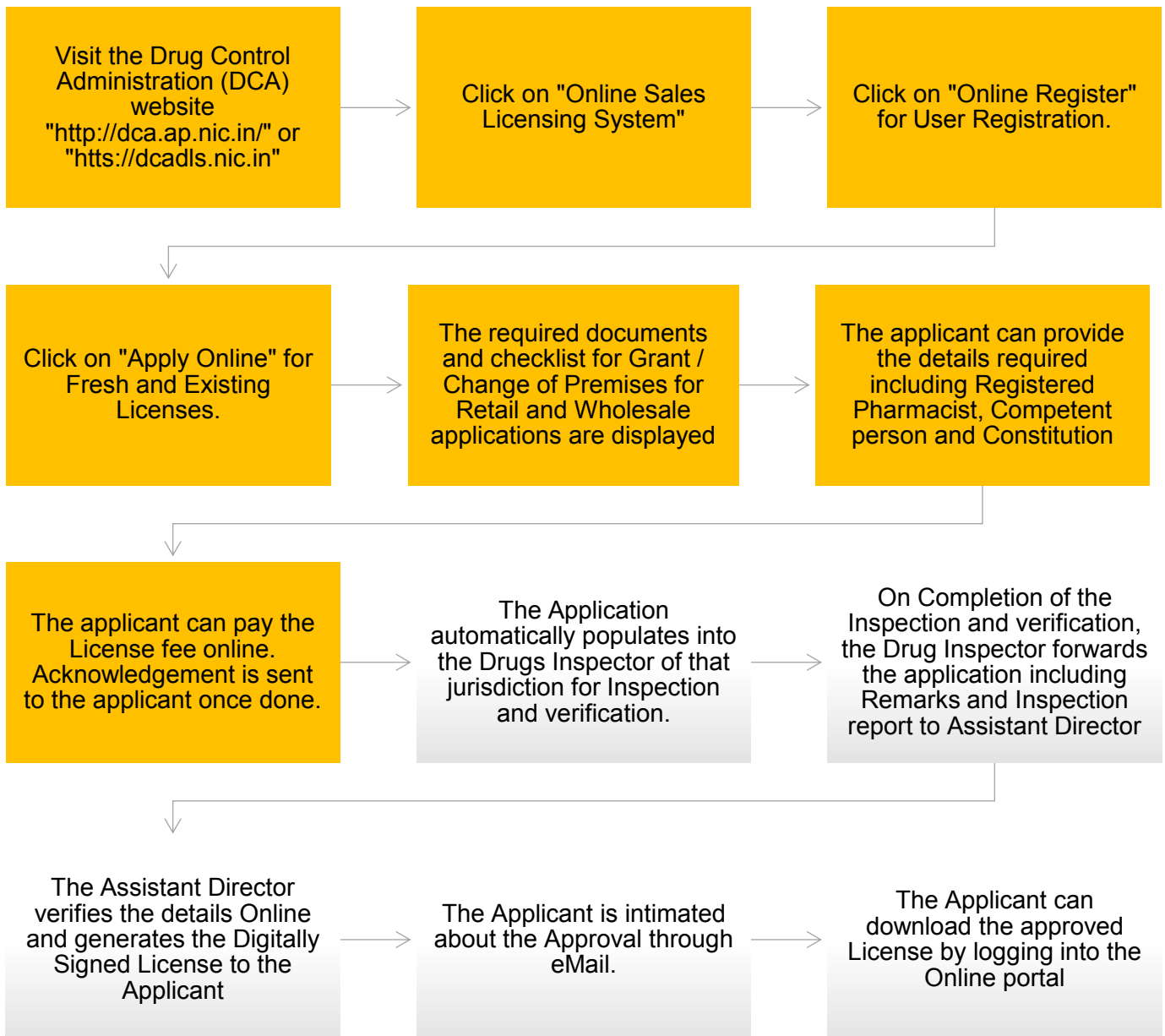


Online Application Procedure for Sales Licenses



Indicates Application Process by User



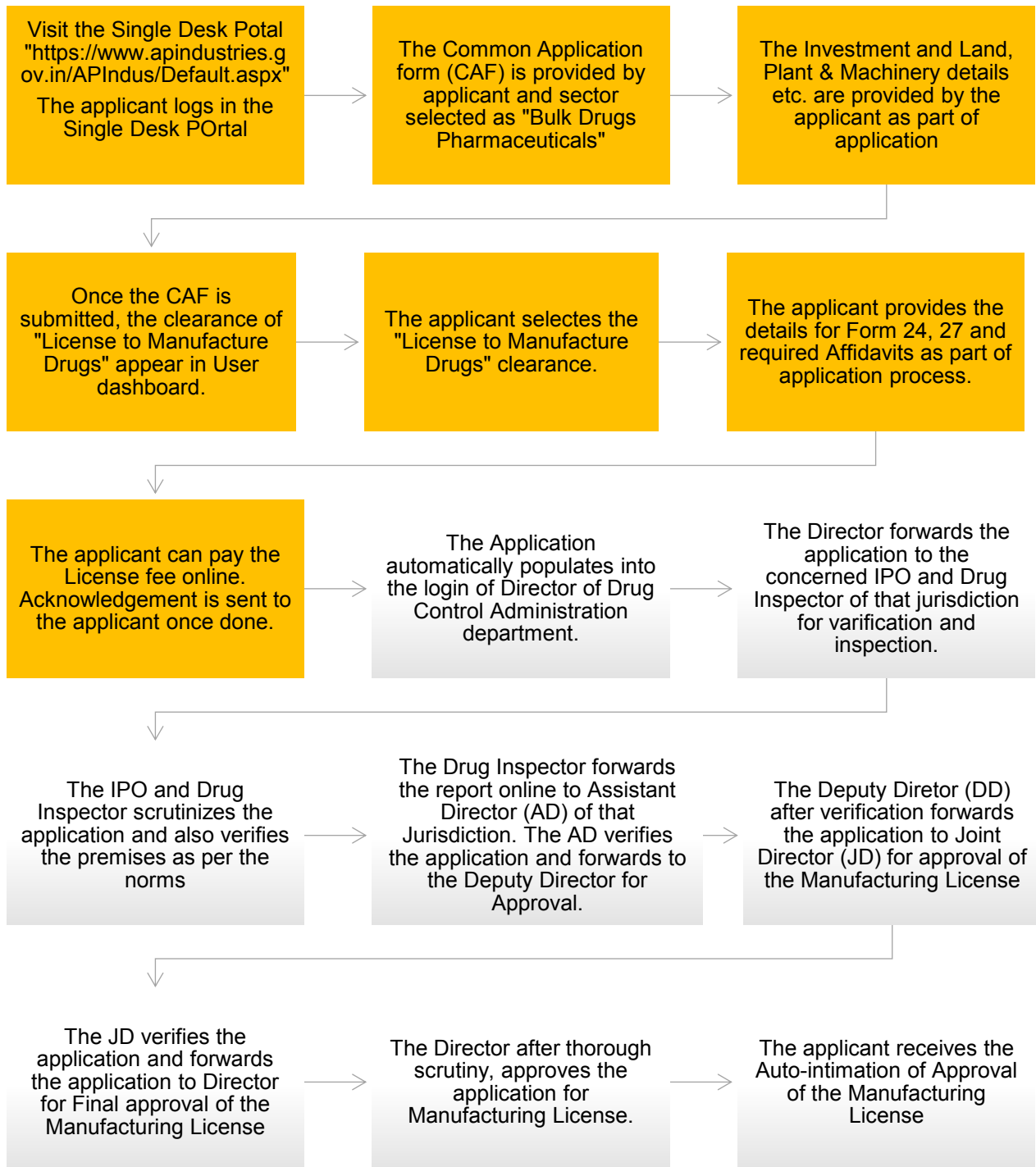
Indicates Department side Processing

Inspection Procedure for Sales License's Application

The following aspects of the Outlet or Premises are inspected by the Drugs Inspector for Grant/ Renewal of sales licenses as per Rule 64 of Drugs and Cosmetics Act 1940 and as per the Rules defined

- ▶ Area of the outlet to verify the compliance with the statutory limits.
- ▶ Provision of good storage facility for the drugs stocked in the premises including Cold Storage such as racks, refrigerator (for cold storage drugs) etc.
- ▶ Details of Pharmacist and Constitution of the Firm

Online Application Procedure for Manufacturing Licenses



Indicates Application Process by User



Indicates Department side Processing

Inspection Procedure for Manufacturing License

The following aspects of the Manufacturing facility are inspected for the Grant/ Renewal of Manufacturing License as per the Schedule M of the Drugs & Cosmetics Act 1940

- ▶ **General Requirements**
 - » Location & Surroundings
 - » Buildings & Premises as per the Factories Act 1948
 - » Water System
 - » Disposal of Waste
- ▶ **Warehousing Area**
 - » Adequate areas which confirm to warehousing of various categories
- ▶ **Production Area**
 - » Designed to allow Uniform Flow and Logical Sequence of Operations
- ▶ **Ancillary Areas**
 - » Rest & Refreshment Rooms
 - » Facilities for changing, storing and washing of clothes
 - » Written instructions for cleaning and disinfection of such areas
- ▶ **Quality Control Area**
 - » Quality control labs which are independent of Production areas
 - » Separate areas for physio-chemical, biological, microbiological analysis.
- ▶ **Personnel**
 - » Competent staff with required qualifications and experience
- ▶ **Health, Clothing and Sanitation of Workers**
 - » Employees undergoing periodical medical examinations and their records thereof