



NEW PROVIDER APPLICATION

Account Setup Instructions:

1. Fill out and email applicable forms to sales@qualgen.us or or fax to 405-286-3755.
2. Make sure to include a copy of DEA
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!



QUALGEN INFORMATION

Qualgen, LLC, located in Edmond, Oklahoma, is a 503B FDA registered outsourcing facility. We specialize in manufacturing bio-identical hormone replacement therapy (BHRT) pellets.

As you may already know, data is highly supportive that BHRT pellets are effective for both the female and male population. On an average BHRT Pellets will deliver consistent doses of either estradiol or testosterone for 4-6 months in men and for 3-5 months in women, depending largely on their activity level. We see more and more physicians utilizing BHRT Pellets as part of their daily treatment for hormone deficiencies.

A little bit about Qualgen and our pellets:

- Qualgen pellets are 99.5% pure testosterone and estradiol and 0.5% stearic acid making them 100% bio-identical.
- We use no other binding agents or chemicals in our pellet production process
- Our pellets are the purest bio-identical pellets on the market, utilizing 0.5% stearic acid, only as a lubricant for our patented pellet machine press
- Third-party testing for potency, endotoxins and sterility (you will have access to all certificate of analysis results on each lot)
- All pellets are sterilized through E-Beam
- We can ship directly to you "not patient specific", giving you the convenience of having pellets on hand for your clients
- One year beyond use dates on all pellets

For questions, or to set up your Qualgen account, please contact the Qualgen sales team at sales@qualgen.us or at 877-780-3369.



NEW PROVIDER APPLICATION

SHIPPING ADDRESS (MUST MATCH DEA)		CLINIC NAME:	
ADDRESS:			
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:			
<p align="center">CURRENT COPY OF DEA MUST BE SENT IN AT TIME OF APPLICATION. ALL LOCATIONS BEING SHIPPED TO MUST HAVE A DEA ON FILE FOR THAT ADDRESS.</p>			
<p>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:</p> <ol style="list-style-type: none"> 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. 			
Date:		Date:	
Physician Signature:		Signature:	
Printed Name/Title		Printed Name/Title:	



DETERMINATION OF CLINICAL DIFFERENCE

This determination of clinical difference is for (please check all that apply):

- Testosterone Pellets
- Estradiol Pellets
- All of the Above

In checking a box for this Determination of Clinical Difference and electronically signing this document, I hereby attest that I am the practitioner who will administer the compounded preparation(s) listed above or I have the authority to make such representations for the practitioner who will administer the compounded preparation(s). Further, in signing this document, I hereby attest that the compounded preparation(s) will only be administered to patients for whom the change from the comparable FDA approved drug produces a clinical difference as indicated below.

Check All That Apply:

- Patient needs a lower dose than is available in the comparable approved drug
- Patient needs a higher dose than is available in the comparable approved drug
- Patient allergy to an ingredient in the comparable approved drug
- Patient intolerance to Polyvinylpyrrolidone
- All of the Above

Practitioner Name: _____

Authorized Agent Name and Title: _____

Signature: _____ Date: _____

**This attestation is a requirement of the FDA Guidance that ALL
503b Outsourcing facilities must adhere to.**

Link to Guidance: [Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry \(fda.gov\)](https://www.fda.gov/oc/503b-outsource-manufacturing-guidance)

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Office of Compliance/OU DLC January 2018 Compounding and Related Documents



PAYMENT AUTHORIZATION FORM

PAYMENT TERMS: ACH INFORMATION MUST BE ON FILE FOR ALL ORDERS OVER \$2,000
CREDIT CARD CAN BE UTILIZED ON ORDERS UNDER \$2,000

Please remit application and payment to: Qualgen | 14844 Bristol Park Blvd., Edmond, OK 73013
phone: 405-551-8216 | fax: 405-286-3755 | email: orders@qualgen.us

Name on Checking Account: _____

Account Number: _____

Routing Number: _____

For payment via credit card:

Credit Card Number: _____

Exp. Date _____ Security Code: _____

Billing Address: _____

Authorized cardholder or checking account signature: _____

Physician Name: _____

Clinic Name: _____

DEA Number: _____

Email Address (for invoices to be sent): _____



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 herby 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 responsibilities 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



ORDER FORM

CLINIC NAME: _____ PHONE: _____

PROVIDER NAME: _____ DEA: _____

ADDRESS: _____ CITY: _____ STATE: _____

EMAIL: _____ SALES REP: _____

ESTRADIOL PELLETS

STRENGTH	BOX 6	BOX 12	BOX 30
6 MG			
10 MG			
12.5 MG			
15 MG			
18 MG			
20 MG			
22 MG			
25 MG			

NOTES (IF ANY)

ALL ORDERS **MUST** BE SHIPPED TO ADDRESS AS LISTED
ON **CURRENT** DEA LICENSE

FAX TO 405-286-3755 OR EMAIL TO ORDERS@QUALGEN.US

TESTOSTERONE PELLETS

STRENGTH	BOX 6	BOX 12	BOX 30
12.5 MG			
25 MG			
37.5 MG			
50 MG			
87.5 MG			
100 MG			
200 MG			
TESTOSTERONE/CHOLESTEROL			
200 MG			
TESTOSTERONE/ANASTRAZOLE COMBO			
200/20 MG			

TESTOSTERONE CYPIONATE

STRENGTH	QTY
200 MG/ML 10 ML MULTI-DOSE VIAL	

TODAY'S DATE: _____

SHIPPING

CHECK ONE:

_____ Standard Overnight

_____ Priority Overnight

_____ 2-Day Express

_____ Regular Ground

*If nothing is checked - orders will be sent 2-day express. Qualgen will pay regular ground on all orders over \$2,000
All orders received after 2 p.m. CST will be processed the following business day.

ANY BROKEN PELLETS ARE TO BE REPORTED IMMEDIATELY.
AN RMA FORM WILL NEED TO ACCOMPANY BROKEN/EXPIRED PELLETS TO RECEIVE REPLACEMENT/CREDIT.
PELLETS THAT HAVE BEEN IN POSSESSION FOR MORE THAN THREE (3) MONTHS WILL NOT QUALIFY FOR RETURN DUE TO EXPIRATION.
PLEASE ORDER ACCORDINGLY.



TROCAR ORDER FORM

CLINIC NAME: _____ PHONE: _____

PROVIDER NAME: _____ DEA: _____

ADDRESS: _____ CITY: _____ STATE: _____

DISPOSABLE KITS - ABS PLASTIC

SIZE	PRICE	QTY	SIZE	PRICE	QTY
3.2 MM - DIAMOND TIP	\$24.93		3.2 MM - DIAMOND TIP	\$29.92	
4.5 MM - DIAMOND TIP	\$27.56		4.5 MM - DIAMOND TIP	\$32.80	
3.2 MM - BEVELED TIP	\$24.00		3.5 MM - BEVELED TIP	\$28.00	
4.5 MM - BEVELED TIP	\$26.00		4.5 MM - BEVELED TIP	\$30.00	

DISPOSABLE KITS - STAINLESS STEEL

REUSABLE SET - SURGICAL STAINLESS STEEL

SIZE	PRICE	QTY	SIZE	PRICE	QTY
3.2 MM - DIAMOND TIP	\$399		3.2 MM - DIAMOND TIP	\$499	
4.5 MM - DIAMOND TIP	\$399		4.5 MM - DIAMOND TIP	\$499	
3.5 MM - BEVELED TIP	\$250				
4.5 MM - BEVELED TIP	\$250				

REUSABLE SET - TITANIUM STEEL

PLEASE NOTE: the turn around time on reusable trocar sets can be longer than the disposable kits.

Qualgen offer trocars at a convenience. We are not the manufacturer and please note that, at times, some trocars may be on backorder.

FAX TO 405-286-3755 OR
EMAIL TO ORDERS@QUALGEN.US

SHIPPING INFORMATION:

TODAY'S DATE _____

CHECK ONE:

GROUND		2-DAY		PRIORITY OVERNIGHT		STANDARD OVERNIGHT	
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*If nothing is checked - orders will be sent 2-day express. Qualgen will pay regular ground on all orders over \$2,000
All orders received after 2 p.m. CST will be processed the following business day.