Qualgen

NEW PROVIDER APPLICATION

Account Setup Instructions:

1. Fill out and email applicable forms to sales@qualgen.us or fax to 405-286-3755.
2. Make sure to include a current DEA registration along with properly executed attestations requested under this application packet.
3. Payment information must be submitted with application.

For any questions regarding your new account, please contact sales@qualgen.us or call 877-780-3369.

For questions regarding orders or payment information, please contact orders@qualgen.us or call 877-780-3369.

Thank you for your interest in working with Qualgen!
We look forward to working with you!

NEW PROVIDER APPLICATION

APPLICANT NAME:	CLINIC NAME:
SHIPPING ADDRESS (MUST MATCH DEA):	
CITY, STATE, ZIP, COUNTRY:	
PHONE:	FAX:
PHYSICIAN NAME:	EMAIL:
OFFICE MANAGER:	EMAIL:
QUALGEN SALES REP:	EMAIL:
SPECIAL SHIPPING INSTRUCTIONS:	
PHYSICIAN INFORMATION (please use another sheet for additional physicians)	
PHYSICIAN NAME:	DEA #:
PHYSICIAN NAME:	DEA #:
PHYSICIAN TRAINING INFORMATION:	
HAVE YOU RECEIVED TRAINING ON THE PELLET IMPLANT PROCESS?	
WHO DID YOU RECEIVE TRAINING FROM?	
DATE OF TRAINING:	
DO YOU NEED ASSISTANCE WITH DOSING? YES ☐ NO ☐	

CURRENT COPY OF DEA CERTIFICATE MUST BE SENT IN AT TIME OF APPLICATION.
ALL LOCATIONS BEING SHIPPED TO MUST HAVE A DEA ON FILE FOR THAT ADDRESS.

The person(s) signing this application, terms & conditions form warrants that the above information is complete and accurate and hereby agrees to the following terms and conditions:

1. The undersigned agrees to immediately notify Qualgen of any change in ownership, form or business name of the entity
2. This document will be as effective in photocopy or fax form as in the original
3. The undersigned acknowledges that Qualgen may limit or discontinue credit at its sole discretion and that the continued extension of credit may require additional information from time to time
4. The undersigned warrants that they have full authority to sign this agreement and obligate the entity hereunder
5. The undersigned agrees that if all invoices are not paid when due, they will accrue late charges at the rate of 18% per annum or the maximum rate allowed by law, whichever is less. If it is necessary to take legal action, jurisdiction shall be the State of Oklahoma and the venue shall be Oklahoma City, Oklahoma. The undersigned agrees to reimburse Qualgen for any attorney fees, court costs or other costs of collection which may be incurred in its efforts to collect any past due debts.
6. The undersigned acknowledges that the order is coming from an electronic system and agrees that the responsibility of receipt of said product will be verified by the undersigned.
7. The undersigned warrants that they have full authority and are licensed and have full authority to procure in the state for which application is being submitted.

Date:	Date:
Physician Signature:	Signature:
Printed Name/Title	Printed Name/Title:
How did you hear about us?	

DETERMINATION OF CLINICAL DIFFERENCES

In signing this document, I, the practitioner, hereby attest that I will administer the compounded preparation(s) listed above or have the authority to make such representations. I further attest that the compounded preparation(s) will only be administered to those individual patients for whom the preparation will produce a clinical difference as compared to the comparable FDA approved drug, unless the drug is in shortage at the time of compounding, distribution and dispensing, as determined by the U.S. FDA's Drug Shortage Listing.

The clinical differences include the following:

- ☐ Patient requires a lower dose than what is available in the comparable approved drug.
- ☐ Patient requires a higher dose than what is available in the comparable approved drug.
- ☐ Patient has an allergy to an ingredient in the comparable approved drug.
- ☐ Patient exhibits intolerance to Polyvinylpyrrolidone.

I acknowledge the need for a provider's signature to validate this determination.

Practitioner Name: _____

Practioner Signature: _____

Authorized Agent Name and Title (if applicable): _____

Authorized Agent Signature (if applicable): _____

Date: _____

This attestation reflects requirements in Section 503B of the Federal Food Drug & Cosmetic Act (which contains Title I of the Drug Quality & Security Act) for documenting the determination of clinical difference for individual patients when using compounded preparations as opposed to FDA approved drug products.

Provider Stock Allotment and Patient Volume Declaration

To better manage our stock levels and ensure timely availability of hormone pellets, we kindly request our providers to share their current patient treatment volumes. This information will help us optimize our stock allotment process and maintain adequate supply levels to meet your needs.

Please complete the following information:

Provider Name: _____

Clinic Name: _____

Monthly Treatment Volume
Understanding your monthly treatment volume by gender will help us allocate stock more effectively. Please provide an approximate number of patients you treat monthly with hormone pellets:

Approximate Number of Men Treated Monthly:

- ◯ Below 10
- ◯ 10-20
- ◯ 21-50
- ◯ 51-100
- ◯ More than 100

Approximate Number of Women Treated Monthly:

- ◯ Below 10
- ◯ 10-20
- ◯ 21-50
- ◯ 51-100
- ◯ More than 100

Additional Information:
Do you anticipate any significant changes in treatment volumes in the upcoming year? (Optional)

- ◯ Increase
- ◯ Decrease
- ◯ No significant change

Comments and Suggestions:
Please use this section to provide any additional comments, concerns, or suggestions that could help us serve you better:

_____

_____

AUTHORIZED AGENT AGREEMENT

Any individual authorized to order under the DEA License Holder will be listed as an "Authorized Agent" on your account.

If additional DEA licenses are being utilized a form will be required for EACH DEA LICENSE.

DEA License Holder: _____ DEA Number: _____

Authorized Agent: _____ Agent Title: _____

Authorized Agent: _____ Agent Title: _____

Authorized Agent: _____ Agent Title: _____

Authorized Agent: _____ Agent Title: _____

Authorized Agent: _____ Agent Title: _____

DEA License Holder Signature: _____

Date: _____

CONTROLLED SUBSTANCES REQUIREMENTS

In order to adhere with state and federal laws, we require the DEA license holder acknowledge the following:

I have reviewed and will comply with the federal Controlled Substances Act, as amended from time to time, and its implementing regulations at Title 21 C.F.R. Section 1301.7(1), et. seq. which, among its many requirements, requires that effective measures have been taken to guard against theft and diversion of any controlled substance

I understand and acknowledge that I will follow and adhere to all state and federal laws regarding inventory, records and prescription requirements for any and all controlled substances.

I further understand and specifically acknowledge that:
1. The Controlled Substances Act provides that every person who dispenses, or who proposes to dispense, any controlled substance shall obtain from DEA a registration issued in accordance with DEA rules and regulations. See 21 U.S.C. 822(a)(2).
2. Unless an exception applies, the Controlled Substances Act requires all practitioners to be registered in the state in which the patients to which they are prescribing controlled substances are located, regardless of whether the prescribing is taking place via telemedicine.
3. Moreover, in addition to this generally applicable registration requirement, the CSA also contains provisions (added by the Ryan Haight Act) expressly requiring a practitioner to be registered in the state in which the patient to whom he is prescribing is located when he or she is engaged in certain forms of telemedicine. Under the CSA, a prescription for a controlled substance issued by means of the Internet must generally be predicated on an in-person medical evaluation. This requirement does not apply, however, when a practitioner is practicing telemedicine as defined by the CSA. The CSA's definition of the practice of telemedicine includes multiple different categories of telemedicine. And, for certain of these categories, the CSA specifically requires a practitioner of telemedicine to have a DEA registration in the state in which the patient is located.
4. No person employed by or affiliated with this application for a new customer registration or who may be involved in acquiring, dispensing, prescribing or administering controlled substances under this application has ever been temporarily or permanently debarred by the U.S. Food & Drug Administration from participating in certain activities or transactions related to FDA-regulated products.
5. No person employed by or affiliated with this application for new customer registration or who may acquire, dispense, prescribe, or administer controlled substances under this application has ever been investigated by state or federal authorities for violation of rule or regulation under either federal or state regulatory regimes for controlled substances.

Signature: _____

Printed Name: _____ Date: _____

PAYMENT AUTHORIZATION FORM

Physician Name: _____ DEA Number: _____

Clinic Name: _____ Email Address: _____

Please select your primary and backup payment method below:

Please remit payment to: Qualgen | 301 Enterprise Dr., Edmond, OK 73013

phone: 405-551-8216 | fax: 405-286-3755 | email: orders@qualgen.us

For payment via ACH:

Primary: ☐

Name on Checking Account: _____

Account Number: _____ Backup: ☐

Routing Number: _____

Email Address (for invoices to be sent): _____

If choosing ACH you must provide credit card information as a backup payment method.

For payment via credit card:

Primary: ☐

Credit Card Number: _____

Exp. Date _____ Security Code: _____ Backup: ☐

Billing Address: _____

Authorized cardholder or checking account signature: _____

Email Address (for invoices to be sent): _____

Please check above which form of payment you wish to be your primary. Any invoices over 30 days old will be processed through the backup payment method provided above. If a credit card is your primary form of payment and is declined twice we will process your ACH immediately. If ACH is your primary payment and it is declined an up charge of 3% will be added to your total invoice.

I have read, understand and agree to the terms and conditions of sale.

Signature: _____

Printed Name: _____ Date: _____

MID-LEVEL PRACTITIONER AFFIRMATION

I. MID LEVEL PRACTITIONER INFORMATION

1. Business phone number _____ Cell _____

2. What is your current practice specialty? _____

3. Pursuant to a collaborative practice agreement I, _____, currently hold with the Supervising Physician named in Section II below, and in compliance with the laws of my State, I, a Mid-Level Practitioner ("MLP"), am authorized to independently place an order with Qualgen, LLC and receive the following medical products:

please check all that apply

3a. Prescription Devices YES ☐ NO ☐

3b. Prescription Drugs YES ☐ NO ☐

3c. Controlled Substances 2 ☐ 2N ☐ 3 ☐ 3N ☐ 4 ☐ 5 ☐

I will notify Qualgen, LLC immediately of any changes relating to the information provided in this Affirmation, including changes to the information provided in the Supervising Physician section.

_____ _____ _____

Signature of Mid-Level Practitioner | State License Number | DEA Registration Number

_____ _____

State Controlled Substances Registration No. *(if applicable)* | State Prescriptive Authority Certificate No. *(if applicable)*

_____

Mid-Level Practitioner Address

II. SUPERVISING PHYSICIAN INFORMATION

Name:	Street Address:
Phone Number:	City, State, Zip:
Current Practice Specialty:	State License Number:
State Controlled Substance Registration Number: *(if applicable)*	DEA Registration:

I hereby affirm that I am the Supervising Physician of record for the MLP designated above, as such, have a current collaborative agreement in place. This collaborative agreement outlines the MLP's scope of practice, as well as, my responsibilites as supervising physician, pursuant to applicable state laws. I, and my practice, are compliant with the laws of the state(s) in which I and my practice treat patients, including, but not limited to, compliance with requirements pertaining to: the number of mid-level practitioners I am authorized to supervise at the time; geographical limitations; and record review practices.

_____ _____

Signature of Supervising Physician | Date