices are critical to maintain throughout the lifecycle of the implementation, with the critical phases being:

- Project start to Go-Live
- Hyper-Care to stability
- Reinforcement throughout the change and release cycles

Set defined project goals, with the first being the main system implementation, know that new releases are coming and continuous optimizations will be required, and plan accordingly. Have a defined roadmap with defined project deadlines.

– Sobe

Any company looking to implement a new global information platform needs to treat the “project” as a transition without a start or stop; go into it knowing there is no end date.

– Cheryl

Establish an approach that allows the team to go into this with eyes-wide open for the upcoming requirements and changes; ensure a mechanism is in place to receive changes and be ready to address them.

– Don

## About the Executive Thought Leaders

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### Sobe Good, Senior Director, Global Head R&D Informatics



As an Industry Expert and Informatics leader, Sobe has over 20 years of experience building and leading Global Informatics Teams and directing large, complex, global and cross-functional enterprise programs. Sobe is differentiated in the industry with her unique background and ability to design strategic and innovative approaches to complex problems and programs, bringing together business leaders to align on strategic requirements that result in technology solutions which are well designed, implemented, adopted and impactful within the organization. Sobe's strengths include Value Generation, Strategic Planning and Analysis, Program Management, Business Process Engineering /Optimization, Organizational Change Management, Comprehensive Training Programs and Enterprise Stakeholder Management.

### Cheryl Ressler, Executive Director Regulatory Operations



Cheryl A. Ressler, RHIA, brings a variety of experiences and capabilities to her role as Executive Director, Regulatory Operations for Regulatory Affairs at Daiichi Sankyo. She has spent 18 years in the pharmaceutical industry as a Regulatory leader, supporting such functions as Strategic Planning, Records Management, Clinical Operations, Information Technology, Regulatory Information Management, Safety, and PROSCI. Mrs. Ressler has led teams spanning multiple organizational units and has been responsible for creating global standards for information exchange within the Drug Development cross-functional organization. She is also an active member of the Leadership Team for the Community of Hope Non-Profit Organization. Cheryl is best known for her critical thinking skills and focus on successful collaboration across many internal/external stakeholders in all regions.

### Don Costello, Senior Director Medical Writing



Don is a Clinical and Scientific Leader with over 30 years of Regional and Global Pharmaceutical experience spanning multiple Therapeutic Areas. Don has managed and led several teams in developing, optimizing and maintaining R&D related initiatives. He is expert in the preparation of clinical regulatory documents, having been responsible for numerous NDAs, MAAs, and sNDAs. With a robust understanding of both Clinical Development and Regulatory Affairs, Don has been able to lead teams through complex change initiatives, providing valuable insights that establish a foundation for optimized cross-functional alignment in both business processes and technology implementations globally.