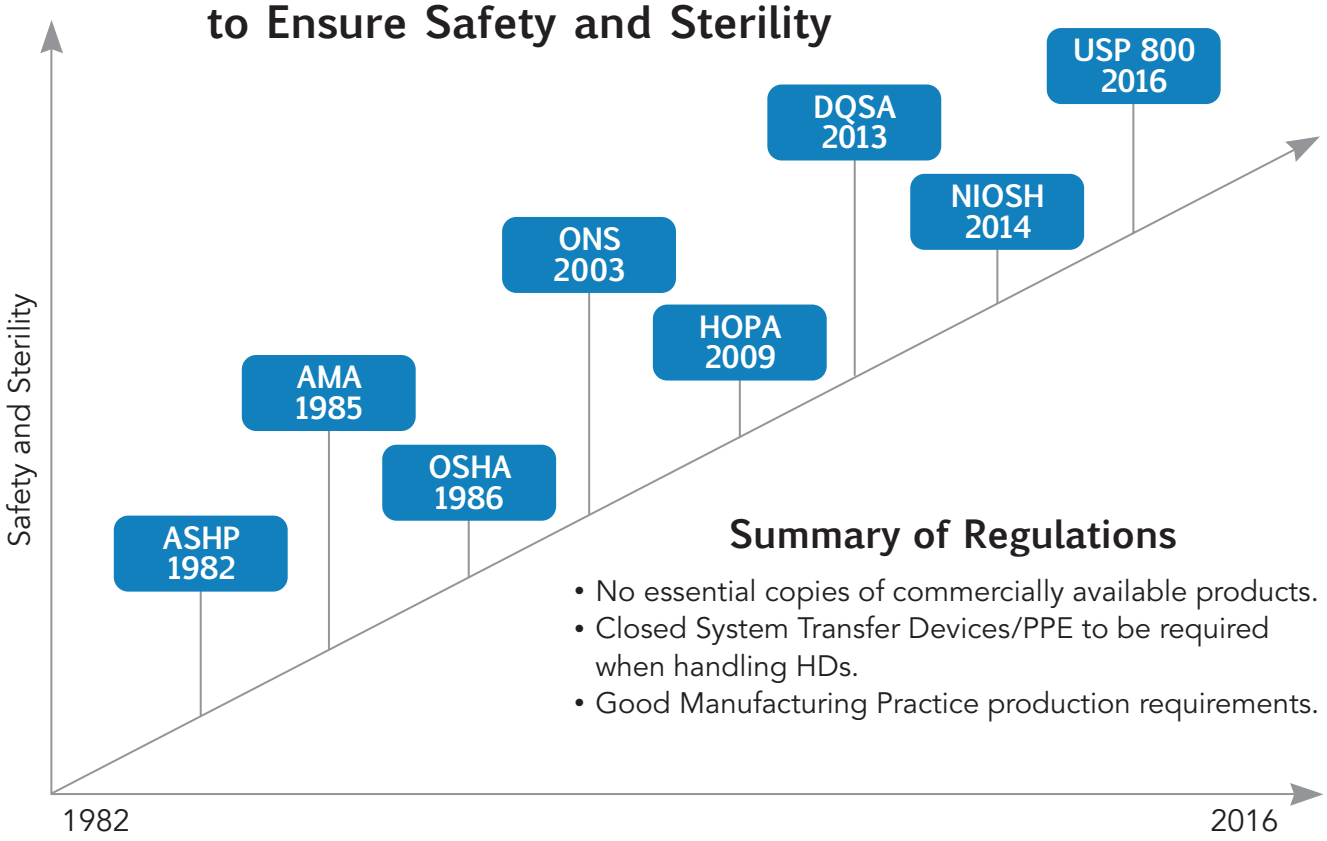
Why risk non-compliance when a simple solution is available?

The Progressive Trend of Regulations to Ensure Safety and Sterility



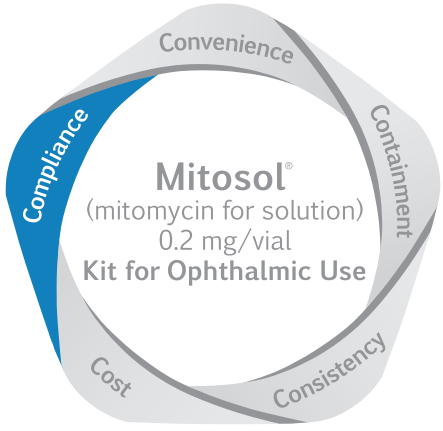
Summary of Regulations

- No essential copies of commercially available products.
- Closed System Transfer Devices/PPE to be required when handling HDs.
- Good Manufacturing Practice production requirements.

Mitosol® is...

- In compliance with federal & state laws, as well as multiple society guidelines.
- The only FDA-approved formulation of ophthalmic MMC.
- Packaged with a Closed-System Transfer Device (CSTD).
- Does not require an advanced prescription.

Mitosol® makes compliance simple.



Mitosol® Facts

FDA-Approved for Ophthalmology	☑
Assured Sterility, Potency, Dosing	☑
AORN Compliant Sterile Transfer	☑
Closed Fluid Transfer	☑
Room Temp Storage	☑
cGMP Manufacturing Controls	☑
Detailed Instructions for Use	☑
NIOSH Compliant Disposal	☑
No "Black Box Warning"	☑
Shelf Life up to 24 months	☑

INDICATION
Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery.

Dosage & Administration
Mitosol® is intended for topical application to the surgical site of glaucoma filtration surgery and must be reconstituted prior to application. Sponges provided within the Mitosol® kit should be fully saturated with the entire reconstituted contents in a manner prescribed in the Instructions For Use. The sponge(s) should be applied to the treatment area for two minutes.
Reconstituted Mitosol® should be used within one hour of reconstitution.

IMPORTANT SAFETY INFORMATION
Contraindications
Mitosol® is contraindicated in patients that have demonstrated a hypersensitivity to mitomycin and in women who are or may become pregnant during therapy.

Warnings & Precautions
Cell Death, mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or sclera damage including thinning or perforation. Direct contact with the corneal endothelium will result in cell death.
Hypotony. The use of mitomycin has been associated with an increased instance of post-operative hypotony.
Cataract Development. Use in phakic patients has been correlated to higher instance of lenticular change and cataract formation.

Adverse Events & Reactions
The most frequent adverse reactions to Mitosol® occur locally and include hypotony, hypotony maculopathy, blebitis, endophthalmitis, vascular reactions, corneal reactions, and cataract.

ASHP- (American Society of Hospital Pharmacists, AMA- American Medical Association, OSHA-Occupational Safety & Health Administration, HOPA – Hematology & Oncology Pharmacy Association, NIOSH-National Institute of Occupational Safety & Health, DQSA- Drug Quality & Security Act, USP800 – U.S. Pharmacopeial Convention (Chapter 800).