

AWARDS SCHEME FOR EXEMPLARY IMPLEMENTATION OF
e-GOVERNANCE INITIATIVES

I. NAME OF CATEGORY- 'EXCELLENCE IN GOVERNMENT PROCESS RE-ENGINEERING'

PROFORMA OF AWARD SPECIFIC
FORMS

**Food & Drugs Control Administration,
Gujarat
Project – DMLA-iDMLA**

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1. Coverage – Geographical and Demographic :-

- i. Comprehensiveness of reach of delivery centers - N numbers
As service is available online and hence reach of delivery centers is comprehensive due to presence of internet connectivity all over the state.
- ii. Number of delivery centers - N numbers
- iii. Geographical
 - a) National level – No of State covered – One State - Gujarat
 - b) State/UT level- No of District covered – 33 Districts
 - c) District level- No of Blocks covered – All units located in Gujarat State

Please give specific details:-

Food & Drugs Control Administration, (FDCA) Gujarat State is regulatory authority for enforcement of Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat. It includes licensing of various drugs manufacturing in the Gujarat State.

Activities to issue and control the Drugs(allopathic) licenses are carried out by office of Commissioner, Food & Drugs Control Administration (FDCA), Gandhinagar. There are **25** circle offices working under the FDCA at district level which enforce the Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat.

The web enabled software is rolled out across the state and operational in all 25 circle offices catering services to 33 districts of Gujarat.

Two web portal is developed to cater the service related to Drugs(allopathic) Manufacturing Licenses.

1. DMLA (Drugs Manufacturing License Allocation for FDCA office users)
<http://dmla.guj.nic.in/mfg/myaccount/Home.aspx>
2. iDMLA (Drugs Manufacturing License Allocation for manufacturers)
<http://idmla.guj.nic.in/mfg/myaccount/Home.aspx>

All Technical Officers and concerned ministerial staff of FDCA have access to the software through DMLA portal.

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More than 1200 drugs (allopathic) manufacturing companies are given a login credentials to access the iDMLA portal which is accessible over the internet from anywhere of the world with no geographical restrictions. The drug manufacturing company may have multiple manufacturing sites and licenses to manufacture drugs. They can maintain their profile through this portal for such multiple units / licenses. Till date more than 4300 manufacturing Licenses and more than 234800 Product licenses are being managed through DMLA/iDMLA.

(iv) Demographic spread (percentage of population covered)

All drug manufacturers located in Gujarat State (100%) covered under the project.

2. **Situation Before the Initiative** (Bottlenecks, Challenges, constraints etc with specific details as to what triggered the Organization to conceptualize this project):

Gujarat State is the hub of Pharmaceutical manufacturing and almost 33 % of total pharmaceuticals manufactured in India is manufactured in Gujarat State.

Food & Drugs Control Administration, (FDCA) Gujarat State is regulatory authority for enforcement of Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat and includes licensing of various drugs manufacturing in the Gujarat State. Commissioner, FDCA is the State Licensing Authority to grant / renew licenses, product licenses, approval of technical persons etc. All such applications are being processed by H.Q., Gandhinagar.

Considering the quantum of work with FDCA, Commissioner, FDCA has also delegated various powers to FDCA's senior officers like Joint Commissioners, Deputy Commissioners and Assistant Commissioner at H.Q., Gandhinagar.

Manual Processing of the applications & lack of tracking system was the common problem same as with any other Government department. The data regarding Licenses, Constitution of the firm, technical Persons, Product Licenses were maintained as physical files only.

In addition to that, the unique problems with the various product licenses granted by FDCA were the complexities and wide range of types of product licenses.

As on date 4317 Drug manufacturing Licenses are operational in Gujarat State.
As on date 230,760 product licenses have been granted by FDCA.

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All these data vary in many aspects and are too complex –

- A manufacturer may have more than one unit in Gujarat State.
- 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, Small Volume Parenterals, Large Volume Parenterals, 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, Gujarat.
- Queries raised by the FDCA officers took several days for manual communication to the applicants and thereby the compliance by the applicant also took another several days. Ultimately, there was delay in granting product licenses.

To track a product license with a particular ingredient / composition was a time consuming task.

Whenever DCGI, Government of India ban a particular API (Bulk Drug) / composition of a formulation, practically, it was not possible to retrieve the information correctly and completely in the given time. It is necessary to ask the manufacturers to stop manufacturing of such banned drugs. RTI applicants ask information of a manufacturer manufacturing a particular drug / formulation. Under such situation also, the retrieval of information was not feasible.

During submission of License renewal application, a manufacturer may or may not include all Product Licenses granted earlier as per their requirement. The list of Product Licenses submitted with the renewal application need to be compared along with the copies of original Product Licenses. The manual process of such application is a tedious & time consuming task.

The manufacturer located at the distance places like Bhuj / Vapi etc. had to travel at least 400 km to reach FDCA Head Quarter at Gandhinagar to apply and know

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the status of the applications and had to make overnight stays for several days at Gandhinagar. Moreover, he may have to return to their working place / company for the compliance of the queries. The entire process was costing not only considerable amount of money but also wastage of important working man-hours'.

In case of epidemic & pandemic situation / short supply of a particular medicine, information of a manufacture manufacturing such medicine was not availed within time frame.

Annual Surveys of the drug manufactured, capital investments etc. by all manufacturers located in Gujarat State and compilation of all information took several months and many a time were not able to complete till the end of the year.

Conventional method of sending circulars through post to pass on particular information to all manufacturers and even to FDCA officers was not prompt, effective and was expensive.

3. **Extent of Process re-engineered** (Processes that have been re-engineered, services which depend on these processes, analysis/re-design of Process workflows – before (As-Is) and after (To-Be) re-engineering; changes in activities and their sequencing; level of automation (Extent of computerization in terms of number of services computerized, Extent to which steps in each service have been ICT-enabled) #)

The complexity of application & grant of product license was simplified and standardized through online application through iDMLA & DMLA.

During submission of License renewal application, a manufacturer may or may not include all Product Licenses granted earlier as per their requirement. The list of Product Licenses submitted with the renewal application need to be compared along with the copies of original Product Licenses. This process was simplified and made more convenient by permitting the applicant firm to select already approved & verified product licenses from the database.

Annual survey – return filing was made online and the manufacturer can enter the details directly through iDMLA and the information of all manufacturers gets

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compiled automatically. This enable FDCA to complete the survey on time and actual data became available.

The numbers of various types of application submitted by the applicant drug manufacturers, processed and disposed can be accessed for any specific period as report. MIS, annual and specific period reports can be easily generated.

4. Strategy Adopted

Gujarat State is the hub of Pharmaceutical manufacturing and almost 33 % of total pharmaceuticals manufactured in India is manufactured in Gujarat State.

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Considering the quantum of work with FDCA, Commissioner, FDCA has also delegated various powers to FDCA's senior officers like Joint Commissioners, Deputy Commissioners and Assistant Commissioner at H.Q., Gandhinagar.

A workflow based application of Drugs (allopathic) Manufacturing License is developed for Food & Drugs Control Administration (FDCA), Health Department, Govt. of Gujarat.

National Informatics Centre, Gujarat State has been entrusted the task to develop the software. Several brain storming sessions between FDCA & NIC team took place before, during & after development of the software.

Two web portals are developed under this project. One portal called iDMLA is a web portal accessible over internet is for the drugs (allopathic) manufacturers and another called DMLA is for FDCA. The online application lodged in iDMLA by applicant is automatically reflected in DMLA (portal for FDCA officers) once registration process is completed.

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DMLA

This is a workflow based application processing and having role based access. The scope of the project is Firm Registration Management, Firm Profile verification and updating, issuance of fresh license, renewal and amendments in existing license, additional product license, Revised Product License, Additional Brands and various types of certificates.

iDMLA

This is a portal for drugs (allopathic) manufacturer where they are registering themselves. After the verification of genuineness of the firm by FDCA, firm is able to login into the portal by providing credentials they have given at the time of registration.

Manufacturer can manage their license & product profile. They can do various on-line applications like Fresh License, Renewal of License, Amendments in License, surrender of license / product license, additional product licenses, application for certificates, approval of Technical Persons etc.

- Web based application accessible over intranet/internet
- Complete workflow based application processing
- Role based access
- Drugs (manufacturer) registration on iDMLA portal. The basic details of Firm Profile is also available to the Drug's manufacturer
- Registering on-line application on portal.
- On-line application status
- News and other alert in the form of E-message to the registered manufacturers(allopathic drugs)
- Intimation of notice to the manufacturer on the portal.
- Alerts to the license holder about the validity of license
- SMS alert on disposal of application

Activities Covered

1. Firm Registration and Verification. Assigning of user credentials to the firm after verifying the genuineness of the firm
2. Managing Firm Profile. This covers License, Technical Persons, Product Licenses, and Certificates etc.
3. On line submission of Various applications and workflow based processing of an applications. Like...
 - a. Additional Product Licenses

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- b. Renewal of Licenses
- c. Surrender of Licenses/Product License
- d. Amendments in License
- e. Application for Technical Person approval
- f. Application to avail various certificates
- 4. Annual Return filing
- 5. News and messaging system
- 6. SMS alerts
- 7. License and Product Licenses Management.

To full fill the above requirements of the detailed study has been conducted and identified the area of computerization.

The main problem with the manual system was not having proper record tracking of drugs manufactures and drugs manufactured by them. Also they have to visit N number of times to the office to get the work done.

The major challenge found during the study were

- To assign the user credentials to all drugs manufacturing firms(allopathic)
- To enter the all legacy data like drugs manufacturing license and products licenses (Approx. 150000 product licenses) granted to them. To enter the existing product license details with its composition details was itself huge task.
- Online submission and processing of various applications

To overcome from above problems the whole project was divided into 3 phases.

Phase-1 The Firm Registration

In this phase all drugs manufactures were asked to register themselves on iDMLA portal and submit the registration slip to the FDCA office with necessary supporting documents to prove the genuineness of the firm.

After verifying the genuineness of the firm by the FDCA officials, the user credentials of the firm, provided by themselves at the time of registration, gets enabled automatically. Then onwards firm can login into the iDMLA portal- a portal of drugs manufacturers.

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Pahese-II Firm Profile Update

During this, manufacturing firms have been asked to update their profile. This includes the existing details of

- Details of the licenses they have
- Approved Product Sections
- Approved products (drugs) with compositions
- Technical Persons they have engaged in manufacturing process.

The above details entered by the firm must get verified by the FDCA office. After verification of the profile, the firm is entitled to submit various applications online through iDMLA portal.

Phase-III Online applications.

Once the firm profile is verified, the manufacturer is now free to lounge various application on iDMLA portal

Thus, project was rolled out across the state by above phase wise. The most complex part of the entire licensing activities like product licenses was focused first. To achieve this, number of interactive workshops in almost all major districts had been arranged with manufactures to train them. These workshops proved beneficial for FDCA, NIC & the applicants. Their valuable feedbacks were also taken into considerations.

5. Technology Platform used-

- Web based application developed in ASP.NET and SQL Server 2008 as a backend. SQL server reporting service has been used.
- Hosted on NIC Data centre and accessible over internet
- Windows 8 server with IIS
- 3 tier application architecture
- Single Sign On – User authentication.
- Role base access of the menu
- Audit trial
- No Service Level Agreement Carried out. Permanent technical support by NIC

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6. **Citizen Centricity**

- The software provided a standardization of most of the product licenses and hence reduction in chances of mistakes and reduction in total time required for expedition of the application.
- It also provided information of the similar product already granted by FDCA Gujarat so that they can be sure that similar product can be granted to their company as well.
- Ease of information access for applicants and FDCA officers.
- In case of application for additional brand or revised product license, the fields of product licenses are retrieved from the database and thereby reducing time, cost and efforts.
- Number of interactive workshops in almost all major districts had been arranged with manufactures to train them. These workshops proved beneficial for FDCA, NIC & the applicants. Their valuable feedbacks were also taken into considerations.
- Senior FDCA officers monitored the project and proposed modifications, as and when required.
- Nominated Assistant Commissioner (Computer) to co-ordinate between FDCA, NIC& stakeholders for any issues related to the software.

7. **User convenience** (Give specific details about the followings #)

- (i) Service delivery channels (Web, email, SMS etc.)
The portal iDMLA is specially lounged for the applicant manufacturers whereby they can enter & update their profile, licenses details, technical persons details, product licenses, online applications etc. The applicant manufactures is intimated the status of the online application like query, approval or cancel/reject through SMS on the mobile number registered by the applicant firm.
- (ii) Completeness of information provided to the users,
The applicant can access complete profile of the firm and all their licenses. The applicant can also access the approved product Licenses through iDMLA.
- (iii) Accessibility (Time Window),
The iDMLA portal is available to the applicant 24X7. Any time. Any where.

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- (iv) Distance required to travel to Access Points
The applicant has access to the iDMLA through desktops / laptops and even through smart phones. No travelling required.
- (v) Facility for online/offline download and online submission of forms,
The applicant requires submitting online application. The approved product licenses and other information can be retrieved as .pdf file and it can be downloaded and saved.
- (vi) status tracking
The advantage of this project is "Status tracking" of any online application.

The applicant manufactures is intimated the status of the online application like query, approval or cancel/reject through SMS on the mobile number registered by the applicant firm.

Applicant can also read the query raised by FDCA officer as the tool tip added to the application number of the iDMLA.

8. **Efficiency Enhancement** (Give specific details about the following #)

- (i) Volume of transactions processed – 58690
- (ii) Coping with transaction volume growth –
Gujarat is a Pharma hub with approx. 30% share. The industry is growing by 12% annually. With the help of this project, FDCA, Gujarat has been successfully able to cope up with increased quantum of work with same strength of manpower.
- (iii) Time taken to process transactions, -
The project has facilitate the applicant and FDCA, Gujarat to process the online application in shorter period. e.g. Approx. 70% Processing period of renewal application has been reduced. Approx. 50% Processing period of product license application has been reduced.
- (iv) Accuracy of output –
The software has proved its robustness with accurate output.
- (v) Number of delays in service delivery –
Delay in services had been rarely observed due to rare power failure or internet / intranet connectivity problems.

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9. Cost effectiveness (Give details about impact on cost incurred w.r.t. overhead cost, direct and indirect cost, man days/man hour required to do a job etc. #)

1. Gujarat State Wide Area Network (GSWAN) across the state already existed. Therefore, no extra cost required to access DMLA by FDCA officers.
2. Internet connectivity obtained through special permission from Government of Gujarat for few district offices where GSWAN connectivity was not available.
3. Optimum usage of limited computers and printers available with FDCA.
4. Gujarat is a pharmaceutical hub of India manufacturing more than 30% of total pharma production. Therefore, quantum and varieties of applications received at FDCA, Gujarat is very high. Thus, vast experience gained by FDCA officers from such applications helped to streamline various procedures to bring harmony / standardization.
5. National Informatics Centre, Gujarat's Team's technical expertise for system requirements, its analysis, database designing, the development part & other technical aspects.
6. Central Server hosting, mirroring of data and regular backups by NIC.
7. Arranging brainstorming workshops with FDCA officers, especially end users, and NIC team at regular intervals to upgrade the DMLA - iDMLA.
8. Encouraging the users to communicate their feedback / suggestion through seminars held.

Though the software development & server hosting was done by Government of India's department - NIC, NIC was required to appoint software engineers for several months to assist the NIC team. FDCA spent total Rs. 35,81,589 for the project. The fund was provided by the Government of Gujarat.

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10. **Capacity Building and Organizational Sustainability** (Give details about hiring skilled staff, imparting training etc.#)

DMLA – iDMLA project is the result of combination of vast experience of FDCA officers and National Informatics Centre, Gujarat's Team's technical expertise. FDCA officers have contributed their expertise in the legal & technical matter and NIC officers have contributed their IT expertise like system requirements, its analysis, database designing, the development part & other technical supports like Central Server hosting, mirroring of data and regular backups. Thus, the entire project may be considered as in house project of Govt. of Gujarat & Govt. of India.

FDCA officers working at district offices and the manufacturers of each district were called for interactive trainings for iDMLA & DMLA. The workshops were not limited to impart training only but to seek their suggestions & feedbacks to improve the project.

The project conceptualization was started in 2008. Firm's registration, data entry for the firm, verification and freezing of data by FDCA officers was a huge task requiring lot of man-hours'. More than 1,50,000 back log entries of product licenses were keyed in, verified and freezed. Trials of online product licenses processing and standardization as pilot project completed and then after online renewal applications were started on date 23rd January 2013. Thus, before commencement of the project adequate checks were made to ensure that the project performs as per the requirements. More than 60000 online applications have been successfully processed. It proves the robustness of the software.

11. **Accountability** (Give details about, impact on transparency of process, fixing responsibilities etc. #)

iDMLA - The applicant firm has been permitted to generate user ID and password for two persons – operator and manager. They have been assigned various level of authority for submitting online application / updating profile.

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DMLA – User ID & Password has been allocated to clerical staff, Drugs Inspectors, Senior Drugs Inspectors, Assistant Commissioners, Deputy Commissioners, Joint Commissioners and Commissioner of FDCA. Depending upon the job authority & responsibility, each person has been given access & authority to certain level of processing the online application and view reports as well.

Log book of each activity performed in iDMLA & DMLA is being maintained by NIC for tracing & fixing responsibility.

12. **Innovation** (Give details on the extent to which re-engineered process is unique, compared to other common process re-engineering efforts, impact on number of steps required, identification and removal of bottlenecks/Irrelevant steps etc. #)
- iDMLA portal access to the manufacturers.
 - Provided user credentials to the manufacturer to manage their profile.
 - They can submit various applications through iDMLA portal.
 - SMS alerts at various stages. The moment FDCA officers raise a query and refer back the application or grant an application, a SMS is sent to the applicant on his registered mobile number.
 - Applicant can also read the query raised by FDCA officer as the tool tip added to the application number of the iDMLA.
 - Huge electronic data of more than 4300 Licenses and more than 234800 Product licenses enable to retrieve information regarding a particular product license with a particular ingredient / detailed composition.
 - Quicker completion of annual survey and compilation of information.
 - Prompt communication with manufacturers for better & effective compliance.
 - Earlier two attempts were made by other regulatory authorities to develop for drug manufacturing license system but their projects could not succeed, as their software could not simplified complexity of the product licenses and they were not user-friendly & speedy. But FDCA, Gujarat's this project has succeeded to over come all issues and brings out the e-solution to drug manufacturing Licensing system.
13. **Appropriate Delegation** (Give details on whether a team involving employees from all levels has been deployed for the project implementation and maintenance, can employees be held accountable for their actions, etc. #)

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DMLA – User ID & Password has been allocated to clerical staff, Drugs Inspectors, Senior Drugs Inspectors, Assistant Commissioners, Deputy Commissioners, Joint Commissioners and Commissioner of FDCA. Depending upon the job authority & responsibility, each person has been given access & authority to certain level of processing the online application and view reports as well.

iDMLA & DMLA portal has distinctive features of appropriate “Power delegation” for employee of the applicant firm and each clerk / officer of FDCA depending upon their assigned job profile.

Log book of each activity performed in iDMLA & DMLA is being maintained by NIC for tracing & fixing responsibility.

14. **Result Achieved/ Value Delivered** to the beneficiary of the project-(share the results, matrices, key learning's, feedback and stakeholders statements that show a positive difference is being made etc):

(i) To organization

- 1) Generation of huge & verified electronic data of more than 4300 Licenses & 234800 product Licenses. FDCA, Gujarat is the first and only State Licensing Authority to have database.
- 2) Ease of retrieval of various types of information for technical matter or RTI application.
- 3) Prompt action, when any ingredient / composition banned by DCGI, New Delhi.
- 4) Prompt communication of queries through SMS / online status. Prompt compliance by the applicant lead to quicker expedition of the application.
- 5) Prompt and correct collection and compilation of information, like drugs manufactured in Gujarat State.
- 6) Better & prompt mass communication with all manufacturers

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and FDCA officers. Better execution.

- 7) Indian Drug Manufacturer's Association (IDMA) has appreciated the project in writing.
- 8) This project has simplified the product licensing processing and thereby saving the time consumption of FDCA officers. The time saved by this project can be productively utilized by FDCA officers in other enforcement activities.

(ii) **To citizen**

- 1) Prompt retrieval of information manufacturing a particular drug helps FDCA to act promptly (e.g. Drugs banned by DCGI, New Delhi) and thereby protecting public health.
- 2) In case of epidemic & pandemic situation / short supply of a particular medicine, information of a manufacture manufacturing such medicine can be availed with just few clicks with the help of this software and thereby FDCA can direct such manufacturers to carter the demand and protect public health.

(iii) **Other stakeholders**

- 1) A firm / company may be having several licenses for one or more than one manufacturing units &/or loan licenses. They can access the information of each licenses 24X7 from any corner of Globe.
- 2) The firm has access to detailed information of any product license and can download as .pdf file and also send it to the buyer in response to business inquiry or even for registration in other countries. Helps to boost business and export too.
- 3) Effective tracking of online application and prompt intimation of grant of product licenses through SMS reduces gestation time for launching a particular product in market.
- 4) The manufacturer located at the distance places like Bhuj / Vapi etc. had to travel at least 400 km to reach FDCA Head Quarter at Gandhinagar to apply and know the status of the applications and had to make overnight stays for several days at Gandhinagar. Moreover, he may have to return to their working place / company for the compliance of the queries. The entire process was costing not only considerable amount of money but also wastage of important working man-hours'.

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15. Extent to which the Objective of the Project is fulfilled-(benefit to the target audience i.e.G2G, G2C, G2B, G2E or any other, size and category of population/stakeholder benefited etc):

The service catered by the DMLA application is of type G2B, G2G& G2E and it has met objectives like standardization of procedures, transparency, accuracy, promptness, retrieval of information etc. It helps FDCA officers to process the complex applications in simplified way.

16. **Adaptability Analysis**

Since the project is related to Drug manufacturing Licensing system based on the Central Act – Drugs & Cosmetics Act – 1940 & Rules -1945, throughout India, the applications are made and process in one language, ENGLISH by all State Licensing Authority & DCGI, New Delhi as well.

The applications are required to comply the requirement of the central Act, their format is standards throughout the country.

The web based technology used to develop the software has inherent ability for scalability.

Therefore, after minor customization, this software is adaptable for all States of India and can be replicated in other states too.

17. Comparative Analysis of earlier Vs new system with respect to the BPR, Change Management, Outcome/benefit, change in legal system, rules and regulations
- The new system has facilitated FDCA officers and drug manufacturers in Gujarat State to bring standardization of procedures, transparency, accuracy, promptness; retrieval of information etc. as compared to the earlier system.
 - Reduction in hurdles.

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- Saves travelling time and cost for a manufacturer as one does not have to visit FDCA office.
- This software has been developed in compliance with current requirement of the Central Act – Drugs & Cosmetics Act 1940 & Rules 1945.

18. Other distinctive features/ accomplishments of the project:

Drugs Control General (India), (DCGI) New Delhi and one State Licensing Authority of a major State manufacturing pharmaceuticals had attempted to develop two software separately in between 2000 to 2005 for drug manufacturing license system but their projects could not succeed because of lots of issues faced by manufacturers and Drug authorities. As theses software could not simplified complexity of the product licenses and they were not user-friendly & speedy, these projects were dropped and the Drug Authorities had to revert back to manual system.

FDCA, Gujarat is the first State Licensing Authority to bring out e-solution in coordination with NIC, Gujarat. This project has been appreciated by many State Licensing Authorities & DCGI, New Delhi, Indian Drug Manufacturers Association (IDMA).

FDCA, Gujarat has an excellent track record in e-governance and FDCA, Gujarat is a recipient of "GOLD AWARD" for "Exemplary reuse of ICT Based Solution" National e-Governance Award, 2012 at Jaipur for its SALES LICENSE project "XLN – Xtended Licnesing & Laboratory Node".