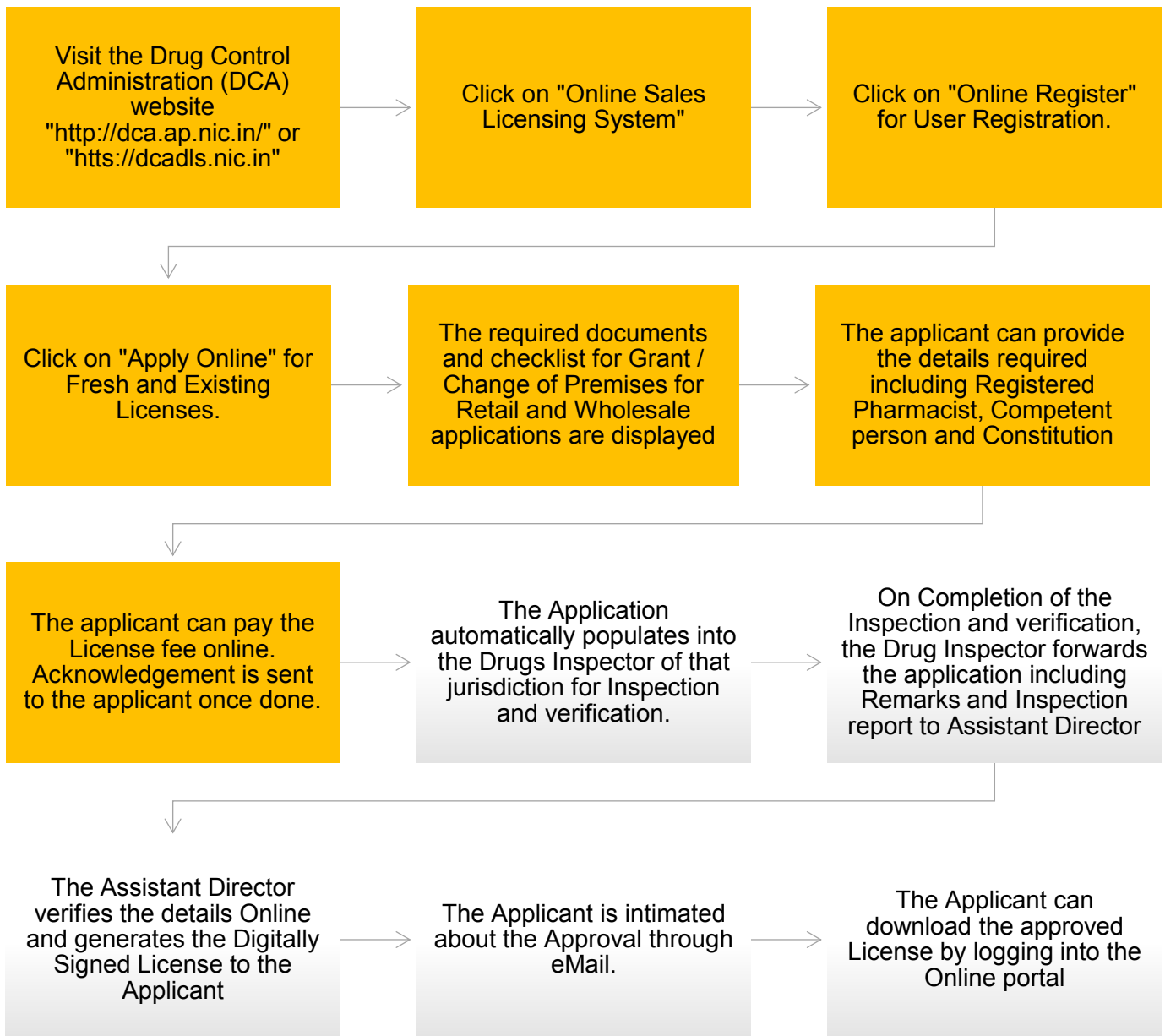


# Online Application Procedure for Sales Licenses



Indicates Application Process by User



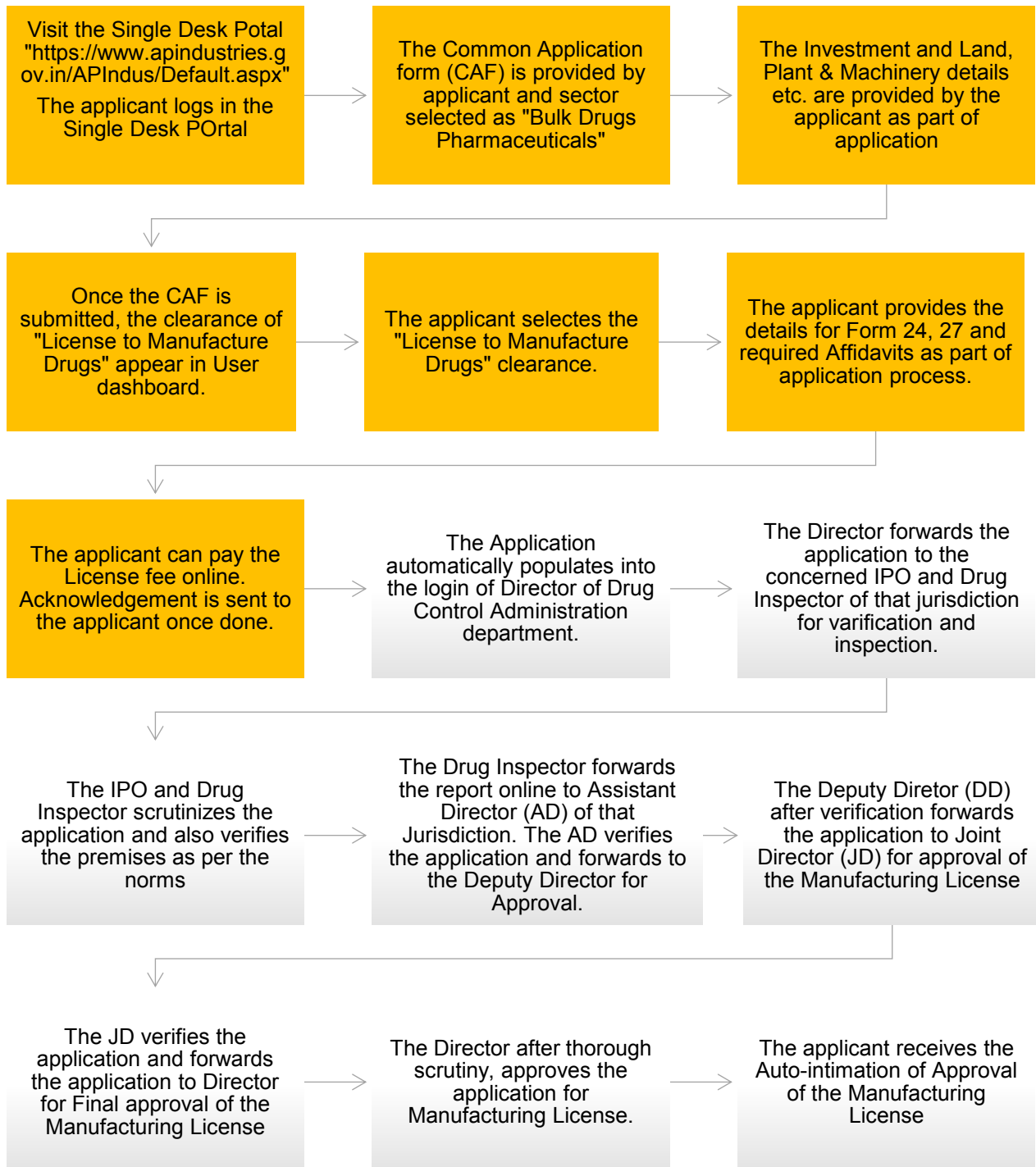
Indicates Department side Processing

## **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



## **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