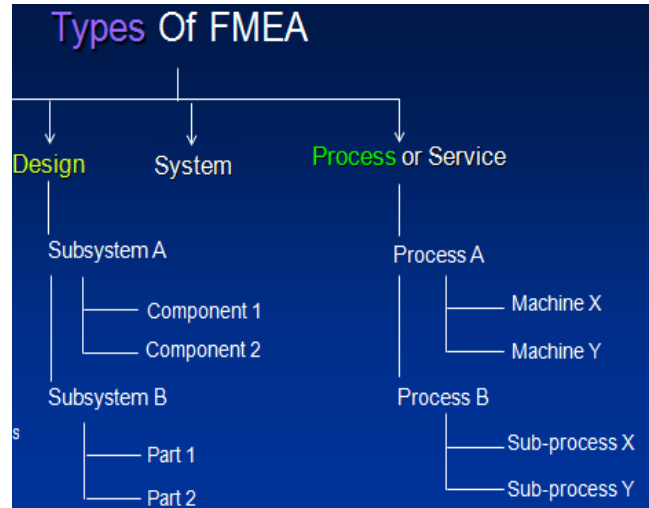


# Failure Mode and Effects Analysis (FMEA)

## Our FMEA Program:

Zebulon Solutions offers a Failure Mode and Effects Analysis (FMEA) program. This is the utilization of the multi-industry review process that was originated in the automotive industry to improve vehicle quality and customer satisfaction. It has now become a standard in medical device, industrial and consumer goods product development for the same reasons. The FMEA process takes a no-nonsense, critical look at designs at the key milestone steps to look for potential failures in the design or manufacturing process before they begin to cost money or lost production.



- ❖ What is required for a Design FMEA (DFMEA)?
  - Concept direction
  - Preliminary Bill of Materials
  - Pre-validation prototypes (if available)
  - Undivided attention of design engineers and program managers.
- ❖ What is required for a Process FMEA (PFMEA)?
  - Preliminary Process Flow diagram
  - Preliminary Control Plan
  - Validated prototype parts
  - Undivided attention of design engineers and industrialization team
- ❖ How does a DFMEA or PFMEA work?
  - We review the design or production process with our customer step by step and rate possible failures for Severity, Occurrence and Detection based on industry standards
  - A level of critical grade will be given based on the potential of the failure
  - A Risk Priority Number (RPN) is then generated showing the most urgent potential problems with the design / process that will require attention.
- ❖ What kind of time and effort commitment is required?
  - A typical FMEA will take a minimum of two days; for complex systems, a week or more
  - As described above, key subject matter experts in the design / process areas are critical to drive the actual content review
  - A typical FMEA is a lock-the-doors / phones-off / no-internet type of working meeting

- ❖ When the FMEA is complete, is that it?
  - No! It is critical to follow up on the potential failure modes that are identified during the FMEA
  - The Risk Priority Number, however, provides an easy to rank order priorities
- ❖ What does Zebulon Solutions bring to the process?
  - We provide a skilled facilitator to manage the process and train the contributors
  - We provide templates and score sheets (see the *Downloads* page of our website)
  - We can optionally provide subject matter experts to bring an outside view
  - We help the team to navigate through the overall process to reach the final goal of finding potential failures before they happen.

If it is reviewing core ME, HW or SW design, end of line test process or final assembly, the FMEA review is THE tool that must be used to ensure that everything has been reviewed prior to releasing to mass production. Without it the only alternative is to wait for the field failures to come into the repair depot.

### **About Zebulon Solutions:**

We're an old-fashioned company providing modern productization solutions. We help customers transform R&D projects into manufacturing ready products. Our services include:

#### ❖ Productization Services

- Product Design
- Analysis
- Industrialization

#### ❖ Productization Management

- Fractional Executive
- Business Consulting
- Program Management

We may start from a napkin, a spec, a prototype or even a product in limited production, but we end with a product that is fully industrialized, cost optimized and manufacturable.

Contact Keith Howard at [keith@zebulonsolutions.com](mailto:keith@zebulonsolutions.com) +1 970 372 9400.