Project Details: NAeG/14-15/00109

Project id -	NAeG/14-15/00109
Name of The Project	Drug Manufacturing License (Allopathic) DMLA iDMLA (httpdmla.guj.nic.in) (httpidmla.guj.nic.in)
Category of Award Applying for	Excellence in Government Process Re-engineering
Date of Launch	23-01-2013
Summary/Objective of the project	Objectives of the project were standardization of procedures, transparency, accuracy, promptness, retrieval of information and processing of various complex applications in simplified way by overcoming the following problems faced by FDCA and the applicant manufacturers:- Manual Processing of the applications & lack of tracking system was the common problem same as with other Government department. The firm wise data were maintained as physical files only. In addition to that, unique problems with various product licenses granted by FDCA were complexities and wide range of types of product licenses. As on date 4317 Drug manufacturing Licenses are operational in Gujarat & 230,760 product licenses have been granted. All these data vary in many aspects and are too complex A manufacturer may have more than one unit in Gujarat. A manufacturer may also have Loan Licenses with multiple parent firms. A manufacturer may have product licenses in the range of 10 to 1500. One product License may have ingredient in the range of 1 to 30. One Product may be in various dosage forms e.g. Tablet, Capsule, Oral Liquid, Injections, Metered Dose Inhalers, Ointment, Cream, Lotion, Nasal drop/spray etc. A product may be of different categories like Bulk Drug, Formulations, Irrigating solutions, Vaccines, r-DNA products, Blood & Blood Products, Diagnostic Reagents, Sutures, Mechanical Contraceptives like condom, Copper T etc. Medical Devices Cardiac Stents, Orthopedic Implants, IOL (Intra Ocular Lenses), IV Sets, Needles, Syringes etc. Every day approx. 150 new product licenses are being processed by FDCA. Queries raised by the FDCA took several days for manual communication to the applicants and thereby compliance also took another several days. Leading to delay in granting product licenses. To track a product license with a particular ingredient / composition was a time consuming task. Practically, it was not possible to retrieve the information correctly and completely of drug banned by GOI and to ask the manufacturers to stop manufacturing of such banned drugs. Similarly, the retrieval of information was not feasible with reference to RTI. During License renewal application, a manufacturer may or may not include all Product Licenses granted. The list of Product Licenses submitted need to be compared along with the copies of original Product Licenses. The manual process is a tedious & time consuming task. The manufacturer located at the distance had to travel at least 400 km to reach FDCA Gandhinagar to apply / know the status of the applications and had to make overnight stays for several days.He may also have to return to their working place for compliance of queries. The entire process was costing money & important working man-hours. In case of epidemic & pandemic situation / short supply of a particular medicine, information of such medicine was not availed promptly. Annual Surveys of the drug manufactured, capital investments etc. by all manufacturers located in Gujarat and compilation of all information took several months and many a time were not able to complete till the end of the year.
Beneficiary of the project	All allopathic drug manufacturers located in Gujarat State. FDCA, Gujarat. Health & Family Welfare Department, GOI and Gujarat State. Citizen of India.
Details of Project Head	
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Name(2nd team member)	Mr. Y.D. Chauhan
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Name(4th team member)	Mr. Rajnish Mahajan
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Name(5th team member)	Mr. Shailesh Shah
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Name(6th team member)	Mr. Pankaj Pathak
Designation(6th team member)	Scientist (D) National Informatics Centre, Gujarat
Supporting documents:-	Award Specific Form Self Certification by the Project Head