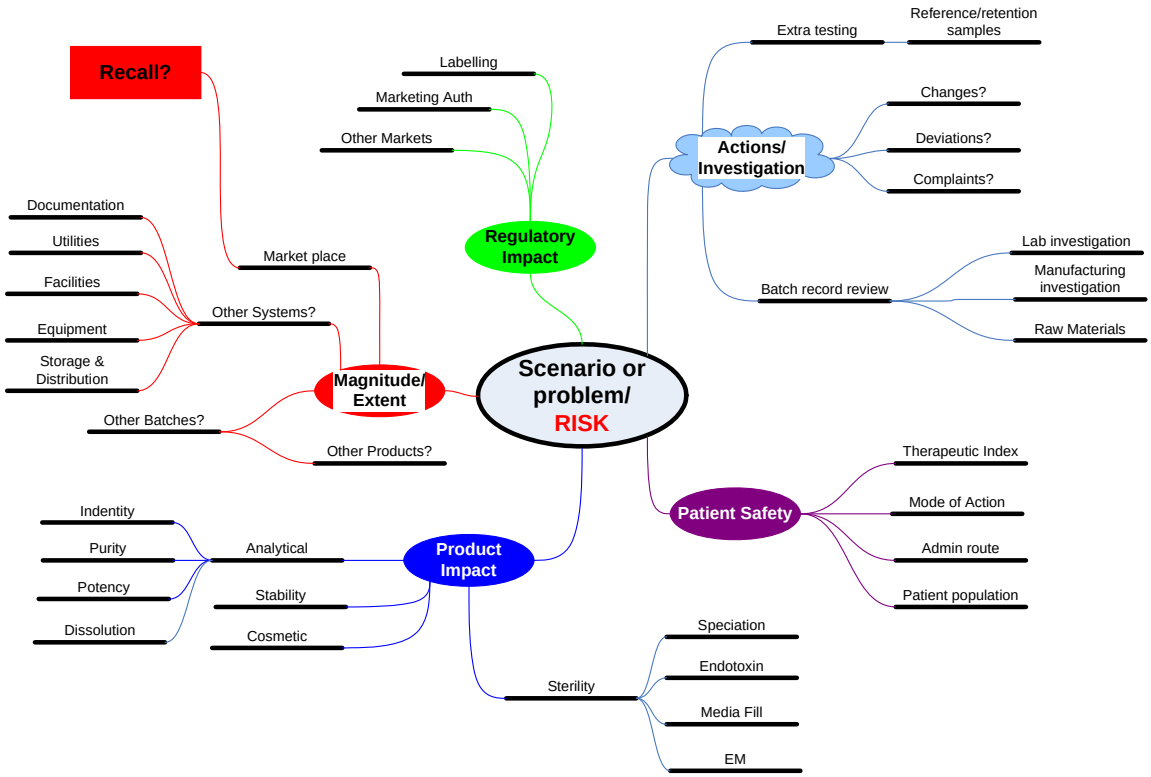
Scenario or problem/ RISK
Recall?
Regulatory Impact
Labelling
Marketing Auth
Other Markets
Actions/ Investigation
Extra testing
Reference/retention samples
Changes?
Deviations?
Complaints?
Batch record review
Lab investigation
Manufacturing investigation
Raw Materials
Magnitude/ Extent
Market place
Other Systems?
Documentation
Utilities
Facilities
Equipment
Storage & Distribution
Other Batches?
Other Products?
Product Impact
Analytical
Indentity
Purity
Potency
Dissolution
Stability
Cosmetic
Sterility
Speciation
Endotoxin
Media Fill
EM
Patient Safety
Therapeutic Index
Mode of Action
Admin route
Patient population