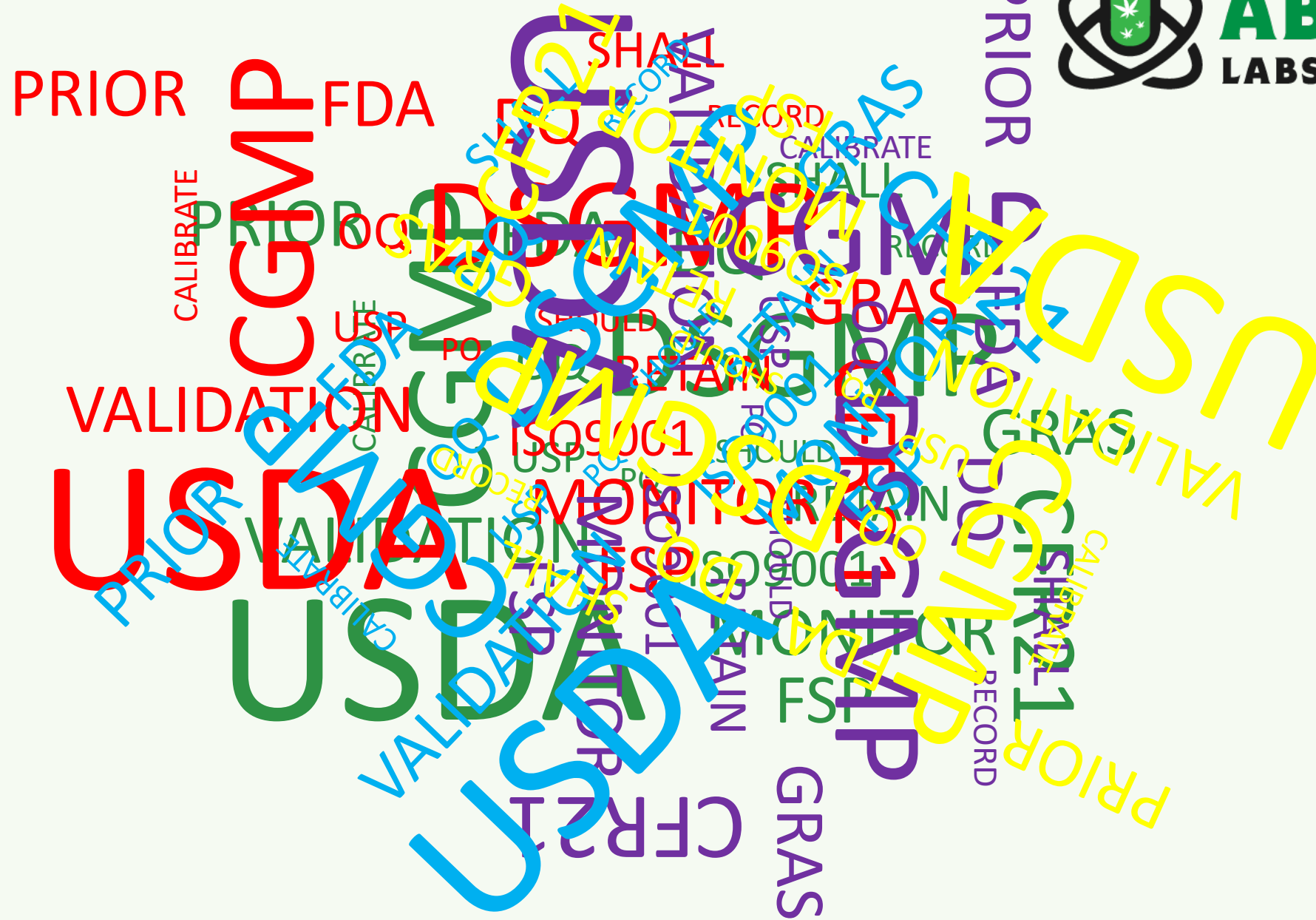




what we RESPECT,
we INSPECT

-Dr. W. Edwards Deming

SHALL
PRIOR FDA DQ RECORD
CALIBRATE CGMP OQ DSGMP
USP PQ SHOULD GRAS
VALIDATION RETAIN
USDA ISO9001 MONITOR CFR21
FSP





Quality Management System

High Quality

Compliant

Safety

Consistent

Hazard Analysis Critical Control Point

HACCP

Quality System

Receiving

Shipping

HACCP

- ✿ Vendor Qualification
- ✿ Training programs
- ✿ Recipes and MFR
- ✿ SOPs and Wis
- ✿ PPE
- ✿ Contamination mitigation
- ✿ Equipment maintenance

Quality Control

- ✿ Receiving and quarantine procedures
- ✿ Sampling protocols
- ✿ Quantitative and Qualitative analyses performed on Raw Materials, Work-in-Process materials, and Finished Goods
- ✿ Equipment calibration and monitoring
- ✿ Batch Review and Lot/Batch Approvals



HACCP

Quality Control

High Quality

Compliant

Safety

Consistent



HACCP

Vendor Qualification

- ✿ Who: Who are the people? Who do you deal with? Do their bios check out? Are they respectful? Are they attentive and interested?
- ✿ What: What is their principal business? Are they the manufacturer or a distributor? What products do they offer? What certifications do they have?
- ✿ Where: Where are they located? Geographical limitations? Is it a real location?
- ✿ How: How do they package and ship? How do they process the material? How is their service?
- ✿ Why: Why are they in business? Why this business? Corporate philosophy, Corporate Mission Statement, Corporate Culture?



HACCP

Vendor Qualification

The Vendor Scorecard: Are they consistent? Has anything changed?



HACCP

Training Programs

Food Safety Program

OSHA

Staff Competency Program

cGMP, ISO

HACCP



Recipe and Process Instructions

- 🌿 Master Formula Record (MFR)
- 🌿 Work Instructions (WI)



HACCP

Standard Operating Procedures (SOPs)

Everything gets an SOP. Abundant Labs has 12 production SOPs,
we have 106 SOPs total!!

HACCP



Personal Protective Equipment (PPE)

Protecting the product, protecting the staff.

HACCP



Contamination Mitigation

Biological
Chemical
Physical

HACCP



Equipment Maintenance

- ✿ Regularly scheduled maintenance
- ✿ Inspection/replacement of consumable pieces, gaskets, seals, bearings

Quality Control Process

Raw Materials

- 🌿 Inspect the packaging, is it damaged?
- 🌿 Does the label match the order?
- 🌿 Is there testing involved? Store in Quarantine?
- 🌿 Sampling Procedures...trust but verify.

Quality Control Process

Work-in-Process

- ✿ Batch tickets created which track lot# and amounts used, specify specifics if different than standard run.
- ✿ Samples of each batch are taken according to sampling protocol
- ✿ Samples are analyzed in house or shipped to third party and results are compared against the product specifications
- ✿ Quality control results are entered into our ERP system, linked with batch#
- ✿ Lot Status is changed from QC Hold to ALL, allowing material to move to next step in processing.

Quality Control Process

Equipment used in Work-in-Process

- ✿ Proper design and development is critical.
- ✿ Adherence to maintenance protocols supports consistency and safety.
- ✿ Regular calibration supports consistency and high quality
- ✿ Procedures and recipes designed to meet specifications consistently.
- ✿ Performance evaluations and monitoring support high quality

Quality Control Process

Finished Goods

- ✿ Samples of each batch are taken according to sampling protocol
- ✿ Samples are analyzed and results are compared against the product specifications
- ✿ Quality control results are entered into our ERP system, linked with batch#
- ✿ Lot Status is changed from QC Hold to ALL, allowing material to be delivered into a sales order in our ERP.

Quality Control Process

Testing Considerations

- ✿ Potency, Conformity, Compliance
- ✿ In-house vs. Third Party
- ✿ Which regulations are you targeting for Residual Solvents, Heavy Metals, Mycotoxins, Bacteria

Quality Control Process

Sales Order Fulfillment...PPPPPP

- 🌿 Clearly communicated customer needs.
- 🌿 Clearly communicated product specifications.
- 🌿 Packaging and labeling approvals
- 🌿 Samples in final packaging held for future testing.



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