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The Role of Regulatory Affairs in Product Development

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Introduction

There are many simple dictionary definitions for Regulatory Affairs, mostly incomplete in so much they fail to recognise that good Regulatory Affairs, when implemented fully, becomes integral to the day to day ways of working for a business. The following definition is a combination of a number of dictionary definitions to illustrate this point.

- Regulate: to control or direct according to rule, principle, or law for accurate and proper functioning

Regulatory Affairs is definitely not a black and white decision-making process as this definition infers. Regulatory Affairs should also not “control”, instead they should “guide”. In reality the Regulatory Affairs professional works in many shades of grey, interpreting regulations and providing advice based on a scientifically derived risk based assessment.

A good regulatory professional maintains a vigilant watch on ever-changing legislation, advises the business of the potential implications of such legislation being implemented and, through consultation with the Legal and Corporate Government Affairs colleagues, is able to provide the Government legislators with sound advice or recommendations upon which good Governments should base their final decisions.

This should include all the regions or countries that the business has a presence.

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Proactive Regulatory Affairs professionals should also provide strategic and technical advice to all levels of the business and at all stages of the product cycle from ideation or concept discussions through to commercialisation, and beyond.

Conversely, proactive engagement with Regulatory Affairs by all levels within the business ensures decision making is consistent, timely, and accounts for all factors, resulting in a considerably reduced launch time for any new product.

This paper identifies where good Regulatory Affairs can make a significant impact on:

Regulatory Affairs “Best Practice”

Before we delve into how Regulatory Affairs should be integrated into the Product Development process, it is appropriate that we clearly identify what good Regulatory Affairs should look like.

Most large companies will have a dedicated team of professionals in a “Regulatory Affairs” department with a clear career path from a junior Regulatory Analyst through to the Regulatory Affairs Manager or Director, depending on the size and scope of the business.

The term “Best Practice” means **“a method or technique that has been generally accepted as superior to any alternatives because it produces results that are superior to those achieved by other means or because it has become a standard way of doing things”**

Unfortunately, smaller and medium sized companies are usually forced to merge or combine roles resulting in there being no dedicated Regulatory Affairs functions and this often results in the Regulatory component of the business requirements being incomplete or inaccurate. Product Developers or QA practitioners usually “double hat” and include Regulatory Affairs responsibilities and often this leads to a conflict of interest with their primary activities.

The following is a model for Regulatory Affairs “Best Practice” that was successfully developed and adopted for the global Regulatory Affairs team of a major corporation. It illustrates the successive incremental increases in Regulatory activities as an organization matures.

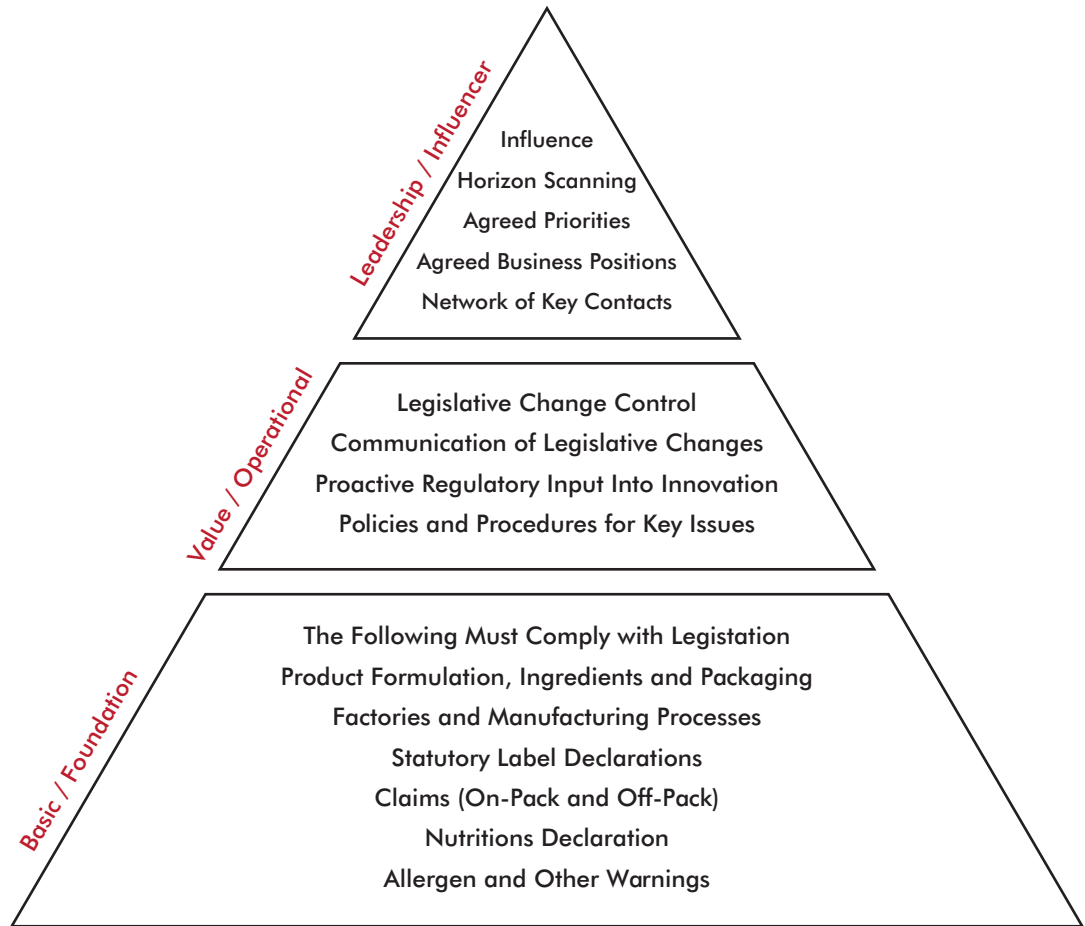


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Basics – Foundation of Pyramid

This is the day to day work that would usually encompass approximately 60% of the Regulatory Affairs department's workload conducted generally by Regulatory Analysts or those developing the base skills in Regulatory Affairs, with the key focus being to:

- Ensure that Product Specifications conform to legislation
- Ensure that ingredients and packaging materials conform to legislation
- Ensure that the statutory declarations on labels conform to legislation
- Ensure that claims on the label are not misleading and are linked to the statutory declarations requirements or standards and are included in claims tables where relevant
- Ensure nutrition declarations can be validated by either calculation from recipe or analysis

November 2, 2017

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- Ensure that allergen cross-contamination risks identified by the HACCP's generate appropriate allergen warnings on labels, and that changes are highlighted adequately for Consumers
- Measure and maintain levels of performance with the aim of **“getting it right the first time”**

Note that the key word is **ENSURE** and not **DO**, meaning that Regulatory Affairs should be conducting the final review and sign off and not necessarily completing all the tasks that lead up to the final review. In many cases if Regulatory Affairs were to be doing all the work and also the final review and sign off it would be a clear conflict of interest. Those responsible for QA and R&D functions should be aiming to “get it right the first time” and as such are ultimately responsible for **DOING** this work as part of their day to day role.

Value/Operational – Middle Layer of Pyramid

This is the role that a middle or upper level Regulatory Affairs Manager / Supervisor would be responsible for. It would usually encompass approximately 30% of the Regulatory Affairs department's workload with the focus being on building internal and external relationships and partnerships based on the company's embedded strategic business direction and ensuring the appropriate policies and guidelines are established. The focus being on:

- Creative and proactive regulatory input into the innovation process, partnering with Commercial, R&D and Legal)
- Collaborating with R&D to evaluate new manufacturing processes, ingredients and packaging against legislation, and legislation changes
- Ensure compliance with nutrition and health claims in collaboration with Commercial, R&D, Legal and Nutrition
- Clear and specific communication of new and changed legislative requirements to the relevant parts of the business – including follow-up to ensure that effective action has been taken. This is a collaboration with R&D, Legal, Supply Chain, Corporate Government Affairs
- Routine policies and procedures (such as product claims, documentation, specifications) are established and embedded in collaboration with Supply Chain, Legal, Corporate Government Affairs and R&D
- Policies regarding sensitive issues (such as GMOs, irradiation, and use of artificial or natural ingredients) are established and embedded in collaboration with Legal, Corporate Government Affairs and R&D



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Leadership/Influencer – Top of Pyramid

While the base and middle sections of the pyramid are essentially upward looking, those activities at the top of the pyramid are downward looking. These are much wider thinking aspects to the Regulatory Affairs department's responsibilities and are generally the responsibility of the Senior Regulatory Affairs Manager or Regulatory Affairs Director, accounting for a very critical 10% of the departments activities. These activities are definitely those where collaboration between Legal and Corporate Government Affairs is mandatory.

- “Horizon scanning” to identify regulatory issues that represent a potential threat or opportunity to the business. Senior business management is to be briefed on the potential business impact of these issues, taking into account the competitive environment and the positions of government, NGOs, pressure groups, media, etc
- Responding directly to Government on behalf of the company on issues relating to changes in Regulations that affect the business
- Business-agreed list of influencing priorities and objectives, with named issue-owners, including business position statements on the influencing priorities and other key issues
- Network of Trade Association contacts and committees plus scientific contacts where issues can be addressed back to Government
- Be aware of, and seek to adopt international guidelines when appropriate

The scope of Regulatory Affairs' role in the Leadership or Influencer area of the pyramid will be determined by the business objectives and the need to change the regulatory environment in order to meet long term sustainability. Most small to medium sized companies do not operate in this area of the best practice pyramid and while this may mean they are unable to proactively engage with Government or NGO's, being engaged with significant Trade Associations may allow them to at least keep up to date with emerging issues, including relevant changes to legislation.

There is little or no value in seeking changes to regulations where the business does not have a strategy in place to participate.

Where small and medium sized businesses may benefit is through the use of Regulatory Affairs consultancies where a proactive participation in Trade Associations and Government activities allows them to monitor changes to regulations on behalf of many businesses. However, it should be noted that in some parts of the world, the Consultancy may not be able to join major Trade Association, or officially act on behalf of the business in Trade Association activities.



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Good Regulatory Affairs must be a proactive role – it cannot be a reactive one otherwise it becomes a “rubber stamp” role to the practices and procedures that the business has already implemented.

Regulatory Affairs achieves this by:

- Proactively engaging with Trade Associations, Government and NGO’s to ensure that businesses not only are kept aware of changes in legislation, but have the ability to influence legislation changes to maximise opportunities to the business
- Proactively maintaining a watching brief on Regulatory, Scientific and Nutrition issues and ensuring the business is aware of impending changes or challenges and the risks associated with them
- Proactively engaging with our internal stakeholders and partners such as Corporate Affairs, Legal, and Commercial
- Building a sound knowledge base within RD&Q to assist those responsible for developing and approving our products
- Creating appropriate procedures and providing training to ensure there is a complete understanding of compliance requirements. This essentially makes the R&D more attuned to any legislative requirements, leading to “smarter” product development
- Proactively engaging with like-minded colleagues across the globe to ensure an understanding exists related to changes in legislation elsewhere in the world and the potential impact these changes may have on our domestic business, as well as potential export markets
- Proactively engaging in the Stage & Gate process to provide business direction in the product development process

Regulatory Affairs should be a focus point for Government agencies as they respond better to companies whose representatives are scientifically accurate and knowledgeable of pertinent regulations. Government agencies, NGO’s and Trade Associations actively seek out comment from those businesses who, through good Regulatory Affairs, can provide scientifically sound knowledge of appropriate legislation.

Stage & Gate process for Product Development

Most businesses operate a stage & gate process, either informally or formally, to progress projects or developments to finalization. The stage & gate process is a project management technique in which any project, business improvement initiative is managed in stages. In between each stage there is a gate where the business



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management (or the project management committee) is required to make decisions, based on all the information available at that time. This could include the business case, risk analysis, resources, and financial measures. In reality, the project should not proceed to the next stage unless all the necessary information is available for the business management to make a full and complete assessment.

However, many small to medium sized businesses don't have a formal process per se, but will recognise the stages described in below.

The role of Regulatory Affairs is such that they touch each and every product, ensuring compliance with local regulations and internal policies and guidelines relating to food labelling, safety and nutrition, and therefore must be considered as an integral part of the stage & gate process.

Regulatory Affairs is more than just ensuring compliance with Labelling regulations. Through the strategic links to trade associations, Government agencies, and NGO's the business is kept abreast of all changes in regulations that may affect the business, as well as key development in food and nutrition science, based upon which they are able to provide direction on the product development process so that the business achieves the best outcome for the business.

Note that a role for the Regulatory Affairs Manager or Director is to be able to influence changes to Government legislation and policy, should this be required to gain a market advantage.

While there are many variations on the Stage & Gate process in its most simple form there should always be the following stages.

1. Idea Development – a feasibility review defining the project
2. Project Development, Design, Testing, and Validation
3. Execution or Project Launch or Commercialisation
4. Project Evaluation post Launch

Stage 2 could be split so that the Testing and Validation processes become the next stage.

Stages 1 through 3 are generally recognized as being “standard practice” and businesses believe that they do these stages well, implementing the appropriate measures (financial, political, sales volumes, etc.) that need to be met in order to pass through the “gates” as the project progresses. In the ideal world, sub-standard projects would be rejected should the measures not be met. This is essentially the deciding role of the “gate keepers”.



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However, many businesses neglect to conduct the Project Evaluation. This is generally done 3-6 months after the project has been finalized and the success, or failure of the project can be measured.

The following identifies the roles and responsibility of Regulatory Affairs in the various phases of the Stage & Gate Product Development process

Idea Development

This is a stage where Regulatory Affairs are often neglected yet they have a critical role to play. Regulatory guidance at the onset of any project often dictates the direction the project can or cannot take.

Engagement at the Idea Development stage:

- Regulatory Affairs can provide guidance on claims, either implicit or inferred, on proposed labels / packaging or in the media.
- Compliance to internal policies and guidelines
- By reviewing the proposed formula, guidance can be provided as to how modifying the formulation may permit additional claims to be made or strengthen current claims
- Allows Regulatory to collaborate with Commercial on positioning of claims, including reviewing competitor products
- Regulatory can advise on specific impending changes to legislation that may impact the project
- If there is a desire to use a formulation or ingredients that are currently non-compliant, Regulatory Affairs may need lodge appropriate applications with Government agencies. This may especially be important where a business has access to a new technology or a new / novel ingredient and gaining access to the market provides a critical “first to market” advantage. Applications to Government to change legislation are often costly and may take a considerable amount of time to realize. Initiating this as soon as possible once the “Idea Development” stage has been passed could save a considerable amount of time in the development cycle. Note that is not a cost that should be borne by Regulatory Affairs. It is a cost of “doing business” and it should be identified in the overall cost of the project.



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Project Development, Design, Testing, and Validation

At this stage, Regulatory Affairs finalizes assessment of any risks and constraints of the final formulation and works in close collaboration with R&D to:

- Build dossier of data required to substantiate any claims, ensuring that all claims are firstly validated and there are processes in place to ensure that all claims will continue to be valid.
- Review and approve specifications developed by R&D, including
 - Raw Materials
 - Formulations
 - Final Product
- Contribute to the labelling design brief by creating (which may be in collaboration with R&D) sections of the mandatory label text, including
 - Nutrition Information Panel
 - Ingredients List
 - Product claims
 - Allergen declarations
- Develop any new internal policies and guidelines ensuring that they are not only clear and concise, but offer flexibility based on a risk assessment. Use real life examples to provide clarity.

Regulatory Affairs should maintain active engagement with R&D and Commercial areas of the business during this stage so they are aware of any issues that have arisen during product development. This could include “minor tweaks” to the formula or changes to components, which were unforeseen or forced by process constraints. Regulatory Affairs should ensure that their original recommendations or advice is still valid and offer the appropriate recommendations to ensure the project stays on track.

Execution or Project Launch or Commercialisation

By now all responsibilities identified in the Project Development & Design stage will have been finalized.

At this stage, the product is about to be manufactured for the first time, but before this, the label artwork will need to be created and approved prior to packaging being created. Regulatory Affairs should not be the only function to sight and approve artwork, hence the need for a structured approach to the approval process, including agreed time frames. Do not underestimate the benefits that a structured artwork



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governance can bring to ensuring artwork is developed and approved in a timely and cost effective manner.

Ideally there should be a RACI* created so there are clear lines of responsibility for sections of the artwork. Commercial, R&D, Packaging, and Legal should all be included with Regulatory Affairs and Legal sighting the artwork after Commercial and R&D. This allows Regulatory Affairs to identify where there are gaps in the approval process and where additional training may be required.

*(RACI stands for: Responsible – Who is completing the task, Accountable – Who is making decisions and taking actions on the task(s), Consulted – Who will be communicated with regarding decisions and tasks and Informed – Who will be updated on decisions and actions during the project.)

For Regulatory Affairs, at this stage there should be a minimal amount of input, assuming there has been full engagement in the first 2 stages.

Project Evaluation

This is a stage that is often ignored or forgotten yet it is very critical in ensuring that mistakes or errors made during the process are clearly identified and mitigating procedures are initiated to ensure they don't reoccur. Importantly it should also be an opportunity to celebrate success.

The decisions, recommendations or advice that Regulatory Affairs provided during the course of the project should also come under review. It is also a trigger for Regulatory Affairs to review guidelines and processes to ensure they are still valid.

In conclusion, Regulatory Affairs professionals should proactively engage and provide strategic and technical advice to all levels of the business to ensure decision-making incorporates regulatory factors that directly impact product launch strategy.

About EAS Consulting Group, LLC

EAS Consulting Group, LLC (EAS) specializes in US Food and Drug Administration (FDA), state and local governmental regulatory matters. Our prime focus is to assist domestic and foreign food, infant formula, pharmaceutical, medical device, tobacco, dietary supplement, and cosmetic firms comply with applicable laws and regulations. EAS is staffed with former FDA and state compliance and inspection officials, and is assisted by an extensive network of over 150 consultants with many years of FDA and industry experience. EAS has organized its independent consultants into Teams to address multi-dimensional, multi-faceted client projects including all aspects of product development.



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Headquartered in Alexandria, VA with consultants and auditors located strategically throughout the U.S. and in various foreign countries, EAS Consulting Group was established as an independent company in October 2006. The company's roots go back nearly a half century to 1960 when Arthur A. Checchi, former FDA Associate Commissioner, founded the company. In 1985 FDA's Director of Regional Operations, Anthony C. Celeste, assumed the leadership of the company. He operated it under the name AAC Consulting Group (AAC). In 2001 the company was acquired by Kendle International, one of the world's largest global clinical research organizations. In 2006 Mr. Edward Steele, then President of AAC and Vice President of the company's Regulatory Affairs Division, acquired the Division of Food, Dietary Supplement, and Cosmetic Consulting from Kendle and formed EAS Consulting Group as an independent company. Since September 2007, pharmaceutical, medical device, tobacco, meats and EPA-based consulting categories have been added to the list of services offered by EAS.