

CPG cGMPs

How do we mitigate or
manage risk?

Has the time come to
Harmonize?



Background

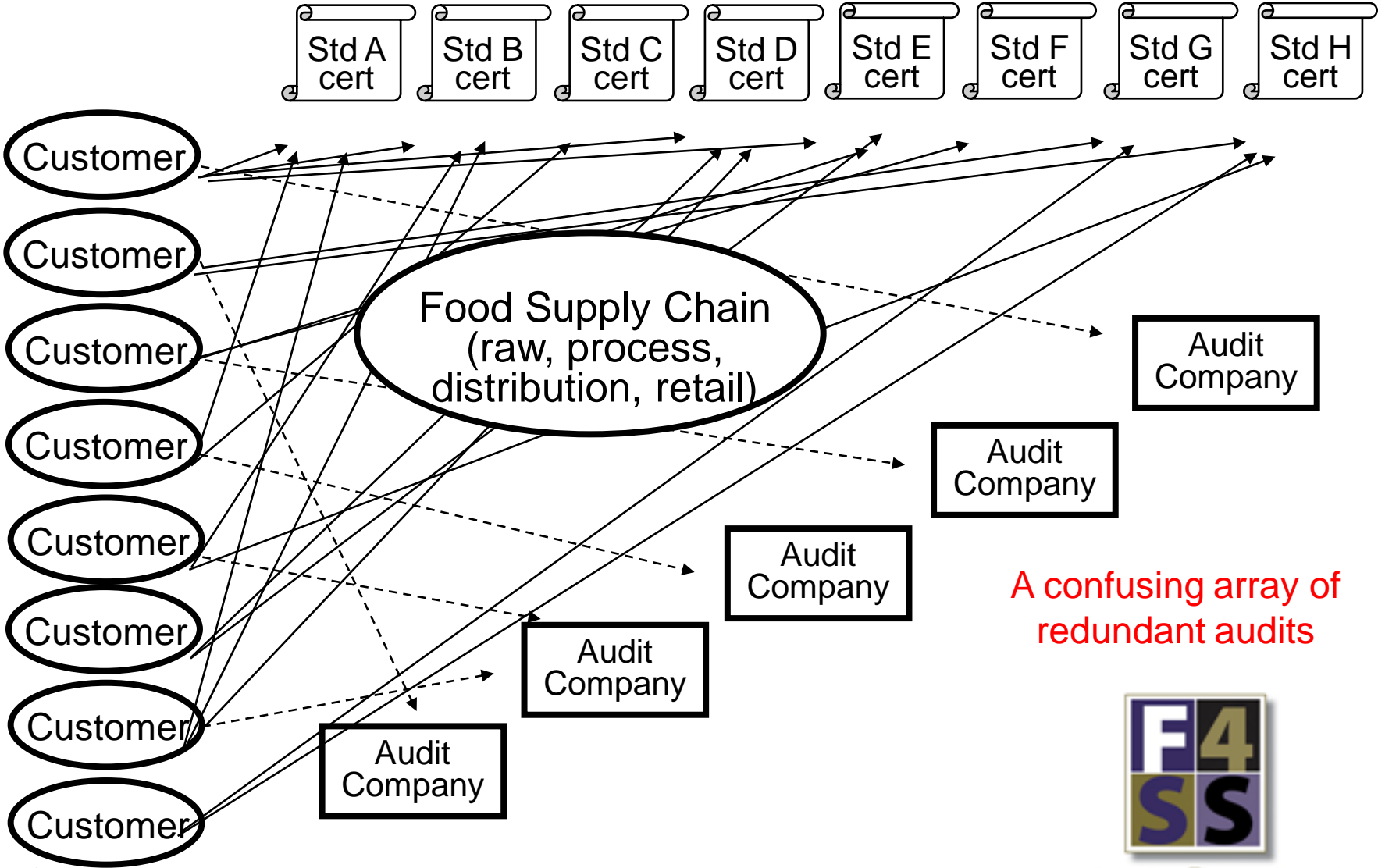
To date, the industry has not unified behind a common standard categorically nor regionally.

Results:

- Fragmented approach.
- Lack of focused execution.



Food: Current Audits & Standards



A confusing array of redundant audits



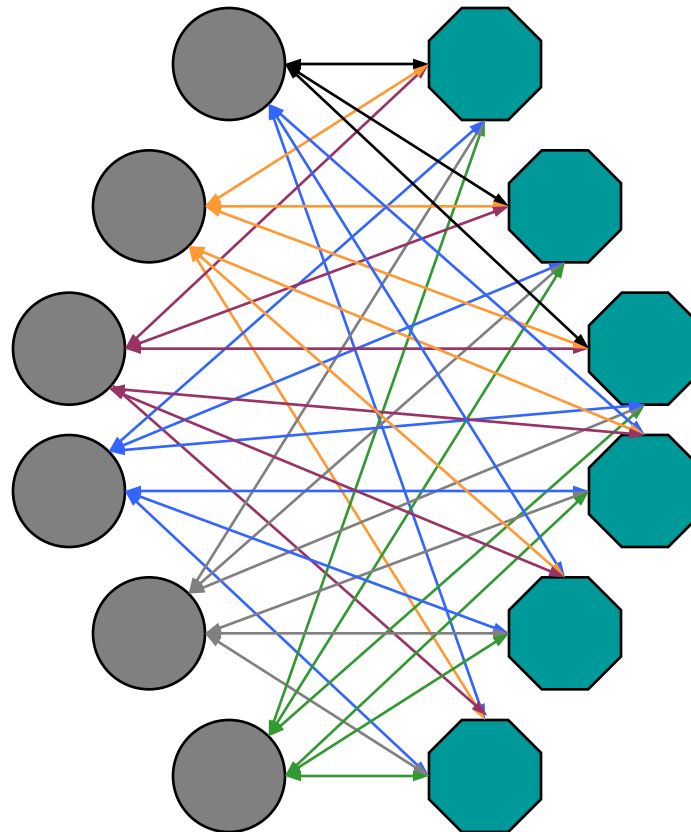


Current Status –

HHBC (home, health & beauty care)

of approaches =
of Marketers

Marketers
(Customers)



Contract
Manufacturers
(Suppliers)



Results of the Current Approach

1. Proliferation of redundant cGMP audits conducted.
2. Use of customer (marketer) internal resources focused on non-proprietary elements of QA systems.
3. Capacity challenge to focus on critical, complex and proprietary/confidential activities (unique technologies).
4. Lack of a consistent, clear set of expectations to the market - fragmented expectations.
5. Reduced Customer and Consumer satisfaction.



Results of Current Approach

6. High cost of poor quality (millions every year).
7. Supplier management to the least common denominator.
8. Reduced supply chain reliability.
9. Inefficient CapEx investment by suppliers through inconsistent and varied customer feedback.
10. Increased complexity and variance risks with suppliers by managing non-proprietary procedure requirements.

and,

11. INCREASED COSTS



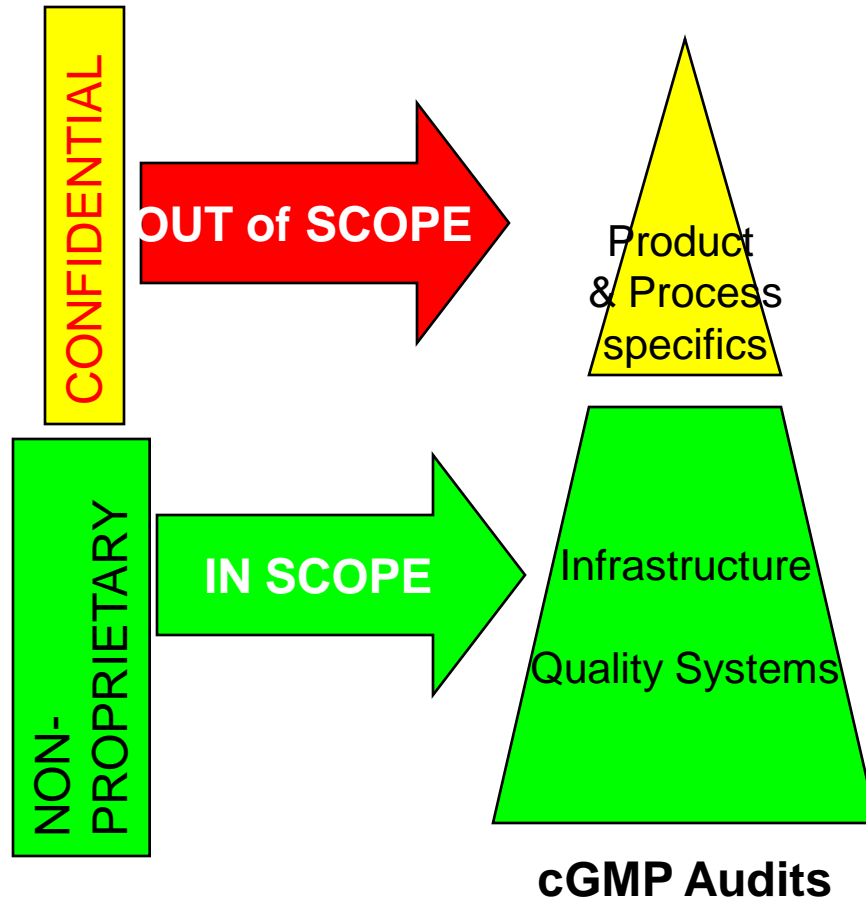
Opportunity

Improve Compliance and Reduce Costs through the application of common, public, non-proprietary, global standards.



Opportunity

Focus on the 80/20: Non-Proprietary Systems



Vision

- Protect consumers and brands by establishing a common framework of cGMP Practices and Audit Standards across the global supply chain
- Create a globally accepted framework to ensure safe products efficiently delivered to consumers.



Benefits of Standardization

1. Improve Customer and Consumer satisfaction.
2. Consolidate number of cGMP audits conducted.
3. Reduce use of internal resources focused on non-proprietary elements of QA systems.
4. Increase focus on critical, complex and proprietary/confidential activities (unique technologies).
5. Communicate clear set of expectations to the market, with critical mass supporting those expectations.



Benefits of Standardization

6. Reduce the cost of poor quality.
7. Provide a better and more consistent over-all assessment of a supplier's capabilities.
8. Improve supply chain reliability.
9. Enable efficient capex investment by suppliers through clear identification of gaps/opportunities.
10. Reduce complexity and variance risks with suppliers by managing fewer non-proprietary procedure requirements.
11. Reduce costs.



Recommendation

The rationale is compelling – the time has come to

**Explore the possibility of
Harmonizing
CPG cGMPs**



Recommendation

Phase 1: Determine the business case for establishing a Common Basis for Cross cGMP Requirements and Common Audit Practices across all CPG Categories.

The proposal will define appropriate outcomes (loss reduction opportunities/benefits), constraints, and risks associated with the project.



Recommendation

If agreed to pursue after Phase 1,

Phase 2: Complete Technical Work Plan to:

- Define and recommend Common cGMP requirements
- Recommend Audit Standards and Approaches
- Establish Implementation Plan and Investment Requirements



Recommendation

Phase 3:

Agreement to Phase 2 Recommendations with
Implementation



Next Steps

May we have your agreement
to collaborate on this initiative
which is vital to the
long term
health of our industry?

