Regulatory Agencies and Compliance

The following article makes generalized statements, and is not intended to be understood as all inclusive, absolutely complete, or to be applicable in absolutely every situation. Its purpose is to provide a framework on which to build a better, deeper understanding of what compliance is.

Regulatory Agencies; who they are and what they do.

Regulatory Agencies are entities that have authority to establish rules, regulations, guidance, and criteria that manufacturers should or must comply with. Failure to comply, or failure to meet established criteria, can result in product recalls, warnings, fines, consent decrees, cease-and-desist orders, injunctions, and in the worst of cases, adverse events, criminal charges and jail time if convicted.

Regulatory Agencies principal function is to regulate, or ensure, that companies operating within a particular industry follow established guidance, and that the products they manufacture, meet established criteria, thus minimizing any risk to consumer health or wellbeing. The agencies measure compliance by way of inspection.

Though regulating agencies have wide-ranging authority, they are generally easy to work with, as long as the companies falling under their jurisdiction are making every reasonable effort to be compliant, and can show conclusive evidence to that end.

To put all this into perspective, the end goal of compliance is simply "control", that is, maintaining control over all the materials and processes that contribute to product quality and therefore product safety, and ultimately, consumer safety (minimized risk to health).

How is control achieved?
Control is achieved by compliance, and compliance can be achieved in the following manner as expressed by a widely used "mantra":

"Say what you do, do what you say you do, and document it."

<u>Say what you do</u>: These are the company SOPs, work instructions, and policies, that must be reflective of the established rules, regulation, and guidance. It is wise to reference the relevant regulation (guidance, CFR, USP, FCC, ATSM, HPUS, NOP, etc.) in each SOP and other company documents. Cross referencing your SOPs to regulation in an index is highly recommended, as it makes verifying compliance level somewhat easier from a "say what you do" standpoint. A cross-reference index allows you to verify that each applicable regulation is incorporated into your SOPs.

<u>Do what you say you do</u>: You must follow your SOPs. If you fail to follow your SOPs, you have "deviated", and are in non-compliance. Deviations and non-compliances are seen to be indicative of a lack of control (generally). However, especially in the case of new SOP's or processes that are difficult to control, you may be forced to deviate because of an unforeseen situation, or something that was not consciously addressed originally. In these situations, a deviation may be approved for that instance, but as a consequence, a change control or CAPA is initiated to avoid future deviations of that type (the SOP is revised). In this manner, control is re-established and documented.

<u>...and document it</u>: The documentation referred to here can be quite extensive depending on the products made (Industry) and the complexity of processes and systems. Following is a list of common documents that are reflective of "control", and are frequently requested for presentation by inspecting agencies or companies seeking to engage in a business relationship.

> SOP Index
> SOP's proper
> Qualification results for each vendor (vendor qualification program)
> Approved vendor list (they have passed the qualification process)
> Master Batch Records (not used directly in production)
> Production Batch Records (actual documents issued for production)
> Raw Material Testing
> Inventory (materials released for production, have been tested/inspected)
> Inventory (quarantine or rejected; cannot be used in production)
> Label Inventory
> Cleaning Validation Protocol (equipment cleaning and sanitizing)
> Cleaning Validation Reports
> Cleaning and Sanitization records (equipment cleaned and "released")
> Process Validation Protocol (shows consistency and control in production)
> Process Validation Reports
> Equipment Calibration (RPM, Temperature, Volume, Weight, etc.)

Product Inspection (QC; containers, closures, safety seals, labels, etc.)
   Finished Product Testing
   Certificates of Analysis
   Product Release; formal approval for distribution, all applicable criteria are met
   Stability Protocol
   Stability Reports
   Non-conformance (a record of product failure)
   Deviation
   CAPA
   Change Control
   Internal Audit Program

Staff
   Hiring Policy
   Job Descriptions
   Organization Chart
   Staff credentials, certifications, diploma, resume/cv, etc.
   Training Program (SOP)
   Training Records

Expiration Dating (including: Best by, Best if used by, Use by, etc.,)
   Depending on the specific type of product, "expiration" dating may or may not be
   required by the regulating agency. The general guidance is simply: the
   manufacturer must make sure that the product is safe and effective until the
   assigned expiration date, and, the determination of the expiration period, must be
   supported by scientific data (e.g., stability study).

With this document, having addressed each topic and item, and executing a proper
and thorough internal audit, you should have a solid idea of your compliance level (or
lack thereof). If you have any questions or would like additional guidance on these or
related topics, please contact us via the "Get in Touch" form on our main page.
Alternatively, give us a call and ask for William Reid (VP of Business Development) at
(770) 932-0280 ext. 206.

Good luck!