

KOL Agreements for Pharmaceutical Companies



USE CASE PROFILE: Pharmaceutical Companies

Challenge: Maintaining Compliance

Key Opinion Leaders (KOLs) play a unique role in the pharmaceutical industry, bringing credibility from their years of industry experience, and KOL events provide unique forums for industry engagement and collaboration. But maintaining compliance with regulations such as FDA 21 CFR Part 11 and the Physician Sunshine Act requires strict, granular accounting of the payments and other transfers of value to physicians and teaching hospitals.

Corporate Integrity Agreements further complicate the process, mandating certain internal compliance programs, reviews, and disclosure requirements. Pharmaceutical companies and medical device manufacturers need a KOL agreement solution that meets regulatory and other compliance requirements without undue burden or expense.

The DocuSign Solution

DocuSign enables you to simplify the KOL agreement process while maintaining regulatory compliance. Participants can register and you can gather their signatures online prior to the event, or on site using mobile devices or tablets. DocuSign offers robust authentication options including digital certificates from SAFE-BioPharma and phone- and knowledge-based authentication, providing you with additional levels of verification should you require it.

Our forms library lets your staff easily select the appropriate forms, and automated reminders help ensure compliance. DocuSign also provides complete reporting, audit trail, and document retention capabilities.

DocuSign Key Benefits

DocuSign can help you ensure all KOL agreements are gathered in compliance with 21 CFR part 11, HIPAA and other regulations. DocuSign can greatly reduce the manual process of gathering signatures, while lowering your risk of non-compliance. Automated online reminders reduce the need for reminder calls. And as a cloud-based solution you can get up and running immediately, realizing faster time to benefit.

Customer Example

KOL Agreements

A Fortune 500 Pharmaceutical company selected DocuSign to streamline agreements with Key Opinion Leaders. Prior to DocuSign, these critical, regulated contracts took over 40 days to complete using a manual, paper-based process. With DocuSign, contracts are entirely digital, are signed in an average of 3 days, and are fully compliant and easily audited.

About DocuSign

DocuSign® is the global standard for electronic signature®. DocuSign accelerates transactions to increase speed to results, reduce costs, and delight customers with the easiest, fastest, most secure global network for sending, signing, tracking, and storing documents in the cloud.



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