# BUSINESS PROCESS DEVELOPMENT THROUGH THE USE OF A MODIFIED AXIOMATIC DESIGN METHODOLOGY

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## ABSTRACT

Today, medical device companies need to be compliant to global regulatory requirements and at the same time, streamline and shorten their product development lifecycle so they can secure the competitive advantages that come from being first to market. That means improving efficiency throughout the product development process, from development through regulatory approvals (around the world), while remaining compliant during all phases of the development. Required product development efforts, however, are constrained by the global regulations and are challenging efficiency throughout the Product Development process. Consequently, there is a recognized and critical need to know and manage this global regulatory knowledge in a way that will ensure global compliance yet also optimize product development activities. In an increasingly global market, filtering through the various distinct country regulations, global directives, standards, national legislation, mandates and guidelines necessary to develop product and ultimately secure regulatory approval can seem to be an insurmountable task. Yet, due to the expansion of global markets and the marketing opportunities that result, understanding and managing the global regulations is more important than ever. Therefore, there is an unfulfilled need to develop a theoretical process to manage these large volumes of information, and a methodology which can be used to manage this huge, diverse and changing knowledge base. This can ultimately contribute to a more efficient product development process while maintaining global compliance.

Without doubt, however, managing this knowledge, communicating this knowledge, and using this knowledge in a way that can also optimize product development efforts is a real challenge. Recognizing the need to operate in a way that meets both the business needs as well as global regulatory requirements is driving medical device companies to design and develop systems or tools to address the challenges of managing regulatory knowledge and subsequent compliance throughout the product development process. Designing these systems or tools to manage compliance knowledge, however, is not typically done using true design methodologies that provide some structure and a systematic approach to its design.

Axiomatic Design for Business Process (ADBP) provides this type of an approach to designing a solution capable of meeting all the stakeholders needs. Based on the known Axiomatic Design Methodology, it is a new and significant technique or design methodology for developing a business process in the regulated industry. The methodology utilizes customer needs as input and produces operational requirements, instructional requirements, and deliverables through the use of matrix methods. This theoretical approach to designing methodologies to manage regulatory knowledge will be a superior approach to designing the most efficient and compliant framework in the regulated medical device industry.

This research has used ADBP to develop the requirements of the design solution to the design challenge including developing the design matrices (DM) for the design solution. Using the System Engineering Principles, together with the design solution, it has developed an overarching operational Compliance Framework.

# BACKGROUND

There are two things driving biomedical companies today to become more operationally efficient: the rapid pace of global competition and an increasingly strict regulatory environment. (MatrixOne, Nov 2003) As an organization and its customer base expand, the organization's focus tends to shift from end users and their requirements to the company's internal stakeholders and business operations or processes [also known as the Quality System] with operational efficiency becoming one of management's chief concerns (Mello, 2002). In the global biomedical device industry, this optimized efficiency must occur under the constraints of world-wide government regulations and the changing country expectations for both operational process and product requirements.

In the medical device industry, minimum operational regulatory requirements are defined, in part, in the process regulations such as ISO 13485:2003 and the US FDA 21 CFR (Code of Federal Regulations) part 820. These regulations place great emphasis on the use of processes and procedures to regulate and control how internal business operations should be performed. In fact, the Code of Federal Regulations part 820 specifically mandates that "Each Manufacturer shall establish and maintain a quality system [business] process that is appropriate for the specific medical devices designed or manufactured, and that meets the requirements of this part." (FDA) Furthermore, in June, 1997, it was mandated by the US FDA that in the biomedical industry, a detailed design control [also sometimes known as product development] business process be included as part of the quality system regulations (QSR) for certain classes of medical devices." (Teixeira, 2003)

Historically, the international and domestic medical device quality system regulations (QSR) were harmonized to have twenty elements to which the regulating bodies required compliance. Therefore, organizations typically had twenty procedures, all individually written to deliver compliance to a specific element of the regulations expected to define the business operations of the organization, and all too often only a pure regurgitation of the regulation content, not considering the collective needs of all stakeholders. This may have produced a 'compliant' procedure that in practice could neither consistently and repeatedly meet the requirements of the regulations nor provide stakeholder satisfaction. In the US, the QSR constitutes the FDA's expectations. It did not take into consideration the specific needs of the company. So when procedures were developed as a regurgitation of the regulations, companies may not have had the most optimized business process. What was seen is that even if the procedures were intended to produce written compliance, what often happened was the stakeholders meant to follow these procedures developed internal "work-arounds" to get to required deliverables or to avoid procedural tasks the stakeholders find non value-added. This now uncontrolled, unrepeatable process led to increased compliance risk [noncompliance] resulting in interrupted production and distribution, product liability exposure and delayed product approvals. From the compliance perspective alone, the US FDA recognized this. Surveys they conducted showed that although medical device manufacturers have defined procedures, 30% still have problems meeting the regulatory requirements (Teixeira, 2003). Likewise, there was also resource drains across the organization associated with addressing noncompliance: completing audit corrective actions, repeating procedural tasks, re-test, re-work, and writing revisions to the procedures. This, in part, has been due to companies establishing procedures and not a business (or quality system) process that fully understands the stakeholders requirements.

Then in 2003, regulatory requirements around business processes changed with the revision of the International Organization for Standardization's Quality System regulation, ISO 13485:2003. This required biomedical device industries to look at their business operations from a process perspective as opposed to the procedural element approach. While the United States did not adopt this approach, most of the rest of the world did and does today. Regardless, one thing remains true whether domestic or international, government enforcement of the regulations is increasing and regulatory agencies are expecting more of biomedical device manufacturers in terms of process efficiency and cross-functional process definition. This is driving organizations to improve their processes in order to meet new regulations and expedite development in the interest of the public health, while still fulfilling their obligation to develop safe and effective products.

As regulatory agencies are recognizing the need for engineered product solutions that can be trusted, the business processes by which these products are created must be reliable, optimized, and robust. This has to be achieved by being well thought through and meeting the requirements of all the stakeholders that define the system. So companies are faced with redesigning how they operate from a more systematic and comprehensive manner under the constraints, expectations, and increasing demands of the regulating bodies.

# PROBLEM

In the biomedical industry, innovation is key. But you can't have innovation without safety, effectiveness and regulatory compliance. And you can't always comply and get to market as quickly and affordably as you'd like. Many companies tend to look at regulatory compliance as a sort of necessary evil that ultimately challenges efficiency throughout the product development process. Yet disaster, in the case of noncompliance, may result in loss of product certification, no regulatory approval, inability to sell the device, or worse yet, harm to a patient. There is a real challenge, then, to striking the balance between compliance and pushing product through the pipeline in a way that secures the competitive advantage of being first to market.

The problem is that the business (quality system) procedures that are responsible for defining the operations surrounding designing, developing, building, and selling this innovative product have typically been only regulation driven, leading to significant inefficiencies resulting in unsatisfactory business operations, slower times to market, poorer product quality, and increased costs. The regulations, however, are only part of the requirements for an optimal business 'process'.

Another and arguably more significant part in this effort is understanding and incorporating the requirements for the business operations from *all* of the stakeholders involved in that process, including the implementers of the process as well as the global regulators. Typically, there are few processes developed using true design methodologies that provide some structure and a systematic approach to its development. Business, or quality system, processes are not typically designed with the same robustness with which the product is designed. It is meeting the totality of the stakeholder requirements within the process that ultimately yields quality. Yet still, the paradigm is hard to shift and process design becomes an exercise in subjective opinion and such other types of ephemeral "tools" from when processes, or more so the procedures that define the process, were defined in a vacuum and primarily to meet regulations. So business (quality system) processes are still often designed without consideration of all stakeholders.

Business processes cannot be created in a vacuum and one size does not fit all. So each manufacturer has the responsibility to establish requirements for the type of product they develop, the countries in which they intend to sell their product, and the people who will be implementing the process. Additionally, they must determine the most value-added operational concept that can implement these processes.

In the governing biomedical Directives, there are required standards that govern process such as Risk Management and those that govern product testing and development, such as Safety standards. Often, there is no dedicated or centralized resource to define, interpret, and educate the division in a consistent and accurate way on which product standards, clauses, test criteria, etc. are applicable for the specific technology, from around the world. This may be left up to the working engineers on the project team. Hence, engineers typically work to comply with these standards in a project by project approach. This increases the adverse potential for complexity, inconsistency, inaccuracy and inefficiency in process and documentation, such as; with requirements management, verification test definitions, protocol development, and regulatory measures for each project of the same product type. They may take a best guess at which product regulations are applicable to the technology being developed, based on a past effort, and usually only as it relates to the United States and the European Union. Many times, the project teams don't find out until either late in the development cycle (after a regulatory submission rejection) or after not being able to sell into a country, which standards and/or national legislations are applicable, or more critically, what the current interpretation and expectation is of the standard requirements. This operational strategy delays the product development lifecycle due to redundant paperwork activities, rework, and redesign and increases regulatory risk to the organization, by creating complicated, variant documentation and a lack of apparent compliance to the technical product standards.

Complicating the situation is that product and process standards are influenced by a current regulatory environment and specific country interpretation or expectations of the standards and regulations that drive the needs and requirements for these types of business processes and product requirements. For example, in the case of a medical device with a radio component, globally many countries might mandate the use of ETSI EN 301 839, Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Radio Equipment in the Frequency Range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories. This is a constraint. Yet, even though a company designs and tests under the constraint of the standard, a specific country may wish for, or expects, verification testing to be done in their own country or by a designated

lab. This is done, for example, in some Asian countries. This is not a constraint of the standard itself, rather an expectation of that country based on the current regulatory environment.

Furthermore, the implementation of regulations and standards in the biomedical device industry has become more risk based, which is widely open to interpretation. So some regulatory requirements might constrain what functions have to be considered in a business operation or process for the regulated industry, but they do not constrain *how* to do this, whereas the "regulatory tolerance" might. In the same way, there are global product standards that can influence the product development business process. These requirements are to the process, as product requirements are to the product they produce. More complicated technology, requiring greater cross-functional involvement and more demanding stakeholder needs, leads to more complex process solutions that result in safe and effective products being developed and manufactured. These types of operational efforts are also challenged by the changing global directives, standards, and national legislation and, in turn, are challenging efficiency throughout the product development lifecycle.

Herein lays the challenge of balancing process that pushes product through the pipeline and at the same time, meeting all stakeholder and compliance requirements. The Product Development, or Design Control, process is the business process biomedical manufacturers most often try to optimize and constantly improve, not only in an effort to meet the changing demands of regulating bodies, but to meet more demanding stakeholder needs, including the regulators. Likewise, there are more challenges with competition. In effect, companies need to reduce time to market, increase product quality, ensure organizational compliance, and decrease development costs. So the design of a business process that optimizes efforts throughout the Product Development Lifecycle can largely lead to the medical device manufacturer's success or failure.

## RESEARCH NEEDS

For many required product development activities the process driving compliance to global regulations *can* be constraining when operationally applied project by project, as is typically the case. That being said, the processes that manage compliance requirements and use these requirements in a way that can also *optimize* business and product development efforts is a real challenge. While there are many tools to help companies manage the resulting deliverables of compliance activities – essential requirements checklists, tracing, etc. - there is still a recognized and critical need to develop a 'process' or system of activities that will manage the global regulatory compliance efforts in a way that will ensure global compliance, optimize product development activities, and prevent disaster. Additionally, there is a need to develop an operational strategy for this type of process or system.

Therefore, medical device companies are faced with redesigning how they operate from a more systematic and comprehensive manner, operating in a way that meets both the business needs of the internal stakeholders as well as new demands and requirements of regulating bodies, thus driving companies to improve their business operating processes or tools, as well as needing to develop the operational strategy or framework for implementing these processes.

While there are many less rigorous ways to design and develop a process, using a rigorous design methodology offered the type of innovative solution to this challenge that when implemented, offers a medical device organization a real competitive advantage.

There are many design methodologies that already exist and some build on the premise of others. One in particular provided the structure and a systematic approach to product development that was useful in addressing this design challenge. Axiomatic Design (AD) is this rigorous system design methodology that provides this type of approach to design. It uses matrix methods to systematically analyze the transformation of stakeholder needs into functional requirements, design parameters, and process variables. It integrates scientific principles and system engineering tools into the design process, in order to improve design activities. The formalities of the AD process could represent a potential solution to the design problem (Easton D. July 2007). However, it was determined that classical AD has some limitations with respect to these regulated industries, as well as other industries which have similar business processes (Easton D. , 2010).

There were challenges with using AD that expanded the rules of Axiomatic Design. For example, Suh describes the design world to include four domains that create demarcation lines between the four different design activities. The product

development process in the regulated medical device industry, however, is unique from other development processes in that it must incorporate the "regulatory tolerance" for the changing global regulatory interpretations and expectations. "Regulatory Tolerance" is a term introduced and defined by this author as "a variable regulatory expectation, interpretation, or guidance, in an individual country or group of countries, based on the current regulatory environment of that country".

The real goal of any overall design effort is to optimize the performance of the system (Hintersteiner, 2000). Consequently, there was an unfulfilled need to develop a design technique or methodology and subsequently a design solution for a "process" or system of activities, which surrounds regulatory compliance, where regulatory compliance is not just a deliverable of the product development process, but a driver to its optimization.

Therefore, there was a need to adapt and expand the AD methodology for this type of industry. As a result, there was also the need to expand the rules of AD as it applies to developing an uncoupled design for a cross functional process. This systematic approach to translating, prioritizing, organizing, analyzing and decision making on design requirements is a superior tool in developing the simplest, most efficient and most compliant business process or system and operational framework, in the regulated biomedical industry.

# AXIOMATIC DESIGN FOR BUSINESS PROCESSES (ADBP)

## General

AD Advances and Applications, by Nam P Suh, states that AD may be used to create such designs as software, manufacturing processes, systems, or organization. As it is described today, applying the AD methodology to the design of a Business Process is complicated and confusing as the methodology is presently defined. As previously stated, while there are many less rigorous ways to design and develop a Business Process, using a design methodology such as Axiomatic Design offers the type of innovative solution to Business Process Design which may offer a biomedical device organization a real competitive advantage. But the confusion using the methodology as defined today lends itself to perceived complexity, the inability or more critically, the disinterest to use the methodology for the application of Business Process design, albeit the robust design approach and the axiomatic principles would be advantageous to designing an innovative Business Process.

While AD Advances and Applications provide examples using AD for a business/organization or a process (manufacturing), it does not for a Business Process. The text describes, for example, that the Process Variables in the Process domain for a "business" might represent the human or financial resources. The Process Variables in the Process Domain for a manufacturing process might specify the manufacturing process variables that can produce the design parameter (Suh, 2001). Neither of these is applicable to designing the "product" of a "Business Process" in a regulated industry. It becomes complicated and confusing, when trying to develop a total design solution for a Business Process, once one gets into the Process Domain. Therefore this research has introduced the required extensions, modifications and clarifications of the design methodology when developing a Business Process to solve the aforementioned problems.

A Business Process in a regulated industry should consist of procedures, instructions, and records or deliverables. Using a robust design methodology to determine the fundamental content at each level of the hierarchy would certainly provide an option that can lead to a truly innovative solution. But if the AD axioms are to hold true in the Business Process design, the domains would require substantial modification.

## ADBP: Domains

In AD, the Customer Domain consists of the customer needs. The Functional domain specifies the functional requirements and constraints necessary to satisfy the customer needs. The physical domain is the domain in which design parameters are chosen to satisfy the functional requirement. The process domain specifies the process variables that can produce the design parameter.

The fundamental concept of Axiomatic Design for Business Process is that there are four domains in the design world for a business process in the regulated industry: Customer, Operational, Instructional, and Deliverable (Figure 1).

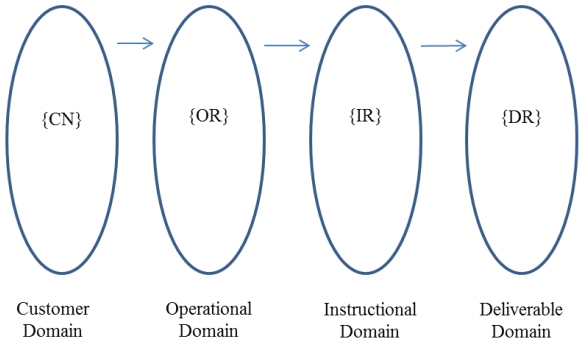


**Figure 1 ADBP Design Domains**

The Customer Domain remains the same and is described by the needs of the stakeholders for the process.

The Functional Domain is renamed the Operational Domain [OD] and is now described by the transformation of customer needs (CN's) into a high-level set of functional or Operational Requirements (OR) that describe "what the process does" to satisfy those CN's. The Operational Requirements become more specific consisting of the system based Standard Operational Requirements and operational constraints of the Business Process.

The Physical Domain is renamed to the Instructional Domain [ID] to better reflect the design activity that occurs at this stage of designing a Business Process in a regulated industry. The Instructional Requirements do not really reflect the design parameters of the Business Process itself, rather they describe the translation of the high-level operational functions to the specific Instruction necessary to complete the standard operation. Therefore, this domain consists of the work instruction or business process steps in an instruction that supports the operational requirements in a procedure.

The Process Domain must also be modified to be the Deliverable Domain. The Deliverable Domain describes the translation of instructional requirements into resulting deliverables or outputs needed to objectively show evidence of implementing the instructional requirements.

## ADBP: Design Axioms

The common elements of all good designs remain the same as described by Nam Suh. Therefore, in ADBP, the same fundamental axioms, albeit with some revision to their definition, govern the analysis and decision making process in developing high quality product or system designs.

1) Independence: This axiom maintains and promotes the independence of various operational requirements, such that instructions may be modified to satisfy a particular operation without affecting the overall operational framework.
2) Information: This axiom states that the information content of alternative designs should be minimized, thus maximizing the success of the design.

The application of the axioms forces an organization and prioritization of requirements. Designs which do not satisfy the Independence Axiom are called coupled. Designs which satisfy the Independence Axiom, in the case of ADBP, are called decoupled. This is a major difference between AD and ADBP. The IRs are to be independent to its immediate operational

requirement, however since a business operates cross-functionally, the individual operations and instructions will integrate. It is the author's experience that this integration is often overlooked, or not fully understood, within the typical design of a business process in the regulated industry.

In an acceptable design meeting the independence axiom, the IRs and ORs are related in such a way that a specific IR can be adjusted to satisfy its corresponding OR, but will impact the other ORs, as necessary, only in the case of integration points. Consequently, the order of adjusting the Instructional Requirements in a decoupled design is important.

Following this practice will result in the necessary steps of the operation being defined as well as how the operations must work together. This should result in pulling the otherwise independent instruction up into the overarching system of operations or operational framework. This approach may also be used for more complex systems where cross functionality is a constraint.

The application of the Information axiom focuses on achieving simplicity in the design and minimizing the information content necessary to select the best design solution. It also focuses on addressing competency or skill of the people implementing the process. The design solution must have the smallest information content and this will be dependent on how experienced or how many resources are intended to implement the process. The least complicated or cumbersome the instruction as per the skill of the cross functional resources, the easier it is to realize achievement to meeting the operational requirements.

## ADBP: Mapping and Hierarchy, Zigzagging and Lensing

The decomposition process to transform the operations into instructions between the domains is systematically analyzed using matrix methods. The design matrix begins with a systems perspective of the process and cross references and maps the instructional requirements from the top level, the operational framework, through each domain and hierarchy.

This alternating between pairs of domains to decompose the operations to instructions to deliverables is referred to as zigzagging as it is with AD. The hierarchies represent the design architecture and the decomposition process establishes the matrix mapping between ORs, IRs, and DRs.

The decomposition between the domains is represented by a design matrix, which shows the relationships between ORs and IRs.

This mapping can be summarized by: {OR} is the OR vector, {IR} is the IR vector, and [I] is the instructional design matrix, {OR} = [I] {IR}. An X or 0 in a cell indicates whether the column's IR affects the row's FR or not. The design matrix between the Operational Domain and the Instructional domain will be decoupled (Equation 1) as opposed to the truly uncouple solution one might seek in pure AD.

$$\begin{Bmatrix} OR1 \\ OR2 \end{Bmatrix} = \begin{bmatrix} X & O \\ X & X \end{bmatrix} \begin{Bmatrix} IR1 \\ IR2 \end{Bmatrix}$$

**Equation 1 ADBP Decoupled Design Equation**

This is because each set of instructions designed in the instructional domain must work together as a system with integration points to each high-level operation in the Operational Domain. The key is to minimize these integration points to what is necessary and most simplistic for the same reasons using the AD methodology recommends gaining a truly uncoupled solution. This will still allow for independence between the instructions, but will support the instructions coming together into one overarching system operational concept.

$$\begin{Bmatrix} IR1 \\ IR2 \end{Bmatrix} = \begin{bmatrix} X & O \\ O & X \end{bmatrix} \begin{Bmatrix} DR1 \\ DR2 \end{Bmatrix}$$

**Equation 2 ADBP Uncoupled Design Equation**

The design matrix between the Instructional Domain and the Deliverables Domain should continue to strive for the uncoupled solution (Equation 2), but decoupled is also acceptable.

## ADBP: Regulatory Lens and Zigzagging

The decomposition of the IR's developed in the Instructional Domain and DR's developed in the Deliverable Domain are complicated by the current regulatory environment and specific country interpretations of the standards and regulations that drive the needs for these types of business processes.

Specifically, according to AD methodology, constraints limit the choice of design parameters. Whereas in ADBP in the global regulated industry, constraints such as those found in process standards like ISO 14971, Medical Devices- Application of Risk Management to Medical Devices, or quality system regulations such as those found in ISO 13485:2003 might operate as a system constraint, one which is imposed by the system in which the design solution, or Business Process, must function.

The implementation of these regulations and standards in the medical device industry, though, has become more risk based. So some regulatory requirements might constrain what functions have to be considered in a Business Process for the regulated industry, but they do not constrain how to do this. Therefore moving from the Operational Domain to the Instructional Domain, the Instructional Requirements that most simply satisfy the Operational Requirements are left up to interpretation, but are still dependent on the current regulatory environment of a given country. This "interpretation" is considered to be a "tolerance" or "ambiguity" to the regulation or standard. Even if a regulatory standard is harmonized across countries, the individual country's regulatory agency may have a different expectation for how to meet the requirements.

The zigzagging process between the modified domains of ADBP, in the specific situation of designing a global Business Process in the Regulated Industry, therefore requires a further need to modify and extend the AD methodology. Key to this significant modification is the introduction of the new term "Regulatory Tolerance" which is created and defined by this author as "a variable regulatory expectation, interpretation, or guidance, in an individual country or group of countries, based on the current regulatory environment of that country". In the regulated industry, it is necessary to review and accommodate this regulatory tolerance. Learning about or addressing this variable tolerance is often done at the later stages of the product development lifecycle, after the rejection of a regulatory submission or the unexpected inability to sell product into a specific country. Therefore, this significant and unique modification and extension of the AD methodology also includes what this author has designed as a Regulatory Lens. The Regulatory Lens is a tool that is placed between the design domains of ADBP. Decomposing of requirements through this regulatory lens, referred to as "lensing", focuses on one requirement then looks at that requirement thru a magnifying glass forcing review of applicable regulatory tolerance at the front end of the lifecycle. When there is the case of possible tolerance, one would need to bounce against this lens, opening the regulatory gate for a specified requirement, as shown in the Regulatory Lens box of Figure 2. When the gate is open, zigzagging occurs as normal between the domains. When the gate is closed by the designer, the zigzagging is halted between the domains and the zigzagging bounces against the closed gate until all country's tolerance for a given requirement is addressed. Once addressed, the gate re-opens and normal zigzagging resumes through the domains. So while a requirement may be for a protocol, regulatory tolerance identifies certain expectations for the execution of the protocol, and decomposing through the Regulatory Lens requires the determination of specific tolerance for each country of interest; such as execution of the protocol must be performed in-country, or by a particular lab.

These two significant and unique modifications and extensions to the AD methodology will simply and systematically address the interpretations of multiple countries for the same basic function resulting in the most robust global solution for the desired Business Process.

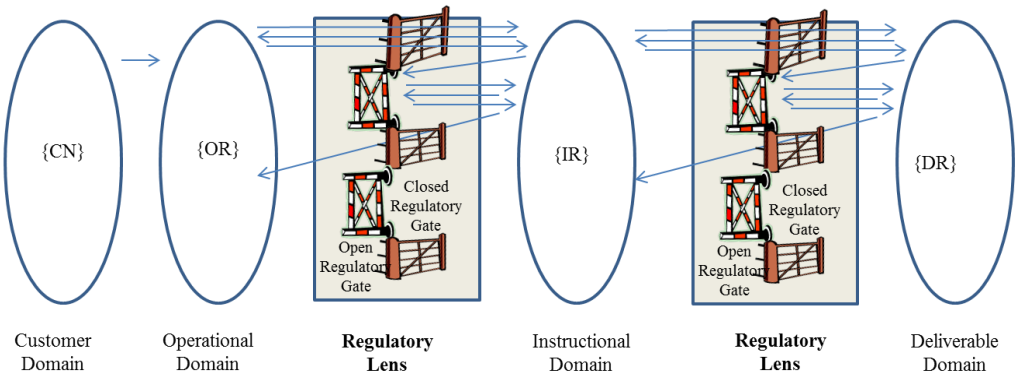


**Figure 2 ADBP Domains with Regulatory Lens**

## COMPLIANCE FRAMEWORK

Applying ADBP led to the creation of the operational framework for developing and implementing a business process around compliance requirements. Typically compliance is addressed for each individual project using the project by project approach shown in Figure 3.

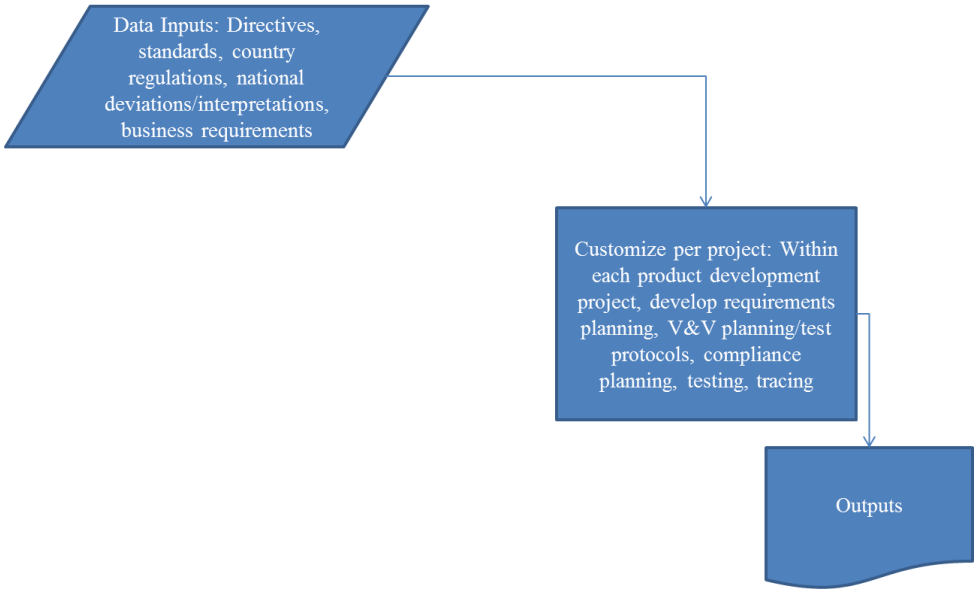


**Figure 3 Project by Project Approach**

The design solution using ADBP has developed a different, better, approach. This operational Compliance Framework is shown in Figure 4 and reflects the decoupled solution resulting from the requirements breakdown. The red box encompasses the part of work that is done comprehensively one time only. This information is reviewed for each project, but only the work pertaining to the delta between a new development project and what has been developed as part of the systematize and standardize part of the concept, in the form of specifications, protocols, instructions, etc. will be leveraged for the individual project. This will thereby give back time to the project teams who would have been addressing these compliance efforts on the project by project approach.

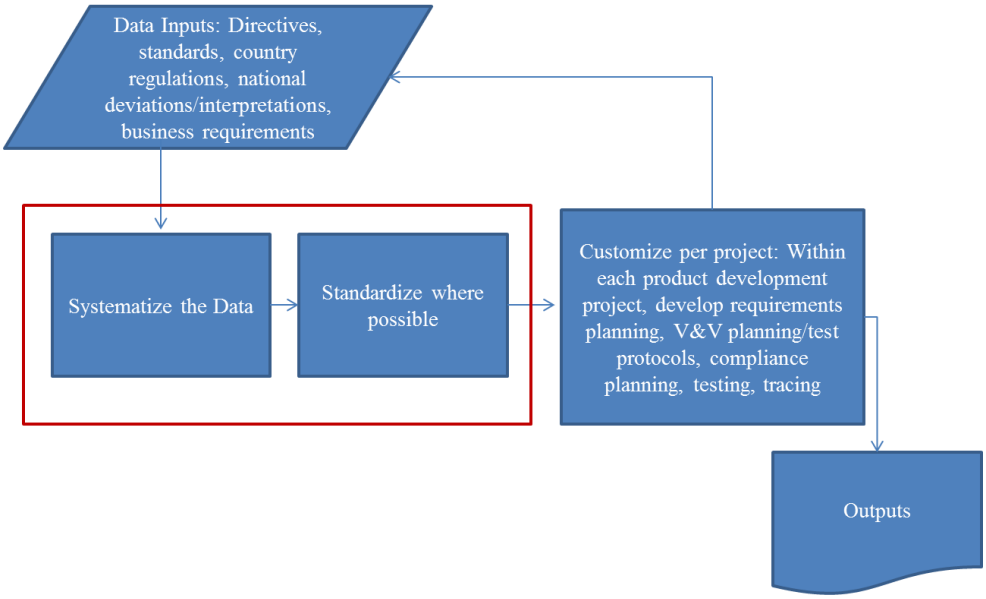


**Figure 4 ADBP Compliance Framework**

## BUSINESS MODEL WITH APPLICATION OF COMPLIANCE FRAMEWORK

Specifically applying the detail of this framework to a product development process such as that identified in the one by the Stanford BioDesign Study (Linehan, Pate-Cornell, & al, 2007) leads to Figure 5, which depicts a high level proposed model of the applied operational framework for developing and implementing a business process around compliance requirements.

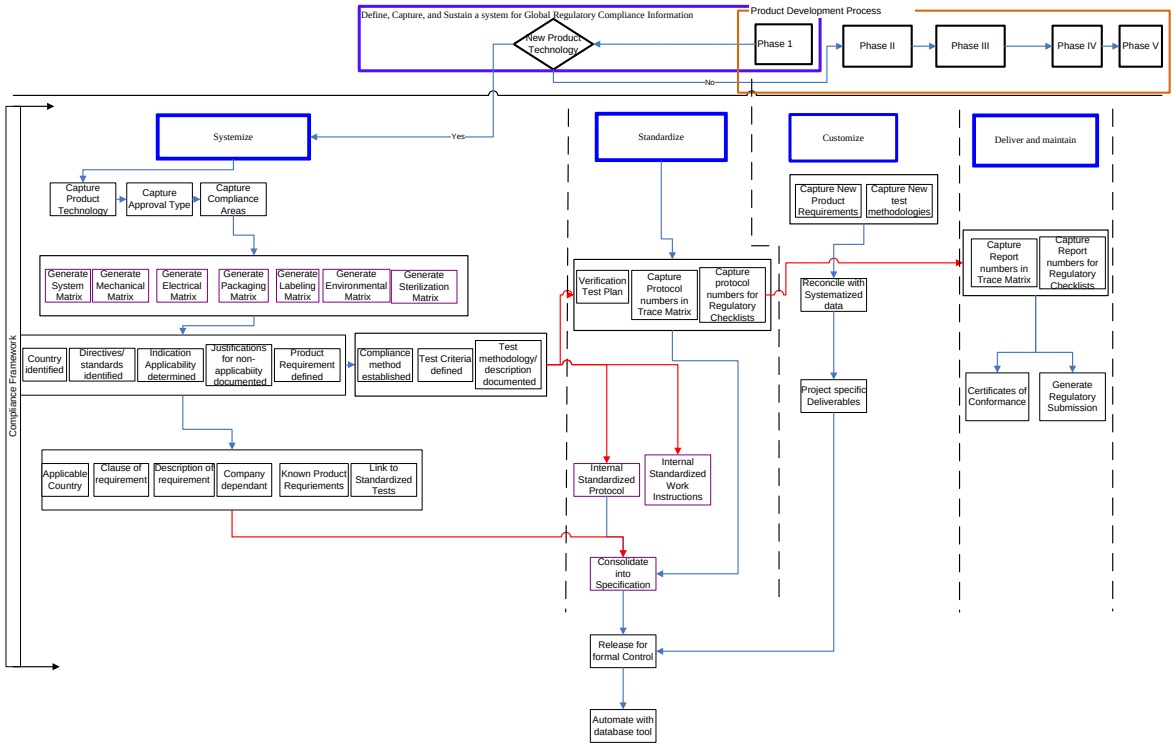


**Figure 5, Applied Compliance Framework**

This model shows the product development process across the top. This is the process in which the details of the framework will integrate. Sections are separated by the dotted lines. Within the bold lined boxes are the functional or Operational Requirements (OR) that describe "what the process does":

| | |
|---|---|
| OR1 | Systemize the approach for compliance requirements |
| OR2 | Standardize the approach where possible |
| OR3 | Customize the information for specific project |
| OR4 | Deliver and maintain compliant products for regulatory approvals for new product, new geographies, new indications, changes to regulatory environment |
| OR5 | Define, Capture, and Sustain a system for Global Regulatory Compliance Information for Product Approvals |

Translation of the operational requirements provides the detail for the operational concept for this model which starts with gathering inputs from worldwide directives, standards, national legislation, and country import/export requirements that are applicable to the organizations devices, as well as gathering requirements from the organization's needs and historical development efforts such as risk management files.

These tools would be initially developed as part of systematizing the information and captured in controlled documents or databases. They can then be introduced into the product development process for each product type. The individual project teams would use these tools, then, to customize the data for a particular project based on the delta of their new product customer requirements. This delta is then captured back into the tools section of the framework as a matter of sustainability. Since this sustainability is part of the framework the data will be inherently maintained in the changing regulatory and competitive business environments.

## CONCLUSION

"By standardizing the development process, the public is assured that critical elements of good design practices are not omitted. But standardization [alone] does not always permit streamlining developmental processes where it would make sense." (Linehan, Pate-Cornell, & al, 2007)

The systematic approach in ADBP to translating, prioritizing, organizing, analyzing and decision making on design requirements proved a superior tool in developing the simplest, most efficient and most compliant business process which led to the innovative and significant Compliance Framework to be used in the regulated biomedical industry.

By following ADBP, the novel and innovative solution was created in a solution neutral environment and not biased by the "ways things have always been done". The modifications and enhancements that created ADBP accounted for the cross functional nature of the business process, the regulatory tolerance see in the regulated industry, the expectations of a design hierarchy that included the overarching process, the instructions to achieve that overarching process, the objective evidence required as part of fulfilling those work instructions and the analysis and prioritization of all such requirements. The overarching process resulted in pulling the otherwise independent instruction up into the overarching system of operations, or the Compliance Framework.

Applying the Operational Compliance Framework that requires the initial systematizing of information affords an organization the opportunity to reduce the iterative loops that pertain to the regulatory efforts in the development process. This systematized information is captured and maintained outside of development specific efforts, then reviewed during each project, but only the work pertaining to the delta between a new development project and what has been maintained as part of the systematized and standardized part of the concept, in the form of specifications, protocols, instructions, etc. will be leveraged for the individual project. This will thereby give back time to the project teams who would have been addressing these compliance efforts on the project by project approach. In addition to the financial savings achieved utilizing this process, the formalism of the process includes a far more requirements traceable process for design and regulatory compliance, with the ultimate goal of safety for the patient.

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