VIEW POINT

LEVERAGING THE BUSINESS-PROCESS-AS-A-SERVICE (BPAAS) MODEL IN REGULATORY AFFAIRS

Abstract

Regulatory affairs refer to the safety and quality regulations to which all healthcare products and service providers must adhere. They have become of prime importance because of the large number of health-related products we interact with every day. Ensuring regulatory compliance is a daunting task because it is a complex and continuously evolving landscape. Digital technologies like AI, and ML have helped regulatory affairs overcome these challenges. BPaaS (Business Process as a Service) models have worked as an effective tool for regulatory affairs to leverage cutting-edge technologies and streamline the process.

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Digital transformation, deployment of the cloud, adoption of automation technologies like AI (Artificial Intelligence), etc., are some of the factors that have fuelled the growth of the Business Process as a Service (BPaaS) market. Data shows that the BPaaS market which was worth $76.41 billion in 2023 is expected to reach $ 92. 06 billion by 2028.

What is BPaaS?

BPaaS refers to a specific type of BPO (Business Process Outsourcing) in which the delivery is made over a cloud services model. Essentially BPaaS provides businesses with the people, processes, and technology required for specific operations on a pay-per-use basis.

Although the description of BPaaS may have a hint of BPO, both are quite different from each other. Business Process Outsourcing is a service in which a company outsources certain processes to a third party. For instance, the outsourcing agency may manage the recruitment process for its clients. BPaaS, on the other hand, is not restricted to just one company. These are cloud-based automation services that a service provider may offer multiple companies.

By using a BPaaS model, businesses can eliminate ownership costs because they can access on-demand solutions for the services required instead of investing the entire package required for a single application. BPaaS streamlines business processes and builds an enterprise architecture that can adapt to changes in the environment.

BPaaS works with SaaS (Software as a Service), PaaS (Platform as a Service) and IaaS (Infrastructure as a Service) to automate processes.

It makes the business agile, minimises costs, and fosters innovation.

BPaaS finds widespread application across sectors such as healthcare, manufacturing, retail, BFSI, and more!

The healthcare sector, in particular, has found BPaaS to be highly effective for managing regulatory affairs.

Let's see how!

What are regulatory affairs?

Regulatory affairs refer to the safety and quality regulations to which all healthcare products and service providers must adhere. Regulatory affairs are not restricted to only hospitals, they extend to all health-related products including pharmaceuticals, medical equipment and devices, biotechnology, etc.

Regulatory affairs are important because of the large number of health-related products we interact with every day. These include prescribed medicines, assistive devices like wheelchairs, skincare products, medical devices like glucose monitors, BP monitors and the currently popular wearable smart devices. These medical devices must function correctly, promote safety, and support health with minimal risk to patients. Regulatory frameworks are established to assess the products before and after they are released to the market.

Healthcare product providers need to comply with the guidelines set forth by regulatory agencies to safeguard public health.

Regulatory bodies ensure that healthcare products are manufactured in compliance with the prescribed frameworks throughout their lifecycle. Regulatory compliance also makes sure that they are marketed to the public for safe handling.

However, ensuring regulatory compliance comes with its own set of challenges:

The regulatory landscape is not only complex but also frequently changing. Healthcare providers need to navigate through a complex maze of laws, guidelines, and regulations that can vary across different regions and countries. Staying updated with these changes and ensuring compliance is a daunting task.

Another challenge that healthcare faces is trying to strike the balance between providing patients timely access to new potentially life-saving drugs and treatments while ensuring that they meet the regulatory standards.

The medical field is known for its fast-paced innovation in medical technology. Regulatory affairs officers need to keep pace with these changes and ensure compliance with innovative drugs, devices, procedures, etc.

The regulatory process is both time-consuming and cost-intensive.

Different methods like harmonising global regulations, risk-based approaches, etc., are being tried out to overcome these challenges. One of the most effective strategies that has emerged to streamline regulatory compliance processes is the implementation of digital technologies.

Tech tools facilitate the collection, analysis, and storage of vast volumes of regulatory data like clinical trial reports, manufacturing data, etc. Advanced analytics and AI (Artificial Intelligence) help to improve decision-making by identifying trends, potential risks, opportunities process optimisation, etc.

Electronic submission and document management streamline the submission process for regulatory affairs professionals and minimise errors.

IoT (Internet of Things) devices facilitate the real-time monitoring of processes and products that help keep them on track.

Technology has also helped create interactive and dynamic digital labels that provide consumers, medical professionals, and regulatory affairs professionals with up-to-date information, instructions, and warnings.

AI and ML forecast regulatory outcomes, optimise trials, analyse safety data, identify risks, and facilitate data-based decision-making.

Regulatory affairs can access cutting-edge technologies through BPaaS to streamline processes.

BPaaS provides comprehensive, scalable, solutions for automating and managing business operations. It relies on digital technologies to streamline and enhance business processes. BPaaS hosts technologies like RPA (Robotic Process Automation), AI (Artificial Intelligence), ML (Machine Learning), etc., to enhance efficiency and outcomes.

BPaaS in regulatory affairs

BPaaS offers built-in compliance frameworks and standardised processes that adhere to industry regulations like GDPR, HIPAA, etc. It secures sensitive patient data with advanced security measures, data encryption, and access controls. BPaaS models manage the complete compliance cycle and reduce financial and legal risks.

BPaaS service providers also manage end-to-end product lifecycle management services. Data management, compliance data management, labelling, and seamless exchange of data between departments, are some of the functions that BPaaS services offer.

In Conclusion

BPaaS provides a cost-effective business process outsourcing service that is delivered through a cloud-based system. BPaaS leverages technologies like AI, ML, Generative AI, etc. to streamline business operations. It is highly effective in enhancing regulatory affairs by automating different processes to minimise errors and enhance speed. It makes the compliance processes intelligent and hence boosts their efficacy.

How can Infosys BPM help?

Infosys BPM provides robust BPaaS services that streamline healthcare services. Our BPaaS solutions are agile in implementation, and facilitate sentience, hyper-productivity, and immersive experience. All our solutions are delivered on an AI-first digital transformation model.

For more information, contact infosysbpm@infosys.com

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