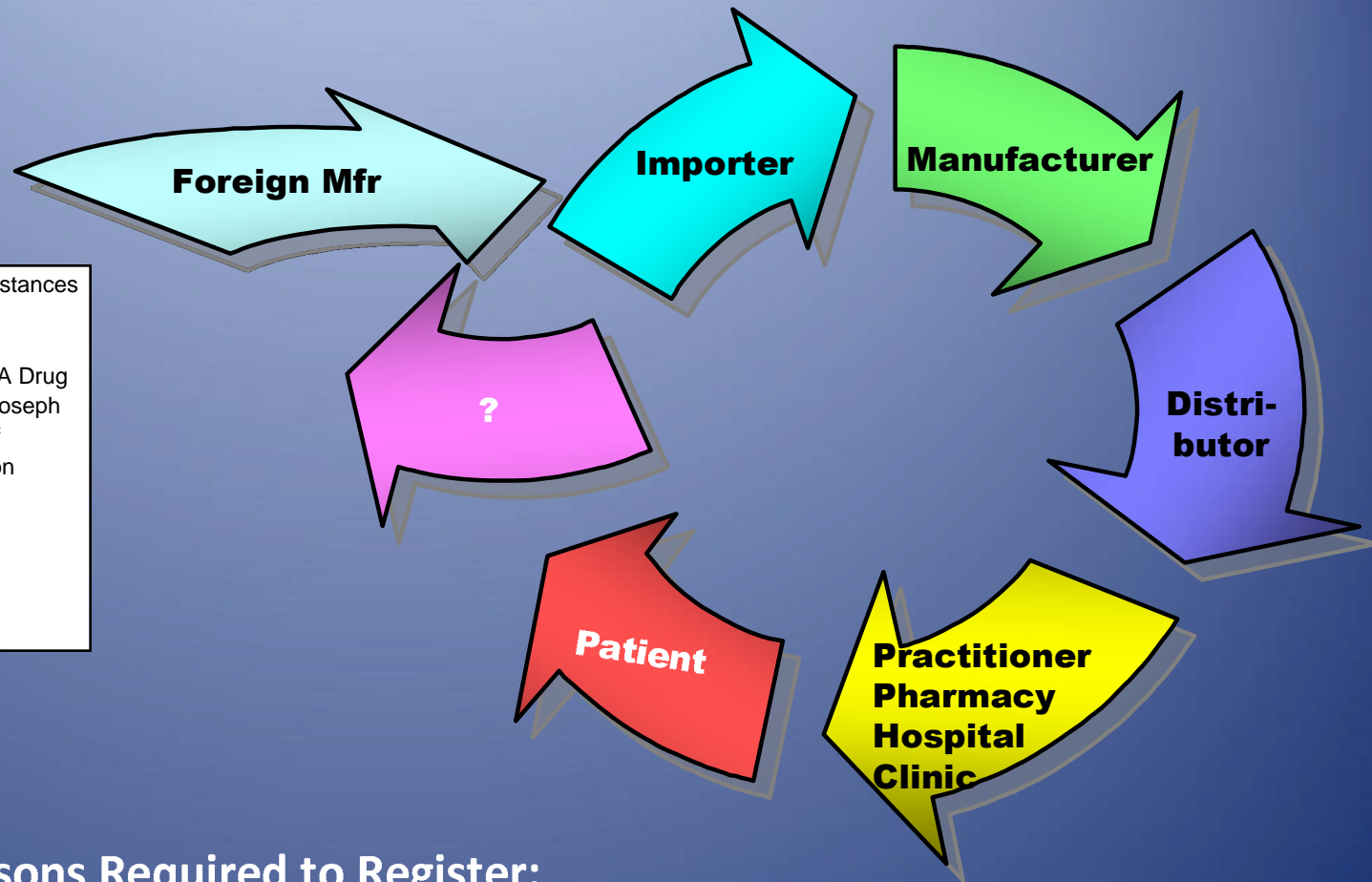


# Closed System of Distribution



Vatex Comment: Tracking of prescribed Controlled Substances ends once the patient leaves the pharmacy.

Presentation to January 24-25, 2013 Meeting of the FDA Drug Safety and Risk Management Advisory Committee by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, U.S. Drug Enforcement Administration

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM337150.pdf>

## Law: 21 USC 822 (a) (1) Persons Required to Register:

“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

## Law: 21 USC 822 (a) (2) Persons Required to Register:

“Every person who dispenses, or who proposes to dispense any controlled substance ...”