4

Components of Regulatory Strategy – The Basics

Melissa Walker, MS, RAC-US, FRAPS

Introduction

A strategy is defined as a careful plan or method for achieving a particular goal usually over a long period of time. The end goal of a regulatory strategy is to obtain safe and effective products for patients who need them for as long as they are needed. To do that as quickly and efficiently as possible, manufacturers must consider a range of factors. A global regulatory strategy is needed for any new product. Where does a regulatory professional start? As the King said to the White Rabbit in Alice in Wonderland, "Begin at the beginning and go on till you come to the end: then stop."

The beginning stage of a global regulatory is the patient need and the company's plan to meet that need. The end comes when the product is no longer used or on the market. During the product's entire lifecycle, the regulatory strategy must be updated constantly to adjust to shifting requirements of patients, physicians, and regulatory agencies. Why start with the product plans? These are the boundaries for the strategy. The countries selected, resources available, and market timing will drive the final strategy.

Gather Information

The regulatory professional should keep in mind that information gathering will be helpful for both the Global Regulatory Strategy (GRS) and the regulatory plan. Think of the strategy as the overall approach to getting the product to market. The GRS should include a top-level summary of what needs to be accomplished to get the product to healthcare professionals and patients. The regulatory plan should be much more detailed, offering direction and requirements to the project team. The difference between these two documents is detailed in the Communicating the Strategy section of this chapter.

Before gathering information, the regulatory professional should make a list of the elements that should be included in the GRS and the regulatory plan. The circumstances surrounding individuals' projects can differ significantly. The GRS contents should reflect the project's nature and should guide both the research and analysis efforts. Other stakeholders' questions, priorities, timing, and outcomes should be incorporated in the research efforts. When assembling the strategy, it is highly likely that some elements will not meet the project team's ideal outcome. These points will need to be defended when the strategy is reviewed. The regulatory professional can minimize the length of the debate by supporting the variation from the ideal with effective data.

The GRS elements and necessary information should be identified, including a brief statement on expectations from the project plan. The team must consider the type of research methodology that will best fit each element. Some elements will require an exploration of something (qualitative research), while others may start with a hypothesis (quantitative research). Some elements may require both. At this initial stage, the regulatory professional should do his or her best to identify the type of research and

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Table 4-1. GRS Simplified Element Table

GRS Element	Project Expectation	Research Methodology	Data Needed
Review time (each target market)	90-180 days	Quantitative & Qualitative	• Published review times (as available) • Previous experience • Regulatory network resources
Available guidance/ standards	Yes	Qualitative	• International standards list • Standards used in previous submissions • Accepted standards declarations (country-specific)
Clinical study needs	None for premarket	Qualitative	• Guidance documents • Previous submissions for competitive products
Environmental trends	None	Qualitative	• Review of public meeting schedules (past and present) • Guidance documents (planned or pending) • Public health issues • Legislative activity

data needed. If the plan features an expectation for the result, it should be listed in the table as well, as it could be the hypothesis for a quantitative research activity. Because this list frequently needs adjustment as the research process moves forward, it should be readily available and edited accordingly.

A simplified example is shown in **Table 4-1**. It is very tempting to jump into a previously assembled strategy and follow its pathway. Time is precious, and every minute that can be saved is a valuable commodity. However, it is important to remember that the path previously followed may not lead to the same conclusion. The regulatory environment is fluid. Requirements can change quickly. These questions should be asked before proceeding to document the strategy:

- Is the clinical application understood?
- Are the business and market objectives understood?
- Are the technology and engineering aspects understood?
- Is the competitive landscape understood?
- Is the regulatory and compliance history of existing products understood, in all desired national markets?
- Are the clinical evidence or clinical trial requirements understood?
- Are there regulatory or clinical practice trends that will affect the product?

If the answer to any of these questions is "no," the team should take the time to conduct further research. With the advent of the internet and generative AI tools, online searches for product information can lead to many sources. Even with almost too much information to sift through, it is worth the effort. The regulatory professional should compile notes on various research areas. Although not everything found during research may go into the regulatory strategy document, it can be very valuable for future research efforts.

This task may appear to require a great deal of research to perform before even starting to assemble the GRS and may take more time than preferred, but it will provide long-term benefits. The more thorough the research, the better the GRS and regulatory plan will be, reducing the number and impact of surprises that often show up over the course of a project.

Product Plan

Questions to answer:

- What device(s) is/are the subject of the plan?
- What countries have been targeted in the product plan?
- What is the desired timeframe for each proposed market introduction?
- Is the device new to the company, or is it an improvement/iteration of an existing device?
- What are the key assumptions in the company's product plan?
- What are the key regulatory risks (and associated schedule risks) in the plan?
- What is the plan to collect supporting data?

To create a regulatory strategy, the regulatory professional first must understand the product, its clinical use, and the countries included in the company's plan. Every segment of an organization desires to be in every available market as quickly as possible. However, the reality is each country will have its own requirements and timing. The costs of obtaining and maintaining a marketing authorization may mean entry into every targeted country may not be reasonable, based on the product's sales potential. Absent

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endless resources, it is important to prioritize the entry into the targeted countries.

Every plan is made with certain assumptions. The team must understand which assumptions, if shown to be false, would result in the project's failure.

For example, Competitor A will be in the European Union (EU) within 1 year. Its new device includes a key design feature that has the potential to shift market share in its direction. Your product's continued success depends on getting to the market first with this key feature to protect your market share. The product is similar to your current product, but several changes are planned before being released onto the market. Development can proceed quickly, and the product can be ready in 9-10 months. Any additional time due to a review delay will mean the market window has closed and Competitor A may take market share. The company's plan assumes:

- Competitor A will deliver on its plan in 1 year, and
- Your product modifications will not require more than the 9-10 month cycle, including development and regulatory body oversight (if needed).

If Competitor A delivers faster than its plan, your company can lose the race. If the product modifications needed require prior review, your company also may lose the race. While the project proceeds, the team should pay careful attention to these assumptions, adjusting the GRS on a regular basis if conditions change.

Another example. An adverse inspection has resulted in closure of the competitor's facility. The company that can increase production to cover the product volume can lock in a multiyear supply contract. The product requires prior review from regulatory authorities, as it is a Class III/high-risk product. To accommodate demand for the product, your company must expand production to a new facility that will supply products in multiple geographies. The plan assumes regulatory approval in one of the major markets (United States (US), EU, or Japan) must be received within 6 months. Without the multiyear supply contract which will, over time, cover the cost of the expansion, the project is not financially feasible. In this case, the key assumptions are:

- The multiyear supply contract can be obtained,
- The new facility receives regulatory approval for production, and
- The regulatory status of the competitor's facility does not change, allowing them to restart production prior to the new facility.

Other types of limitations also will affect the GRS. Product plans for the same product may be very different based on the company's size and nature. For example, how would a GRS differ for the following: a small company (fewer than 50 employees, venture-funded, no currently marketed products), or a large company (more than 10,000 employees, profitable, fully developed product lines currently marketed)?

Small, venture-funded companies often have scarce time and resources. The first product may have enough features and capability to get clinical use; getting a product's first iteration on the market can mean the organization's continued viability. A 6-month delay means the company has fewer resources for commercial launch. Larger companies may not be as sensitive to similar time or resource constraints, as their continued viability is not at risk.

In any case, make a what-if list of the development or regulatory events that could change the assumptions that drive the GRS. For example, identify the priority for the new design features. Which ones could be pushed to the next iteration if the release schedule accelerates?

The variations are virtually endless. Unless the regulatory strategy considers the limitations built into the plan, the project is designed for failure.

Regulatory History

Questions to be answered:

- Are similar devices already in (or out of) the target marketplace(s)?
- What data were required for existing devices' clearances or approvals?
- How long were the review processes?
- Who manufactures or distributes similar devices?
- Have the existing devices' manufacturers had findings or observations during regulatory or conformity assessment bodies' inspections (those who make audit or inspection reports publicly available)?
- Were clinical studies required?
- What are the common types of device failures?
- Have there been any recalls of existing devices?
- What guidance documents or performance standards are available?
- Does the device have any other uses apart from the targeted indications?

Researching the regulatory history of a medical device can be very time-consuming. This is especially true when the product plan includes multiple countries. It is a simpler process if the GRS is for an extension of an existing product line in the same target countries, rather than an entirely new product type. If no internal product history exists, each country will require more research. Countries publish

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varying amounts of information about a particular product's review and compliance history.

In this exercise, the regulatory professional is assembling a puzzle but may not have all the pieces from official sources. Not all the important information required will be found on regulatory agency websites or in written guidance. Often, the critical information needed will be found in other regulatory professionals' experience. Leverage the experience of company colleagues, consultants, distributors, or attorneys. The recent growth of such social media outlets as Regulatory Affairs Professionals Society Regulatory Exchange and LinkedIn make it easier to access a broad range of expertise. Useful blogs address particular topics and can be searched online. Commercial news services that specialize in the medical device industry also may provide valuable information.

The device's classification in each country should be identified first. Classification schemes have much in common and often use a risk-based approach that can be different in important ways. For example, Japan has four classifications (I, II, III, and IV), while the US has three (I, II, and III). Under the EU Medical Device Regulation,[1] there are four risk-based classes (I, IIa, IIb, and III). What is considered a Class II device in the US may be Class III in the EU due to differing definitions and rules within each device class. The submission type required within a particular class also may be different. In Japan, the application type depends on whether the device is "new," "improved" or "me-too."[2] International standards' applicability also can influence the required application type. This level of detail should be captured in regulatory research.

Information about competitive devices and their manufacturers generally is available from various stakeholders within the company. Because the US publishes a significant amount of information on devices and their manufacturers, researching the US Food and Drug Administration (FDA) websites is a good starting place. Identifying the US product code (or codes) enables a search of the 510(k) or premarket approval databases. This will provide a list of manufacturers and sponsors with a US regulatory history with the device or technology. Using the company and trade names enables a search of other individual country regulatory agency websites.

Any regulatory agency website search will have limitations. For example, only portions of the information needed may be available to the general public. Only a few countries have a process for obtaining information by request (e.g., the US Freedom of Information Act), and their respective agencies have a reputation for slow responses. Search terms need to be broad enough to capture what is needed but narrow enough to limit the results to a manageable number. Company names and trade names also can vary from country to country, leading to missed references under an alternate name. A product marketed by one company today may have been approved/cleared by a different company. Companies are acquired or may change their corporate names, making the history of a particular product important.

Often, the competitor's website can be a good source of product information. Many companies will publish labeling content and list the markets where products are sold. Product information also may be available through customer service request.

The estimated review time is a key GRS piece. If specific data already are available for similar products through the regulatory process, a range can be established based on prior experience. The regulatory professional should be cautious when assembling the GRS estimates. Multiple factors influence the final review time. Even within device types (same generic name), devices' nature can differ significantly. For example, a diagnostic programmable computer may be a device intended for collecting ambulatory heart rhythms or producing complex cardiac electrical maps during invasive catheterization procedures. Used under different conditions, these two devices are very different. When assessing review times, make sure devices with comparable intended uses are considered. Technology's complexity, inclusion of clinical data, need for additional test data and even the time of year (holidays can mean longer timeframes) can influence the review time. It generally is best to consider the most recent reviews of similar devices for the estimate as well as the range of review times.

Anticipating the need for clinical trials is a key GRS element. A thorough GRS will examine the need for pre- or post-approval studies. The need for clinical data can vary significantly from country to country, even for the same product. There may be specific patient population reasons for a clinical data requirement. It also may be related to the device's classification. Regulatory agencies may publish summaries of safety and effectiveness data provided in regulatory submissions, including clinical studies. Clinical studies also are described either in medical or scientific publications or on websites such as clinicaltrials.gov, providing a significant amount of valuable insight for the GRS. Over time, types of devices that initially required clinical data may not always do so for subsequent approvals. As clinicians, sponsors, and regulators become familiar with a device type, preapproval clinical trials may be unnecessary.

Product recall records are available on many regulatory agency websites. The records may be in a

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Table 4-2. Regulatory History Considerations

Question	Considerations
Who manufactures or distributes similar devices?	Identify companies that manufacture or distribute similar devices. Monitor their regulatory activities on a regular basis. The sudden appearance of a new competitor's product may require a reassessment of your development project.
Are similar devices already in (or out of) the target marketplace(s)?	Identify similar devices that are currently marketed as well as those that are no longer marketed. Device designs and functions can evolve over time. A particular device that is no longer available may be obsolete or have been superseded by a new model. The device's market life may have been cut short by a design issue that resulted in a recall or unacceptable failure/injury profile.
What data were required for existing devices' clearances or approvals?	Regulatory research into what was required by the country's regulatory authority provides clues into testing and performance standards. Be cautious about accepting historical precedence at face value, as technology and clinical treatment standards can change over time. Expected risk mitigations built into device designs can require alternative testing. Combining multiple functions into a single device may also indicate a need to deviate from previous historical precedents.
How long will the review process require?	When information is available about review times, it is tempting to accept those numbers at face value. An average number of days for submission to approval may provide some assistance to answer this perpetual stakeholder question. Consider the relative complexity of the submission when estimating review time. New capabilities absent from competitors' devices can mean longer review times. A device design that includes new technology or adds a new software algorithm can also increase the complexity of the review and result in longer review times. Determine the estimated time needed for the review based on comparable submissions already completed.
Have the existing devices' manufacturers had findings or observations during regulatory or conformity assessment bodies' inspections (those who make audit or inspection reports publicly available)?	Regulatory findings generated during inspections can provide examples of nonconformances. For example, citations reporting failure to properly report adverse events can provide clues about regulatory body expectations. Notations about inadequate validations or absent cybersecurity controls are also very informative.
Were clinical studies required?	The need for clinical data to support a marketing submission is a key question for the development team. Often, the presence of clinical study information appears inconsistent. Some devices may include clinical data while other devices of the same type and purpose do not. Examine the devices that were subject to clinical data requirement and compare the design, indications, and function of those that did not. Note whether the submission was the first for the Sponsor or if it was a modification to a previously marketed device.
What are the common types of device failures or product recalls?	Review any available information relating to device failures or recalls even if the information comes from a country not included in the product plan. While device models may differ somewhat from country to country, review and consider applicability to the design of the device being developed.
What guidance documents or performance standards are available?	Regulatory agencies produce guidance documents associated with a type of device, technology, and indication, as well as regulatory processes. Look for guidance related to other types of devices that use the same or similar technology. New technologies and new intended uses may not have established guidance documents.
Does the device have any other uses apart from the targeted indications?	It is important to understand whether a device labeled for one indication is also usable for a different indication. The risks associated with one use may not be the same as a second use. Additional controls or design capabilities may need to be included in the development plan.

database specific to a particular product or found in summary form within annual reports from the regulatory agency. These records can provide information on several GRS aspects. Products frequently associated with recalls may be subject to more regulatory scrutiny. Understanding what types of recalls (and the reasons for them) reported for similar products also will contribute to review time estimates, risk analyses, and overall regulatory environment surrounding the product.

The GRS should include a review and assessment of device problem reports and safety alerts. These types of reports are available on regulatory agency websites. A review of these types of reports will provide failure modes and use errors for the development team. The regulatory professional should put themself in the role of a regulator, which provides insight into the problems that may arise. **Table 4-2** provides additional considerations.

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Table 4-3. Tools or Treatment

Characteristic	Medical Device Tool	Medical Device Therapy
Primary Purpose	Assist in diagnosis, treatment, or monitoring of medical procedures	Directly treat or manage a specific medical condition
Interaction	Provides information or mechanical assistance	Directly intervenes to improve patient health or function
Mechanism	Observes, measures, or supports medical procedures	Actively corrects, replaces, or supports bodily functions
Examples	Stethoscope, Blood Pressure monitor, X-Ray machine, Surgical instruments	Pacemaker, prosthetic limb, hearing aid, Cochlear

Clinical Application

Questions to be answered:

- What are the clinical conditions that apply to the device?
- Who will be using the device?
- Where will the device be used?
- How will the device be used?
- What other devices will be used with the device?
- Are there off-label uses for the product?

To understand the answers to these questions, the regulatory professional needs to clearly understand whether the device functions as a tool or a therapy (see **Table 4-3**). Having a clear understanding of the circumstances surrounding the use of the device and the patient's clinical condition is critical for a thorough, clearly crafted, GRS. This information can come from internal experts in the organization's marketing, R&D, and/or clinical groups. To be fully informed, it is often necessary to look at outside sources. To understand how regulatory agencies view treatments, it is important to look for clinical summaries or disease-specific guidance published by regulatory agencies.

For example, in the US, current clinical practice summaries are published by both the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services. AHRQ publishes clinical guidelines and recommendations for healthcare professionals, as well as clinical condition reports for consumers. These agencies review a wide variety of medical interventions and the products used for them. Their efforts are aimed at educating healthcare professionals but also are very useful in understanding the regulator's perspective on clinical use.

The location of the device's use affects its development and even classification. For example, a cardiac defibrillator is used to terminate cardiac dysrhythmia. If this device will be used by physicians in a catheterization lab, the design considerations are very different than if it will be placed in a high school gym for the general public to use in emergencies.

It is important to remember that standard clinical practices for treatments may vary from country to country or even region to region. These differences can be minor or major, based on the devices or drugs currently approved or available to local healthcare providers. Many peer-reviewed clinical publications, such as the New England Journal of Medicine or the Journal of the American Medical Association, are available on the internet, but often are pay-per-view. These global publications are good sources for understanding evolving research and scientific explorations around a particular clinical condition or treatment. It is recommended that regulatory professionals have a solid understanding of current clinical practice before embarking on a detailed review of published literature. The US National Library of Medicine's MEDLINE/PubMed service[3] provides a broad spectrum of resources.

Even if a regulatory professional believes he or she has a good understanding of the clinical condition being treated, it is always a good idea to find resources that provide the most up-to-date information about the condition.

Technology and Engineering

Questions to be answered:

- Is this a new technology?
- Is this a new application of existing technology?
- Is the technology used in other devices?
- What materials are used in the device?
- What problems have been reported with existing devices using the same technology?
- Does the application of technology pose any new questions or risks?
- What evidence is needed to support regulatory approvals in each target market?

Because regulatory professionals come from a wide variety of backgrounds, from biology to engineering to psychology, it is important to establish a broad base

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of understanding across multiple disciplines. Medical device technology and engineering aspects range from simple to complex. A handheld instrument's engineering and design are much different than those of a robotic radiosurgery system. A clear understanding of a device's scientific principles is a necessary piece of a thorough GRS.

Device technologies often appear in multiple clinical specialties. Technology that begins in one area (e.g., radiofrequency probes for cutting and coagulating tissue in general surgery procedures) can expand to additional clinical specialties (e.g., intracardiac ablation to treat cardiac arrhythmias). Often, relevant similarities exist in technical requirements or risk factors. Technical risks and failure modes for one clinical application can easily apply to another application. Ultrasound energy can be used for imaging or coagulating/ablating tissue. A failure mode for either device can present risks to the system's safety and effectiveness.

Examining benefits, risks, and failure modes of devices using the same technology also will provide insight into how a regulator may perceive the benefits and risks new device. Regulatory professionals should remember regulators have a much broader visibility into a technology's clinical uses than any one company. Problems seen in other clinical applications easily can lead to additional questions about a new use of an old technology. Thoroughly analyzing the technology's existing clinical uses is time well spent.

Environmental Influences

Questions to be answered:

- Are there any ongoing public health issues associated with the condition being treated or devices currently on the market?
- Are there any public meetings (previously held or planned) relevant to the device or its clinical use?
- Are new guidance documents planned, or have any been issued (or withdrawn) since the last product?
- Are revisions to relevant existing standards (national or international, mandatory or voluntary) under consideration or in the works? Are new standards being developed?
- What are the relevant trends in clinical literature, (e.g., changing standards in clinical practice), such as adjunctive therapies used with devices?
- Are there ongoing discussions of, or work on, changes in the legislative or regulatory framework in key markets of interest?

Environmental changes come in all shapes and sizes. They can have a positive or negative impact on industry, clinical practice, patients, and even regulatory professionals! Such changes can be related to a particular product, as when a new performance standard is published. Regulation changes commonly come through agency announcements that are analyzed and debated in the public arena. Perhaps a device is "down classified," reducing the regulatory requirements and opening the door to the entry of new competitors into the space. New guidance documents or standards can be posted for weeks, months or even years prior to implementation. A public meeting is held to discuss a particular issue that reveals a regulatory agency's perspective. These types of environmental changes are visible and happen over a manageable period of time. Administration changes can also be a catalyst for significant policy changes.

Other types of environmental changes may occur quickly. Generally, these tend to be in response to a very visible public health issue. A series of recalls may trigger a change in the performance standard for a device. A serious problem triggering a recall for one company's product may trigger a review of all products of that type. Insurance reimbursement changes result in the abandonment (or adoption) of a particular device or clinical use. Postmarket event analyses can lead to a safety alert followed by the withdrawal of the product's approval. A class action lawsuit may be filed on an entire product type. All these scenarios can contribute to shifts in both the regulatory and clinical practice environments.

If a public health issue arises, some regulatory changes are likely to occur. This is particularly true when the issue has a significant risk for harm, affects a significant number of people, and is highly publicized. How quickly the regulatory change occurs depends on the nature of the change needed. Changes requiring legislation can take considerable time. Debates and discussions within legislative bodies often require months to years. Reviewing or monitoring legislative activities becomes key in both generating a GSR and executing the strategy. Health issues significant enough to trigger a change in one country have a high potential of triggering similar actions by regulatory authorities in other counties. In most instances, legislative activities generate mounds of documentation and public visibility. Information regarding these types of activities is generally available and should be considered as an important consideration in preparing a GRS.

If a change requires regulation or guidance modification, implementation time can vary from months to years. As is the case with legislation, many regulatory authorities follow a process that provides an opportunity for public review and comment on proposed changes.

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A change in practice, however, can come very quickly, with no advance notice or warning. Regulatory authorities have a clear view of the presence and cause of product problems. This knowledge can affect many aspects of similar products' reviews and requirements, without prior signals to sponsors. Anticipating these types of changes – identifying the invisible regulatory risks – is an important aspect to consider in both GSR generation and regulatory plan execution.

This can be the most difficult element of a GRS. Keeping current on environmental changes is a huge challenge for the regulatory professional, who should use his or her network of other regulatory professionals in addition to available public information. Combining these resources provides the best support for the strategy.

Resources

- What regulatory resources are needed to support the GRS?
- What type of expertise is needed?
- Can the project be supported by external resources?
- What in-country resources are available to support registrations there?

Creating and executing a GRS requires considerable time and effort. Although the team often focuses on what happens following the submission, creating and organizing the submission is no small task. This is particularly true when the product plan schedule calls for simultaneous or overlapping submission dates. It often is easier for stakeholders to understand the need for an additional engineer than for more regulatory staff. Thus, the GRS resource section is critical to project success.

Many methods exist for estimating the resources needed to execute the GRS successfully. Project management software programs can be helpful, and a spreadsheet program can be used to determine where resources may be constrained. Requests for additional resources will be scrutinized closely. The GRS should make a solid case for additional support.

Regulatory staff often are spread over multiple projects and responsibilities. Each project has its own timeline and milestones. As a shared resource, regulatory staff must balance their workload around each team's schedule. The team must carefully consider this variable when developing the resource plan. Project teams focus on their projects and make them their first priorities. The should be allowed sufficient time for submission preparation, review, and editing. Even final submission preparations (e.g., electronic format, multiple paper copies) take time and should be included in the plan.

Some project aspects may require different areas of expertise not available within the organization. This applies to regulatory and other functions. For example, if the project is the first to require a clinical trial, study design, statistics, or US Investigational Device Exemption, it may require submission expertise. If the project incorporates a new software program, regulatory expertise in this area may be needed. It is necessary to determine whether this resource should be a permanent staff addition or an external resource. Adding a consultant will take time to identify and familiarize the person or firm with the project. This task also should be considered in the resource analysis.

Assemble the Strategy

- What elements comprise the GRS versus the regulatory plan?
- What types of analyses are needed?
- What if analysis results differ from the product plan?
- What resources are needed to execute the strategy successfully?

Various stakeholders' interests will depend on the project's nature, as well as the regulatory research results. At minimum, the GRS summary should address the following:

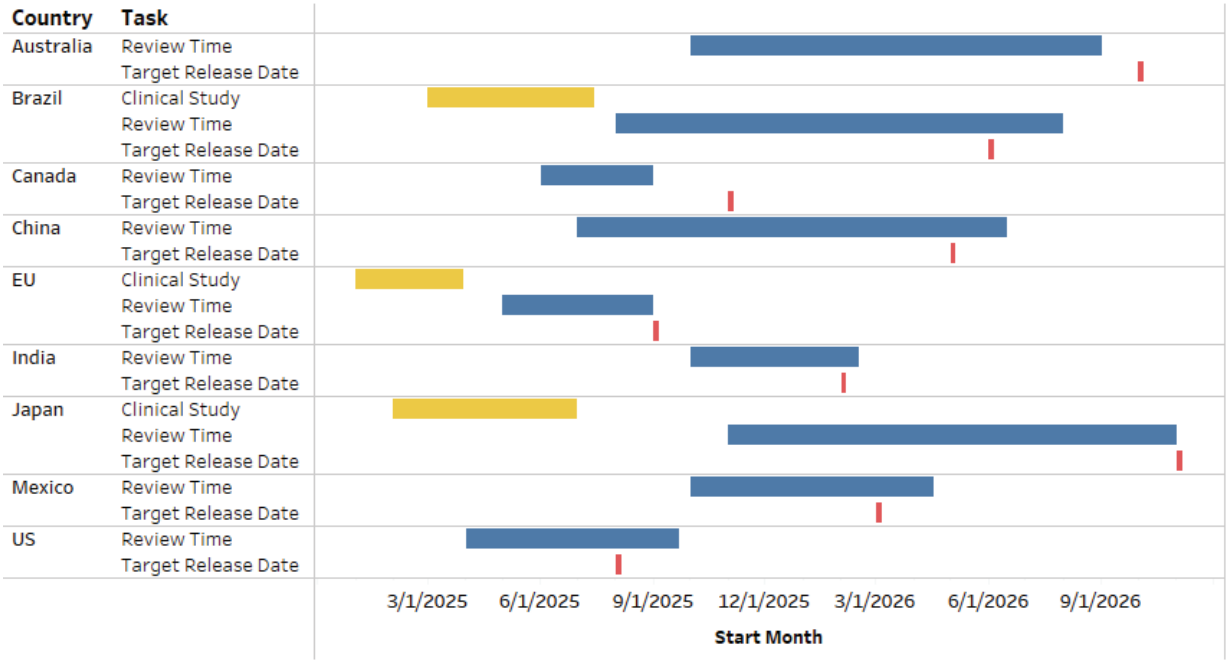
- Brief device description and indication statement
- List of countries (in order of market preference)
- For each country
- Regulatory path
- Particular points of regulatory concern
- Clinical trial requirements
- Approximate preparation and review time
- Regulatory risk areas
- Regulatory areas to be monitored as the project proceeds
- Required resources

The regulatory plan should detail the GRS topics since it is the development team's guideline. This plan also will be the basis for regulatory project management.

- Key milestones
- Design and testing requirements
- Clinical data requirements
- Relevant guidance documents and standards[4,5]
- Risk analysis elements
- Resources used for the plan (e.g., websites, publications)

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Figure 4-1. Comparison of Target Market Release Timelines



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Using the information collected, the team should analyze the relevant data for each element identified in the content list, paying careful attention to those elements that do not appear to meet the project team's needs (or desires). In particular, the planned market release dates may not be coordinated with the projected review processes. See **Figure 4-1** for the countries wherein the Target Release Date does not follow the completion of the regulatory review. These elements may require more supporting data than the ones matching project team assumptions.

For example, the product plan often underestimates a particular market's review time. The project team will want the review to be as quick as possible. Team members may have had previous experience with a similar product and have mental benchmarks on the review time length or have misinterpreted relevant published data. If review time data are available for similar products, experienced regulatory personnel should analyze reviews of other products over an appropriate time period. Providing an answer based on proper data interpretation rather than individuals' experiences will lend credibility to the estimate and decrease the opportunity for debate when the GRS is presented.

The element table should be reviewed before starting research. Two new columns can be added: Analysis Result and Presentation. Analysis results drive both the presentation's nature and how it is incorporated into the GRS and regulatory plan. A simplified example of the expanded element table is shown in **Table 4-4**.

Communicating the Strategy

Once the team collects and analyzes the information for creating a regulatory, it must be communicated clearly. The audience is likely to be a range of company stakeholders. Not all audience members will want to review a 25-page report. A two-page executive summary of conclusions at the beginning of the report will make the information easier to understand and absorb. Graphic presentations also are simpler to understand quickly. References should be added to show data sources and provide greater credibility.

Summary Presentation

The Device

A summary should describe the device briefly, including any features or benefits critical to the product's success.

The Big Picture

To present an overview of each country's review process timeline, a presentation like the one in **Figure 4-1** can provide an easily understood comparison

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Table 4-4. Expanded Example of the GRS Element Table

GRS Element	Company Expectation	Research Methodology	Data Needed	Analysis Result	Presentation
Review times	90 days	Quantitative Qualitative	• Published review times for similar products (if available) • Regulatory network resources—individual submission experiences	180 days	Graphic
Available standards	Yes	Qualitative	• International standards list • Standards accepted in previous submissions • Accepted standards declarations (country-specific)	Six relevant standards	Statement (GRS) Listing (regulatory plan)
Clinical study needs	None	Qualitative	• Guidance documents • Previous submissions for competitive products	Performance standard available. No clinical data required.	Statement (GRS) Provided (regulatory plan)
Environmental trends	None	Qualitative	• Review public meeting schedules (past and present) • Guidance documents planned or pending • Public health issues • Legislative activity	Issues identified with technology in a different clinical use	Description (GRS) Details for risk mitigation (regulatory plan)
Resources	None	Qualitative and Quantitative	• Format and content for filings in each country • Available staffing levels	Simultaneous submissions require additional regulatory staff	Graphic or tabular (GRS) Details for each filing (regulatory plan)

with each target market's release. This presentation type also is useful for reporting strategy updates.

Should any particular country's review time not meet the product plan's original expectations, a graphic data presentation should be considered to determine approximate review times.

Regulatory Submission Requirements

Regulatory classification, submission type, clinical data requirement, and estimated review time overview is helpful. Usually, a tabular presentation works well (see **Table 4-5**).

Regulatory Risks

This GRS section should address only those risks outside typical development and regulatory risks. These risks may surface due to a lack of information on a particular topic or direct knowledge of changes in the regulatory environment. **Table 4-6** shows one way to summarize the possible risks detected during research.

Areas to Monitor

Every strategy operates under assumptions based on the product plan and regulatory research results. The regulatory professional should make a list of these assumptions and decide when and how they should be re-verified during the project. These are areas that will need regular review. Naturally, the items cited in the regulatory risks section will also be included in a monitoring plan.

The monitoring frequency for each area should be integrated into the regulatory plan and assigned to the appropriate team member(s).

Resources Required

If the analysis finds additional resources will be required, careful attention must be paid to the presentation for this GRS element. The GRS stakeholder audience will not necessarily understand the level of effort required to manage the project's regulatory elements effectively.

The timing and resources needed to accomplish the product plan should be presented. If there is resistance to adding the needed resources, the regulatory professional should be prepared to offer an alternative

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Table 4-5. Regulatory Submission Requirements

Country	Classification	Type of Submission	Clinical Data	Estimated Review Time
US	II	510(k)	No	6 months
EU	III	Design dossier	Yes	4 months
Canada	II	MDL application	No	2 months
Mexico	II	Equivalency review	No	8 months
Brazil	III	Cadastro registration	Yes	9 months
India	Listed Device	Device registration certificate application	No	8 months
China	II	Registration dossier	No	15 months
Japan	III	New device, clinical data required	Yes	12 months
Australia	III	Design dossier and application audit	No	10 months

option using available resources, showing the consequences of fewer resources in understandable terms. Often, this means shifts in market introduction timing (for this project or others), which will reduce the revenue generated within that country or region.

Credibility is a major factor in this presentation. To make a credible argument, the regulatory professional must provide a thorough, data-driven analysis of why added resources are needed.

Conclusion

The following points are key to developing a global regulatory strategy:

- The team should develop a checklist of all the information needed, starting with business objectives. The questions provided in this chapter are not intended to be all inclusive. They should be used as a guide and tailored according to the project's nature and subject.

Table 4-6. Summary of Regulatory Risks

Country	Risk	Description	Mitigation
US	Potential need for clinical data	Clinical data have been required for some existing products but not all. The FDA may not accept a rationale for why clinical data are not necessary.	Request a pre-submission meeting to discuss the project and ascertain the agency's opinion.
EU	Device description changes within the directive	Recent events have triggered a review of the rules relevant to this type of device. There is potential for a change in testing or design requirements.	Monitor the discussions and guidance published by regulators.
Canada	None identified	N/A	N/A
Mexico	Slower clearance in the US will delay initiation of the Mexico submission and review.	Based on the regulatory plan, clearance in the US is required prior to submitting in this market.	Prepare to use an alternate regulatory path by engaging a distributor with existing product approvals for a similar product.
Brazil	Laws and regulations currently are fluctuating.	Requirements are likely to change over the course of the project, resulting in the need for additional test data and the possibility of a clinical study.	Monitor legislative and regulatory activities. Engage a local, in-country consultant to monitor and report on changes as they occur.
India	None identified	N/A	N/A
China	Delays in market entry	Identifying an in-country representative is necessary before submission and commercialization.	Identify the representative by the end of January.

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- Some countries have more expedient approval processes if the device has an EU CE Mark, an FDA clearance, or approval and/or marketing authorization in the country of origin. The team should consider these factors when devising the strategy.
- A complete strategy should consider potential changes during plan execution.
- The team should create a routine process for both developing and monitoring all regulatory strategies.
- Any new elements in a device deserve special attention. Although many potential changes can occur during device development and marketing, a new element can offer the most unknowns. Understandably, regulatory authorities are cautious when faced with a new technology or clinical application. Unexpected questions may arise during the review, as reviewers need to become comfortable with the new device. Careful attention to a device's new element(s) can mitigate much of this risk.
- Generating a GRS is a team activity and should include the project team or other stakeholders (see Chapter 2 on Development and Implementation of Regulatory Strategies for Medical Devices). This approach keeps them involved and manages their expectations as to the output. During research, some twists and turns may arise. Working closely with the project team allows a focus on what is important for the ultimate success of the project.

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5

Setting up a Quality Management System

Susumu Nozawa, RAC-EU, RAC-US, FRAPS

Introduction

Manufacturers seeking to build a Quality Management System (QMS) from scratch can face challenges, especially when they fail to follow the appropriate regulatory standards or compliance guidelines. Management system standards make best practices available to organizations of all sizes, in all sectors. Any organization can implement a system to improve efficiency and effectiveness and manage its way of doing things by:

- Ensuring nothing important is omitted;
- Clearly defining who is responsible;
- Describing what to do, why, when, how, and where;
- Ensuring that people are not just doing their own thing; and
- Ensuring that the organization goes about its business in an orderly way.[1]

Quality management is the set of coordinated activities to direct and control an organization with regard to quality.[2] QMSs are central to the medical device regulatory process to ensure that safe products entering the market perform as intended. Key criteria for setting up a QMS include streamlining and automating design documentation and quality processes to align with major industry regulations and standards. This chapter focuses on International Organization for Standardization (ISO) 9001 and ISO 13485,[3,4] and subsequently, US Food and Drug Administration (FDA) Quality Management System Regulation (QMSR)[5] contained in 21 CFR 820. ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes is a QMS standard based on ISO 9001 Quality Management Systems Requirements. The ISO 9000 series, originally published in 1987, was based on the British Standards Institution (BSI) BS 5750 series of standards.[6] ISO 9001 covers both product quality assurance (providing confidence that quality requirements will be fulfilled) and enhanced customer satisfaction. Key differences between ISO 9001 and ISO 13485 are shown in **Table 5-1**. Similarities

Table 5-1. Key Differences Between ISO 9001 and ISO 13485

ISO 9001	ISO 13485
6 documents	27 documents
Aims for customer satisfaction through continuous improvement	Does not include customer satisfaction and continuous improvement as objectives
Covers all products	Different requirements for different types of products
Basis for voluntary certification	Basis for regulatory certification

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