Step-by-Step Procedure

Application for Grant & Renewal of Drug Manufacturing License

1) Application Submission and Fee Payment by the Applicant

Online Registration

Visit Drug Control Administration website "**www.dca.telangana.gov.in**"
And select the tab "**Online Drug Licensing System**"

Select "**Apply Online**" - First Time Applicants need to Register Under "**New Users**" by filing in the details including the license information, and obtain a **User ID and password** for login.

Confirmation to New Users/Applicants will be sent to their mail-id/ through SMS on the registered mobile number. Once registered, Applicant can now **Log-in to proceed with the online application.**

Filing Application, Uploading Documents and Fees Payment

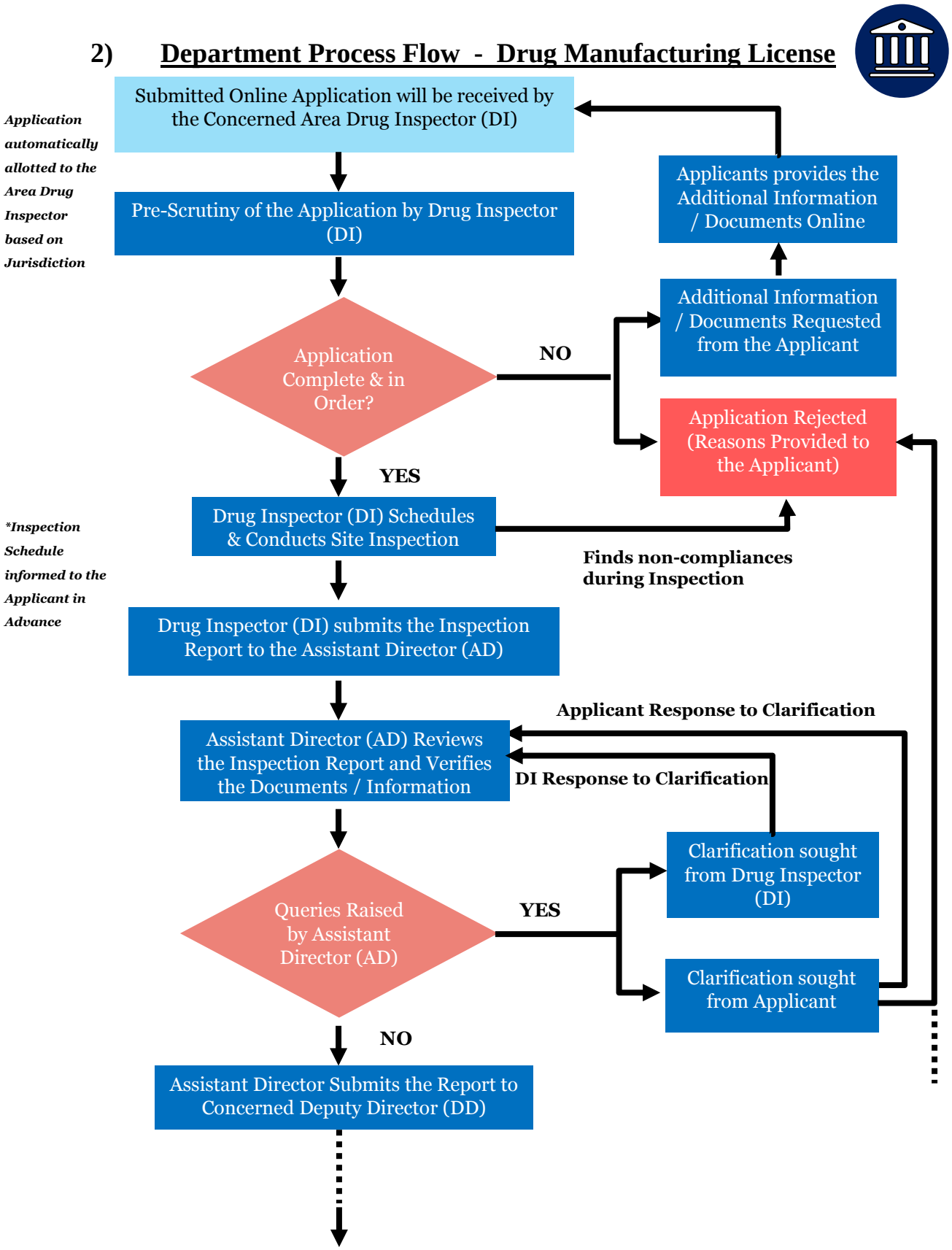
Select the service category and type of License from the drop down list. For e.g - Under **Manufacturing** - Bulk drugs, formulations etc, then the type i.e Grant / Renewal / Amendment

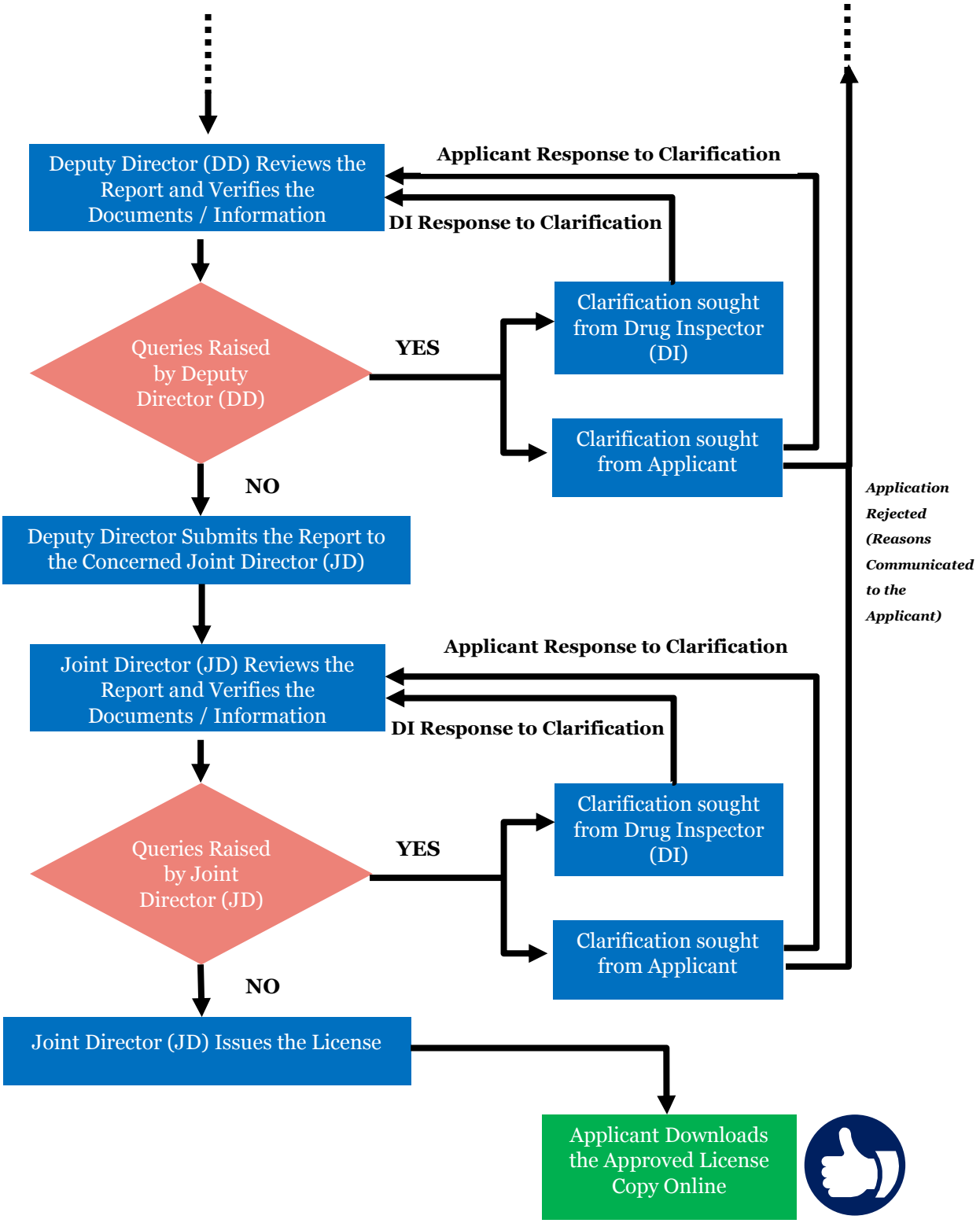
Checklist / Documents to be submitted for each services are available under "**How to Apply**" tab at home page. Checklist as per the License selected is also provided during the application process. Applicant need to prepare the soft copies of all the documents required for desired licences.

Applicant need to fill in the - firm details, constitution details, technical staff and other required information, and upload documents as per the checklist. (Application can be saved and pages can be revisited to make any changes before submission)

License Fee to be Paid and Application Submitted (Acknowledgement of Fee Payment & Application Submission Confirmation will be sent to the Applicant's registerd maid ID / through SMS

2) Department Process Flow - Drug Manufacturing License




Deputy Director (DD) Reviews the Report and Verifies the Documents / Information
Applicant Response to Clarification
DI Response to Clarification
Queries Raised by Deputy Director (DD)
YES
Clarification sought from Drug Inspector (DI)
Clarification sought from Applicant
NO
Application Rejected (Reasons Communicated to the Applicant)
Deputy Director Submits the Report to the Concerned Joint Director (JD)
Joint Director (JD) Reviews the Report and Verifies the Documents / Information
Applicant Response to Clarification
DI Response to Clarification
Queries Raised by Joint Director (JD)
YES
Clarification sought from Drug Inspector (DI)
Clarification sought from Applicant
NO
Joint Director (JD) Issues the License
Applicant Downloads the Approved License Copy Online

*Inspection Procedure

The inspector shall verify the following aspects at the time of inspection of the facility for ***grant/ renewal of manufacturing licenses:***

- Production area of the facility to verify the uni-flow of various operations carried out in the respective modules.
- Design of the facility for proper segregation of areas meant for various activities.
- Installation of the required equipment along with the qualification status.
- Purified water generation and distribution system and the status of validation.
- Air Handling Units validations along with the zoning classification (air classification), pressure differentials in various areas of the production modules.
- Material movement and men movement in the production areas to ensure regarding the no chance of cross contamination/ mix up.
- Quality Control laboratory to verify the instruments & calibration status (analytical capabilities of firm).
- Warehousing facilities of the firm for raw materials and finished products.
- Required capabilities of Technical Staff for manufacturing and testing.
- To verify the compliance of the facility with the provisions of Good Manufacturing Practices as per Schedule M (general requirements and specific requirements) and Good Laboratory Practices as per Schedule L-1 of Drugs and Cosmetics Act 1940 and Rules made thereunder.

Timeline for Grant & Renewal of Drug Manufacturing License

14 Working Days