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NEXT-GEN COMPLIANCE ENHANCEMENT: Lachman Consultant Services, Inc. CEO Talks Agility, Integrity And Harmony

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Time-sensitive therapies require agility in addressing compliance issues, and growing R&D costs and product complexity call for regulatory and technical expertise that can deliver solutions. Lachman Consultants President/CEO, Frances Zipp, discusses these issues and answers questions on navigating new tech, data integrity and regulatory harmonization.

What do you feel will be the most significant regulatory-compliance challenges confronting the pharmaceutical and biotechnology industries in the US and worldwide over the next five years?

Navigating through the new technologies with the regulators. The pace of change in industry in some ways has outpaced the pace of adoption and learning within the regulatory agencies, so many approaches to applications and compliance are decided "on the fly," making the landscape potentially shifting and inconsistent. For next-generation companies and products, most regulatory and compliance decisions, regulations and norms will have been decided by early adopters and pioneers. This could lead to unrealistic or unachievable expectations. On the contrary, the industry could also find itself facing compliance challenges as the regulators catch up to the new technology and products, potentially enacting new requirements for already established products.

Do you think regulatory harmonization in (bio)pharmaceuticals, whether regionally or globally, will continue to gain pace – despite current contradictory trends such as the UK's Brexit break with the European Union?

Regulatory harmonization is absolutely necessary, and the industry will continue to be crippled in many areas if harmonization doesn't continue. The impact of Brexit on the harmonization efforts currently in place will take some time to sort out, but the foundation for continued harmonization is already laid. All major regulatory agencies have adopted ICH standards; the eCTD format for applications is currently in use. The FDA commissioner has stated that he is requesting ICH to look at Harmonization of Standards for Generic Development. With the continued implementation of the EU/US MRA for sharing of inspection information, the number of inspections is expected to decrease; however, how inspections are conducted, and the information required to comply still differ between inspectorates so there is still progress to be made. Various industry groups are working on some efforts to increase harmonization, but it is still a slow process.

Data are increasingly the product in today's industry. What are the particular compliance and integrity challenges of dealing with the huge volumes of data now generated at every stage of the pharmaceutical-product life cycle?

Data integrity concerns are clearly still foremost in the eyes of the regulators as well as industry. The global regulators have become more sophisticated in their approach for investigating data integrity issues during inspections. Data integrity breaches not only affect marketed products, but also affect data generated in support of applications, and this may be data that have been generated years before. Additionally, there are more and more sources of data being generated at locations not familiar with data integrity. Hospitals, clinics and early-phase research locations have all been hit with data integrity breaches. About 40% of Warning Letters issued by FDA since 2015 have data integrity lapses cited in addition to other issues.

How are recent trends in pharmaceutical product development, such as highly targeted biologics, a focus on orphan and speciality indications, or the emergence of gene and cell therapies, likely to affect regulatory and compliance issues in years to come?

These new trends in therapies require industry and the regulators to become agile in their ability to address issues. For example, some individualized therapies need to be tested and released within hours of manufacture so as to get them into the patient. In the event that there Is something that needs to be investigated, the timeline is quite short, so creative compliance responses are required.

Do you feel regulatory authorities around the world are becoming more stringent/vigilant or more flexible in the face of growing product complexity and R&D costs, coupled with rising patient and health-system demand for cutting-edge therapies?

In some cases, I do feel that the regulators are becoming more flexible in relation to cutting-edge therapies. The fast track approval process and the breakthrough therapies have brought many needed drugs to the market quickly and allowed companies to resolve potential compliance and/or regulatory issues independently.