

Six-Sigma Made Simple
How Do You Manage Large Manufacturing Projects?



Let's say you have to make a new product and you are about to have a conference call with an important customer.

This customer wants to make a filter that is going to be FDA Regulated, and you will have to do validations:

IQ: Installation Qualification; **OQ:** Operational Qualification; **PQ:** Performance Qualification.

At ATL Medical/ Pharmaceutical, we use the **Six-Sigma** Approach of **DMAIC**: Define, Measure, Analyze, Improve, Control. The beginning is the most important! **Define** what it is the product will do, then define the manner in which you will build it. Once defined, you will know what to **Measure**. These are the "Critical To Quality" (CTQ) features of the product/ process. Once you know what to measure, you then have the opportunity to **Analyze** the measurements for stability and capability.

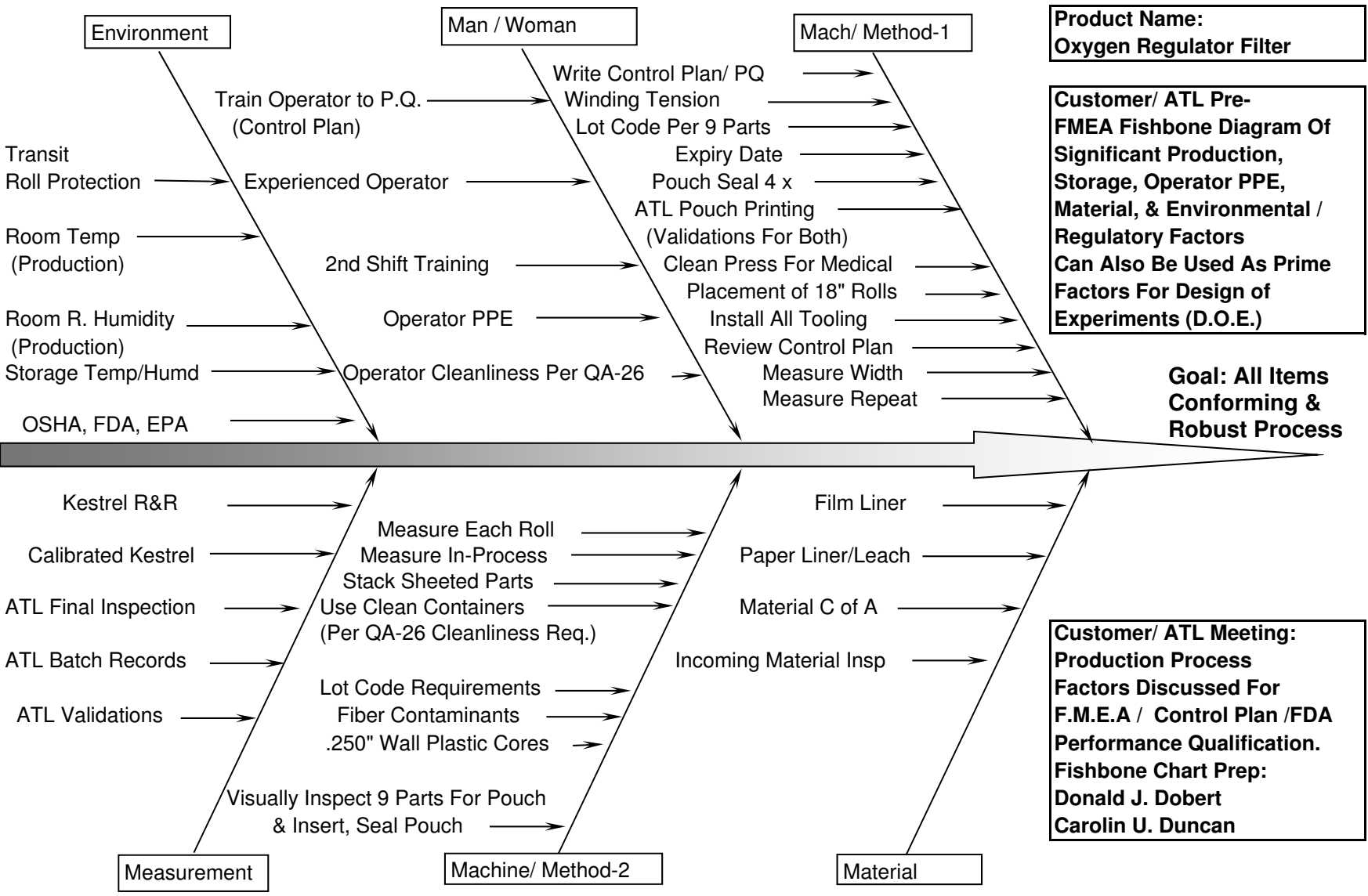
Okay, so now you have defined, measured, and analyzed. If your process is stable and capable, great. If not, **Improve**. (Actually, you improve on a continuous basis, poor process or great process). The fifth element of DMAIC is **Control**.

Control can be what you make it. If FDA Regulated, you need to do validations (IQ-OQ-PQ). ATL has white papers to explain.

A roadmap of doing a large disposable medical device project might look like this:

- 1 APQP (Advanced Product Quality Planning)
- 2 Flow Chart of the Process or **Ishikawa Fishbone Diagram** (Example Below)
- 3 Design/ Process FMEA (Failure Modes & Effects Analysis)
- 4 Pareto Rank Order of High Risk Priority Numbers (RPN's) For CTQ's
(A CTQ is an item that is "critical to quality")
- 5 Make a Control Plan or Performance Qualification
- 6 Train Employees to the job requirements
- 7 Follow the Control Plan via your Quality Management System

We said the beginning is very important, remember? To start, discuss the key characteristics of the product/ process with a team. List the items discussed and place them into categories that include the 4 M's (manpower, methods, machines, materials). Add measurement and environment as categories. Then construct a fishbone diagram (**example below**). Now you have your beginning! We suggest you check out other ATL Medical/ Pharmaceutical white papers that explain APQP, FMEA, Validations, Flow Charts, Quality.



Significant Factors (Random Order) For Typical Production