



Fundamentals of Quality Systems

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Outline

Mission: To introduce the basic concepts, purpose, and implementation of quality systems that are applicable to the brewing industry.

- What
- Why
- How



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What?



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WHAT is a quality system?

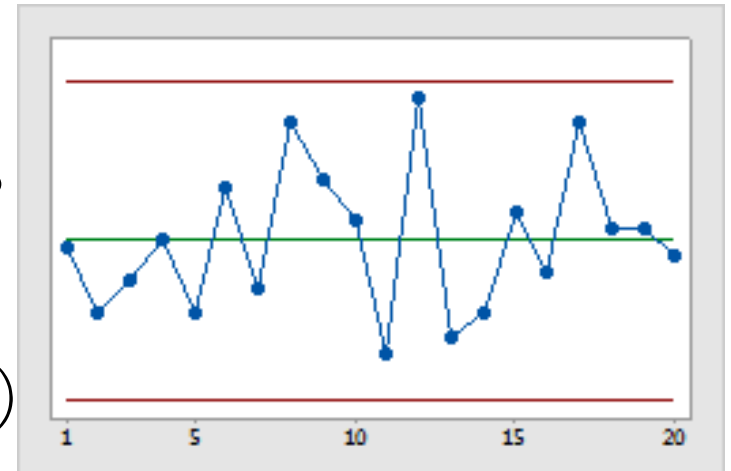
“Quality Systems drive towards process **centerline** and aim to improve **product quality** and consistency to meet customer expectations”



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Drive to Centerline

- Setting, and adhering to, specifications in the **process**
 - Define the process standards
 - Measure them (control points)
 - Record and organize the information
 - Use the data in short interval control
- A controlled process in an efficient process



Product Quality

- Product Quality = Product Consistency
 - Preference is not quality
 - Define the standard of quality (i.e. Specifications)
 - Objectively abide by these specifications
 - Consistency in product is achieved by consistency in process
- Consumer Expectations



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Elements of a Quality System

- Risk Management
- Document Control
- Plans for nonconformity
- Traceability
- Process management
- Maintenance Plans
- Quality Records



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Food Safety Modernization Act (FSMA) Preventative Controls for Human Food

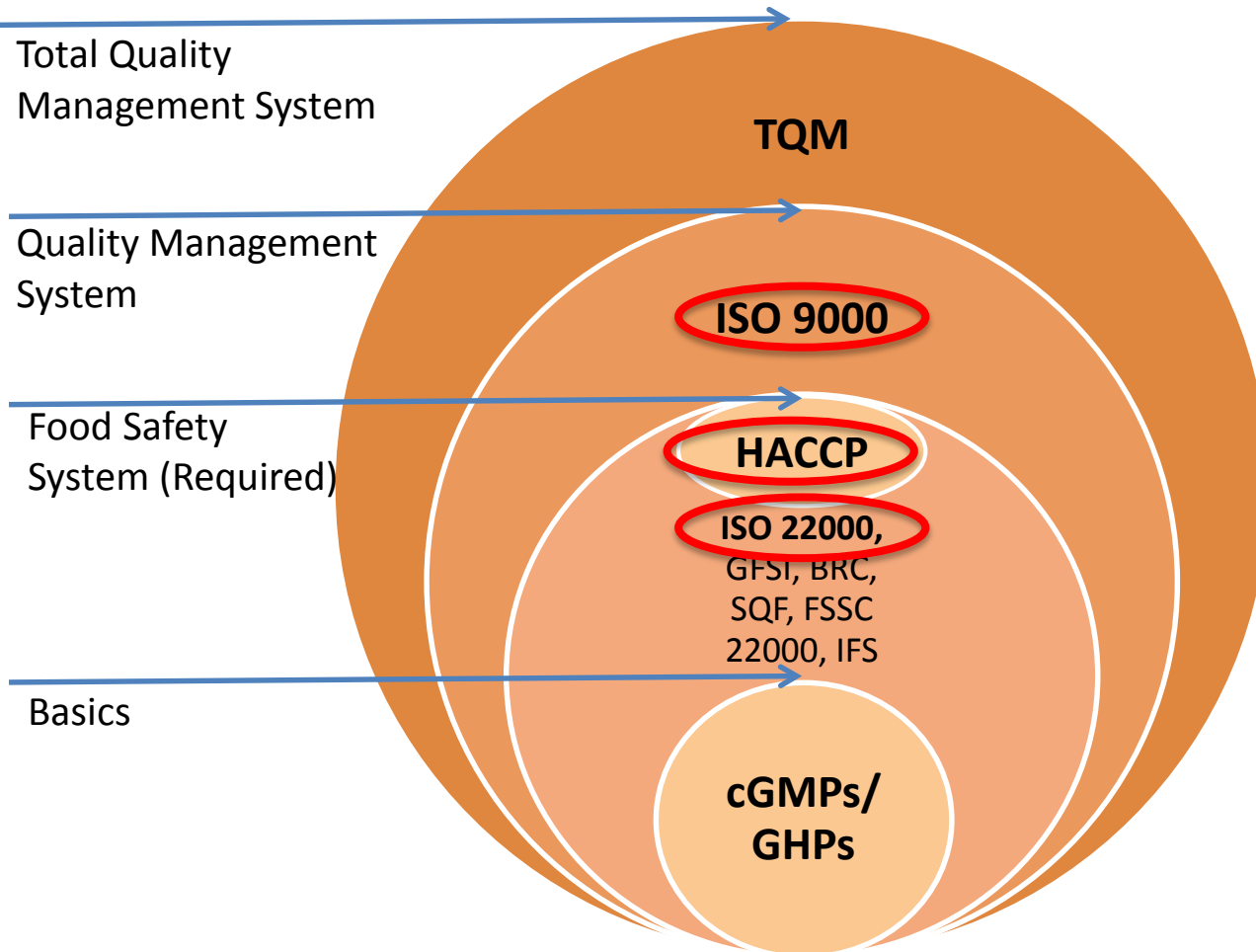
- All food production facilities (including breweries) need food safety plans
- Key requirement:

“Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventative controls”



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WHAT quality systems are available?



- ISO 22000 – International Organization of Standardization (food safety management system)
- GFSI – Global Food Safety Initiative
- BRC – British Retail Consortium
- SQF – Safe Quality Food
- FSSC 22000 – Food Safety System Certification
- IFS – International Food Standards
- HACCP – Hazard Analysis and Critical Control Points
- cGMP – current Good Manufacturing Practices
- GHP – Good Hygienic Practices



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HACCP – Hazard Analysis and Critical Control Points

ISO 22000 – International Organization for Standardization – **Food Safety** Management System

ISO 9000 – International Organization for Standardization – **Quality** Management Systems



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Elements of a Food Safety System

- Hazard Analysis Critical Control Points (HACCP)
- Prerequisite Programs (PRP)
 - Current Good Manufacturing Practices (cGMPs)
 - Basic (i.e. supplier control)
 - Operational (i.e. broken glass)
- Recall plan



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Hazard Analysis Critical Control Points

7 Principles

1. Conduct a hazard analysis

2. Determine critical control points (CCP)

3. Establish critical limits

4. Establish monitoring procedures

5. Establish corrective actions

6. Establish verification procedures

7. Establish record-keeping and documentation procedures



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International Organization for Standardization

What is ISO?

- ISO is an international non-governmental standard-setting organization composed of representatives from various standards organizations
 - Headquartered in Geneva, Switzerland
 - Founded in 1947 and currently has 162 participating countries
- Covers everything from occupational health and safety (ISO45001) food safety (ISO22000) and environmental (ISO14000)



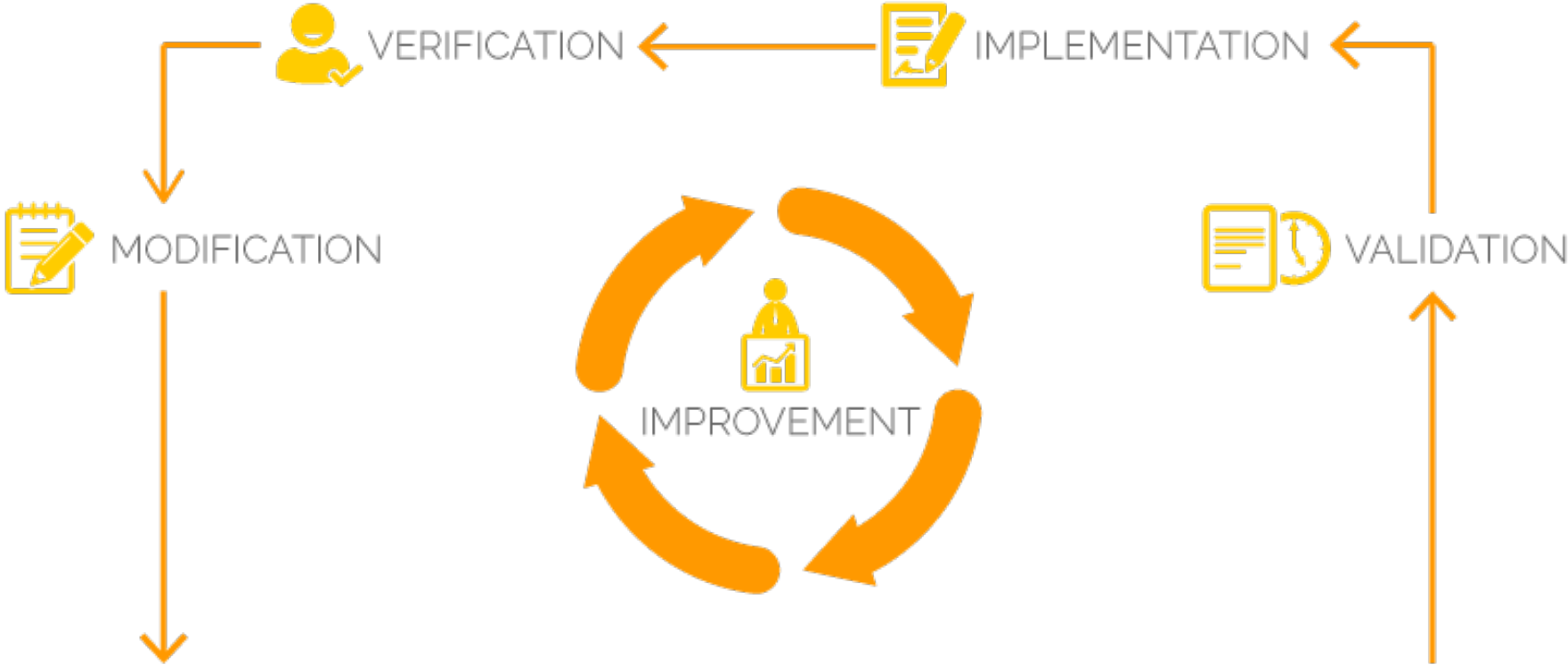
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ISO 9000 vs. ISO 9001

- **ISO 9000**
 - Family of standards
 - Fundamentals and vocabulary
- **ISO 9001**
 - Standard within the ISO 9000 family
 - Requirements of having a QMS
 - ISO 9001 Certification



ISO 22000



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Why?



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Risk Mitigation

- Regulatory compliance
[OSHA, FDA (FSMA), TTB etc.]
- Label compliance
- Avoid recalls
- Meet consumer expectations
- Keep consumers safe!



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An Example: SO₂

- Federal regulation states <10ppm must be labeled “contains sulfites”
- Commonly produced by yeast, usually in 3-5ppm
- SO₂ Production increases when yeast is stressed:
 - Serial repitches / First pitch
 - Oxygen in yeast holding tubs
 - High alcohol fermentations
 - Temperature fluctuations
 - High sulfate content in water



How?



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Implementation

- There is no recipe book for implementation
- The biggest requirement of a QMS is specificity to YOUR process
- Therefore, an implemented QMS would take infinitely different forms
- But we will pitch an example...



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An Implemented QS for ABV

- Define: alcohol content at end of fermentation
 - 4.6% +/- 0.2% (v/v)
- Measure:
 - Fermentation rate: Gravity readings every 12 hours
 - Ensure hydrometer temperature correction is carried out and that employees are trained
 - *Validate final alcohol with alcolyzer
 - Train operators and have posted operating procedures
 - Clean between uses with proper cleaning stock, thoroughly cleaned weekly, calibrated bi-annually
- Record:
 - Record and organize hydrometer readings
 - Have current values displayed
 - Maintain and plot these records for reference
 - Have expected fermentation rates for brands
 - Keep records of final alcohol content by batch
 - Maintain records for reference and audit purposes
 - Plot these values to establish curve and drive to centerline
- React:
 - Use data for short interval control
- Plan
 - Have corrective action plans in place in event of a quality miss
 - Audit your own process to assess areas for improvement



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If you are looking to implement...

- Familiarize yourself with the QS language
- Find your fit
- Begin looking into standards, training, certifications, etc.

FDA.gov - How to develop a food safety plan

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517391.pdf>

ISO website

<https://www.iso.org/iso-22000-food-safety-management.html>

3rd party ISO dealer

<http://asq.org/learn-about-quality/iso-9000/overview/overview.html>



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Takeaways

- A process in control is an efficient process
- Define, Measure, Record, React
- Quality is specific to each product. Quality systems are specific to each process.
- Don't try this alone!



Thank you!

Image Sources (in order of appearance):

<https://leansixsigma.community/blog/view/160/using-control-charts-to-detect-common-cause-variation-and-special-cause-variation>

https://www.linkedin.com/mpr/mpr/shrinknp_400_400/AEEAAQAAAAAAAAAISAAAJDJkMTMzM2U1LTVhN2EtNDA3Ny05M2NkLTlkNjY3NGMyMTJjNw.jpg

<http://aqualitysystems.gr/wp-content/uploads/2016/12/ISO-22000-diagram.jpg>



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