

CASE STUDY: REGULATORY COMPLIANT SOP



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DEFINITION

A Regulatory Compliant Standard Operating Procedure is a written document / instruction that is approved by all parties along the supply chain which details all steps and activities of a process or procedure specific to ensuring compliance with all global regulations for pharmaceutical storage and distribution. Procedures should describe the different operations which may affect the quality of the products or of the distribution activity (e.g. receipt and checking of deliveries, storage, cleaning and maintenance of the premises, recording of the storage conditions, security of stock on site and consignment in transit, returned products, etc.) The procedure should be carried out without any deviation or modification to guarantee the expected outcome. Any modification or deviation is thoroughly investigated and outcomes of the investigation documented according to the LifeConEx Investigation Procedure Process.

Source: WHO TRS 937 Annex 5, Sections 5,6,9,11,12 &14. EU GMP Part 1 4.19-4.26. EU GDP (94/C 63/03) 6. ISO 13485:2003.4.2.1b/d

BACKGROUND

A global biopharmaceutical manufacturer was experiencing major losses in product out of their facility in Los Angeles (LAX) because of the insufficient quality control of their SOPs. For example, the manufacturer would secure the product out of their European facility and ship to South America instead of securing product out of their much closer LAX facility because of a perceived lack of quality internally. The challenges centered on the following:

- The LAX facility had no system to keep track of their existing cold chain network (i.e. they often didn't know how to get their consignees involved when establishing a new trade lane or what documentation was relevant).
- Trade lane management was performed solely through the forwarder, which provided no regulatory compliance as SOPs were not being implemented per trade lane.
- Because of costs and inexperience with the pharmaceutical service levels available with the airlines out of LAX, the manufacturer was shipping product as general cargo.

APPROACH

Due to a successful relationship with the same manufacturer out of their facility in Europe, LifeConEx was recommended to support the LAX branch with their process management.

- LifeConEx immediately began to push for an awareness of who the airline carriers and partners were for each trade lane out of LAX.
- LifeConEx designed and implemented all SOPs at the origin, transit point, and destination for the required forty trade lanes and trained the manufacturer, forwarder, and airline on each.



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APPROACH (Continued)

- Pre-Approval processes were put in place with governmental and regulatory bodies to ensure that prior approval was given regarding storage capabilities at destination.

RESULTS

The manufacturer no longer wanted their products to be booked as general cargo and understood the value of booking with the correct pharma service level. There was now an awareness that the destination needed to be more involved in the process for efficient transportation, care, and delivery.

- As a result of this continuous improvement through LifeConEx involvement, regulatory compliant processes were implemented for each trade lane out of LAX.

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"I like challenges - whether finding a suitable routing to obscure locations or reacting quickly with the customer on an emergency vaccine to coordinate with origin, destination and carrier to write a viable SOP for monitoring purposes in an abbreviated timeframe. Having the knowledge, proper contacts and cooperation with all parties is key to the LifeConEx process. I thrive on positive feedback from the customers, carriers and freight forwarders. We are always improving our processes and learning from each other, which keeps us motivated to continue to excel as leaders in the industry."

Jan Cahill joined LifeConEx 4 years ago. Her prior experience includes Express Consignment Courier - liaison with U.S. Government Agencies; International Logistics Manager for Importer; Ocean, and Air Exports including Letters of Credit, plus bonded warehouse, container freight station and NVOCC for Freight Forwarder.

ABOUT LifeConEx

LifeConEx offers peace of mind as the only industry-specific, end-to-end cold chain management solutions provider for the life science industry worldwide. With oversight of the entire global landscape, LifeConEx designs and orchestrates the shipment process end-to-end proactively and reactively, assuring the integrity of your product's desired condition. You experience shorter cycle times, a reduction in temperature excursions, and far fewer damages than typically experienced by shippers. LifeConEx it & Live your Life.

LifeConEx is supply chain party neutral (airlines, forwarders, truckers, packaging, and technology).
