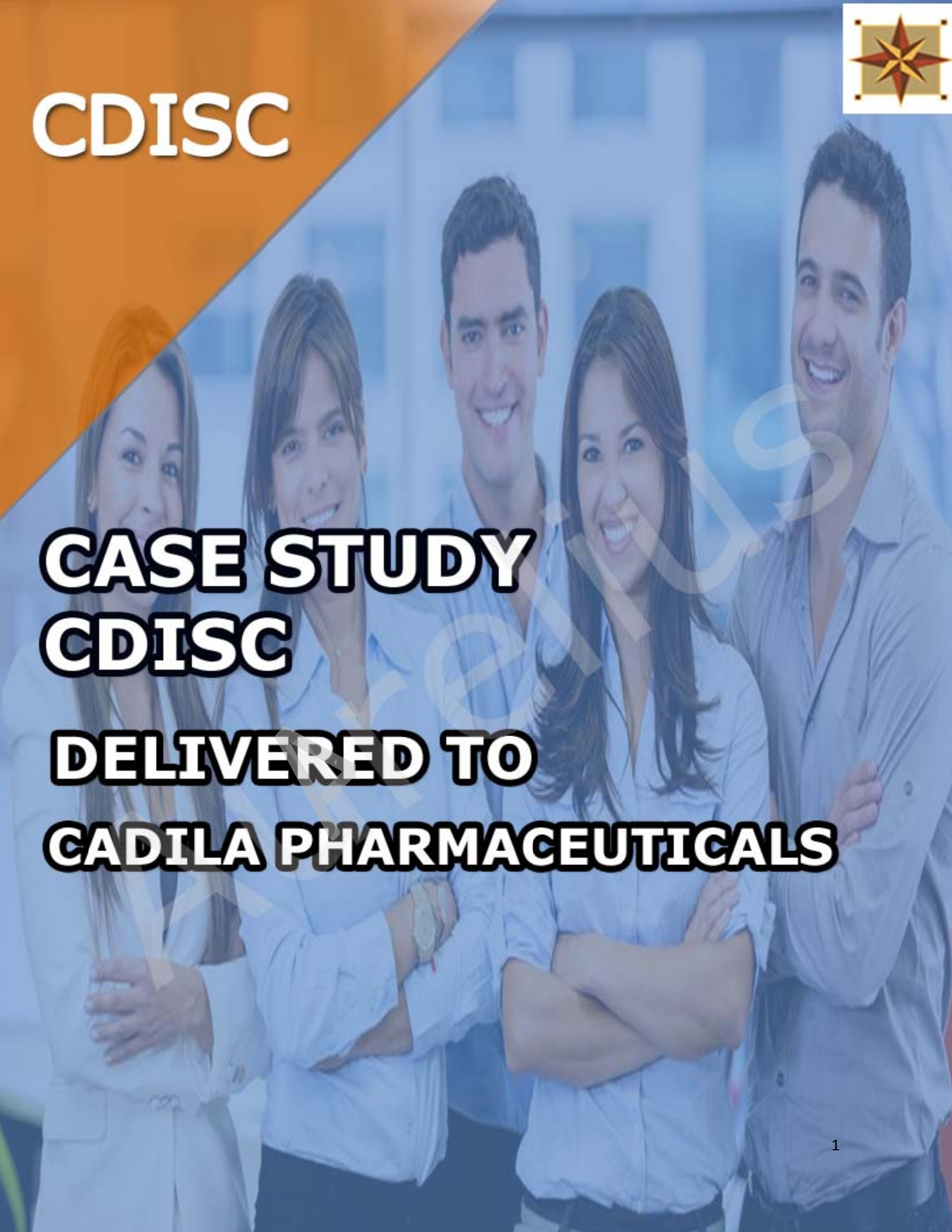
CDISC

CASE STUDY CDISC

DELIVERED TO CADILA PHARMACEUTICALS



Contents

CDISC Training Delivered to Cadila Pharmaceuticals

Client: Cadila Pharmaceuticals

Industry: Pharmaceutical

Cadila Pharmaceuticals is an Indian Multinational Pharmaceutical company which operates out of Ahmadabad, Gujarat. Founded in 1951, the company has been developing and manufacturing finished formulations and pharmaceutical ingredients in almost 100 countries. Their company has been instrumental in developing formulations across various therapeutic areas such as cardiovascular, gastrointestinal, analgesics, antibiotics, respiratory, anti-invectives and other different kinds of respiratory agents, anti-diabetics etc.

Cadila Pharmaceutical also has an established and dedicated Research and Development center at Dholka, Gujarat which is manned by 300 scientists. The organizations has been the first Indian firm which was able to get a new investigational drug approved by USFDA for pulmonary tuberculosis, lung cancer, prostate cancer, bladder cancer and melanoma. Ten ANDAs have been submitted, by the organization and it has various connections with the different institutions for research such as Department of Biotechnology, UDSC, IISC, etc.

Their brand provides generic formulations which cover more than 45 therapeutic segments and 12 specialized domains. More than 50 APIs and intermediates are offered by the organizations and also provide contract research and contract manufacturing as services.

Technology: Clinical Data Interchange Standards Consortium

Domain: Healthcare and clinical standards development

The CDISC or Clinical Data Interchange Standards Consortium is essentially an open and multi-disciplinary non-profit organization which develops standards for clinical data interchange. CDISC has an operational data model which is designed so that the regulatory-compliant acquisitions can be facilitated, archived and provide exchange of data and meta-data required for clinical research studies. The operational data model is entirely vendor neutral, platform independent and provides for the interchange and archiving of clinical study data.

CDISC also provides a BRIDG model and a SHARE model. The CDISC model is used for unifying the clinical research studies by defining basic elements of the research studies such as investigator, subject, study, intervention and more.

The CDISC SHARE is a metadata repository which provides support for the development of governance, publishing and consumption of various CDISC standards in the various human and machine-readable formats. Through SHARE, users are able to find and gain insight of the rich metadata which is stored on to the CDISC system. SHARE provides the capabilities of integrating and tracing the clinical data end to end and further providing collaborative standards development environment.

Challenges Faced By the client:

The Food and Drug Administration (FDA or USFDA) requires all the submissions for approval of the various new and abbreviated drugs to be done as per the CDISC standards. This means that the client working in the development of drugs approval and development required all their proposals to be formatted and structured as per the requirements of the CDISC standards. Together with FDA, almost all the regulatory bodies throughout the globe were pushing towards systems and proposals which follow CDISC guidelines. This called for an extensive deployment and development of a model for proposal structuring in line with the CDISC guidelines.

This requires that their workforce has in-depth knowledge and understanding of the various CDISC standards and how they can be implemented and organized in their proposals to ensure that their applications are not rejected and go through without any hassles.

So far, Client had been employing third party vendors who performed the job of developing the proposals for submissions and the client only had partial control over their working and operations. They were also incurring huge costs for these outsourced tasks from the third party vendors. The client was incurring almost 30 percent overhead costs on their proposal development and submission procedures due to the outsourcing which was making a direct hit on their profits and returns.

The need of the hour was to develop an in-house model which can take care of the tasks being outsourced and do it in a very structured and efficient manner. The goal was to provide the client with the requisite capabilities and knowledge so that they do not have to rely on third party vendors and be able to develop proposals on their own without any hassles.

Why Aurelius

Aurelius has been providing support and consultancy to pharmaceutical organizations for a long period of time and understands how important it is to have knowledge in CDISC norms in order to make the data quickly understandable and appropriable.

Aurelius was able to create a highly structured consultative learning solution which was more in lines of consultancy to provide Cadila Pharmaceutical with the required knowledge of CDISC guidelines and norms. The biggest task was to integrate all the updated guidelines in the learning solution and deliver them in accordance with the various specific requirements as per the specific domains in which the client works and develops its medicinal products. The aim was to help the clients create their very own CDISC based deliverables internally without creating any dependencies on the various external vendors for doing the task.

With the help of Aurelius, the client was able to form an in house team comprising of programmers and statisticians who can work with the various proposals and create deliverables as per the exact guidelines of the CDISC norms. Consequently, the client no longer needed to depend on the external vendors and was able to increase their own profit and returns by eliminating over-head costs.

With Aurelius, Cadila Pharma gained the advantages of legacy integration and complete on-shore and offshore support which helped them since the beginning of the learning program and continued post program completion to provide support when and if needed. The entire learning solution was developed by a dedicated team which sourced the subject matter expert needed to deliver the content of the program in a very efficient manner. This SME was searched for globally to have a global exposure and experience of the pharmaceutical industry, owing to the global nature of operations of the client.

The entire learning solution was coupled with various practical exercises in which the participants were required to develop dummy proposals as per CDISC

guidelines, initially under the guidance of the Subject Matter Expert and further late on their own. This helped them develop a clearer understanding of the procedures involved in developing such proposals to ensure their capabilities post program-completion.

Solution and Post Solutions Benefits

The entire learning solution on CDISC standards was built in two parts of theory and application wherein, the participants were required to understand the theories and norms initially and then put them to practice by developing proposals and systems which can be put up to the FDA authorities. These dummy proposals went a long way in clarifying the concepts of the participants. Further, extend doubt clearing sessions made sure that the client's workforce was absolutely clear on all the facets of CDISC.

Post-completion of the learning solution, Cadila pharma has been able to develop their in-house team and no longer seeks support of third party agents for developing proposals. This has led to an overall increase of almost 40 percent in their returns due to the reduction in costs occurred by outsourcing. Moreover, within a few months they were able to gain their ROI in the learning solution and further gain profits. Now they are able to develop complete proposals which are in line with the CDISC standards and have very high chances of approval by the FDA and other authorities.