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.

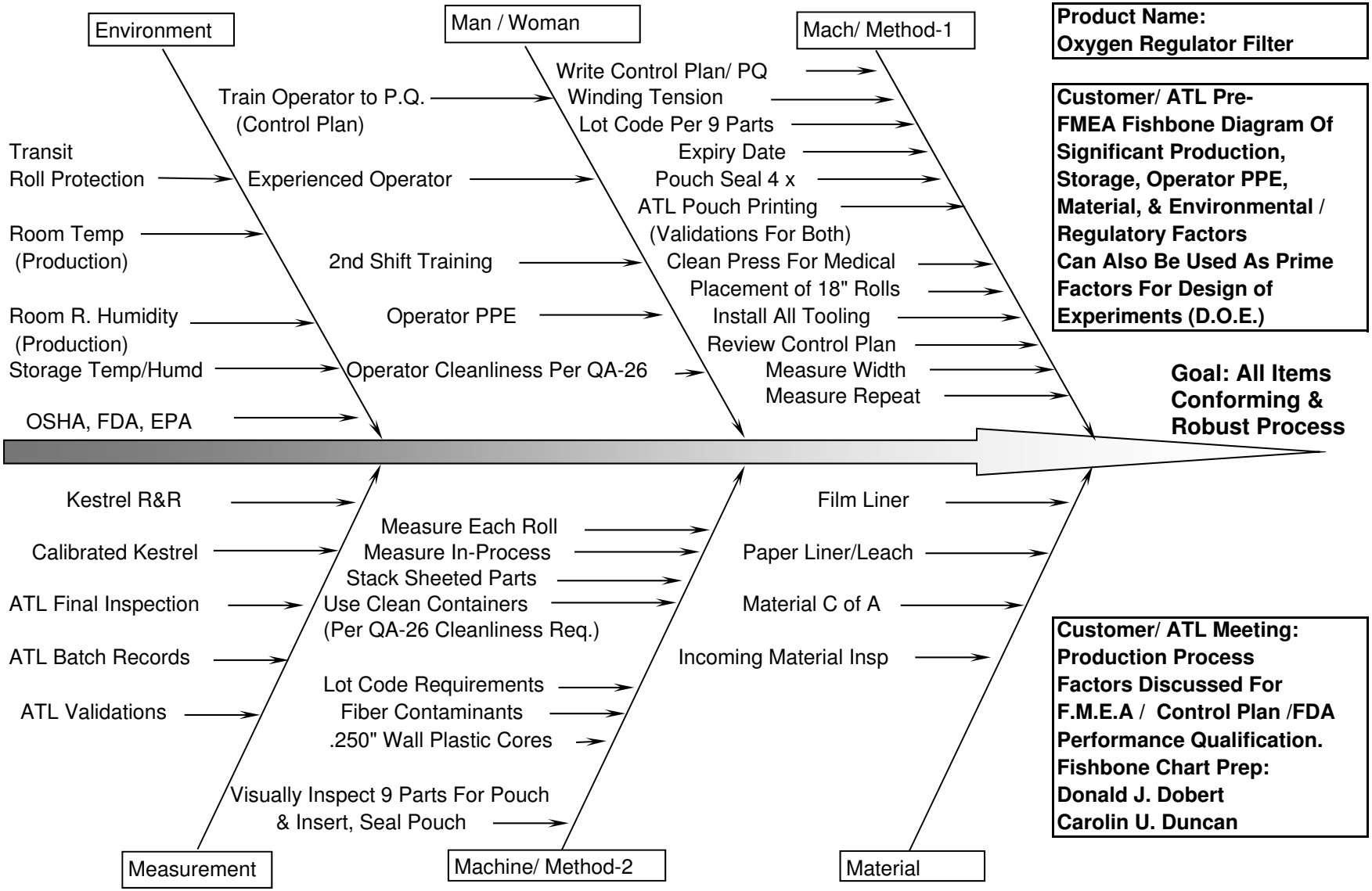
Okay, so now you have defined, measured, and analyzed. If your process is stable and capable, great. If not, **Improve.**
(Actually, you improve on a continuous basis, poor process or great process).
The fifth element of DMAIC is **Control.**

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

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