

Enhancement of the Quality Control Program

Brevitas Consulting is an external CDCB partner brought on to assist in program enhancements by bringing industry best practices

About Us

- Founded in 2010
- An ISO9001:2015 certified company serving global leaders in the life sciences industry with process improvements and quality management systems
- Our team brings over 650+ years of experience managing multi-disciplined teams, resolving complex issues, and driving change in organizations

Our Mission

Help organizations achieve tangible results and lasting improvements via successful program management, continuous improvement, and effective management of change.

Our Team



Anil Peer

Principal Consultant



Alexandra Marzo

SME – QMS



Boris Danilov

SME – IT



Anika Krish

Consultant

Our Services

Program
Improvements

Data Integrity
Compliance

Regulatory
Inspection and
Certification
Support

Program and
Project
Management

Training
Development

Operational
Readiness

Our Partnership with CDCB

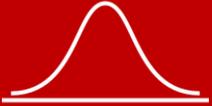


Brevitas has been onboarded as a third-party to provide an objective and impartial look into the current CDCB evaluation and certification program

Our Goal

- ➔ Identify process improvement opportunities to enhance efficiencies
- ➔ Prioritize and implement these improvements while closely monitoring their impact on the overall process
- ➔ Implement a continuous improvement cycle by assessing the improvements, modify if applicable, and continue to leverage the working efficiencies

Sample Projects – Quality & Compliance & Process Improvement

Development of QMS			Harmonization of Standard Operating Procedures as “Lean” Operations Initiative
Deviation Management to Address Key Compliance & Production Issues			Compliance Support to Expedite Closure of Quality Notifications
GMP Certification Readiness			6 Sigma Project Management Rollout with Training and Execution
Implementation of a Data Integrity Compliance Program			Training Program Development and Rollout

Business Challenge

A Client was under a tight timeline to reduce and refine their documentation across multiple global sites while still maintaining compliance with FDA, EU, and Canadian regulations.

Results Achieved



After an extensive review of all documentation and SOPs, a **reduction of 50%** was seen resulting in leaner operations and overall operational efficiency.



With refined procedures, deviations were minimized and training requirements for new personnel were reduced.

Business Challenge

In preparation for a regulatory audit, a client required an assessment, with implementation of the corrective actions, regarding their data quality and integrity throughout their manufacturing process.

Results Achieved



Developed and implemented a Data Integrity Program and Assessment Tool to enhance data accuracy and reliability, leading to better decision-making and compliance.



Through risk assessments, we enhanced data quality and reduced the risk of non-compliance, ensuring trustworthy data for regulatory reviews.

Business Challenge

An outcome from a regulatory audit left a Client with a tight timeline to close an exhaustive number of notifications from the agency. This Client required hands on support to close these notifications and ensure prevention in the future.

Results Achieved

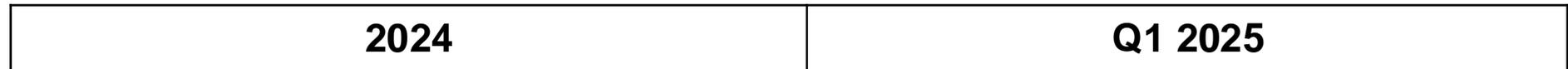


Through data analysis and root cause analysis, the client saw a **50% reduction** in the **open notifications** within a 6-month timeframe.

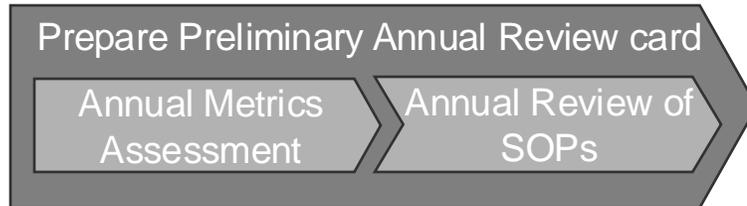


Implemented an effective root cause corrective actions (RCCA) and change control management procedure to help reduce the number of notifications in the future.

On-boarding Status



Review Report Cards sent to Labs and Nominators

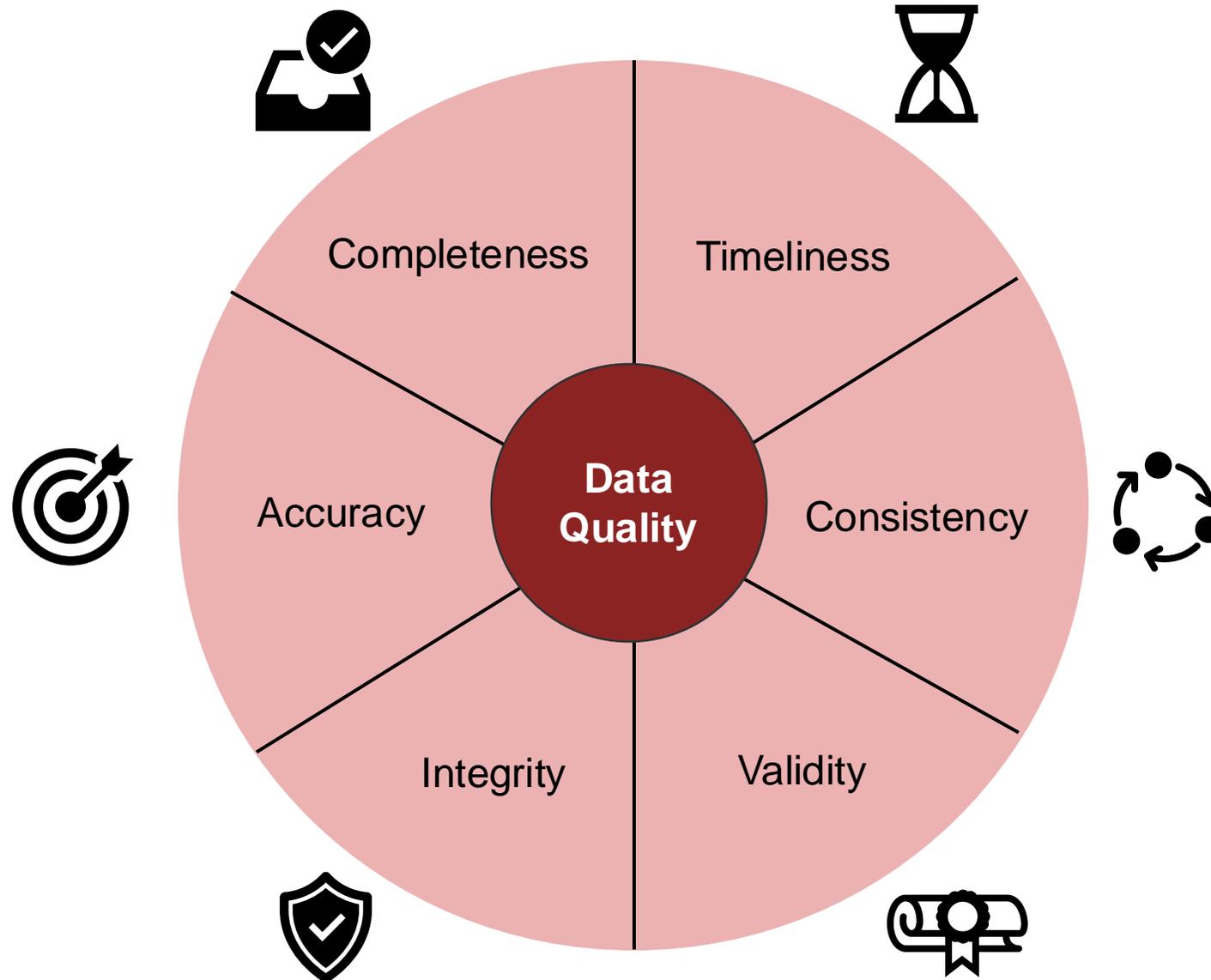


Schedule Annual Review

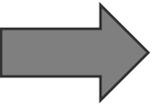
Provide Final Report



Data Quality



The Impact of Poor Data Quality



Inaccurate Analytics



Reduced Efficiency



Missed Opportunities



Reputational Damage



Waste of Time and Money



The Benefit of CDCB

- CDCB collaborates with U.S. and global partners to produce premier dairy genetic evaluations and data services
- These services benefit dairy farmers worldwide as they work to improve the health and productivity of their cattle
- CDCB hosts the world's largest database devoted to dairy cattle performance used for both data analytics and research institutions
- CDCB continues to lead the industry in providing the gold standard in genomic evaluations and novel management tools

The Importance of a Quality Control Program



The CDBC Certification Process

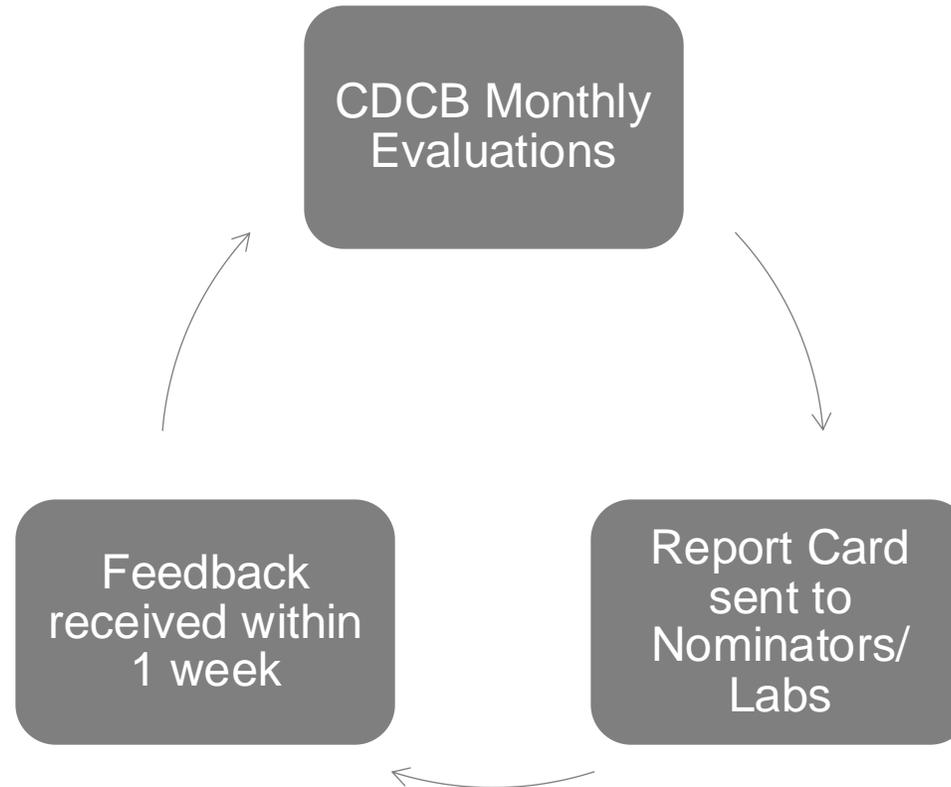


One Time Process

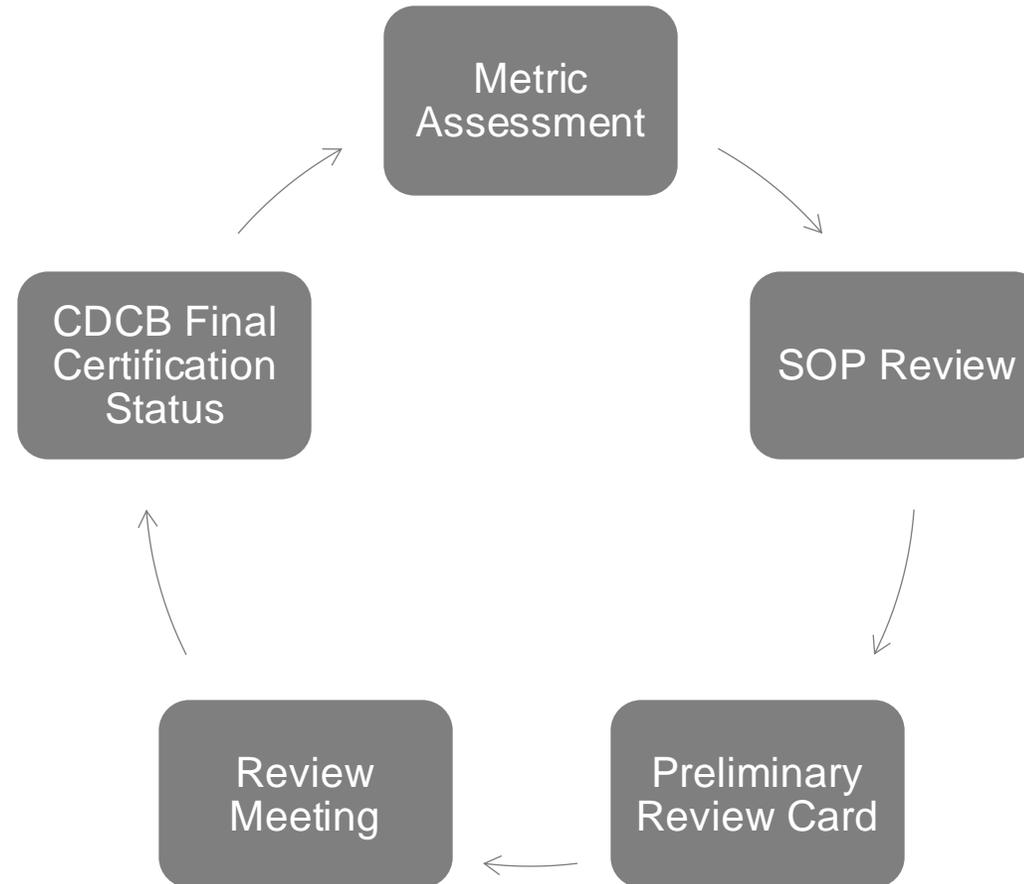


Repeated Annually

The CDCB Certification Process

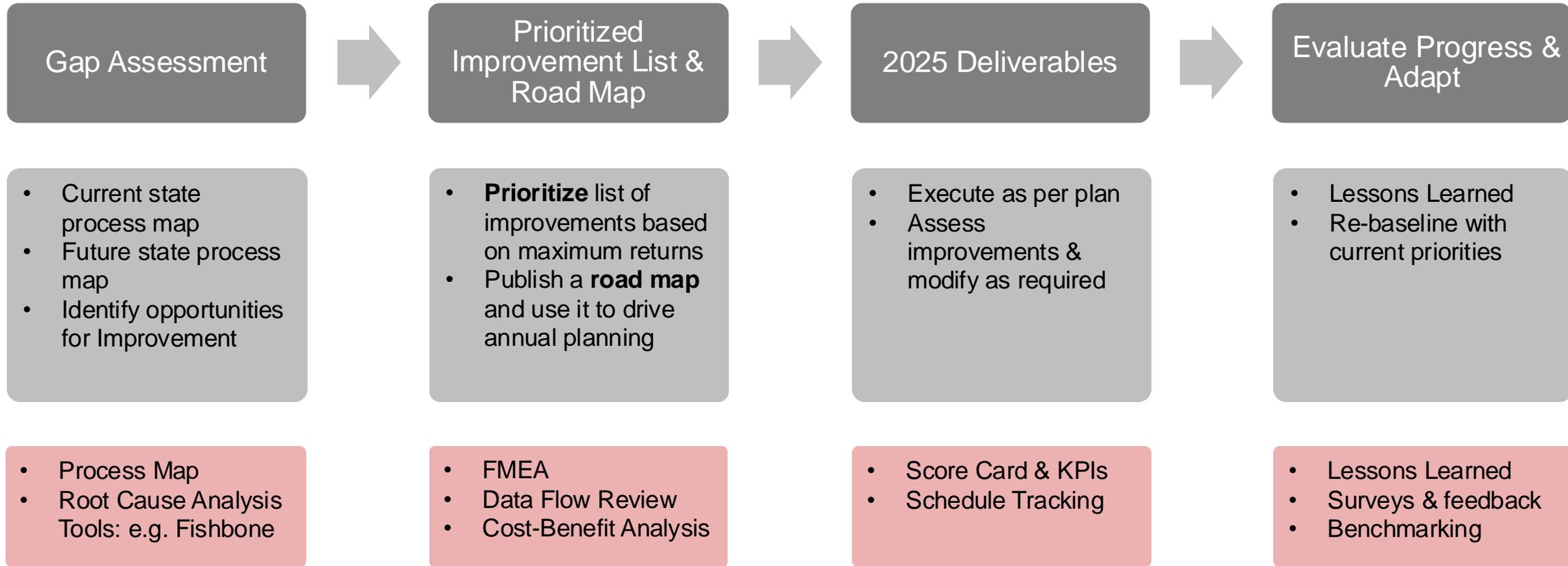


The CDCB Certification Process

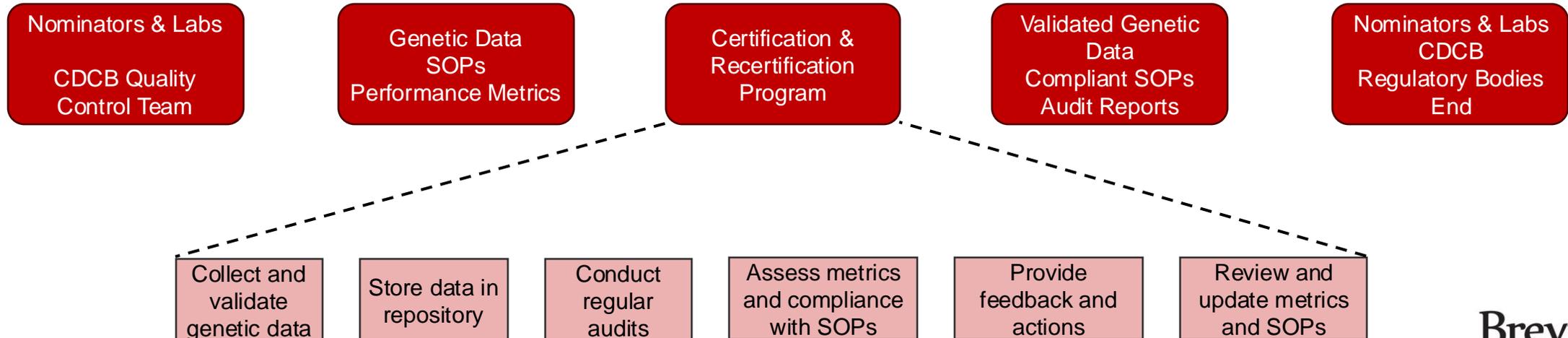
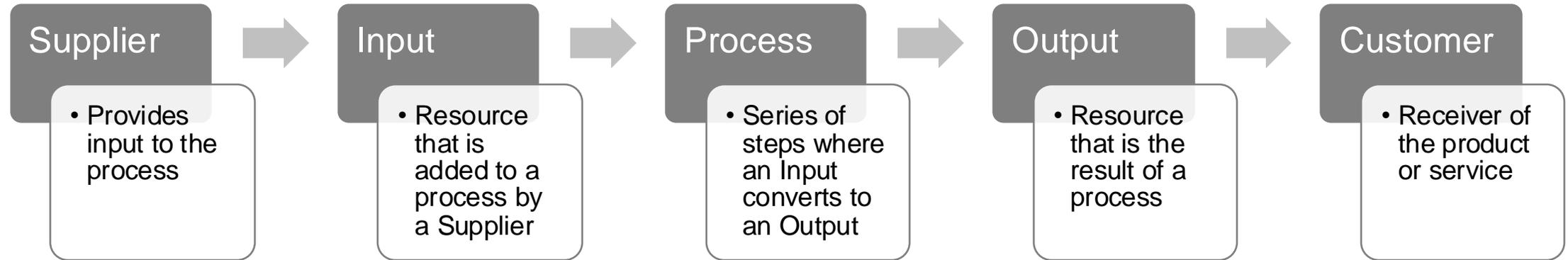


Our Approach to Process Improvement

Overall Approach



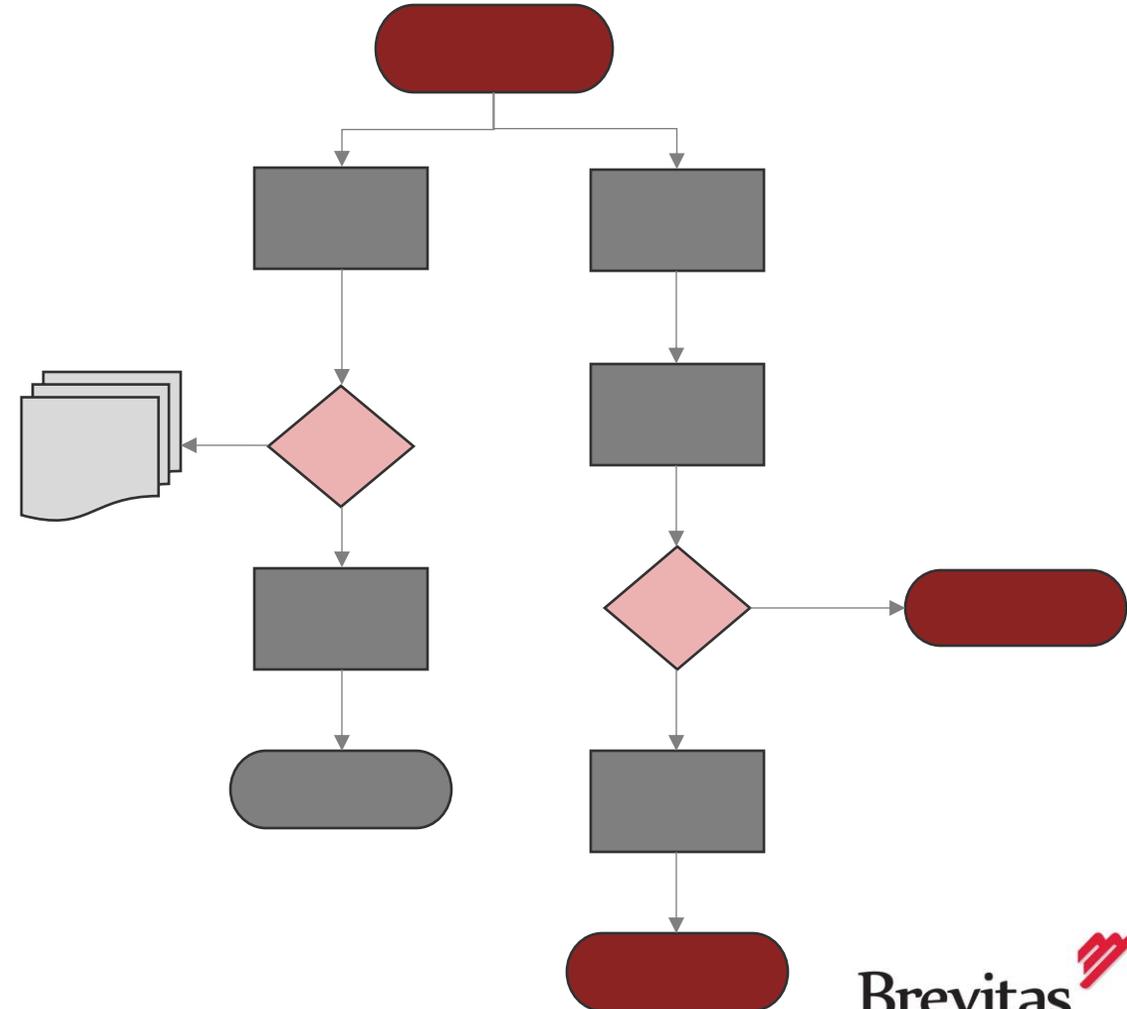
Process Improvement Tools: SIPOC



Process Improvement Tools: Process Map

Benefits

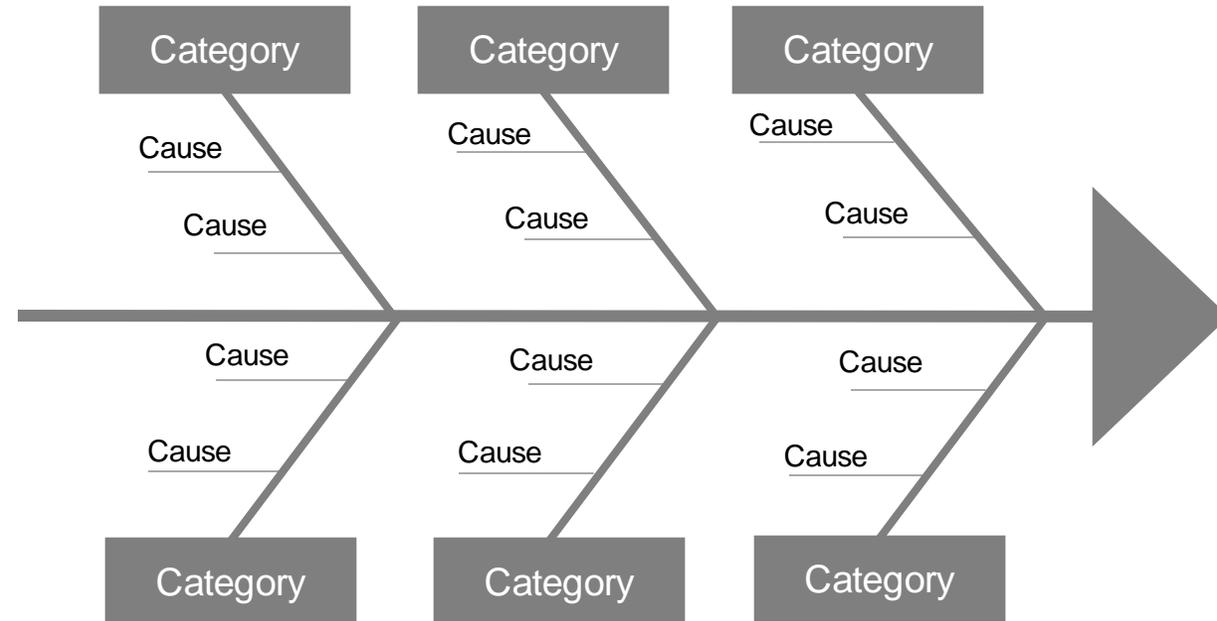
1. Helps to identify potential problems and bottlenecks
2. Helps to increase efficiency by improving the process and creating consistency
3. Helps clarify roles and responsibilities
4. Helps with scenario testing



Process Improvement Tools: Fishbone

Benefits

Visualize possible causes of problem by sorting them into useful categories



Process Improvement Tools: FMEA

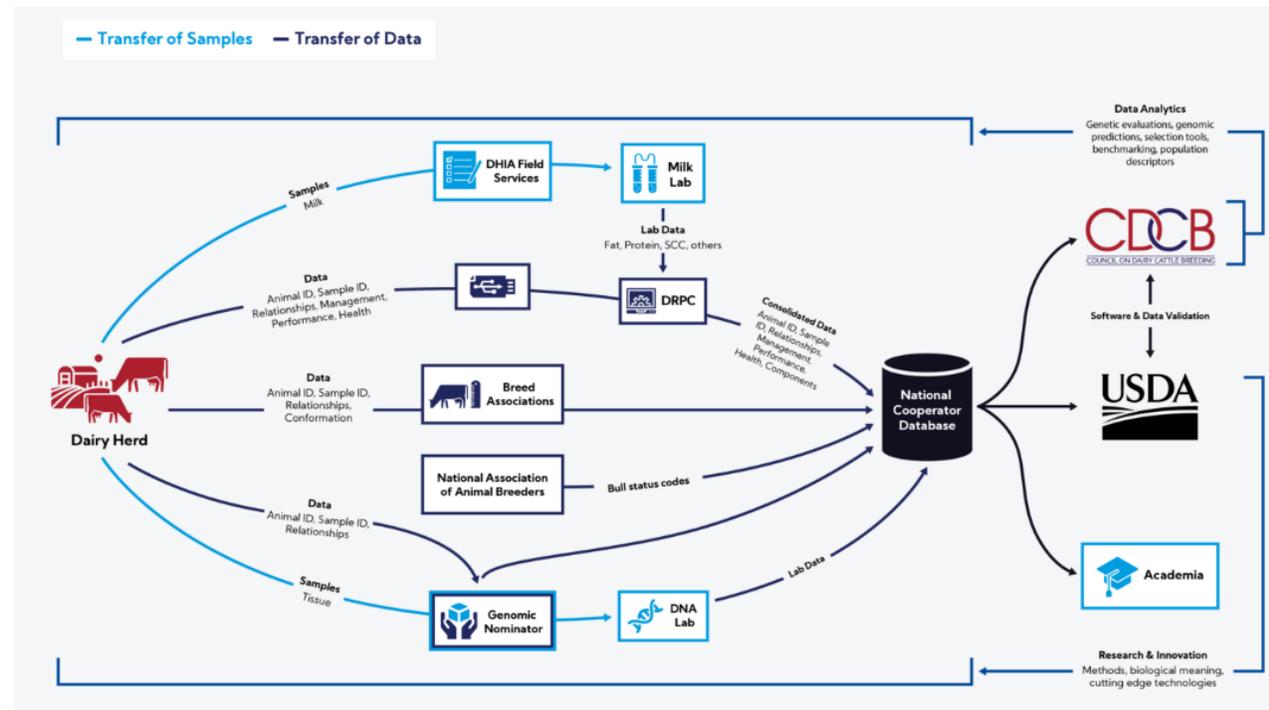
Benefits

1. Helps to prevent failures or reduce their impact
2. Reduce costs and risks associated with failures
3. Can improve quality, reliability, and safety of a system
4. Can lead to improved customer satisfaction and loyalty

ID	Item	Function	Potential Failure Mode(s)	Potential Failure Effect(s)	Severity (1-5)	Potential Cause(s)	Occurrence (1-5)	Current Control (Prevention)	Current Controls (Detection)	Detection (1-5)	RPN (\$ x O x D)	Recommended Action(s)	Responsibility and Target Completion Date	Actions Taken	Severity (1-5)	Occurrence (1-5)	Detection (1-5)	RPN (\$ x O x D)

Process Improvement Tools: Data Flow Review

Data audits help to ensure transparency about who is using sensitive data and for what purpose. Help to assess if data is secure, remains compliant and can be used for the intended use.



Conclusion & Next Steps

Our Commitment

- Continue to provide objective and impartial evaluations
- Collaborate closely to identify and implement process improvements
- Ensure effectiveness within the continuous improvement cycle

Next Steps

Review Findings

Share detailed findings and recommendations with CDCB Team

Implementation Plan

Develop a phased implementation plan for prioritized improvements

Continuous Monitoring

Establish metrics and monitoring mechanisms to assess the impact of implemented changes

Feedback Loop

Regularly solicit feedback from stakeholders to refine and enhance processes further



Thank You

North Carolina – USA



300-2530 Meridian Parkway
Durham, NC 27713



1 (844) 312-7337



info@brevitas.us



www.brevitas.us

Ontario - CANADA



24-70 East Beaver Creek Rd
Richmond Hill, ON L4B 3B2



1 (647) 689-7758