

# Where and Why

- **Automotive**

QS9000 paragraph 4.2

Cited in the AIAG APQP Manual

- **Process Safety Management Act (PSM)**

CFR 1910.1199999999 lists the process FMEA as one of about 6 methods to evaluate hazards

Example: ICI Explosives - Hazardous Operability Studies

- **FDA - GMPs**

One of several methods that should be used to verify a new design (21CFR Part 820). Inspector's check list questions cover use of the Design FMEA.

- **ISO 9001/2**

Requires Preventative Actions. The utilization of FMEAs is one continuous improvement tool which can satisfy the requirement (ISO9001, Section 4.14)

- **ISO14000**

Can be used to evaluate potential hazards and their accompanying risks.

# Qs9000 Documentation Deve Tool For Automotive Parts Manufacturers

**Richard Bailey**



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