WHO/COPP APPLICATION WORKFLOW VIA ONDLS

End-to-End Process Flow

1 PHASE 1 ONDLS REGISTRATION

- 1 Create ONDLS Account
- Company Type?
  - Public Ltd / Private Ltd / OPC / Trust / Society → Create 2 Accounts Corporate Account + Manufacturing Site Account
  - Proprietor / Partnership / HUF / Government → Create 1 Account (Dual Role – Corporate + Manufacturing Site)
- **Loan License (If Applicable)**
  - Owner must be registered on ONDLS
  - Loaner account created under owner
  - Uses owner's technical staff & approved products only
- **Add Technical Persons**
  - Each person registers individually
  - Unique Technical ID generated
  - Complete profile (qualification, experience, certifications)
- Profiles Complete? — No → back to Add Technical Persons
- Yes → **Add Old License Data**
  - Enter license details
  - Map Technical Persons
  - Map Products
- **Submit to State Authority**
- Apply for WHO Endorsement / COPP
- **State Approval**
- Approved? — No → Correct & Resubmit
- Yes → License & Products Visible on ONDLS → Add / Update Product Details (If not already added)

2 PHASE 2 PRODUCT DATA COMPLETION

- **Add Product History** (For each product)
  - Product approved through endorsement? Yes / No
    - If Yes: Enter endorsement number, date & document
    - If No: Use license first approval date
  - WHO-GMP Details
    - Cert. No., Approval date, Last inspection date, Document
  - COPP Details (if available)
    - COPP No., Approval date, WHO document, Last inspection date
    - Only first COPP per product
- **Add Additional Details**
  - Add Brand Name (No approval required)
  - Add Excipients not approved on license (Used for COPP annexure)
- **Check WHO Certificate Status**
  - **A. Valid WHO Certificate Exists**
    - Product already WHO approved → Apply for COPP Directly
    - Product NOT WHO approved → Apply for WHO Endorsement / COPP; Inspection may be required
  - **B. No Valid WHO Certificate**
    - Apply for WHO Certification
    - Inspection required
    - (If country selected, COPP generated along with new WHO certificate)

3 PHASE 3 APPLICATION SUBMISSION

- **Submit Application**
  - Submit to
    - State Authority
    - Zonal Authority (if inspection involved)
- **Inspection (If Applicable)**
  - Conducted by Zone
  - Inspection may be waived in some cases
- Inspection Required? — No → **Approval Process**: State / Zone review and approval
- Yes → Inspection Conducted by Zone → Approval Process

4 PHASE 4 CERTIFICATE ISSUANCE

- **WHO Certificate Issued**
  - Issued per site
  - Valid for 3 years
- **14 COPP Issued**
  - Issued per product
  - Valid up to 3 years
  - Validity always linked to WHO certificate
- **Monitor Validity & Renew**
  - Renew WHO certificate before expiry to maintain validity of all COPPs

5 PHASE 5 POST-APPROVAL ACTIVITIES

- **Add New Products (If Needed)**
  - Use "Add More" option in ONDLS and repeat approval workflow
- **End**
  - Process complete

PRE-SUBMISSION CHECKLIST

- ✓ Technical persons fully approved
- ✓ License approved by State
- ✓ Product history complete
- ✓ WHO / COPP data correctly entered
- ✓ All required documents uploaded
- ✓ Correct application type selected

KEY NOTES

- WHO certificate is valid for 3 years (per site)
- COPP is product-wise, maximum 3 years
- All COPPs expire with WHO certificate
- State approval is mandatory for license and product visibility on ONDLS
- Incomplete data or documents may lead to rejection or delay

LEGEND

- Process Flow
- Rework / Loop Back
- Decision Point
- System / Action Step
- Optional / Conditional

DOCUMENTS (Indicative)

- Manufacturing License Copy
- WHO-GMP Certificate
- COPP (if available)
- Endorsement Documents (if any)
- Product Permission Documents
- Site Master File
- Other supporting documents as applicable