Organizing your Global Labeling Function – what is the optimal structure?

Is the current structure of your Labeling function the best fit for your company, and how can you improve it going forward?

The growing importance of End-to-End Labeling

Labeling is growing in importance. Regulators are increasingly emphasizing the need to deliver accurate, relevant and informative product information, not just to themselves but to prescribers and patients, in order to better inform prescribing and treatment decisions, minimize medication errors, and speed up identification and reporting of undesirable risks and adverse events. Particular emphasis has been on:

Compliance in line with regional and local regulations

Efficiency and Timeliness delivering up-to-date information, particularly benefit-risk information, to the end-users as quickly as possible without sacrificing quality. This requires connected, end-to-end processes which are streamlined and operated at maximum efficiency by competent and knowledgeable personnel. Good process design, leveraging technologies to support workflow automation, manage labeling content, end-to-end tracking and reporting, is key here.

Patient-centric labeling content so that it is accessible, understandable and meaningful to the target patient populations. This is where Labeling can deliver real-world value in improving health outcomes.

Given the need to be compliant, operationally efficient, and patient-centric all at the same time, what is the optimal organizational model for a Global Labeling function?

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Since 2001, our proprietary networks have brought together 60+ leaders in Regulatory Affairs to network and share ideas on how to tackle the latest strategic challenges. Our networks give us benchmark insights into the latest industry trends and enable us to future-proof your strategy and operations.

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The labelnet forum

Organizational structure has a high impact on business. It influences flexibility and performance and that in turn impacts quality, costs and results.

End-to-End (E2E) Labeling, a framework for linking and integrating traditional Labeling which focuses on the management of Core Company Datasheets (CCDS), regional and local product information (PI) for prescribers and patients, with Development, Pharmacovigilance, Medical Affairs, Artwork, Packaging, Supply Chain, Market Access, and other functions and activities associated with the generation and flow of product information, has been developed through **labelnet**, a global network of leaders in Labeling, **labelnet**, currently consists of 29 member companies representing a mix of large and mid-sized Pharma companies worldwide.

At a recent **labelnet** forum, **labelnet** members discussed the potential structural scenarios for a global Labeling function within a Pharma organization. We reviewed detailed matrices looking at all aspects of organizational design: the interfaces and hand-offs between global, regional and local functions, reporting lines, remit and scope, process ownership, roles and responsibilities, and interfaces with upstream and downstream activities involved in end-to-end Labeling. Not surprisingly, we discovered that:

- There is no “one size fits all” model that companies can easily pick for their organizational design
- Your Labeling organization needs to be strategically aligned to your business, but there are clear trends in the types of design that are suited to certain types of companies

Drivers that determine your Labeling approach

An organization’s structure depends on a wide set of variables, including strategy, portfolio size and mix, geographical spread, capacity, competencies, processes, the propensity to outsource, and the level of adopting innovative technologies within the organization. The wider corporate landscape (e.g. centralized vs. decentralized corporate model, therapeutic area alignment, preferred reporting lines) and just as importantly culture, will also significantly influence the structure of your Labeling organization.

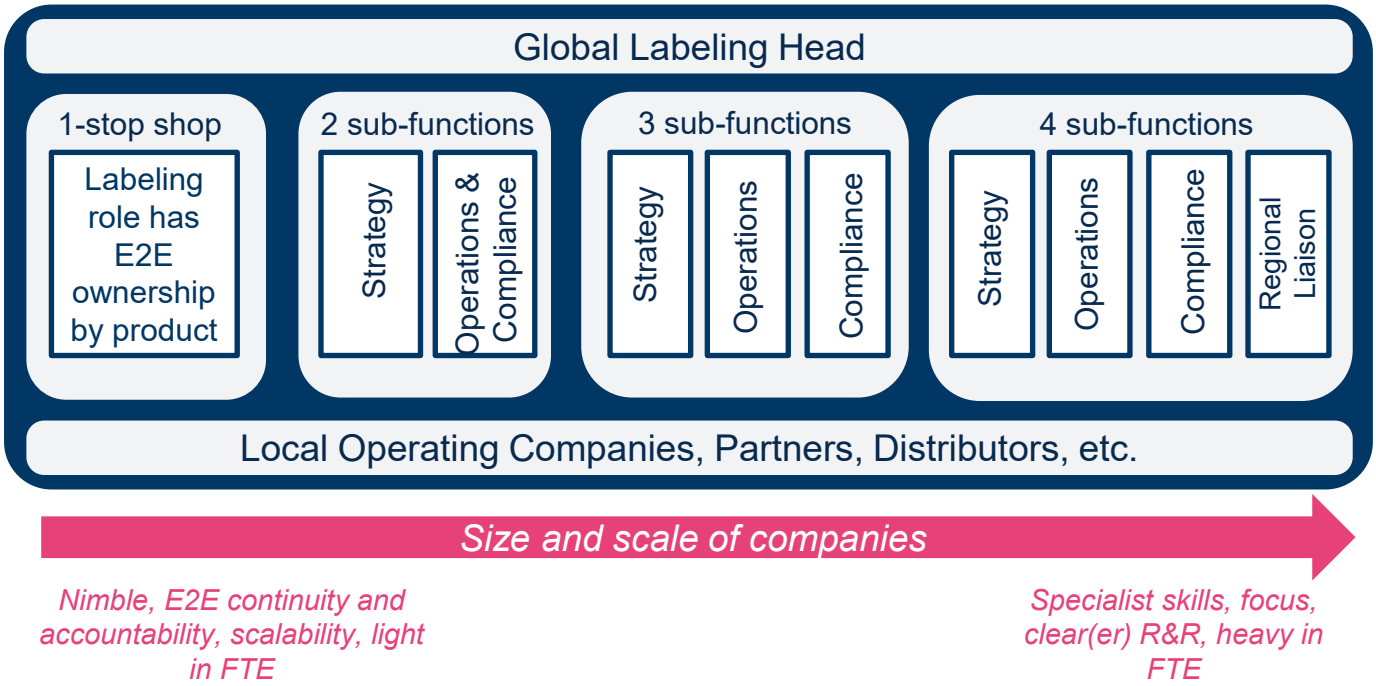
As Labeling is centered on product information management and distribution, the complexity of your products has a major impact on designing the organizational structure. Biologics, combination products, highly innovative molecules with diverse indications, are some examples which require more strategic resources to create and manage their labeling content, be it residing in the CCDS, regional or local PI. Meanwhile, devices and combination products typically require supplementary labeling information in relation to operating the mechanical part of the products. This includes Instructions for Use (IFU), manuals, quick-start guides and diagrams. In addition, the development process for devices and combination products is very different. All these requirements demand specialist knowledge when it comes to Labeling.

Labeling organizational models often reflect the 'roots', or evolution of a company in relation to maturity and culture. Often, we find younger Biotech companies which have experienced rapid growth, while still managing a relatively narrow portfolio of innovative high-value products, have a simpler and leaner organizational structure than mature companies with large portfolios of products with a diverse mix: innovators, well-established products, consumer products and generics. History of recruiting and retaining generalists versus specialists, as well as the internal culture of cross-discipline training, role rotation and empowerment will also have an influence of what is the best fit structure for a particular organization.

Regardless of the organizational model adopted for Labeling, labelnet members agree that there are four primary functional capabilities that are prerequisites to a successful high-performing global Labeling function. These are:

1. Strategy: To develop and refine the right Labeling message and Labeling content, across the Development and Product Lifecycle, as early as possible
2. Operations: The engine of Labeling, managing and coordinating to ensure all aspects of Labeling content (Core, Regional/Local PI, Artwork, etc.) are up-to-date, of high quality and changes are implemented in a timely manner across the global network of affiliates, regional offices and partners
3. Compliance: The eyes and ears of Labeling; to track, monitor and report the health and performance of the Labeling system i.e. processes, governance and organizational effectiveness, across the global network. Particularly important are linkages with upstream (PV, Medical, Development) and downstream (Supply Chain, Commercial) activities to ensure E2E compliance globally across functions which are dependent on approved Labeling information
4. Regional Liaison: To provide a local connection with Local Operating Companies (LOCs) and partners, and in some cases perform operational tasks specifically for the regions

The most common organizational models for Global Labeling



One-Stop Shop

In this model, most Labeling activities are being performed by a generalist labeling role. Sometimes, this role may be further absorbed or integrated into a wider Regulatory Affairs role. In a more evolved form, the generalist Labeling role may have E2E ownership by product or product groups. This "one-stop shop" model places emphasis on strategic and E2E focus over pure operational efficiency. As such, this type of model is

more suited to organizations with a small number of products, or products which require dedicated resources due to their nature or complexity. Typically, a Labeling organization which has adopted the one-stop shop model will have fewer than 20 full-time equivalent (FTEs) employees within their global Labeling function.

The benefits of this model are that there are often global Labeling leads per product, which provide good visibility across regions and affiliates. It achieves good E2E oversight on a product-by-product basis. A generalist role also provides ample opportunities for personal development and is attractive for some Labeling professionals, especially entrepreneurial individuals who value the opportunity to rapidly broaden their skill-sets and thrive in a dynamic environment.

Challenges can include inconsistencies in approach across products or therapy areas, while the low degree of specialization can cause problems when new product types, such as Medical Devices and Combination products, are introduced into the portfolio. It is also challenging to recruit professionals who possess all the pre-requisites: experience in Labeling, CMC, strategy and operations. With this model, Labeling professionals may find that operational tasks have a tendency to consume most of their time, at the expense of the more strategic activities. As a lot of the emphasis is placed on individual ownership, this model is not a good fit for organizations with high staff turnover.

Strategy and Operations

This type of Labeling organization has two core sub-functions, providing a balance between focus and hand-off's, with separate resourcing for Labeling content and strategy and for operational activities.

This structure sometimes sees further sub-division within the Operations team, with semi-dedicated resources focusing on one or more aspects of planning, co-ordination, submission, implementation, tracking and reporting, while allowing sufficient degree of interactions as the personnel with specialist focus are not overly separated from each other but reside in the same sub-function. This model is common in mid-size Pharma companies with 'typical' portfolios of a **labelnet** member company – mix of innovators and well established products, medium size portfolio with products of low-to-medium Labeling complexity, and would suit a global Labeling function of between approximately 10 and 30 FTEs.

Challenges can arise, however. Managed inappropriately, this 2-function model can create a segregation of capabilities and knowledge, reduced opportunities for personal development, and the sometimes cited mis-conception that strategy development is a higher value-adding role than one focused on operational aspects, which could impact staff motivation if left unmanaged. The flip side of this is that this model will suit individuals who have a natural preference for specialism. It will also facilitate easier recruitment of qualified personnel as the typical roles are more defined and less generalist in nature when compared with the previous model.

Strategy, Operations and Compliance

A variant of the Strategy and Operations model is achieved by the addition of a third sub-function focusing on E2E Labeling compliance. This is a direct response to the increasing regulatory emphasis on E2E Labeling oversight, and the need to demonstrate oversight through E2E tracking ("signal to patient"), metrics and KPIs reporting, with strong links between PV, Labeling, artwork and supply chain, data governance and inspection readiness.

Labeling compliance, in the broadest sense, is about complying with regulations, timeliness of delivery, and quality of Labeling content. While the focus for many of these groups originally was on process compliance, increasingly Labeling content alignment between regional / local PI content, artwork and packaging with core datasheets and other source documents is becoming part of their remit.

This model benefits from a concentration of skills, having one designated E2E compliance owner, stronger links to downstream Labeling implementation (artwork, packaging, master data, supply chain) activities and a focus on compliance through clearly defined metrics and KPIs.

Typically, companies with highly decentralised global network of LOCs (affiliates, partners, regional hubs), and those whose Labeling-related functions have traditionally worked disparately, where E2E Labeling oversight is not easily achieved, reap the greatest benefits from this model. It seems to be more common in larger organizations, typically with more than 30 FTE within their Labeling functions.

The challenges in making this model work effectively are largely similar to the previous model, in that the level of specialism and separation between each sub-function are further increased, personnel may find themselves with fewer opportunities to take on adjacent roles and develop new skills, and collaboration between sub-functions need to be carefully managed, so that they do not become unintentionally 'siloed' over time.

Strategy, Operations and Compliance, with Regional Liaison

A further variant of the previous structure is a 4-function model with a regional liaison sub-function, typically with connections with a regional hub structure globally. The rationale of creating a dedicated Regional Liaison sub-function is to pay particular emphasis on the vital role of LOCs (affiliates, partners, regional hubs), whose tasks typically include, but are not limited to:

- Local / Regional label creation, update and maintenance
- Translation and adaptation of core and/or reference labels
- Preparation of Heath Authority submissions
- Managing the interface and relationships with Health Authorities
- Managing and implementing Labeling deviations
- Ensuring compliance to local requirements
- Tracking and reporting status
- Collating and analyzing local and regional Labeling and regulatory intelligence

While the addition of a dedicated regional liaison sub-function could be applied to all three previous models discussed so far, it seems to be more common as an extension to the 3-sub-function model, which tends to be the model adopted by the larger organizations with the corresponding greater needs for focused regional liaison.

Partner interaction is key and usually occurs via Affiliates. Tight connections with Affiliates allows for better management of local activities, better collaboration and oversight. The right organizational model balances the need to support Affiliates in partner management, whilst providing an appropriate degree of freedom to operate and local ownership, a balance between 'Laissez-faire' and too much centralized intervention.

Building a more effective Global Labeling function – Identifying which model will work for you

Looking at the distribution of these models, **labelnet** members revealed that the 3- and 4-sub-function models are predominant across mid to large size companies.

The larger an organization becomes, the more likely it is to veer towards greater specialism within its functions, often driven by the efficiency gains (through economies of scale), scalability to deal with higher volumes of workload, and the pursuit for consistencies in labeling approach and labeling content quality across large portfolios of products, something inspectors often comment upon. They tend to have clearer roles and responsibilities and are high in FTEs.

In some large companies, we observe the shift of some or most local operating companies' Labeling to regional hubs. The tasks vary by company but typically include handling HA queries and local submission packs, translations, regulatory intelligence, and coordination of the implementation of artwork and packs.

We have established that, when designing a high-performance Labeling organization to deliver the three core values for Labeling, we need to have a Global Labeling organization which ensures labeling compliance, maintain operational efficiency and promote patient-centricity. In addition, one needs to incorporate the overarching principle for E2E Labeling, that is to achieve full E2E governance, oversight and alignment across global, regional and local operations. A clear model with direct communications and feedback between local and global, perhaps leveraging the use of regional hubs, allows for a more efficient collaboration and joint-ownership and therefore more effective oversight of activities from global to local. Clearly defined roles and responsibilities for all functions in your organization strengthens the E2E Labeling process. A model which delivers strong interfaces with Development, PV, Medical, Artwork, Supply Chain and Commercial and SC is another pre-requisite in achieving E2E oversight and compliance for Labeling. The immediate effect is a positive impact on quality and compliance.

Conclusion

An effective, balanced and fit-for-purpose organizational structure is only one part of the equation for a high-performing Labeling function. There is no single right answer to organizational design, which is situational, dependent on context, scale and strategy, scope and remit. It requires a considered approach, taking into account both internal and external perspectives to assess and weigh up the options and respective benefits of each model. Only then will you find the best fit for your company – to be fully equipped to manage the Labeling business of today and of the future.

labelnet and labelconnect members - 2018

About the Authors

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With extensive experience within industry and in consulting, Denis has a special focus in Labeling, in strategy development, cross functional process design, and implementation, and links with product development and early access programs. He is the co-founder and lead of **labelnet** and co-founder of **rimnet**.

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