

Good Manufacturing Practices: Preparing for Regulations

John H. Lauterbach, PhD, DABT

Lauterbach & Associates, LLC

Macon, GA 31210-4708 USA

Outline for presentation

- Background
- Objective for presentations
- Preparing for GMP
- Keeping the costs in control
- Conclusions

Background

- Much has been said about FDA bill, especially about marketing restrictions, costs of compliance, and product testing
- However, perhaps the most serious problem for the smaller companies may be complying with Good Manufacturing Practices (GMP)
- How the smaller tobacco manufacturers make use of the four-year time delay before they must meet GMP rules may be critical to the survival of their businesses

Good manufacturing practices – adopted from Section 906(e)

- In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to cGMP, or HACCP methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter

Objectives for presentation

- Review some basic concepts related to Good Manufacturing Practices
- Explain why we do not know what final rules will be
- Outline things we need to start doing
- Show importance of working together so that we do not have to duplicate expensive work items unnecessarily

What are cGMP and HACCP?

- cGMP – current Good Manufacturing Practices
 - Regulations depend on type of product being manufactured
 - Pharmaceuticals
 - Over-the-counter (OTC) drugs
 - Medical devices
 - Dietary supplements (nutraceuticals)
 - Foods
 - Rules change with time – that is why the “c” for current
 - Write down what we do, then do what we have written
- HACCP– Hazard Analysis and Critical Control Point
 - Control the process instead of the end product
 - Space-age concept – NASA didn’t want food-sick astronauts

In the next breaths – also adopted from Section 906(e)

- Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established
- The Secretary shall – before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated

What may have been the thinking behind section 906(e)?

- If tobacco manufacturers have to be cGMP, then it will be easy for FDA to find out
 - How they are designing their products
 - What they are really doing in their factories
- Views held by some that tobacco-related health effects may come from agrochemical residues and/or improper manufacturing processes
- Competitive advantage through regulations
 - Legislation recognizes differences in financial resources
 - Importance of Tobacco Products Scientific Advisory Committee (TPSAC) in setting regulations

Can any good come from cGMP and HACCP?

- Potential favorable outcomes from cGMP and HACCP
 - More consistent products (reduced costs)
 - Improved consumer satisfaction (improved sales)
 - Reduced chances of adverse events and product recalls (very costly investigations and recalls that hurt our image)

How can we get started if we don't know the rules?

- FDA needs to decide how its is going to view tobacco and tobacco products for cGMP and HACCP regulations
 - Modify existing ones such as those for food, medical devices or develop new regulations specifically for tobacco
 - It is likely that quality systems such as those for medical devices will be required
 - Best case: tobacco treated similar to food and reasonable GMP regulations for cigarettes and other smoking articles
 - Worst case: tobacco treated as a pharmaceutical product and medical device regulations for cigarettes, cigars, etc.
- TPSAC needs to keep GMP regulations reasonable and affordable

First steps

- If nothing else, it is time to start reading
 - There are many books, journals, web-based newsletters, and other publications, some free, some not
 - FDA web pages (free)
 - Current Good Manufacturing Practices (cGMPs) for food and dietary supplements and related materials
 - <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/default.htm>
 - Appendix E of above has table comparing food GMPs with medical device and pharmaceutical GMPs and ISO 9001 requirements
- A walk around your facilities with building-related GMPs in mind will likely be helpful in beginning to estimate extent of things you will likely need to do

Why we need to work together

- Many companies retain one or more consulting groups to help them meet GMP requirements
 - Costs of consultants and related employee time
 - Commonality of documentation
 - Commonality of tasks among various small manufacturers
 - Facilities inspection
 - Employee training
 - On-line and off-line measurement systems
 - Data reporting systems (electronic, paper reports)
- We can each pay the consultants for everything or we can share the costs of common tasks and only pay on our own for unique elements

Other opportunities for sharing costs

- Testing costs
 - Costs of required testing (for example, smoke analytes)
 - Costs of testing to confirm that certificates-of-analysis (COA) that you are relying on are accurate
 - Will need to be done periodically
 - Pricy – could be \$1000+ for data to confirm that the COA for lot of cased, cut, and flavored US-style blend is accurate
 - Group purchases of testing services to get volume discounts
- Development of processes for investigating adverse events and similar incidents
 - Common approach to adverse event reporting
 - Identification of laboratory capabilities

Conclusions

- The time to start developing plans to meet GMP regulations is now
 - While rules have not been issued, we can make educated estimates of minimum requirements
 - If we start now, we can better manage costs of compliance
 - We should also see benefits in product consistency
- We need to work together to make sure that costs of meeting initial GMP requirements are affordable
- We need to work together to ensure related costs of GMP compliance are affordable