Ensuring an Effective Tobacco and Nicotine Regulatory Framework

Katherine Ciambrone, Senior Vice President and Chief Compliance Officer, ITG Brands
Stacey Gagosian, Managing Director of Public Policy, Truth Initiative
David Sweanor, Adjunct Professor of Law, University of Ottawa
Moderated by **Scott Ballin**, Tobacco and Health Policy Consultant

FDLI

OPPORTUNITIES FOR MODERNIZED APPROACH

Katherine Ciambrone

FDLI Nicotine and Tobacco Conference

October 2018

CHALLENGE

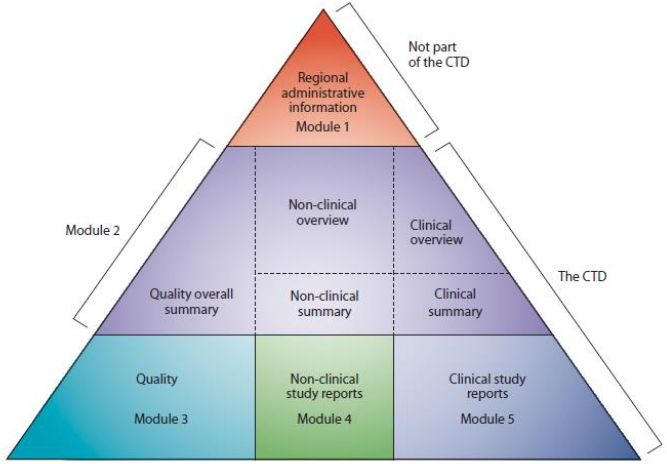
- Absent an agreed and transparent approach, tobacco regulators and industry:
  - Use different formats, content and terminology in regulatory filings
  - Take different approaches in determining which product characteristics are most critical to a tobacco product's quality, compliance and considerations on the impact on public health.
- **Result:**
  - Same words used for different definitions confuses regulators
  - Attributes of a tobacco product appear to treated with the same criticality.
  - No definition of 'significant'
  - Loss of time, reputation and resources, for both regulators and industry
  - Diminished ability to prioritize & focus on products that truly raise different questions of public health.

PROPOSED PATH FORWARD

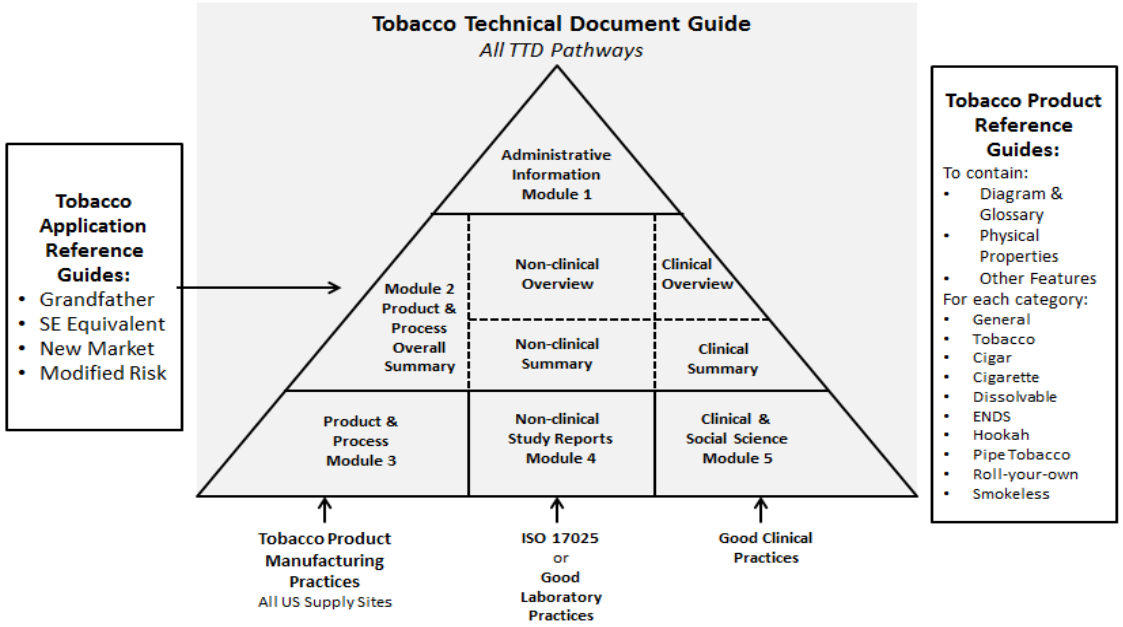
- Propose that a standardized regulatory framework for tobacco products could be achieved by utilizing:
  - A Tobacco Technical Document (similar to ICH CTD M4)
  - Standardized Product Guidelines & Glossaries
  - A Risk-based End-to-end Control Strategy (similar to ICH Q8: Pharm Dev, Q9: Quality Risk Mgmt, Q10: Quality System)
  - A Decision-tree approach (similar to FDA CDRH 510(k)) to allow certain changes for products on the market

STANDARD STRUCTURE FOR FILES

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.



ICH M4 : The Common Technical Document

- Revolutionised the regulatory review processes
- led to harmonised electronic submission
- enabled implementation of good review practices
- for industries, it has eliminated the need to reformat the information for submission

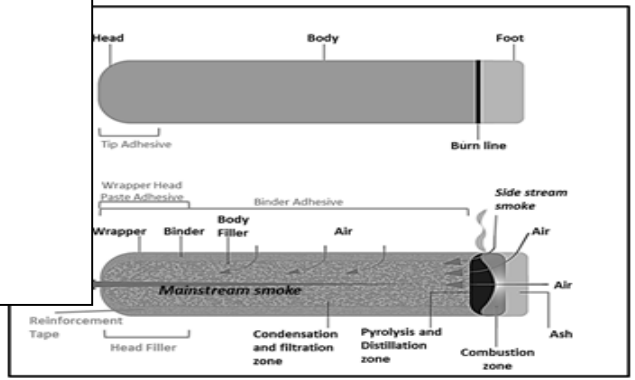
STANDARD GUIDELINES/GLOSSARIES

Tobacco Product Reference:
Machine Made Cigars

Table of Contents

Example only

MMCs will have all components illustrated below. Black text terms are generally all MMC formats.



Cigar Components

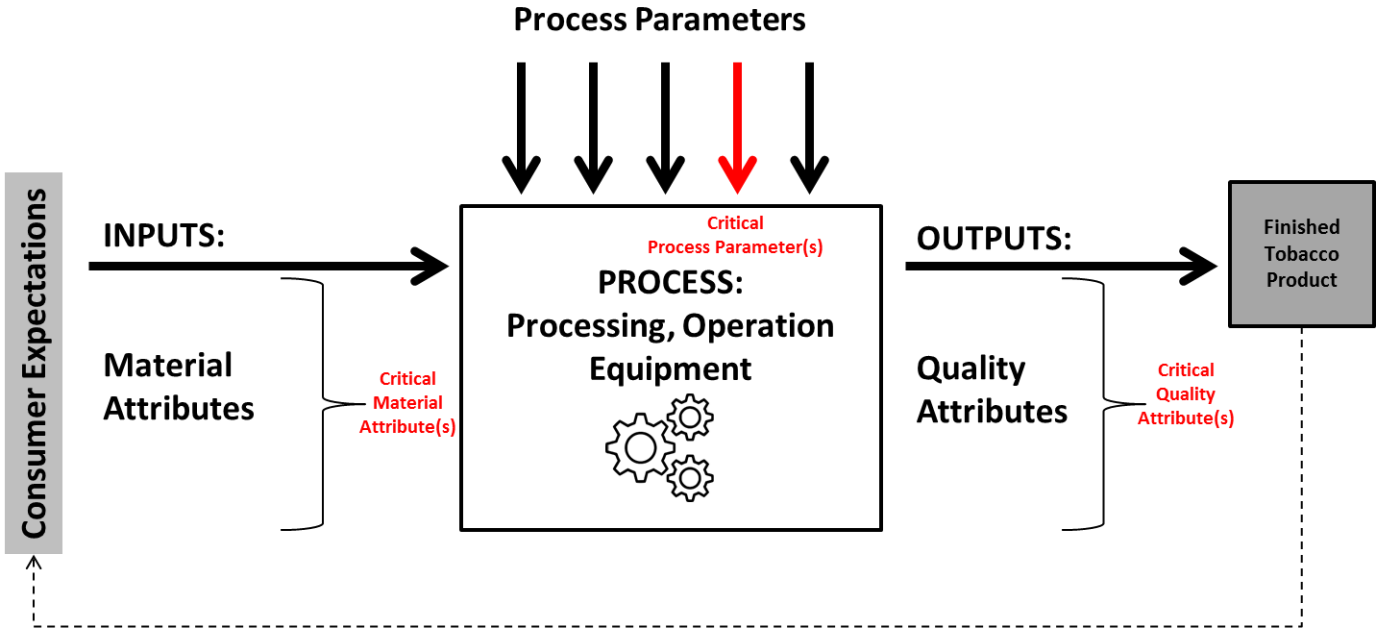
Term	Definition
Binder	Tobacco used to hold together the filler can either be a natural leaf or homogenized leaf material
Binder Adhesive	Adhesive used to seal the Binder (sometimes referred to as glue)
Body	The portion of cigar that contains the tobacco rod
Body Filler	Tobacco used in the Body section of the cigar, can be in the form of long filler, short filler, threshed filler or cut filler
Cap	Small round piece of tobacco at Head of the cigar
Condensation and filtration zone	In the low-temperature zone where condensation and filtration occur while light gases diffuse out and air diffuses in
Filler - Head	Tobacco used in the Head section
Filter	Comprised typically of acetate tow used for filtration

Module 1: Administrative Information

Product Properties
type (e.g., box, film, sleeve, none) quantity (e.g., 1 cigar, 5 cigars) izing Flavor (e.g., none, whiskey) e.g., 150mm, 200mm) .g., 8mm, 10mm) material (e.g., Tobacco Type or HTP) al properties needed to uniquely identify the oduct (if applicable)
type (e.g., box, booklet) quantity (e.g., 10 wrappers, 20 leaves) izing Flavor (e.g., none, tobacco, menthol, al properties needed to uniquely identify the oduct (if applicable)
type (e.g., bag, pouch) quantity (e.g., 20 g, 16 ounces) izing Flavor (e.g., none, menthol, cherry) cut size (e.g., 15 cuts per inch) al properties needed to uniquely identify the oduct (if applicable)
v co-packaged tobacco product composed of gar tobacco products, include all properties

STANDARD CONTROL STRATEGY

Goal: Understand the relationship between Material Attributes, Process Parameters & Quality Attributes to determine **which characteristics are most critical** to a tobacco product's quality, compliance and considerations on the impact on public health.



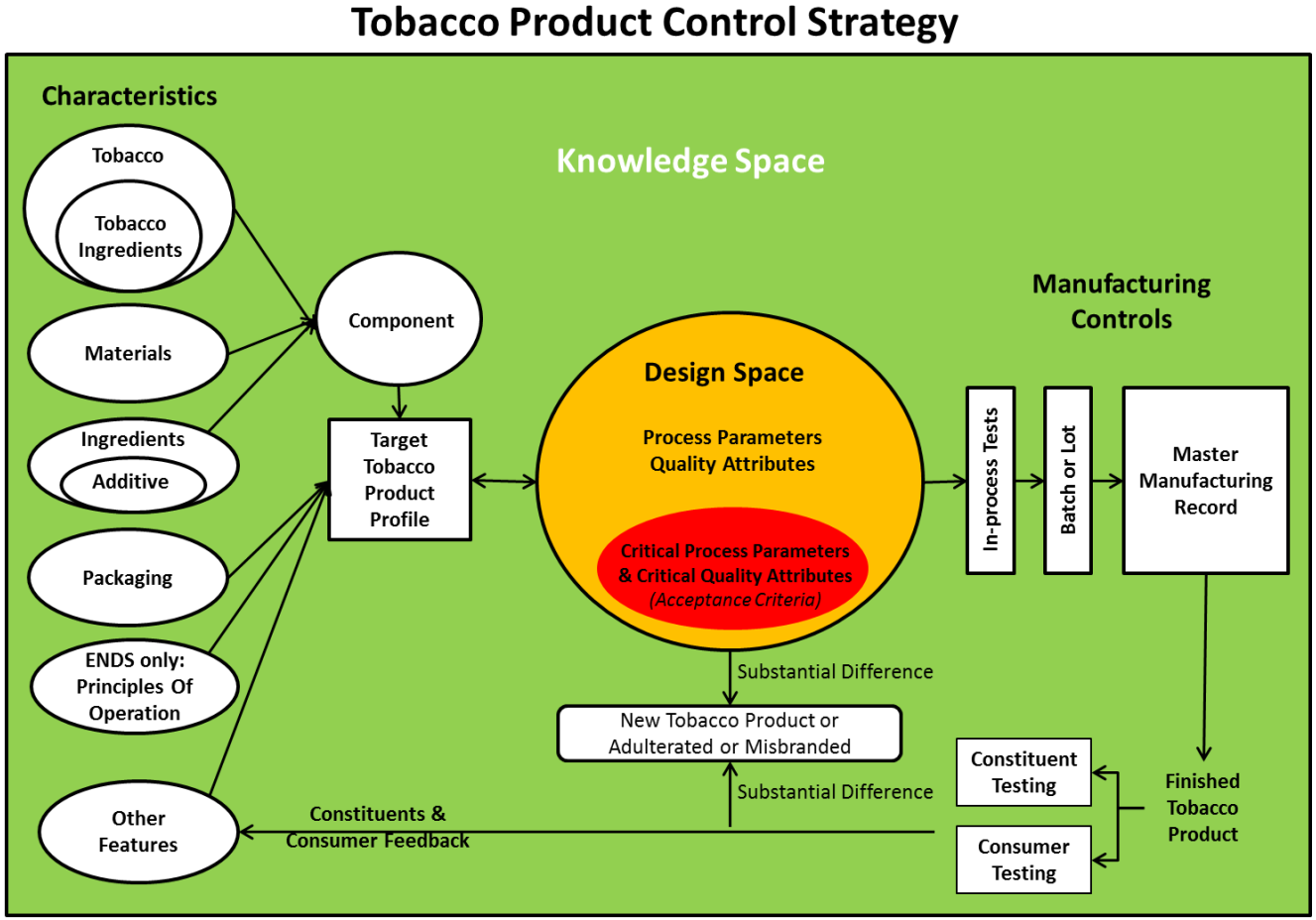
PROCESS

1. Determine potential variables that could impact goal
2. Determine risks that have ‘actual’ impact
3. Document risk mitigation activities
4. Establish the Target and Acceptable Ranges

STEP 6:

Maintain end-to-end records of the tobacco product control strategy

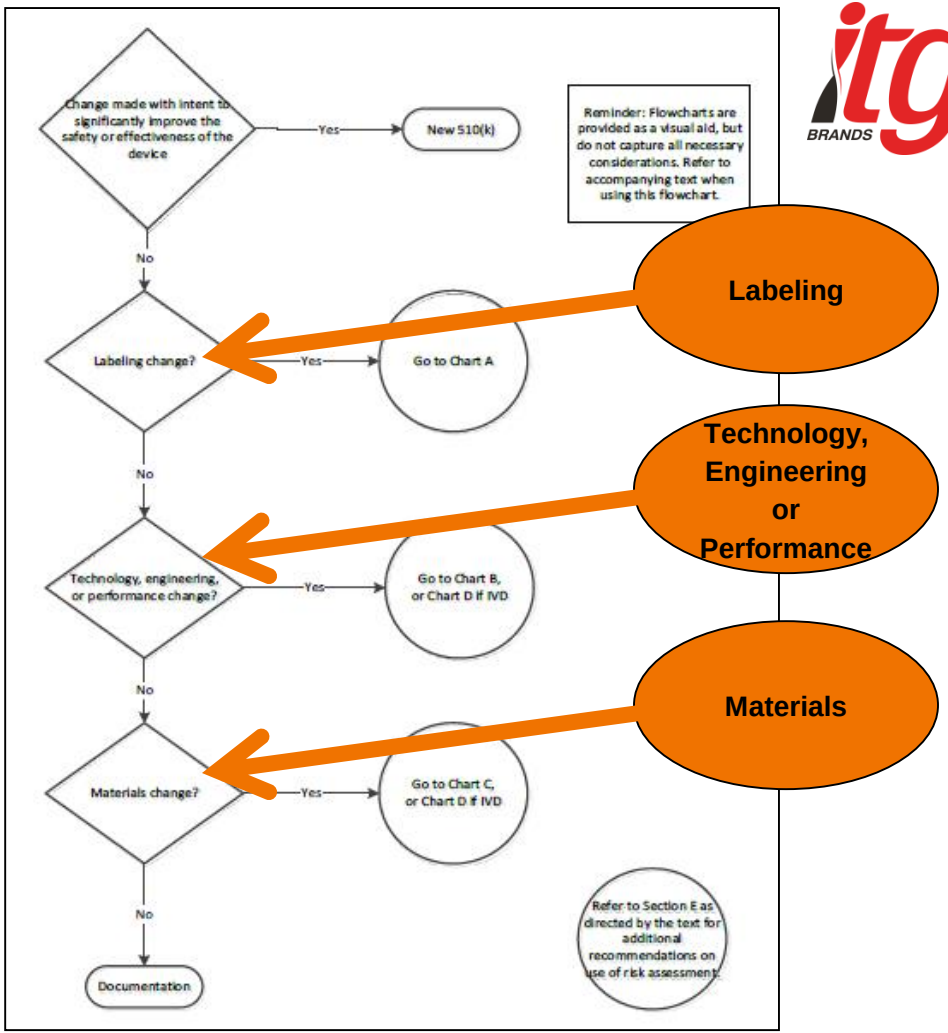
Continue to build Knowledge Space to facilitate further enhancement of Goal and to support "510k type" changes to Market Order products.



Attribute: Materials, Characteristics, Components, Constituents
Parameter: Process, Operations, Equipment settings

STANDARD APPROACH FOR MARKET APPROVED PRODUCTS

- The first question is whether the change is being made **<u>with the intent</u>** to significantly improve the safety or effectiveness of the device, for example, to significantly improve clinical outcomes, to mitigate a known risk, in response to adverse events, etc. ***If not, you should continue to follow the logic scheme shown:***
  - ***Labeling***
  - ***Technology***
  - ***Materials***
- 510(k)



RISK-BASED REGULATORY FRAMEWORK

Alignment:
Standard format, content & terminology in regulatory files

PROCESS

PRODUCT

Product Understanding:
ICH Approach could build common understanding by identifying critical characteristics to a tobacco product's quality, compliance and considerations on the impact on public health.

+

Product Maintenance:
Device 510 (K) Approach could establish the decision tree approach to apply agreed principles into published guidance.

Underpinned by:
TPMPs and a robust in-place, in-use and effective Quality Management System.

REFERENCES

- INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE ICH HARMONISED TRIPARTITE GUIDELINE
  - M4 : The Common Technical Document
  - SPECIFICATIONS: TEST PROCEDURES AND ACCEPTANCE CRITERIA FOR NEW DRUG SUBSTANCES AND NEW DRUG PRODUCTS: CHEMICAL SUBSTANCES Q6A Current Step 4 version dated 6 October 1999
  - PHARMACEUTICAL DEVELOPMENT Q8(R2) Current Step 4 version dated August 2009
  - QUALITY RISK MANAGEMENT Q9 Current Step 4 version dated 9 November 2005
  - PHARMACEUTICAL QUALITY SYSTEM Q10 Current Step 4 version dated 4 June 2008
- Guidance for Industry Process Validation: General Principles and Practices, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM) January 2011, Current Good Manufacturing Practices (CGMP), Revision 1
- How to Identify Critical Quality Attributes and Critical Process Parameters, Jennifer Maguire, Ph.D., Daniel Peng, Ph.D., Office of Process and Facility (OPF), OPQ/CDER/FDA, FDA/PQRI 2nd Conference, North Bethesda, Maryland, October 6, 2015
- Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and Food and Drug Administration Staff, Document issued on October 25, 2017. Additional FDA information website on 510(k) Submission Methods