

COMPANY PROFILE:

Our client is one of the leading establishments in Pharmaceutical industry engaged in pharmaceutical development and manufacturing solutions through collaborative ventures and consumer products division having diverse product categories like Vitamins & Nutrition, Dermatological & Antacids, and Analgesis. This Group has approximately 35 plants in 8 states of India including R&D Centers, some of which are located out of India. This Group has received the prestigious award "Safe Organization of the year" from OSHA Association.

CHALLENGES:

Section 134(5)(f) of The Companies Act, 2013 specifies that the directors should have a proper system to ensure compliance with the provisions of all applicable laws and that such systems were adequate and operating effectively.

Pharmacy Industry is mainly regulated by Department of Pharmaceutical under Ministry of Chemical and Fertilizers. There are critical compliance under Drugs and Cosmetic Act, 1940, Pharmacy Act, 1948, Narcotic Drugs and Psychotropic Substance Act, 1985, Medicinal and Toilet Preparations Act, 1956 and last but not the least the policies specified by National Pharmaceutical Pricing Authority (NPPA).

Apart from the legislations issued by regulatory bodies there are approximately 50 Acts applicable to the manufacturing units and back office including but not limited to Labour Laws, Environment Health and Safety Laws, IPR Laws, Commercial Laws etc. Under these Acts, the number of compliance items are going into hundreds and thus compliance management becomes a vital and critical area to deal with.

HOW DID AVANTIS HELP?

Avantis conducted a thorough analysis of the client's business, entities, locations and regulatory environment. Based on these, Avantis created a comprehensive list of client specific applicable compliances. The team of experts worked with various location heads / department heads and CXOs and identified a list of all the users along with their roles (performers, reviewers, approvers and management personnel) and mapped the appropriate compliances to the identified users. All the users had personalized dashboards along with configuration of automated reminders, alerts and escalations. Compliance calendar was automatically generated for each user. Avantis configured 45 users and mapped 2000 compliances in the system.

Avantis Softech LLP through its "AVACOM" has provided a solution to make the compliance management simple and system based. It has provided separate dashboards to different users to comply with applicable laws and compliances. The users get system based reminders to comply with applicable legal compliances which are based on legal due dates. To have a control over the compliance management, it has provided a separate dashboard to each user including the management which facilitates the management to know the status of compliances, the dedicated responsible person and the due dates, etc., in advance.