

Can Fire Departments, Ambulances and EMS Fill Medical Oxygen?

Any fire company, ambulance, emergency medical service (EMS), etc. that fills its own medical oxygen cylinders are actually drug manufacturers. This is true whether they cascade into Medical E's from T's or if they actually have a bulk tank and cryo pump. The term "repacker" actually does not apply to EMSs.

In Duane Sylvia's own words, these organizations are accountable for all CGMP regulations... except one. They are not required to register/list with the agency.

EMSs are required to have a QCU, proper training, proper equipment, testing equipment, SOPs, records, proper labels, etc. They will need a Servomex, vacuum pump, manifold, etc.

An EMS may not sell the medical oxygen as a separate line item on an invoice, but the cost can be included as a part of the entire service.

Because they are not required to register/list with the FDA, they are almost never inspected. The FDA is exercising "enforcement discretion" with EMSs. The effect of this is that EMSs are typically not actually following CGMP at all. In fact, they often use their supplier's labels.... which creates additional exposure for the supplier.

This is one case where a drug manufacturer is permitted to sell medical oxygen to a non-registered organization and without a prescription.