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Convergence of regulatory expectations

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As biosimilar regulatory environment evolves, there is a trend for a convergence on regulatory expectations. This trend is driven by economic forces and is forcing companies that have local quality systems and local regulatory practices to change very rapidly. This trend is affecting how R & D is conducted, how clones and cell lines are acquired, the building of talent and the leveraging of external expertise and resources. The regulatory convergence is creating an internal dynamic that is introducing the need to have one quality system from R & D through commercialization. Biosciences Founder Robert Salcedo will explain how these trends are affecting the way companies are evolving. The development of biosimilar for local markets has been the staple for most companies who are starting their companies. They took advantage of the lack of definition and in some cases low regulatory barrier of entry to launch products. The perfect examples are the number of biosimilars that are already in emerging markets in Asia, Latin America and Africa. As the industry matures and companies look towards bigger piece of the pie they are realizing that local regulations are slowly evolving and starting to resemble the stringent regulatory requirements that are present in both US and EU. The opportunity to enter the US and EU market, combined with globalization goals for biosimilar companies has created dynamic where local and global regulatory expectations are converging. The US and EU market size is projected to be greater $0.5 trillion dollars by 2020 and biosimilars are expected to be more than $200B depending on which financial forecast is being utilized. This phenomenon is forcing local companies adapt to their R & D and quality practices that has been traditionally focused on local regulatory requirements with a rapid alignment with global standards.

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