

TEXAS STAR PHARMACY QUALITY ASSURANCE CHECKLIST

Quality, Safety and Consistency is Our Policy



At Texas Star Pharmacy, we have independent Quality Assurance and Quality Control programs to ensure that our products and patient care meet high quality standards and requirements. Our commitment is to provide a level of service that delivers safe compounded products consistently that patients and physicians can depend upon. There is no compromise when it comes to your patients and your practice!

We use industry leading practices to meet your needs. We model our operations to meet USP <795> and USP <797> guidelines.

When choosing a compounding pharmacy you want to feel confident that you will receive the highest quality compounded products and unparalleled patient care.

The following are some questions that you should ask when selecting a compounding pharmacy.

THE ORGANIZATION

Does your pharmacy have specific assignment of quality functional responsibilities as defined in a Quality Assurance plan?

INDEPENDENT STANDARD REVIEWS

In addition to your pharmacy license do you have a State Board of Pharmacy sterile compounding license? This is required in the state of Texas.

COMMITMENT

Is your pharmacy committed to and in compliance with USP <795> Pharmaceutical Compounding - Non-sterile preparations?

Is your pharmacy committed to and in compliance with USP <797> guidelines for sterile compounding?

DOCUMENTATION

Are all significant procedures performed in the pharmacy covered by Standard Operating Procedures (SOP's)?

Is the Pharmacy's Quality Assurance plan reviewed annually and when changes are made to the plan?

Does the pharmacy maintain both a master formula and lot-specific compounding history records for all compounds?

Does the pharmacy's master formula document the name, strength, and dosage form of the compounded product, all ingredients and their quantities, assigned a beyond-use date, record the equipment to be used, mixing instructions and packaging instructions? (This documentation ensures that the compound is prepared consistently to reproduce the same each and every time).

Does your pharmacy prepare a formulation checklist and perform a design review process to determine acceptable strength, quality, and purity of a new formulation request?

THE FACILITY

Does your pharmacy's facility meet or exceed U.S.P. Guidelines for compounding pharmacies?

Does your pharmacy perform sterile filling in a class 100 (ISO Class 5) laminar flow hood located within class 10,000 (ISO Class 7) clean room?

Does your pharmacy have separate areas dedicated to perform sterile and non-sterile compounding, product inspections, labeling, raw material storage, and dispensing?

■■■ ENVIRONMENTAL MONITORING ■■■

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| <input checked="" type="checkbox"/> | Does your pharmacy perform daily monitoring and documentation of sterile and non-sterile compounding areas, and final product storage for temperature and humidity? |
| <input checked="" type="checkbox"/> | Does your pharmacy perform daily, weekly, and quarterly cleaning to assure a clean and safe facility? |

■■■ PERSONNEL ■■■

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| <input checked="" type="checkbox"/> | Is your pharmacy's staff properly trained to perform aseptic manipulation skills, gowning technique, clean-room use, and successfully perform media fills every six months? |
| <input checked="" type="checkbox"/> | Does your pharmacy's staff take steps to minimize error and maximize the prescriber's intent for the patient during the compounding process? |

■■■ COMPOUNDING MATERIALS ■■■

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| <input checked="" type="checkbox"/> | Does your pharmacy purchase pharmaceutical-grade chemicals (USP, NF equivalent) from FDA-registered suppliers? |
| <input checked="" type="checkbox"/> | Does your pharmacy obtain and keep Certificates of Analysis for all raw materials used in compounding? |

■■■ QUALITY CONTROL ■■■

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| <input checked="" type="checkbox"/> | Does your pharmacy perform sterility testing according to USP <71>? |
| <input checked="" type="checkbox"/> | Does your pharmacy verify the potency of finished compounds through weight, volume and yield checks? |
| <input checked="" type="checkbox"/> | Does your pharmacy perform post-filtration filter-integrity testing? |
| <input checked="" type="checkbox"/> | Does your pharmacy have systems in place for handling complaints and investigating sterility failures and adverse events? |
| <input checked="" type="checkbox"/> | Does your pharmacy have the scale hooked to the computer using bar-code technology to ensure consistent batches? |
| <input checked="" type="checkbox"/> | Is every step of the compounding process from prescribing to compounding and labeling through dispensing reviewed and verified by a licensed pharmacist? |

Thank You for Choosing Texas Star Pharmacy!



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