



Life Sciences Consulting and Outsourcing

Kinapse White Paper

Regulators keep the pipeline flowing

Challenging Regulatory Affairs groups to contribute more to demonstrating medical added value

Expertise ► Collaboration ► Innovation ► Results

- **Regulatory Affairs organisations have been viewed by colleagues as organisations with a negative perspective but the best Regulatory Affairs organisations take a proactive, market-led approach, helping colleagues get to “yes”**
- **International trend for reduction in NCE approvals could in part be linked to the difficulty of demonstrating medical added value**
- **Imperative that Big Pharma’s Regulatory Affairs groups stand up to be counted as key advocates for making medical added value compelling**
- **Difficulty lies in maintaining baseline activities while freeing top people to support Development and Commercial colleagues in making the case for your major products**
- **There are four key levers to pull to get your Regulatory Affairs team reoriented beyond the minutiae of the regulations and become outward-looking, patient-focussed and business-driven**

Introduction

Any reader familiar with scuba-diving will know that a diver’s regulator delivers breathing gas on demand at ambient pressure. That is, it keeps the diver’s pipeline working safely and efficaciously, whatever the pressure in the tank. It is a simple logical leap to take this description and apply it to the Regulatory Affairs group in any global pharmaceutical company: whatever the pressure from the R&D and Commercial organisations, it is the job of the Regulatory Affairs group to only allow flow from the pipe that is safe and effective. What you may find harder to apply to Regulatory Affairs groups in your experience is that modern Scuba regulators default to “open”. In other words, unless explicitly handled otherwise, the pipeline will continue to flow. It is the contention of this paper that, in the current industry environment, pharmaceutical Regulatory Affairs groups should likewise be designed to keep pipelines safely open.

Frequently, Regulatory Affairs organisations have been viewed as naysayers by their colleagues, as organisations dedicated to ensuring that no products are allowed to market or even submitted without the required safety, efficacy and quality information. This is clearly unavoidable in the prevailing regulatory environment but, couched in such terms, it is an undeniably negative perspective. Mounting external pressures, however, should motivate the best Regulatory Affairs organisations to take a proactive, market-led approach, helping colleagues get to “yes”, rather than just being the group that has to say “no”.

As Figure 1 above shows, recent years have shown an international trend for reduction in NCE approvals, which the FDA attributes to declining productivity but, viewed from within the industry, could in part be linked to the difficulty of demonstrating medical added value.

Regulatory Challenges

Alongside this trend which impacts everyone in the industry, a recent survey of the biggest regulatory challenges across global markets identified some key concerns for Regulatory professionals. In the USA, eCTD and compliance with the Structured Product Label (SPL) stood out as the biggest challenges, with risk management planning and the FDA’s safety “Tome” widely considered problematic.

Outside the US, 50% of the respondents highlighted eCTD and changes in the EU, including the EU Clinical Trial Directive and the expansion to 27 EU countries, each of which has its idiosyncrasies. Furthermore, the respondents said a major challenge is dealing with the lack of harmonization of regulatory agency perspectives. Notwithstanding the work of ICH, there is significant variability across regions and in national health

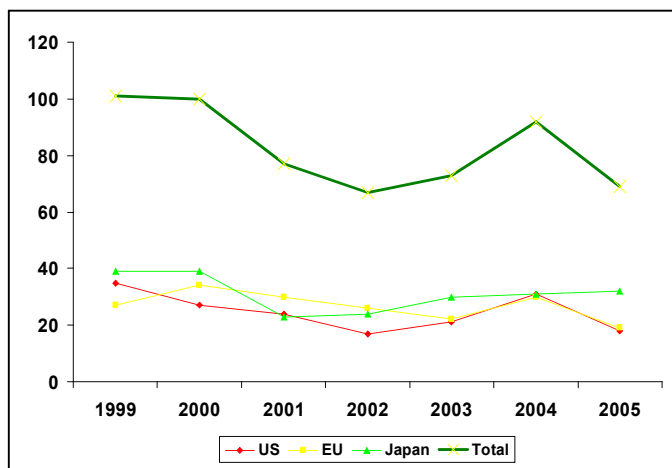


Figure 1: Decreasing NCE approvals over time

authorities – and even below national level where Italy, for example, is increasingly challenged by different views taken by different agencies in different parts of the country.

Notwithstanding that all these issues create genuine obstacles for Regulatory Affairs professionals, what is most striking in this survey of regulatory challenges is the absence of any reference to the general industry pressures. The key points brought up by Regulatory Affairs respondents the world over are narrow issues, primarily affecting their specialization rather than views of how Regulatory Affairs groups could – and should – be addressing the bigger picture problems affecting the business that they are paid to service. In an industry facing growing cost and productivity pressure, any internal group that is not explicitly part of the solution is going to be vulnerable to identification as part of the problem, with outsourcing, offshoring and downsizing the inevitable consequences.

Characteristics increasingly in demand are:

Aiming not only at approval but best possible approval

- Development and Commercial executives require Regulatory staff who are able to represent the company position effectively to regulatory agencies, understanding both the product and also the agencies and their processes

Influencing and negotiating using good people skills

- Regulatory staff should be able to interact credibly and intelligently with external experts involved in Regulatory review, in addition to undertaking timely and effective negotiations with the agencies themselves

Predicting rather than reacting to environmental changes

- Regional Regulatory executives identify that their organizations should proactively work to shape the future of regulation – be it in off-label prescribing, compliance, reimbursement and pricing - be able to predict changes in the regulatory environment well in advance and prepare to meet them

Skilfully positioning submissions/ labels/ SmPCs for medical added value

- Commercial executives want to see Regulatory staff who understand the product and are equipped to make the case to agencies and Key Opinion Leaders for its medical added value

Staying abreast of global and regional issues

- Global Pharmaceutical Regulatory Affairs organizations should orient their regulatory strategy to promote market access in key markets worldwide, avoiding the missed global opportunities of focusing too much on their headquarters' country/region

Comments based on interviews with executives in several Top 10 global pharmaceutical companies during Kinapse consulting projects in 2006

Responding to Industry Needs

When executives like Jeffrey Kindler, recently-appointed CEO of Pfizer, stand up and proclaim that the industry needs “to prove the value of our medicines in new and compelling ways”, it is imperative that Big Pharma’s Regulatory Affairs groups stand up to be counted as key advocates for making that value plain. Increasingly stringent requirements from regulatory agencies, escalating demands at the fourth hurdle and rising competition to Big Pharma from generics are three key value pressure points which can impact an entire global pharmaceutical company but which Regulatory Affairs staff are ideally placed to relieve. Enhancing PILs, creating improved decision-making tools for healthcare professionals and building holistic healthcare solutions around products rather than just selling the product itself are all useful tactics.

Over recent consulting projects in Regulatory Affairs, Kinapse staff have noted that the most impressive groups and individuals in this field are moving far ahead of the traditional – and often unfair – stereotype of bureaucratic Regulatory Affairs staff (see sidebar).

While routine maintenance and quality assurance work must obviously continue, Regulatory Affairs groups should aim beyond approval and reorient their highly-skilled people to such high value behaviours listed in the sidebar, under the umbrella of what is frequently described by top-end Regulatory professionals as “market access” activity, making best use of networks inside and outside their own company.

Reorienting the Regulatory Team

The difficulty lies in finding the resource to maintain baseline activities, while freeing up your top people to get out there and support Development and Commercial staff in making the case for the medical-added value of your major products. This isn’t necessarily simple but there are four key levers to pull to get your Regulatory Affairs team reoriented:

Process improvement

Reducing handovers, concentrating senior roles on high-value tasks

Productivity enhancement

Tracking activity to see who’s spending how long doing what and then intelligently refocusing resources

Global sourcing

Identifying routine business processes suitable to offshore

Organisation redesign

Retuning your structure to take advantage of all the above

Regulatory Affairs activities

External relationship building

- Proactive contacts with healthcare professionals, KOLs
- Enhancing relationships with regulatory agencies

Focusing on high-value work

- Exploiting regulatory intelligence to make compelling cases for increased market access
- Using advocacy and relationship management to shape the environment
- Global sourcing of baseline activities e.g. Maintenance

Regulatory risk management

- Optimising the risk/benefit balance
- Promoting medical added value

Enterprise outcomes

Beyond approval to best approval

Cross-functional effort to grow market share

Increased efficiency of routine maintenance

Optimal use of marketed products

Figure 2: Regulatory inputs and enterprise outcomes

Taking such internal measures is the best way to get your group outward-looking, patient-focussed and business-driven. Exploiting these levers to move beyond the minutiae of the regulations themselves to the big ticket items like medical added value is the best way for Regulators to continue to assure R&D and Commercial executives that they are delivering value for money for all the stakeholders concerned. Regulatory professionals must be seen to be keeping the pipeline flowing.

References

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About Kinapse

Kinapse provides specialist information processing services and business consulting to life sciences R&D organisations at unmatched value.

The Kinapse novel delivery model brings together in global project teams the very best people in a wide range of R&D domains with total commitment to the success of our clients.

The delivery model is differentiated from conventional R&D services companies by:

- Integrated onshore-offshore teams, tailored to client requirements;
- Industry-veteran consulting partners who bring deep experience and expertise in specific functional areas;
- Exclusive service partners with distinctive, complementary services.

Kinapse personnel have worked in consulting and information processing with many of the world's top pharmaceutical and biotechnology companies.

Recent Regulatory and Safety engagements include:

- Redesign of a global Regulatory Affairs group operating model for a Top 10 global Pharma
- Productivity diagnostic of Regulatory Affairs groups in EU marketing companies for a Top 10 global Pharma
- Assessment of Safety activities amenable to offshoring for a Top 10 global Pharma
- Information processing services for several major global pharmas including NTA-CTD conversion and safety variations



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