



## EPIC JOURNEY IN SETTING GLOBAL COMPLIANCE PROGRAM FOR BIOCON BIOLOGICS

Working in the pharma space, inspired by the human immune system, Biocon's philosophical approach towards building an effective ethics program is to develop a strong system that promotes and sustains ethical behaviour and a culture that addresses bad behaviour

Written by Akhilesh Nand, General Counsel and Chief Governance, Risk and Compliance Officer and Karthik K Saravanan, AVP, Deputy General Counsel and Global Head of Ethics and Compliance, Biocon Biologics

The revised US Federal Sentencing Guidelines, make specific reference to the need to promote a culture that “encourages ethical conduct” and a “commitment to compliance with the law.” The inspiration for this is that having an effective ethics program that can reduce fines by up to 90 percent.

We would like to share key highlights of an interesting journey underway at Biocon Biologics in setting up the global ethics and compliance program. While the Company turned one year old in June 2020, we are determined to adopt best practices when it comes to setting up the compliance and ethics program that effectively focuses on addressing all of the parameters set forth in the gold standards of compliance, including Department of Justice (DOJ) guidelines. The approach for us is simple: we want to ensure all employees within the organization are adequately trained and have consistently developed the ability to think rationally as opposed to rationalizing the actions taken.

With this simple goal in mind, we looked at various resources and benchmarking data sets of best practices from various sources. More importantly, as a member of the Business Ethics Leadership Alliance (BELA) community offered by Ethisphere allowed us a significant head start, as it gave us invaluable data into how the World's Most Ethical Companies are addressing ethics and compliance issues globally. Looking at trends and patterns from the data set, we quickly realized that substantial effort is spent on training and educating employees to make right decision.

As you read this article, it is important to note that we have successfully developed many tools internally or are close to finalizing technology. Our strategies include:

### Flipping the Pyramid

Typically, the compliance function aims to prevent issues in the following order of priority: preventing criminal conduct, preventing regulatory violations, preventing civil liability, preventing unethical conduct, preventing ethically questionable conduct (lawful but awful), and promoting ethical culture. The order of priority is based on the following two questions: “If we solved all ethical problems, would we also solve all or most of our compliance problems?” and “If we solved all compliance problems, would we also solve all or most of our ethical problems?” The immediate answer was to focus on building an ethical culture as the first priority and modify the pyramid to serve the company and its shareholders in the best possible way.

### Knowing the Boundaries

Realizing the importance of understanding the regulatory landscape, we initiated internal research focused on identifying the key laws, regulations, guidelines, and industry-specific mandates and best practices. This led to a deep understanding of various issues, empowering us to effectively build consequences and an

effectiveness-based compliance program. In particular, understanding the DOJ guidelines, the US Federal Sentencing Guidelines for Organizations, OIG guidelines, and corporate integrity agreements provided the team with a broader understanding of what we intended to achieve and how any ethics and compliance program will be assessed for effectiveness. With ever-growing enforcement actions against the best of the best companies, it is now part of our team's DNA to consistently review our program—and we are a research-led function.

### Viewing the Code as a Standard Operation Procedure

Traditionally, employees at all levels are aware of the existence of the Code of Conduct. However, not everyone is well versed when it comes to key expectations. What is the point in having a cumbersome 40-page document that is only reviewed for the purpose of annual certification? Some of the critical questions can be addressed in a systematic manner, starting with the Code of Conduct (COC) assessment report from Ethisphere that clearly articulates the evaluation criteria along with recommendations. It would be appropriate to benchmark the COC on two parameters—content and effectiveness. Implementation of the COC can be improved through avoiding lengthy paragraphs and including FAQs, examples, illustrations, and bullet points on key expectations. The agenda is, how can the COC become the standard operation procedure guiding ethical conduct in day-to-day operations?

### Understanding that Learning is Not Child's Play

Not all initiatives lead to positive impact and, needless to say, "with chaos comes movement and with clarity comes progress." With that in mind, we first looked at what can impact positive change and quickly realized micro-learning videos are a great way to engage employees. Employees tend to lose interest in lengthy videos and materials that do not address practical scenarios. After engaging with industry leaders, we chose the "Compliance Wave" database as the perfect solution that offered many animated training videos covering various topics including gifts, conflicts of interest, third party training material, export control laws, etc. Progressing through gamification ensured every audience, including millennials, remained interested. "The Kahoot!" game-based learning platform is another exciting tool we evaluated that allows us to engage an audience of 2000+ in remote locations equally, through customizable quizzes and live polls to get the pulse of the audience.

### Using on-demand Code videos

Every company spends significant efforts and dollars to educate employees on ethical conduct. One set of training does not fit all, and hence, to make the training more relevant, it is important to identify specific needs and generate training materials. That's not new or novel. The key innovation we are incorporating is making the learning mobile. With the simple use of technology, any micro-learning video can be hosted on Microsoft Stream—the video service in Microsoft 365—makes it easy to create, securely share, and interact, whether in a team or across your organization. Using a QR code generator, one can easily generate a QR code for the video link, and the code can be printed in any training material, including posters and banners. Now any employee with access to the QR code can just scan and readily listen to the audio-visual micro-learning videos. Based on the number of views, analytics can lead to more focused training, ensuring no physical and mental fatigue.

### Using an Avatar to Spread Culture

We all like one or more fictional characters. If you have kids at home, you will quickly realize that they are more likely to gravitate to messages delivered by a character as opposed to stringent guidelines. This led to an approach where we are introducing—an avatar-like animated lion we call LEO—Local Ethics Officer. We are engaging the employees through a survey to name the character, which creates a personal connection, and we don't have to worry about LEO joining a competitor. An avatar-based training program encourages employees at all levels to take the role of LEO and become an effective ambassador for the ethics program.

### Branding Tour Initiative

For any initiative to get noticed, it is important to have branding elements considered. We have branded our program as "EPIC" for a good reason. EPIC stands for Ethics Program and Integrated Compliance. As you will observe, ethics is at the forefront, and integrating compliance initiatives serves as the cornerstone for all our efforts in building one of the finest and most ethical companies. From an optics standpoint, the word EPIC has promoted positive energy, and we are internally marketing it as a journey that everyone can play a key role in and lead.

### Building What We Can

Not having many IT professionals in our manufacturing-driven organization never limited our ability to internally design and develop tools. In record time, we have built and are building various tools, including an opinions repository to retain key compliance learning, a tool to track and maintain investigations, a claims and

litigation tracker that specifically documents the lessons learned in order to revamp the compliance program, a compliance certification tool for both internal stakeholders and third-party suppliers and partners, and Microsoft Teams for collaborating, to name a few. The potential to use chat bots to effectively communicate with employees and answer FAQs-related to ethical conduct is immense and is targeted on engaging and educating.

### Partnering with the Best Law Firms


While access to various technology leads to independently operating with confidence, it is also important to have the right law firm as a partner in the quest for excellence. In this aspect, we believed running an RFP to select firms that operate in the biosimilar space would be appropriate. With a focus on an alternate fee arrangement and tons of value-added service, we were able to narrow down the best proposals, and it also gave us access to pick the best model for the most cost-effective negotiation. We highly recommend this approach, as it yields the best results in tough budget times.


Read the complete article on Ethisphere Magazine website.

### About Biocon

**Biocon Biologics** is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated "pure play" biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions.

### Author Biographies

 **Akhilesh Nand** joined Biocon in 2015 and currently serves as SVP, General Counsel and Chief Governance, Risk and Compliance Officer of Biocon Biologics. He has over two decades of experience in providing strategic advice to the Board of Directors and company executives facing unsettled or complex legal issues, and he assists them in efficiently solving problems and minimizing risk.

 **Karthik Kannappan Saravanan** is AVP, Deputy General Counsel and Global Head of Ethics and Compliance at Biocon Biologics. With 15+ years of relevant work experience, he is responsible for driving all corporate and strategic initiatives and to advise in setting up business and process in new and developed markets.