Pharmaceutical Manufacturer License Application Packet

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In order to process your request:
Mail your application with initial documentation and your check or money order payable to:
Department of Health
PO Box 1099
Olympia, WA 98507-1099

Send other documents not sent with initial application to:
Pharmacy Quality Assurance
Commission Credentialing
PO Box 47877
Olympia, WA 98504-7877

Contact us:
360-236-4700

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov
Application Instructions Checklist

When your application for pharmaceutical manufacturer license is received by the Department of Health, you will be notified of any outstanding documentation needed to complete the process.

Note: If you are applying for a Control Substance Act registration in addition to your manufacturer license, be sure to send the additional nonrefundable fee.

All non-resident and out-of-state applicants must provide a copy of the resident license and last inspection.

Indicate type of application—new, change of ownership, change of location, or name change.

- **New**—First time requesting a manufacturer license.
- **Change of Ownership**—When name of legal owner/operator changes resulting from the sale of licensed agency.
- **Change of Location**—Changing the location address of manufacturer. Be sure to include your current license number.
- **Name change only**—Changing the name of your manufacturer. Be sure to list your current facility name.

☐ Check One:
Please check your legal owner/operator business structure type according to your Washington State Master Business License.

☐ Application Fee: you can check the fee page for current fees.

☐ 1. Demographic Information:

  **Uniform Business Identifier Number (UBI #):** Enter your Washington State UBI #. All Washington State businesses must have UBI #s. City, county, and state government documents also have UBI #s.

  **Federal ID Number (FEIN #):** Enter your Federal ID Number, if the business has been issued one.

  **Legal Owner/Operator Name:** Enter the owner’s name as it appears on the UBI/Master Business License.

  **Mailing Address:** Enter the owner’s complete mailing address.

  **Phone and Fax Numbers:** Enter the owner’s phone and fax numbers.

  **Email and Web Address:** Enter your email address, if you have one.

  **Facility/Agency Name:** Enter the agency’s name as advertised on signs, brochures or Web site.
**Physical Address:** Enter the agency’s physical street location including city, state, zip code, and county.

**Phone and Fax Numbers:** Enter the agency’s phone and fax number.

**Mailing Address:** Enter the agency’s mailing address, if different than physical address.

☐ **2. Facility Specific Information:**

  **Type of Manufacturer:** Check all types of manufacturers that apply.

  **Drug Enforcement Administration (DEA) Number:** Enter your DEA Registration Number.

  **Background Questions:** Check yes or no and if you check yes, list and explain on a separate sheet of paper.

☐ **3. Contact Information:**

  Enter name, title, phone number, fax number, and email address.

☐ **4. Additional Information:**

  **Corporation Information:** Enter date of incorporation, corporate number, and state of corporation.

  **Legal Owner:** List the names, titles, addresses, and phone numbers of the corporate officers, partners, members, managers, etc. Attach an additional sheet of paper as needed.

  **Change of Ownership Information:** List the previous legal owner name, previous name of facility, previous license number, effective date of ownership change and physical address, if applicable.

☐ **Signature:**

  Signature of legal owner or authorized representative.

  Date signed.

  Print name of legal owner or authorized representative.

  Print title of legal owner or authorized representative.
**Pharmaceutical Manufacturer License Application**

This is for:

- [ ] New
- [ ] Change of Ownership
- [ ] Change of Location—Current License # ________________

- [ ] Name Change Only—Current Facility Name ________________________________________

### Check One

- [ ] Association
- [ ] Corporation
- [ ] Federal Government Agency
- [ ] Limited Liability Company
- [ ] Limited Liability Partnership
- [ ] Limited Partnership
- [ ] Municipality (City)
- [ ] Municipality (County)
- [ ] Non-Profit Corporation
- [ ] Partnership
- [ ] Sole Proprietor
- [ ] State Government Agency
- [ ] Tribal Government Agency
- [ ] Trust

### 1. Demographic Information

<table>
<thead>
<tr>
<th>UBI #</th>
<th>Federal Tax ID (FEIN) #</th>
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Legal Owner/Operator Name

Mailing Address

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<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>County</th>
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<th>Phone (enter 10 digit #)</th>
<th>Fax (enter 10 digit #)</th>
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Email Address

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<th>Email Address</th>
<th>Web Address:</th>
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Facility/Agency Name (Business name as advertised on signs or Web site)

Physical Address

<table>
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<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>County</th>
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<tr>
<th>Facility Phone (enter 10 digit #)</th>
<th>Fax (enter 10 digit #)</th>
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Mailing Address (If different than physical address)

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2. Facility Specific Information

Type of Manufacturer (Check all that apply):

- [ ] Controlled Substance Manufacturer (provide DEA#)
- [ ] Non-controlled Substance Manufacturer
- [ ] Repackager

Drug Enforcement Administration (DEA) Registration Number

Background Questions

1. Have any applicants, partners, or managers had a suspension, revocation, or restriction of a professional license?  
If yes, list and explain on a separate sheet of paper.

2. Have any applicants, partners, or managers been found guilty of a drug or controlled substance violation?  
If yes, list and explain on a separate sheet of paper.

3. Has any owner or officer ever been found guilty of a drug, controlled substance, or moral turpitude violation?  
If yes, attach an explanation in detail, providing the circumstances, places, dates, and outcomes.

3. Contact Information

<table>
<thead>
<tr>
<th>Responsible Person for Facility</th>
<th>Phone (Enter 10 digit #)</th>
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<tbody>
<tr>
<td>Title of Responsible Person for Facility</td>
<td>Email Address</td>
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<tr>
<td>Contact Person for Regulatory Issues</td>
<td>Phone (Enter 10 digit #)</td>
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<tr>
<td>Title of Contact Person for Regulatory Issues</td>
<td>Email Address</td>
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### 4. Additional Information

<table>
<thead>
<tr>
<th>Date of Incorporation</th>
<th>Corporate Number</th>
<th>State of Corporation</th>
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#### Legal Owner Information—attach additional sheets as needed

List names, addresses, phone numbers, and titles of corporate officers, partners, members, managers, etc.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Phone (Enter 10 digit #)</th>
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#### Change of Ownership Information

- Previous Name of Legal Owner
- Previous Name of Facility
- Previous Pharmacy License #
  - Effective Date of Ownership Change
- Physical Address

#### Signature

I certify that I have receive, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.

______________________________  _______________________________
Signature of Owner/Authorized Representative                         Date

______________________________  _______________________________
Print Name                          Print Title
RCW/WAC and Online Web Site Links

RCW/WAC Links

Uniform Disciplinary Act, UDA RCW 18.130
Administrative Procedure Act, APA RCW 34.05
Administrative procedures and requirements, WAC 246-12
Pharmaceutical Manufacturing Laws, RCW 69.38
Pharmaceutical Manufacturing Rules, WAC 246-945-550

Online
Pharmacy Quality Assurance Commission, Web Page