



# REGULATORY SOLUTIONS PROGRAM

Powered by Sweetgrass GxP

## Regulatory Solutions and Services for 503A and 503B Compounding Pharmacies



Regulatory compliance to FDA, DEA, and State Board regulations can prove to be a confusing and ever changing landscape. Letco's Regulatory Solutions Program provides peace of mind and expert services that address all of your compliance needs with confidence and industry leading price points that support your business. Some of the services we provide include:

- USP <795>, <797>, <800> Compliance and Readiness Assessments
- USP <795>, <797>, <800> Customizable SOP Libraries
- Staff Training Programs tailored for each pharmacy
- 503B Outsourcing Compliance and Quality Assurance
- Mitigation and Remediation Services (FDA, DEA, State Boards, etc.)

To provide best-in-class regulatory solutions to compounding pharmacies Letco has entered into a partnership with Sweetgrass GxP:

- Exclusive Partnership with Letco focused on compounding pharmacies
- Expert deliverables and approaches specifically designed to support compounding pharmacies
- Veteran Owned Services Firm with 20+ years of compliance support to a wide array of pharmacy partners
- For more information on Sweetgrass visit, [www.sweetgrassgxp.com](http://www.sweetgrassgxp.com)

### CUSTOMER TESTIMONIAL

*"I love being in the compounding business, one that provides quality care and amazing health outcomes for my patients. It is my belief success will come to those compounders maintaining regulatory compliance while preserving a high level of patient care. To that end, Letco's Regulatory Solutions Program provided a very valuable service that I expect will save me \$20,000 or more. I would heartily recommend the program to any compounding pharmacist serious about future success in this industry."*

- Jim Hrcir RPh, Owner - Las Colinas, Compounding and Wellness Pharmacy





## INTRODUCTORY PRICING

SOLUTION	LIST	DISCOUNT
Compliance and readiness assessment (<795>, <797>, <800>)	\$4,975	<b>\$3,980</b>
SOP Libraries	\$3,475*	<b>\$2,780*</b>
SOP Modification and Staff Training	\$150/hr	<b>\$120/hr</b>
Post assessment observation closure	\$150/hr	<b>\$120/hr</b>
Mitigation and Remediation Services (FDA, DEA, State Boards, etc.)	\$300/hr	<b>\$240/hr</b>

**Note:** Out of pocket expenses billed at cost, call for pricing on all other Sweetgrass services

\*Starts at

## HOW TO GET STARTED

1. Call Letco Professional Services at 877.LETCORX to discuss your pharmacy's regulatory needs and review the services we have available to address your specific situation
2. A Sweetgrass GxP representative will contact you within two business days to discuss the proposed scope of work and individualized approach for your pharmacy
3. After discussing your needs with Sweetgrass GxP, receive a written proposal for services to address your specific requirements

## CUSTOMER TESTIMONIAL

*"I want to thank Letco for providing a valuable and comprehensive USP <800> compliance readiness assessment for my pharmacy. I interacted with a team of experts that reviewed my SOP's, facility design, and current operations in a professional and non-intrusive manner. The written deliverables were outstanding and skillfully highlighted areas for improvement. The services and information Letco provided are just what compounding pharmacies need to prepare for the challenges that lie ahead."*

- Tony Jones RPh, Owner - Pencil Compounding Pharmacy

For more information on Letco's Regulatory Solutions Program please visit [letcomed.com](http://letcomed.com)

**WE'RE LETCO, LET US HELP.**

## CONTACT INFORMATION

CONTACT METHOD	SWEETGRASS	LETCO
Website	www.sweetgrassgxp.com	www.letcomed.com
Client Services (SG) Customer Service (Letco)	636-209-1929	800-239-5288
Email	sweetgrass@letcomedical.com	info@letcomedical.com
Address	Sweetgrass GxP Group, LLC 1408 N. Westshore Boulevard Suite 704 Tampa, Florida 33607	Letco Medical, LLC 460 E. Swedesford Road Suite 2040 Wayne, PA 19083

## FREQUENTLY ASKED QUESTIONS

QUESTION	ANSWER
<b>Q1:</b> How do I make an inquiry about the <b>Regulatory Solutions Program</b> ?	Letco's Professional Services Team conducts the initial customer assessment; they may be reached directly at 877.LETCORX or via email at: support@letcomed.com.
<b>Q2:</b> What services are offered through the <b>Regulatory Solutions Program</b> ?	Our partnership with Sweetgrass provides all regulatory services a 503A or 503B pharmacy may need – regardless of the challenge.  Offerings are a mix of proactive and preventative services, as well as reactive and outsourcing capabilities.
<b>Q3:</b> How do I become eligible to participate in the <b>Regulatory Solutions Program</b> ?	The only requirement is to be an established Letco customer in good standing.
<b>Q4:</b> How is billing handled for the <b>Regulatory Solutions Program</b> ?	All services are initiated by developing a Statement of Work with mutual sign-off to ensure both parties agree to and understand the fees for services.  Billing occurs once all activities outlined on the mutually agreed-upon Statement of Work are complete.
<b>Q5:</b> Why does Letco believe the <b>Regulatory Solutions Program</b> is best in class for compounding pharmacies?	Letco and Sweetgrass spent six months developing this new program, investing numerous hours crafting and refining the methodologies and deliverables specific to the needs of compounding pharmacies and today's regulatory environment.  Our deliverables are best in class.  No other compounding supplier can match the quality of services and deliverables at the price points offered by Letco's Regulatory Solutions Program.
<b>Q6:</b> How soon will I be able to schedule a pro-active service (e.g., site assessment)?	Typically, site visits occur within two to four weeks of the Statement of Work being fully-executed.
<b>Q7:</b> How do I know if I need any services related to USP <800>?	Please see the USP <800> FAQs posted on our website at www.LetcoMed.com.

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