

# 8<sup>TH</sup> ASIAN BIOLOGICS AND BIOSIMILARS CONGRESS

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## Convergence of regulatory expectations

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As biosimilar regulatory environment evolve, 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 this trends are affecting the ways company are evolving.

## Biography

Robert Salcedo has over 25 years of experience in biotechnology. He has worked for both Amgen and Genentech. He also leads a start-up biosimilar company. He is the Co-Founder of Biosciences Corp and Biosimilar Solutions which are dedicated in helping both biotech and biosimilar companies to develop their strategy and bring products to commercialization.

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