APPLYING TOBACCO PRODUCT MANUFACTURING PRACTICES TO EXISTING TOBACCO MANUFACTURING PROCESSES

Lillian Ortega, Lise Fraissinet, Chris Woodruff, Randy Freund, Kevin Burd - Chemular Inc, Hudson MI, USA

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ABSTRACT

On March 10, 2023, the US Food and Drug Administration (FDA) issued the proposed rule “Requirements for Tobacco Product Manufacturing Practice” (TPMP) 21 CFR Part 1120 for manufacturers of finished and bulk tobacco products. The proposed requirements provide a framework for tobacco product design and development, risk assessment, manufacturing traceability, and Corrective and Preventive Action (CAPA) documented processes to help protect the public health by minimizing or preventing contamination, incorporating traceability down to batch ingredients, reducing additional risks to users and non-users, and ensuring product conformity and consistency. FDA acknowledges in the proposed rule, industry-leading tobacco product manufacturers are practicing elements of quality management systems (QMS) to support their manufacturing processes and traceability observed during Agency inspections. As the proposed TPMP rule undergoes the rulemaking process, it provides ample time for tobacco product manufacturers to conduct a robust assessment of their current QMS in place and a gap analysis to identify potential deficiencies needing remedy to ensure compliance with future TPMPs. Presented below are the proposed TPMP requirements highlighting the differences between existing GMPs, identifying the keys to successfully conducting a gap analysis between existing manufacturing processes and the proposed TPMP and best practices for implementing changes to manufacturing processes to comply with the TPMP rule.

AGENCY SCOPE FOR TPMP REQUIREMENTS

Minimize or Prevent	Product problems and health issues not normally associated with use of tobacco product
Ensure	Tobacco products are manufactured to conform to established specifications
Identify and investigate	Nonconforming tobacco products
Prevent	Contamination of tobacco products (i.e., Metal, Glass, Leachables, Pest, Mold etc.)

Who needs to comply with TPMP?

- Foreign and Domestic finished tobacco product manufacturers
- Foreign and Domestic bulk tobacco product manufacturers
- Specification developers
- Contract manufacturers
- Importers

Who will be indirectly impacted?

- Suppliers
- Distributors
- Contract Testing Laboratories

TPMP SUBPARTS AND REQUIREMENTS

Figure 1. TPMP Subparts

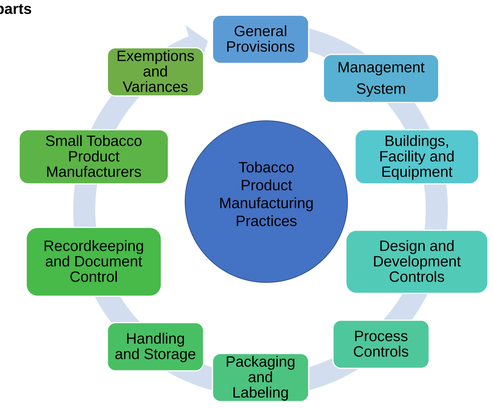

Table 1. TPMP Requirement Sections

Subpart	Sections	
Management System Requirements	Organization and Personnel Corrective & Preventive actions	Tobacco Product Complaints
Building, Facilities & Equipment	Personnel Practices Equipment	Building, Facilities & Grounds Environmental Controls
Design and Development Controls	Risk Management Design and Development	Master Manufacturing Controls
Process Controls	Purchasing controls Production processes & controls Production record Nonconforming tobacco product	Reprocessing & rework Acceptance activities Laboratory controls Sampling Returned tobacco product
Handling, Storage, & Distribution	Handling & storage	Distribution
Recordkeeping & Document Controls	Recordkeeping & document control requirements	
Exemptions & Variances	Exemptions & variances Petition for an exemption or variance Referral to TPSAC	Petition determination Hearing

COMPARING TPMP TO OTHER INDUSTRY STANDARDS

TPMP, Medical Device Quality System Regulations at 21 CFR 820, and Good Manufacturing Practices (cGMPs) at 21 CFR 210, all serve the overarching purpose of ensuring that products are produced with consistency, adhering to the highest quality standards. While they share this common goal, they diverge in their specific features, objectives, and focal areas. The TPMP is sculpted to address the nuances of the tobacco industry, whereas the 21 CFR 820 and 21 CFR 210 have their roots firmly planted in the medical device and pharmaceutical sectors respectively. The FDA recognizes the valuable insights these frameworks offer. However, it also underscores that not all elements of these regulations can be seamlessly transposed onto the tobacco sector due to fundamental differences between tobacco products and FDA-regulated medical products.

Table 2. Key Similarities and Differences at a Glance

Requirement	TPMP (1120) Tobacco Products	QSR (820) Medical Devices	cGMP (210 & 211) Drugs
Quality Control/Assurance Unit	Not Included as a Specific Requirement*	Included	Included
Master Manufacturing Records	Included	Included	Included
Stability Testing	Not Included as a Specific Requirement**	Not Included	Included
Supplier Qualifications	Included	Included	Included
Design Controls	Included	Included	Included
Production and Process Controls	Included	Included	Included
Batch Release Testing	Not Included as a Specific Requirement***	Not Included as a Specific Requirement***	Included

*TPMP does not propose a Quality Assurance Unit is a requirement, but it alludes to have qualified trained staff responsible for quality assurance.
** TPMP does not require stability testing and batch releasing testing explicitly however the FDA does explain in the proposed rule due to the broad scope and requirements for design, process and storage conditions which are sufficient to address stability of the tobacco product.
*** Medical Device QSR does not explicitly require batch release testing however the verification of finished device specs are embedded within the design validation and design transfer control requirements

COMPARATIVE GAP ANALYSIS

Conducting a comparative gap analysis between existing manufacturing operations and TPMP requirements is a critical exercise. This analysis acts as a diagnostic tool, identifying areas where current practices may fall short of regulatory expectations. Furthermore, this analysis is essential for preemptively identifying and mitigating potential compliance risks, thereby reducing the likelihood of regulatory actions.

Figure 2. Gap Identification Flowchart

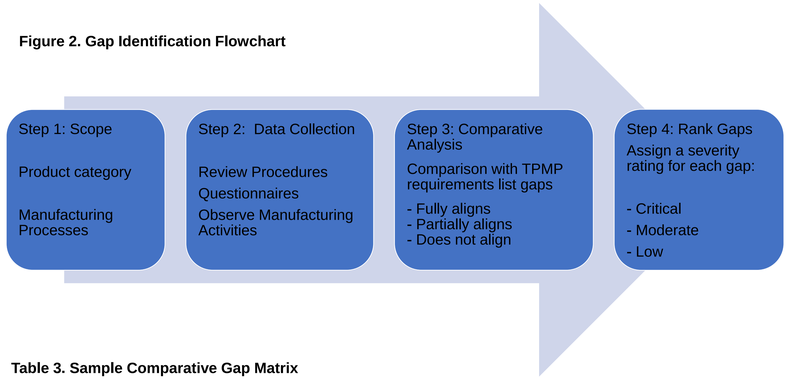

Table 3. Sample Comparative Gap Matrix

TPMP Sections	Specific Requirements	Current Process	SOP/ Work Instructions	Training/ Competency/ Records	Documentation/ Records of Activity	Level of Risk/ Fully align Partially align Does not align
Organization Structure	Organization Chart Executive Responsibility Approval authority					Fully Align- No risk
Personnel qualifications/ Training	Adequate staff Training Modules Procedures					Partially Align - Minor Risk
Complaint Handling	• Receipt • Evaluate • Investigation • Outcome Documentation					Does not Align – High Risk
Corrective Action and Preventive Actions	• Investigation • Verification/ Validation • Effectiveness • Process changes • Disseminating					Does not Align- High Risk

BRIDGING THE GAPS - IMPLEMENTATION STRATEGY

In the quest to align existing operations with Tobacco Product Manufacturing Practices (TPMPs), a comprehensive gap analysis is the critical first step, but the journey doesn't end there. Bridging these gaps demands a strategic, organized, and tailored approach. The implementation strategy prioritizes the most critical gaps, those that have direct implications on product quality and regulatory compliance.

Figure 3. Implementation Plan

BEST PRACTICES FOR TPMP IMPLEMENTATION

Cost	Ensuring financial commitments for the implementation plan including computer systems, hiring employees and new processes. It's crucial for the organization to have a detailed plan to cover the full cost.
Time and Resources	Implementing TPMPs is a demanding endeavor that places additional pressures on current staff and resources. It's essential to have cross functional teams to bolster support.
Supply Chain	Engage with suppliers early and maintain open communication to mitigate and plan for any process changes to the supplier activities and potential disruptions thru the implementation process.
Workforce	Both new and seasoned employees will require training to execute TPMPs. Consider organizing a mix of in-house training sessions and external workshops to cater to different learning preferences
Procedures	TPMP mandates the establishment of detailed procedures and rigorous recordkeeping. Updating or setting up a new QMS can pose a considerable challenge. Initiate a phased approach for procedure updates.
Process	The plan may call for modifications to the manufacturing processes, leading to disruptions to operations. Plan for scheduled downtime and ensure stakeholders are informed.

CONCLUSIONS

The FDA's proposed TPMP rule for tobacco product manufacturing introduces a comprehensive framework that emphasizes design, development, risk assessment, manufacturing traceability, and CAPA processes. Derived from extensive observations and data accumulated from inspections across diverse tobacco product categories, the proposed Rule recognizes the efforts of tobacco manufacturers that have already implemented elements of quality management systems. Standardized manufacturing practices should not be perceived as merely another regulatory hurdle; instead, they present a positive evolution for the industry. Such standards not only elevate the industry's credibility but also prioritize the well-being of the end users.

As the proposed rule progresses through the rule making process, it offers manufacturers a crucial opportunity to review and optimize their existing quality management systems, emphasizes the need for a thorough gap analysis. This ensures not only conformity with the soon-to-be-established regulations but also emphasizing the overarching objective of safeguarding public health by maintaining consistent and uncontaminated tobacco products. TPMPs stand as a central pillar in this critical effort. These practices provide a framework that helps prevent contamination, ensures consistent product conformance, and enables effective tracking and tracing of products from raw materials through production and into distribution..

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